VERMONT GUIDE TO HEALTH CARE LAW



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INTRODUCTION

The Vermont Medical Society is proud to release this 2022 edition of the online Vermont Guide to Health Care Law. Work on the Guide was supported by many of the leading law firms and attorneys around the state. It is designed to give physicians and health care facilities a fundamental understanding of legal and regulatory requirements that affect the delivery of health care in Vermont today.

This guide is organized so that users may readily find the information that they seek. Topics are organized in alphabetical order. May chapters are organized in a question-and-answer format to present material in a manner that directly responds to frequently asked questions.

We are very grateful to the attorneys and other experts whose research, writing, and editing made this guide possible. Despite their busy schedules, they devoted many, many volunteer hours to this project. Their dedication, knowledge and experience made the guide the high-quality resource that it is. We couldn't have done it without them. Thank you also to Birdie Pauley of the Vermont Medical Society staff who led the efforts to coordinate with authors and format the latest edition, and to the authors and editors of prior editions of the Guide who gave us the foundation from which to work.

Please send your comments or questions about the guide to Jessa Barnard at the Vermont Medical Society, jbarnard@vtmd.org.

DISCLAIMER

Please note that although information contained in the Guide relates to legal issues, this information is intended to be used for informational and educational purposes only. The information in the Guide is not to be used as legal advice. Persons seeking legal advice should consult a lawyer.

The Guide sponsor, authors and editors intend to provide information that is accurate and useful to health care professionals and facilities. Information about legal issues, however, may become outdated and not all information could be included in the Guide nor have all Chapters been updated on the same schedule as others. The Guide sponsor, authors and editors disclaim liability for any consequences related to any decisions or results, arising out of or based on, any use or interpretation of information contained in or omitted from the Vermont Guide to Health Care Law

VERMONT GUIDE TO HEALTH CARE LAW

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BUSINESS ISSUES

Topics Covered in this Chapter: <u>Structure/Choice of Entity</u> <u>Sole Proprietorships</u> <u>Corporations</u> <u>Partnerships</u> <u>Limited Liability Companies</u> <u>Corporate and LLC Formalities</u> <u>Partner/Shareholder/Member Agreements</u> <u>Opening A Medical Practice</u> <u>Closing A Medical Practice</u> <u>About the Author</u>

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This chapter discusses the structure of various business entities and other issues to be considered in opening and closing a medical practice.

STRUCTURE/CHOICE OF ENTITY

One of the first decisions to be made as a business owner is how the business should be structured. The decision should be made only after consulting with an accountant and an attorney. There are several choices for creating an entity through which to do business. The most widely used entities for physicians and other health care professionals are professional corporations, partnerships, limited liability partnerships, or professional limited liability companies. Many factors should be considered in determining which entity is the most well suited for health care practitioners.

Regardless of the type of business entity, a physician or health care professional is personally liable for negligence or wrongful conduct while rendering professional services. A professional cannot shield himself from professional liability by creating an entity. However, creating an entity may protect a physician from:

- general business liabilities (e.g. patient or employee accidents);
- liabilities to unsecured business creditors; and
- personal liability for another practitioner's professional malpractice

Note that most entities are created by making a filing with the Vermont Secretary of State. These filings are now made online at <u>https://sos.vermont.gov</u>. This website contains helpful information and a list of all fees and forms. You can also search for name availability on the website.

SOLE PROPRIETORSHIPS

A sole proprietorship is a business owned and operated by one person. The business and the individual proprietor are one and the same. Sole proprietors own all the assets of the business

and the profits generated by it. They also assume full responsibility for all of the business liabilities and debts. There is no entity protection from general liability for the owner. For this reason, most physicians form an entity through which to operate a medical practice. There are no filings required or contracts required to create a sole proprietorship. However, if the sole proprietor uses a business name (known as a "d/b/a" or tradename or assumed business name), he/she should register the business name as an assumed business name with the Vermont Secretary of State. The registration costs \$50.00 and gives the sole proprietor the right to use the registered business name for five years (and it may be renewed again and again).

CORPORATIONS

What is a corporation?

A corporation is a separate legal person under the law. A Vermont corporation is created under the laws of the state of Vermont. The owners of a corporation are its shareholders. The shareholders elect a board of directors to oversee major policies and decisions. The corporation does not dissolve when its shareholders change. The greatest advantage to operating a business as a corporation is that the corporation, and not its shareholders, officers or directors, is liable for the debts and obligations of the corporation. While there are exceptions to this rule, generally the owners of the corporation cannot be held personally liable for corporate obligations. This is the fundamental difference between operating as a corporation as compared to a sole proprietorship.

How is a corporation created?

A corporation must be created under state law. This is done by filing Articles of Incorporation with the Vermont Secretary of State's office. This is now an online process. You will need a corporate name, physical and mailing address, registered agent, and number of board members in order to complete the Articles of Incorporation. When the Articles of Incorporation are received and accepted by the Vermont Secretary of State, it will issue official as-filed Articles of Incorporation.

See Vermont Business Corporations Act, 11A V.S.A. § 1.01 through § 21.14.

What is a professional corporation?

A professional corporation is an entity allowed to be used by certain licensed professionals. The key to a professional corporation is that the professionals get the benefit of the corporate form for the business aspects of the practice, but do not get protection from liability for damages caused by the provision of the professional service. This means that if a physician commits malpractice, that physician can be held personally liable even though he/she operates as a professional corporation.

Vermont's professional corporation statute was substantially revised in July 2002. (11 V.S.A. §§ 815-881). This professional corporation law does the following:

- broadens the ownership of a professional corporation and allows various different types of professionals to incorporate together;
- permits existing professional corporations to remain under the old statute or elect to be governed by the new law;
- authorizes any licensing authority to restrict the professional corporation's behavior in the interest of public protection; and

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• sets out general procedures for the acquisition and disposition of the shares of stock of a professional corporation shareholder.

Are there ongoing administrative requirements of operating the corporate form?

Yes, corporations have ongoing administrative requirements, including filing documents with the Vermont Secretary of State's office, the federal Internal Revenue Service, the Vermont Department of Taxes, and the Vermont Department of Labor. Every for-profit corporation must file an annual report with the Vermont Secretary of State's office. Every corporation must hold an annual meeting of stockholders, and must document these meetings in its corporate record book. The definition of meeting has been broadened to include "any structured communications conducted by participants in person or through the use of electronic or telecommunications medium permitting simultaneous or sequentially structured communications for the purpose of reaching a collective agreement." 11A V.S.A. §140(26). The shareholders and directors may also use a unanimous written consent in lieu of a meeting to vote on matters. Every for-profit corporation must issue shares of stock to its shareholders and document the consideration received for the shares of stock.

What is a C corporation?

A "C" corporation is a standard business corporation. A "C" corporation's earnings are taxed at the corporate level and income to the shareholders is taxed at the personal income tax level.

What is an S corporation?

An "S" corporation is a small business corporation that elects to pass corporate income, losses, deductions and credits through to its shareholders under the Internal Revenue Code. The profit and loss of an S corporation normally passes through to the shareholders in proportion to their shares in the corporation. The shareholders report the profit or loss on their individual tax returns. A professional corporation may elect to be treated as an S corporation or may remain as a C corporation. An S election is made by filing IRS Form 2553 with the IRS. An S corporation has certain limitations including a limit on the number of shareholders (100), a requirement that shareholders be U.S. citizens or resident aliens, and a restriction to only one type of stock. All eligible shareholders must be individuals, estates, certain defined trusts, or certain tax-exempt organizations. Internal Revenue Code section 1361 sets forth complete rules relating to S corporations.

To Do List for Forming a Corporation

Below is a list of tasks to be done when creating a corporation:

Lawyer

- 1. Draft Articles of Incorporation for review by client
- 2. File Articles with Vermont Secretary of State
- 3. Draft Bylaws
- 4. Prepare Organizational Board Meeting Resolutions
- 5. Issue Stock Certificates to Shareholders

Accountant

- 1. Obtain Taxpayer Id Number (EIN) from IRS
- 2. Discuss with client whether to file S election with IRS

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3. Obtain all required business tax account numbers from Vermont Department of Taxes

Medical Practice

- 1. Open bank accounts
- 2. Hold a Board of Director organizational meeting and elect officers
- 3. Obtain insurance
- 4. If the corporation has employees, obtain workmen's compensation coverage, unemployment compensation insurance
- 5. If the corporation has employees, post all labor/employee posters

PARTNERSHIPS

A partnership is an association of two or more persons to carry on as co-owners of a business for profit. Vermont's law provides basic definitions and rules about partnerships some of which can be varied by a partnership agreement. For income tax purposes, a partnership is generally treated as a pass-through entity. The partnership itself does not pay income taxes. The partners report the business profits or losses on their personal income tax returns.

What is a general partnership and how is it created?

A general partnership is an association where each owner has unlimited liability. Many partnerships are created without a written agreement. There are many advantages to using a written agreement, including the certainty the partners achieve about their business relationship. If there is no partnership agreement, then the rights and duties of the partners are controlled by Vermont law (See, Title 11, Vermont Statutes Annotated, Chapter 22, 11 V.S.A. § 3201 et seq.).

What is a limited partnership?

A limited partnership is a partnership formed by two or more persons having one or more general partners and one or more limited partners. A general partner is personally liable for the debts and obligations of the partnership. A limited partner may not participate in the control of the business. Typically, a limited partner is not liable for the obligations of a limited partnership (unless he or she is also a general partner or unless he/she participates in the control of the business). A limited partnership is formed by filing a Certificate of Limited Partnership in the office of the Vermont Secretary of State. The Certificate must contain the following information: the office and the address of the registered agent; the name and business address of each general partner; the name and residential address of the partners, and amount of cash and description of agreed value of other property contributed by each limited partner; the latest date upon which the limited partnership is to dissolve. (See, 11 V.S.A. § 3401 et seq.).

What is a limited liability partnership?

A limited liability partnership is a partnership that voluntarily registers with the Vermont Secretary of State as an LLP. Vermont law specifically allows any partnership to register as an LLP. The LLP form shields the individual partners from personal liability for partnership debts. The partner may lose all he/she invested (his partnership interest) but the partner's personal assets cannot be used to satisfy the debts of the LLP. Thus, a partner in an LLP has similar protection as a stockholder in a corporation. To create an LLP, the partnership must file an LLP Statement of Qualification with the Vermont Secretary of State. An LLP must end its name with the words "Registered Limited Liability Partnership," "Limited Liability Partnership," "RLLP" or "LLP." (See, 11 V.S.A. § 3291 et seq.).

LIMITED LIABILITY COMPANIES

What is a limited liability company?

A limited liability company ("LLC") is an entity formed under Vermont law that has elements of both a corporation and a partnership. An LLC is treated like a corporation for purposes of limited liability, and as a partnership (if properly structured) for purposes of income taxation. In order to form an LLC, one must file Articles of Organization with the Vermont Secretary of State. The name of a limited liability company must contain the words "limited liability company" or "limited company" or the abbreviation "LLC" or "LC." (See, 11 V.S.A. § 4001 et seq.).

Can one physician form an LLC?

Yes, in Vermont an LLC may be created by one person and that person shall be the sole member (owner). The LLC will protect the sole member from liability for obligations of the LLC.

What is an Operating Agreement?

An Operating Agreement is a private document that sets forth the governance rules for the LLC. The Operating Agreement does not get filed with the Vermont Secretary of State. Many of the provisions of the Vermont LLC statute can be altered or varied by agreement among the LLC members in the Operating Agreement. The Operating Agreement should specify whether the LLC will be managed by its members or by one or more managers. It should also address the following topics:

- how a new member is added to the LLC;
- how the members vote;
- how a member can withdraw or be forced out of the LLC;
- who makes tax and accounting decisions for the LLC; and
- how the LLC assets will be distributed upon dissolution.

Can licensed professionals create an LLC?

Yes, licensed professionals can form a professional limited liability company; however, professionals are also governed by the licensing laws and by Vermont's professional corporation act. Section 3012(c) of the Limited Liability Company Act (11 V.S.A. § 4011(g)) states that a "limited liability company . . . shall engage in rendering professional services only to the extent that, and subject to the conditions and limitations under which, a professional corporation may engage in rendering professional services." The name of a professional limited liability company must contain the words "professional limited liability company" or the abbreviation "PLC" or "PLLC." The members of a PLC shall be treated in the same manner as shareholders of a professional corporation. The managers of a PLC shall be treated in the same manner as directors of a professional corporation.

How will an LLC be taxed?

An LLC can elect to be taxed as a corporation or as a pass-through entity. If the LLC has a single member and elects pass-through treatment, it will be treated as a sole proprietorship. If the LLC has more than one member and elects pass-through treatment, it will be treated as a partnership. An LLC may also elect to be treated as an S corporation.

CORPORATE AND LLC FORMALITIES

There are certain formalities that a corporation and LLC should comply with in order for it to maintain its status as a separate legal entity, and ensure that the members and shareholders have limited liability to the extent allowed by law, as follows:

- 1. Maintain a separate bank account and financial records for the entity.
- 2. Execute the governing documents (Bylaws or Operating Agreement).
- 3. Obtain all necessary business tax account numbers from the Vermont Department of Taxes.
- 4. File an annual report with Vermont Secretary of State.
- 5. Always represent yourself as a duly authorized agent of the entity so that third parties know that they are dealing with an entity and not a sole proprietorship or general partnership.
- 6. Obtain all-risk insurance, including liability insurance, to provide coverage as appropriate.
- 7. Do not add a member to the LLC or a shareholder to the corporation without consulting with legal counsel.
- 8. Work with your accountant to ensure that all ongoing necessary state and federal tax filings get made.

PARTNER/SHAREHOLDER/MEMBER AGREEMENTS

Regardless of the type of entity used, if the entity is owned by more than one physician, the physicians should enter into an agreement governing their relationship. If the physicians are doing business as a corporation, they should enter a shareholder agreement. If the physicians are doing business as a partnership, they should enter a partnership agreement. If the physicians are doing business as a limited liability company, they should enter an operating agreement. These agreements should document the following: how decisions will be made; how profits will be shared; how disputes will be resolved; how future owners will be admitted to the entity; how owners will be bought out; and, what happens upon the death or disability of an owner.

FOREIGN (NON-VERMONT) ENTITY DOING BUSINESS IN VERMONT

An existing out-of-state entity that wishes to do business in Vermont needs to obtain a Certificate of Authority from the Vermont Secretary of State prior to doing business here.

OPENING A MEDICAL PRACTICE

What issues should be considered in opening a practice?

The first issue is the choice of entity issue discussed above. Once the type of entity is selected, the physicians involved should agree on the terms of the appropriate governing agreements. The physicians should contact the local hospital for information about social supports such as the local community mental health agencies and the local agencies on aging. The physicians should determine what medical services the practice will offer, such as lab or x-ray.

Before opening a practice consider the following:

- Create a business plan and pro forma financial statements
- Review choice of entity
- Review licensing requirements
- Look for office space. You may need a lawyer to review a commercial lease for you. Or you may choose to purchase property. In either case you will need a medical office design.
- Billing
- Medical malpractice insurance
- Obtaining provider numbers for Medicaid, Medicare and health insurance companies
- Technology and information system needs
- Policies and procedures manual, including HIPAA and OIG compliance plans
- HR issues employee policies and handbooks; employee benefits

These topics are discussed below.

Licensing

The physician must ensure that he/she has all required professional licenses. Licensing in Vermont is obtained from the Vermont Department of Health, Vermont Department of Medical Practice. The website (<u>http://healthvermont.gov/systems/medical-practice-board</u>) has an e-licensing function. Health care professionals who are licensed or certified by the Board can apply for and renew a license or certification, check the status of an application, or update profile information.

Office Space/Equipment/Other Issues

The physician will need to obtain office space for the practice, which involves leasing or purchasing property. The type of service being offered by the physician will often determine the type of space and equipment the physician will need. The physicians need to determine what information and communication systems will be used by the practice. The physician practice will need to obtain insurance to protect against various risks, including all risk insurance protecting against damage to the premises and equipment, general liability insurance, and professional liability insurance. The physician should consider advertising the practice. The physician should determine whether the practice will need to obtain the services of a billing company.

Employees

If the physician hires staff for the office, the physician practice will need to comply with state and federal laws regarding employees and will need to adopt certain employment policies. (See Chapter on Employment Law).

If the physician has previously worked for another practice or medical center, the physician should review his/her employment contract and/or personnel policies to determine whether there are restrictive covenants that prevent the physician from practicing in certain geographical areas. The physician may need to obtain medical records of patients from the patients' former providers. The physician should prepare a consent form that patients can sign.

What resources are available to provide information on opening a practice?

The physician should check various websites for tips on opening a practice and sample forms and contracts, including the websites for the American Medical Association and the American Academy of Family Physicians.

CLOSING A MEDICAL PRACTICE

The physician must plan ahead before closing a medical practice. The physician must address the following issues in closing the practice: notification to patients; notification to employees; notification to malpractice and general liability insurers; cancellation of contracts with practice management companies or billing companies; termination of equipment leases; disposal or storage of patient records; and disposal of drug samples. Additionally, if the medical practice is organized as an entity such as a corporation or LLC, the physician must wind up and dissolve the business entity after the closure of the practice.

If the physician intends to sell the medical practice, instead of closing it, then the physician will need to have the practice valued and marketed. The physician will need to hire an accountant and attorney for help in structuring the sale and in negotiating the terms of the sale.

Further guidance on closing a practice can be found from your state or national medical societies; also see the Maine Medical Association <u>Physician's Guide to Closing a Medical</u> <u>Practice</u> (noting that this reflects some Maine state-specific laws).

How should a physician notify patients?

A physician is generally under an ethical and legal obligation to provide services to a patient as long as the patient needs them. In order to avoid a claim of abandonment, the physician should take several steps to terminate the physician-patient relationship. (Abandonment is defined as the termination of the physician patient relationship at an unreasonable time and without giving the patient the chance to find an appropriate replacement.)

The physician should initially notify all patients by a letter which informs the patient of the date the physician will stop practicing and the method by which patients can obtain their medical records or have them transferred to another physician. Ideally, the letter would be sent by certified mail, return receipt requested, but the cost may be prohibitive. The patient notification should include: a brief explanation of the reason for terminating the patient relationship; agreement to continue to provide medical treatment for a reasonable period such as 30 days to allow the patient to find another physician; and, a consent form which the patient can sign in order to authorize the transfer of his or her medical records to the new physician.

The physician should make a list of patients to whom the notice should be sent. Identifying patients could be done by running a list of new patients and patients whom visited the practice during the prior two or three years. The physician should not send a notice to patients of other physicians that he or she shared call coverage with, or patients whom were seen through a hospital consult.

The Vermont Board of Medical Practice website contains an Advisory (from 1999) about the requirement of notifying patients of the termination of the physician-patient relationship. See

http://healthvermont.gov/sites/default/files/documents/2016/12/BMP_Policies_Termination%20 of%20Relationship.pdf. For more information, see the Guide Sections on Initiation and Termination of the Physician-Patient Relationship and Risk Management.

Should the physician refer patients to another physician?

If at all possible, the physician closing a medical practice should avoid referring patients to another named physician. Such a referral puts the referring physician at risk of a claim for negligent referral. The physician should instead refer their patients to general resources such as the Board of Medical Practice, their local hospital or insurance carrier. Additionally, patients who are under the physician's ongoing care may require additional arrangements.

Are there employee notice requirements upon the closure of a physician practice?

In Vermont, there are no statutory requirements for notifying employees in a particular manner. The physician should review any employment contracts between the physician practice and its employees. The physician should also review any existing personnel policies or employee handbooks to determine the rights of employees. The physician practice must provide written notice of the termination date of benefits. The physician practice may have certain obligations under COBRA.

Is there a risk of notifying employees about a planned practice closure too early?

Yes, when a physician notifies his/her employees that the practice will be closing, there is a risk that the employees may immediately search for a new job and leave the physician's practice prior to the closure date. To avoid this, and provide an incentive for employees to remain at the practice, the physician may want to offer a bonus to any employee who works at the practice until the closing date.

How should the physician handle patient records upon the closure of the practice?

Upon the request of the patient, the physician would send a copy of the patient's records to a new physician or to the patient. In either case, the physician should retain the original (or retain access to the original). The physician should store the original records in a safe place, such as a commercial storage firm. The physician should ask the storage company to enter into a confidentiality agreement so that the physician meets his/her legal obligation to keep patient records confidential. For more information on the length of time to retain records, see the section on Medical Records.

How should the physician dispose of drug samples?

Hopefully your practice already monitors drug samples, organizes them, checks expiration dates, maintains distribution papers in case there is a recall, and keeps the medicines physically secured.

When a practice closes, it may still have possession of unused drugs or drug samples. The physician practice should return any unopened bottles to the distributor or manufacturer to obtain a refund if possible. The physician practice may also return drug samples to the drug company representatives who visit the practice. The physician may also check with the local hospital or local pharmacist for suggestions on how to dispose of the drug samples. There are also comprehensive medical waste disposal companies that can be hired to provide technical advice and disposal services.

Vermont Guide to Health Care Law

ABOUT THE AUTHOR

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CONSENT, PRIVACY, AND MEDICAL RECORDS

Topics Covered in this Chapter: <u>Informed Consent for Treatment</u> <u>Privacy and Medical Information</u> <u>Medical Records</u> <u>Law Enforcement</u> <u>Minors</u> About the Authors

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INFORMED CONSENT FOR TREATMENT

Legal Overview

What are the legal principles supporting a patient's right to informed consent?

Common law in the United States has long recognized that "every human being of adult years and sound mind has the right to determine what shall be done with [their] own body". (*See Schloendorff v the Society of the New York Hospital*, 105 N.E. 92 (N.Y. 1914)). Initially, this right was defined in terms of an individual's right to be free of unwanted bodily invasion—essentially that a person cannot be "touched" without their explicit permission. "Touching" an individual without their permission constitutes a battery. In health care, a person who has not given permission, or consent, to a "touching" by a health care provider for medical treatment is considered to have a cause of action against the health care provider for a battery. Over time, courts have interpreted a failure to gain adequate informed consent as a matter of provider negligence.

What is a battery?

A battery is an intentional act that results in harmful contact with another. In health care, a provider commits a battery if the provider performs a procedure for which the patient has not given consent. A defense to a claim of battery is that the patient consented to the contact.

What is negligence?

In Vermont, professional medical negligence occurs when a health care provider lacks the knowledge to or fails to exercise the requisite standard of care (defined below) and, as proximate result, the patient suffers injuries that would not otherwise have been incurred. Standard of care is established by the degree of knowledge or skill possessed or the degree of care ordinarily exercised by a reasonably skillful, careful, and prudent health care professional engaged in a similar practice under the same or similar circumstances. In health care settings, professional negligence serves as the basis for medical malpractice claims. <u>12 V.S.A. § 1908</u>.

What is the current law in Vermont regarding the principle of an individual's right to informed consent?

The duty of a health care provider to obtain consent from a patient for treatment is defined by statute in most states, including Vermont. The Vermont statutes define this duty by limiting the scope of a medical malpractice action based on lack of informed consent, and by outlining a hospital patient's rights to information and consent in the <u>Bill of Rights for Hospital Patients</u>. <u>12</u> V.S.A. § 1909, <u>18 V.S.A. § 1852</u>(3) and (4).

Under Vermont law, hospital patients have a right to be provided with the information necessary to provide informed consent. The Vermont Bill of Rights for Hospital Patients provides the inpatient the affirmative "right to obtain, from the physician coordinating [their] care, complete and current information concerning diagnosis, treatment, and any known prognosis in terms the patient can reasonably be expected to understand." The patient has the right, except in emergencies, to receive from the physician information necessary to give informed consent prior to the start of any procedure or treatment. Such information should include the medically significant risks involved with this procedure or treatment, the probable duration of incapacity and any medically significant alternatives. <u>18 V.S.A. § 1852</u>(3) and (4).

Nursing home residents have a right to be fully informed, by a physician, of medical diagnosis and treatment, and have the right to participate in planning medical treatment or refuse to participate in experimental research. <u>33 V.S.A. 7301(2)(C).</u>

Additionally, patients in a palliative care or pain management program must be informed of "all evidence-based options for care and treatment, including palliative care, in order to make a fully informed patient choice". *See Patient's Bill of Rights for Palliative Care and Pain Management*, 18 V.S.A. § 1871.

Note that these patient rights are also set forth in the <u>Medicare Hospital Conditions for</u> <u>Participation: Patient's Rights.</u> <u>42 C.F.R. § 482.13(b)(2)</u>.

What is the current law in Vermont regarding the principle of a provider's duty to gain a patient's informed consent?

The Vermont medical malpractice statute defines "informed consent" in the negative (i.e., the consequences of a *lack* of informed consent). Under the statute, a lack of informed consent is defined as the following:

- The failure of the person providing professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation; or
- The failure to provide a reasonable answer to any specific question about foreseeable risks and benefits. Additionally, a medical practitioner has a duty to provide and not withhold any information requested by the patient.

<u>12 V.S.A. § 1909</u>(a) and (d).

What is the difference between an allegation of battery where the patient has provided no consent to the treatment or procedure and an allegation of medical malpractice where the patient argues that the provider failed to meet the standards of informed consent?

A battery requires a complete lack of consent. Where a medical professional performs a treatment or procedure for which there is no consent, the patient has a cause of action for battery—an intentional contact or invasion which causes harm.

An action for medical malpractice (or negligence) requires a lack of *informed* consent. Where the patient has provided consent for the treatment or procedure but receives inadequate disclosure of the alternatives and foreseeable risks and benefits of the alternatives, the cause of action and liability are based on a lack of *informed* consent and the patient may have a claim of medical malpractice against the health care provider for failing to provide the necessary disclosures. *Christman v. Davis*, 179 Vt. 99, 101-102 (2005).

What information must the health care professional disclose to the patient before informed consent can be fairly given?

The professional must give the patient information regarding:

- The specific procedure or treatment, or both;
- The medically significant risks involved;
- The probable duration of incapacitation;
- The name(s) of the person(s) responsible for performing the procedures or treatment; and
- Where medically significant alternatives for care or treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information.
- *See* <u>18 V.S.A. § 1852</u>(a)(4).

What risks, benefits and alternatives must be disclosed for a patient to provide informed consent?

The treating professional must disclose any "reasonably foreseeable risks and benefits that a reasonable medical practitioner under similar circumstances would have disclosed." <u>12 V.S.A.</u> § 1909(a)(1). Further, a patient is entitled to a reasonable answer to any specific questions about foreseeable risks and benefits, and a medical practitioner shall not withhold any requested information. <u>12 V.S.A.</u> § 1909(d). Essentially, the medical professional must provide the patient with sufficient information to permit the patient to make a knowledgeable evaluation of the treatment or procedure. Additionally, the treating professional must disclose medically significant alternatives for care or treatment and provide a patient with information regarding medical alternatives if the patient requests such information. <u>18 V.S.A. § 1852(a)(4)</u>.

Can a medical professional be held liable for failing to address every known risk or alternative to a procedure or treatment when gaining patient informed consent?

No, when reviewing information with a patient to gain informed consent there is no expectation that the information discussed be an exhaustive list of all known risks, alternatives, details, etc. It is not considered failure to obtain informed consent under the following circumstances:

• The risk not disclosed is too commonly known to require disclosure and that the risk is not substantial;

- The patient has assured the health care provider that they would undergo the treatment procedure or procedures regardless of the risk involved; or
- The patient indicated to the medical practitioner that they did not want to be informed of the matters to which they would be entitled to be informed;
- Consent either by the patient or on behalf of the patient was not reasonably possible (e.g., as a result of the patient's incapacity and the unavailability of any patient representative); or
- A reasonably prudent person in the patient's position would have undergone the treatment or procedure if they had been fully informed.

<u>12 V.S.A. § 1909(c)</u>.

Must a medical professional obtain informed consent in an emergency?

There is an emergency exception to informed consent based on the premise that a reasonable person would want medical care in an emergency even if they, or their representative(s), were unable to provide consent at the time of treatment. Vermont law specifies that when emergency treatment is provided, there can be no cause of action for medical malpractice based on a lack of informed consent. <u>12 V.S.A. § 1909(b)</u>; see also <u>18 V.S.A. § 1852(4)</u> (patient right to informed consent except in emergencies).

Any discussion about informed consent or exceptions to informed consent should be documented in the medical record including the reasons for any exception. An executed patient consent form should be maintained in the medical record or, in the case of an exception or emergency, the provider should list the reason(s) for not obtaining patient informed consent.

Must a patient be advised of the foreseeable risks and benefits of a treatment or procedure in the event that the health care provider believes that this information would adversely affect the patient's condition?

Yes, a patient must be advised of the foreseeable risks and benefits of a treatment or procedure even if the provider believes that the information would adversely affect the patient's condition. Vermont law does not recognize "therapeutic non-disclosure" in which a health care provider would withhold information from a patient to prevent adverse impact to the patient's condition.

If a patient gives informed consent to a treatment or procedure, but the health care provider performs a different treatment or procedure, does the patient have a cause of action for battery? Does the patient have a cause of action for malpractice due to a lack of informed consent?

A patient's consent is effective for a particular procedure or treatment or for "substantially the same" proposed conduct. Whether consent is effective for a different treatment or procedure with similar risks and benefits depends upon whether the different conduct or procedure that was performed was "within the bounds" of the conduct for which consent was obtained. *Christman v. Davis*, 179 Vt. 99, 105 (2005). In *Christman v. Davis*, the Vermont Supreme Court held that a "less-extensive operation than discussed with the patient" (i.e., a flap procedure was conducted when the patient had consented to a tissue graft to address a dental root issue) was within the bounds of the patient's original consent and, thus, there could be no cause of action for battery.

What type of evidence must be produced by a patient at trial to support a charge of medical malpractice as a result of lack of informed consent?

Vermont law requires that a patient establish the standard of care for the treatment or procedure that was not met or for which insufficient information was provided to give informed consent, that the health care provider breached that standard, and that as a proximate result, the patient suffered injury. <u>12 V.S.A. § 1908</u>. The law places an affirmative burden on the patient to establish a claim of medical malpractice for insufficient informed consent through expert testimony. *Christman v. Davis*, 179 Vt. 99, 102 (2005); see also <u>12 V.S.A. § 1909</u> (medical malpractice for insufficient informed consent through expert testimony). Courts have interpreted this law to mean that generally the standard of care can only be proved by expert testimony. *Lockwood v. Lord*, 163 Vt. 210, 213 (1994), see also *Larson v. Candlish*, 144 Vt. 499 (1984). The limited "Common Knowledge Exception" to this rule removes the requirement for expert testimony "if the alleged violation of the standard of care is so apparent that it can be understood by a layperson without the aid of medical experts". *Provost v. Fletcher Allen Health Care, Inc.*, 179 Vt. 545, 547 (2005).

Procedural Issues

Must a patient's consent be provided in writing to qualify as informed consent?

While there is no specific legal requirement that informed consent be provided in writing, obtaining written acknowledgement is prudent and is considered the accepted practice. Additionally, for professionals treating patients in a hospital or ambulatory care setting or performing surgery, properly executed informed consent forms must be included in a patient's record to meet the Medicare Conditions of Participation. *See* <u>42 C.F.R. §§ 482.13</u> (CMS Patient's Rights), <u>482.24</u> (Properly executed written patient informed consent must be in the patient's medical record), and <u>482.51</u> (requires properly executed informed consent before surgery). Additionally, for Joint Commission Accreditation, hospitals must be able to demonstrate that there are established policies and processes for obtaining informed consent and provide evidence that such consents are being obtained. *See* Joint Commission Standard PFR.5.1.-5.4.

Additionally, certain programs in Vermont require a patient's written informed consent, for example:

- The <u>Rules for Prescribing of Opioids for Pain</u> require patient informed consent in writing meeting specific elements listed in the Rules—before a provider can prescribe opioids for acute or chronic pain treatment. [See Informed Consent: Special Considerations for Substance Use and Substance Use Disorder for more detail]
- When a minor, fourteen (14) years of age or over, gives informed consent for voluntary admission for inpatient mental health evaluation and treatment, this consent shall be in writing with specific criteria. [See Informed Consent: Special Considerations for Minor Consent for more detail.]

Who is responsible for securing informed consent?

The health care provider who will be providing treatment has the duty to secure the patient's informed consent. Although the health care provider need not perform this task personally, the provider is the one who faces liability if a patient is not properly informed or does not provide consent. Regardless of which health care provider secures the consent, a patient has a right under

the <u>Vermont Bill of Rights for Hospital Patients</u> to obtain information regarding their diagnosis, treatment, and prognosis from the physician who is coordinating the patient's care. <u>18 V.S.A.</u> <u>§ 1852</u>(a)(3).

How must the information be disclosed to a patient?

A face-to-face explanation is advisable although, not necessarily required. Providing the patient with written, digital or visual information about the risks, benefits and alternatives may also satisfy the standard in many instances. However, any communication must be meaningful such that the patient needs to be able to read or understand the language and vocabulary utilized. Additionally, although informed consent is a process rather than a form, documenting the process in the medical record is important to demonstrate the information provided by the professional to the patient, the questions asked by the patient, and evidence of the patient's signature at the time such information is given.

For what treatments or procedures is informed consent required?

Vermont law does not generally designate the types of treatment, procedure or surgeries that require the professional to obtain a patient's informed consent before acting. Rather, the law provides for a cause of action for failing to obtain informed consent. See <u>12 VSA § 1909(a)</u> and (d). However, a defense to a claim of medical malpractice for lack of informed consent may be based on allegations that the risk that was not disclosed is so commonly known and insubstantial that informed consent was not necessary. <u>12 V.S.A. § 1909(c)(1)</u>. Thus, disclosing risks that are commonly known or insubstantial is not necessary to gain informed consent and if a treatment or procedure carries only commonly known or insubstantial risk informed consent is not requisite.

Vermont law also requires informed consent for the prescription of opioid medications in certain circumstances. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, *effective July 2017*. See also Sub-Chapter "Special Considerations for Substance Use and Substance Use Disorder Treatment".

What if a patient refuses treatment or wishes to withdraw consent?

A patient with decision-making capacity has the right to refuse treatment, choose between treatment options, or withdraw consent. If a patient does refuse treatment, they should be informed of the medical consequences of that action and that decision should be documented. Many providers choose to have an individual sign a written release to document refusal of treatment. <u>18</u> <u>V.S.A. § 1852(a)(5)</u>.

What if a patient lacks decision-making capacity to give informed consent?

If a patient lacks decision-making capacity to give informed consent, a surrogate decision maker must be identified to provide informed consent. If identifying a surrogate decision maker will result in a delay that might increase the risk of death or physical harm, emergency care can be provided without informed consent.

See also the Vermont Guide to Health Care Law chapter entitled, "Professional Liability" for more information related to Advanced Directives for Health Care.

When is a health care professional required to discuss the impact a medical condition or medication will have on a patient's ability to safely operate a vehicle?

In accordance with National Transportation Safety Board ("NTSB") recommendations directed at medical and pharmacy licensing boards, health care providers should routinely discuss with patients the effect that medical condition and medication use may have on the ability to safely operate a vehicle in any mode of transportation. <u>Case Analysis and Reporting Online</u>.

See also the Vermont Guide to Health Care Law chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>".

The American Medical Association ("AMA") provides physicians with ethical guidance about having a candid discussion with a patient and their family in deciding whether and how a patient's medical condition may impair driving. Physicians must balance the duty of confidentiality to their patient with the protection of public safety. <u>AMA Code of Medical Ethical Opinion 8.2: Impaired Drivers and Their Physicians.</u>

For further information please visit the Vermont DMV Mature Drivers Website: <u>https://dmv.vermont.gov/licenses/mature-drivers (last visited August 17, 2021);</u> Vermont DMV Universal Medical Evaluation/Progress Report and Driver Eyesight Evaluation.

See also the Vermont Guide to Health Care Law chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

Must a patient's informed consent be obtained when providing telehealth services? Must it be in writing?

Patient-informed consent is required when providing telehealth services. Consent does not, however, have to be in writing. If the patient gives verbal consent, this must be documented in the medical record. For services provided on an ongoing basis, the provider is only required to obtain consent at the first episode of care. Telehealth informed consent must be explained in a language that is easily understood by the patient. See <u>18 V.S.A. § 9361</u> and <u>8 V.S.A. § 4100k</u>.

For an audio-only telehealth visit, patient informed consent—oral or written—is required prior to the first audio-only visit and must be documented or included in the medical record. Provider must also document the reasons for audio-only telehealth services and why it is clinically appropriate. $\underline{8}$ <u>V.S.A. § 4100k</u>. Informed consent for an audio-only telehealth visit must include the following elements:

- Patient is entitled to choose services by audio-only telephone, in-person, or by telemedicine;
- Receiving services by audio-only telehealth must not preclude in-person or telemedicine follow-up;
- Provider must explain the pros and cons of audio-only telehealth services;
- Patient must be informed and may approve of others who can listen or participate in audioonly telehealth visit;
- Patient must be provided information on billing to insurance plan and their out-of-pocket responsibility; and
- Patient must be alerted that not all health plans will provide coverage for audio-only telehealth services.

Consent for Treatment with Opioid Prescriptions

What are the requirements for informed consent for prescribing opiate medications?

Prior to writing a prescription for an opioid Schedule II, III, or IV to any patient for the first time health care providers must do the following:

- Consider non-opioid and non-pharmacological treatment;
- Query the Vermont Prescription Monitoring System (See <u>Vermont Prescription</u> <u>Monitoring System Rule</u> and Sub-Chapter on Medical Records: Pharmacists and Prescription Records);
- Have an in-person discussion with the patient (or a parent, guardian, or legal representative if the patient is a minor or lacks legal competence) regarding the potential side effects, risks of dependence and overdose, alternative treatments, appropriate tapering, and safe storage and disposal of opioid medications;
- Provide the patient with the <u>Vermont Department of Health Patient Education Sheet</u> (last visited August 16, 2021) or a written alternative including all topics covered in the Department-published sheet and written in a fifth-grade reading level or lower; and
- Receive, and include in the patient's medical record, a signed informed consent from the patient (or from the patient's parent, guardian or legal representative if the patient is a minor or lacks the capacity to provide informed consent) that includes:
 - \circ Information regarding the drug's potential for misuse, abuse, diversion, and addiction;
 - Potential side effects;
 - Tolerance;
 - The risks associated with the drug for life-threatening respiratory depression;
 - Potentially fatal overdose as a result of accidental exposure, especially in children;
 - Neonatal opioid withdrawal syndrome; and
 - Potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates.

VT Rules Governing the Prescribing of Opioids for Pain, Section 4.3, effective March 1, 2019.

What are the requirements for gaining patient informed consent when prescribing opiates for chronic pain?

In addition to the requirements described above, before providers prescribe opioids for the treatment of chronic pain (i.e., pain lasting longer than 90 days), providers must also receive and include in the patient's medical record a signed Controlled Substance Treatment Agreement from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, and safe storage and disposal of medication. The agreement must also include other requirements as determined by the provider, such as directly observed urine drug testing and pill counts to reasonably and timely inform the provider if the patient is misusing the prescribed substance. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 6.2.1.5, *effective March 1, 2019*. The Controlled Substance Treatment Agreement must be reviewed by the provider and the patient no less than every 365 days to reevaluate the patient. The review must be documented in the patient's medical record. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 6.4.1, *effective March 1, 2019*.

The provider must also ask, and document asking, the patient (or the parent, guardian or legal representative as necessary) if the patient currently, or has recently, been dispensed methadone or buprenorphine or been prescribed or taken any other controlled substance. The provider must explain to the patient, and document the explanation, that this information is important for the patient's safety and that the patient is required by law to disclose this information. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 6.2.1.4, *effective March 1, 2019; and* <u>18</u> <u>V.S.A. § 4223</u>.

Prior to prescribing a Morphine Milligram Equivalent ("MME") Daily Dose of 90 (a calculator for MME can be found on the Department of Health's website) for chronic pain, the provider must have an in-person discussion with the patient (or a parent, guardian or legal representative as necessary) regarding the increased risk of fatal and non-fatal overdose and any precautions the patient should take. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 6.4.2.7, *effective March 1, 2019*. Prior to prescribing a dose of opioids or a combination of opioids that exceeds a MME Daily Dose of 90, the provider must conduct, and document in the medical record, a review of the patient's Controlled Substance Treatment Agreement and Informed Consent, making any necessary revisions, including pill counts and directly observed urine testing to monitor adherence and possible use of other substances. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 6.4.2.4, *effective March 1, 2019*.

These requirements regarding the prescription of opioids for the treatment of chronic pain do not apply to the treatment of patients with chronic pain associated with cancer or cancer treatment, palliative care, end-of-life and hospice care, or patients in skilled and intermediate care nursing facilities. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 6.2.1.4, *effective July 2017*.

Are there different requirements for gaining patient informed consent when prescribing extended release hydrocodones and oxycodones without abuse-deterrent opioid formulations?

In addition to the other requirements for the prescription of opioids, including those pertaining to prescriptions for chronic pain, prior to prescribing extended release Hydrocodones and Oxycodones that are not abuse-deterrent opioids, a provider must receive and include in the patient's medical record a signed Controlled Substance Treatment Agreement from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, safe storage and disposal of medication, and urine testing (no less frequently than annually with the actual frequency to be determined by the clinician on the basis of the patient's risk assessment and ongoing behavior). The agreement must also include other requirements as determined by the provider, such as directly observed urine drug testing and pill counts to reasonably and timely inform the provider if the patient is misusing the prescribed substance. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 8.1.6, *effective July 2017*.

Providers prescribing these medications must have follow-up visits with and evaluations of the patient no less frequently than every 90 days and, during these follow-up appointments, must document that the provider has explained and received acknowledgement from the patient (or a parent, guardian or legal representative as necessary) that a violation of the Controlled Substance Treatment Agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering

or discontinuing the prescription. <u>VT Rules Governing the Prescribing of Opioids for Pain</u>, Section 8.2, *effective March 1, 2019*.

What are the requirements for patient informed consent when prescribing opiates for hospice services, palliative care at end-of-life, and end-of-life care?

Hospice services, palliative care services at end-of-life, and end-of-life care services are exempt from the other requirements for the prescription of opioids described above. Rather, prior to prescribing an opioid to a patient receiving one of these services, a prescriber shall inform the patient (or if the patient lacks the capacity to provide informed consent, the patient's legal representative) regarding safe storage and disposal for patients receiving an opioid outside of a health care setting. The prescriber shall also provide the patient with the <u>Department of Health patient education sheet</u> and shall receive a signed informed consent from the patient (or from the patient's parent, guardian or legal representative if the patient is a minor or lacks the capacity to provide informed consent). The informed consent shall contain the following information:

- the drug's potential for misuse, abuse, diversion, and addiction;
- potential side effects;
- tolerance;
- the risks associated with the drug for life-threatening respiratory depression;
- potentially fatal overdose as a result of accidental exposure, especially in children; and
- potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates.

VT Rules Governing the Prescribing of Opioids for Pain, Section 9.2, effective March 1, 2019.

PRIVACY AND MEDICAL INFORMATION

What federal rules govern the confidentiality of medical records in Vermont?

Laws pertaining to patient confidentiality and medical records are described below. Where records for pharmacy, minors, substance use disorder treatment, or mental health treatment are at issue, there are additional federal and state laws to consider as discussed in the following Sub-Chapters: Special Considerations for Pharmacists and Pharmacy Records; Special Considerations for Minors; Special Considerations for Substance Use and Substance Use Disorder Treatment; and Special Considerations for Mental Health Treatment.

Federal Law

HIPAA

Health care providers must consider the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as modified by the American Recovery and Reinvestment Act of 2009 (the "Health Information Technology for Economic and Clinical Health" ("HITECH") Act), and its implementing regulations governing the electronic transfer and security of data and the privacy of medical information (collectively, "HIPAA Privacy and Security Rules"). *See* 45 C.F.R. Parts <u>160</u> and <u>164</u>. The HIPAA Privacy and Security Rules allow a provider to use and disclose patient protected health information for (1) providing treatment to the individual patient, (2) seeking payment for services, and (3) the provider's "health care operations." Disclosures for other purposes, if not otherwise specifically permitted under the HIPAA Privacy and Security Rules, require patient authorization.

Under the HIPAA Privacy and Security Rules, protected health information or "PHI" refers to individually identifiable health information, including demographic data, that relates to an individual's past, present, or future physical or mental health condition; the provision of health care to the individual, or the past, present, or future payment for the provision of health care to that individual. This excludes health care provider employment records (generally protected by labor laws) and education records (generally protected by the Family Educational Rights and Privacy Act, 20 U.S.C. § 1232g).

The HIPAA Privacy and Security Rules provide a baseline for protecting the privacy of identifiable health information, but they do not preempt state laws that are more protective of privacy or provide greater patient rights to access information.

Part 2

Substance Use Disorder ("SUD") treatment records maintained by a federally-assisted SUD treatment center or program are further protected by federal law under <u>42 C.F.R. Part 2</u> ("Part 2"). Part 2 requires individual consent before any information identifying an individual as having a diagnosis of SUD or receiving SUD treatment can be shared, with several substantive and procedural requirements for obtaining and documenting individual consent. See the Sub-Chapter "Special Considerations for Substance Use and Substance Use Disorder" for further detail.

Anticipated Updates to HIPAA and Part 2

In 2021, the Department of Health and Human Services ("DHHS"), Office of Civil Rights ("OCR") released a notice of proposed rulemaking introducing proposed updates to HIPAA, and shortly after, the DHHS, Substance Abuse and Mental Health Services Administration ("SAMHSA") announced that they would be working with OCR to update Part 2 to more closely align with requirements under the HIPAA Privacy and Security Rules. As this is an area of evolving law, it is advisable to seek out the most up-to-date legal and medical resources.

Information Blocking

The 21st Century Cures Act ("Cures Act"), revised in 2016, regulates how electronic medical records are accessed, used, and exchanged. The Cures Act outlines several provisions to prevent information blocking in health care ("The Information Blocking Rule") and to promote health care data interoperability ("Interoperability Rules"). The Information Blocking Rule prohibits actors—including health care providers, health information networks or exchanges, and certified health information technology developers—from engaging in practices that are likely to interfere with the access, exchange, or use of electronic health information ("EHI"), unless required by law or covered by an exception. The Information Blocking Rule does not require an actor to disclose EHI if doing so would violate state or federal law (e.g., HIPAA, Part 2 etc.). Under the Information Blocking Rules, a provider must respond to EHI requests without unreasonable delay and in the manner requested. <u>45 C.F.R. Part 171</u>.

What state rules govern the confidentiality of medical records in Vermont?

Vermont law adopts the HIPAA Privacy and Security Rules' requirements for the disclosure of protected health information. <u>18 V.S.A. § 1881</u>. In 2019, the Vermont Supreme Court extended the applicability of the HIPAA Privacy and Security Rules more generally in the case of *Lawson v. Halpern-Reiss and Central Vermont Medical Center*. This decision held that a nurse, who disclosed to a law enforcement officer that a patient, who was intoxicated and recently

discharged, was likely to operate a motor vehicle, did not violate that patient's right to privacy as disclosure was necessary and permissible to prevent imminent and serious harm to public health and safety. In so holding, the court established the HIPAA Privacy and Security Rules as the privacy standard in Vermont. *Lawson v. Halpern-Reiss*, 210 Vt. 224 (2019).

Patient Privilege

The Vermont patient privilege statute protects communication between a patient and their provider from being used against the patient in legal proceedings (e.g., when a provider is called as a witness in court, in response to a request for medical records for litigation, etc.). <u>12 V.S.A. § 1612</u>. The patient privilege statute prevents doctors, chiropractors, dentists, nurses, and mental health professionals from disclosing any information acquired in attending a patient unless the patient waives the confidentiality or it is waived by an express provision of law. <u>12 V.S.A. § 1612</u>.

In addition to requiring a patient's authorization for the provider to disclose or a waiver under an express provision of law, the statute provides the following notable exceptions to Vermont's patient privilege statute:

- A dentist is required to disclose information necessary for identification of a patient;
- Physicians, dentists, chiropractors, and nurses are required to disclose information indicating a that a patient who is under the age of sixteen (16) is the victim of a crime;
- A physician, chiropractor, or nurse are required to disclose information related to the mental or physical conditions of a deceased patient unless that information would disgrace the memory of the decedent unless waived by (1) the decedent's personal representative, surviving spouse, or next of kin; (2) in litigation where the interests of the personal representative are adverse to those of the estate or any interested party; or (3) when the validity of the will is in question; and
- Any provider limited by patient privilege may disclose information regarding the mental or physical condition of a deceased patient upon request of the Chief Medical Examiner.

<u>12 V.S.A. § 1612(b)</u> and (c).

Up until 2019, the patient privilege statute was considered stricter than the HIPAA Privacy and Security Rules—thus requiring a patient's consent to release PHI for the purposes of treatment, payment, or operations. In *Lawson*, the court established that Vermont would follow the HIPAA Privacy and Security Rules, and, as such, patient consent for release of PHI for treatment, payment, or operations is no longer necessary. *Lawson v. Halpern-Reiss*, 210 Vt. 224 (2019).

Patient Rights

Hospital patients are further protected by the confidentiality provisions contained in the Vermont Bill of Rights for Hospital Patients, which requires that the patient authorize the release or use of their records outside of the treatment team or the facility. <u>18 V.S.A. § 1852</u>(7).

Nursing Home Residents are further protected by the Nursing Home Residents' Bill of Rights, which also requires that the resident authorize release or use of their records outside of the facility. <u>33 V.S.A. § 7301(2)(H)</u>. A nursing home resident's record may be released without authorization when the resident is transferred to another health care institution or when required by a third-party payment contract.

MEDICAL RECORDS

General Overview

What data is considered to be part of a patient's medical record?

Vermont law does not expressly define the parameters of a patient's medical record. Generally, a patient's medical record is a collection of a patient's clinical data and medical history, including demographic information, vital signs, diagnoses, medications, treatment plans, progress notes, complaints, immunization dates, allergies, radiology images, and laboratory and test results. Medical records may be maintained in paper or electronic form.

What data is considered to be part of the patient's designated record set and legal health record?

The HIPAA Privacy Rule grants individuals the right to request and access their own protected health information ("PHI") in the designated record set maintained by a health care provider. $\underline{45}$ C.F.R. § 164.524.

The designated record set includes (45 C.F.R. § 164.501):

- the medical records and billing records about individuals maintained by or for a health care provider;
- the enrollment, payment, claims adjudication and case or medical management record systems maintained by or for a health plan; or
- any records that are used, in whole or part, by or for the covered entity to make decisions about individuals.

The designated record set excludes psychotherapy notes and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. $\underline{45 \text{ C.F.R.}}$ <u>§ 164.524</u>.

The designated record set will generally constitute the legal health record or the official business record of an organization for evidentiary purposes. Components of the legal health record support decisions made in a patient's health care, support revenue sought from third-party payers, document the services provided as legal testimony regarding a patient's injury, illness, response to treatment, and caregiver decisions, and serve as the organization's business and legal record.

Who owns the medical record?

Although the medical record contains patient information, the record belongs to the licensed organization or health care provider group who creates or maintains the record in order to provide medical services to the patient. As discussed below, federal and state law provide patients with the right to access their own medical information.

When a provider leaves a group practice, what happens to the medical records?

Medical records belong to the group practice, unless a provider's employment or practice agreement provides otherwise. Patients, however, may always request that a copy of their medical record information be forwarded to themselves or to another physician or practice.

What rules govern a patient's access to their medical record?

Vermont Law

Under Vermont law, practitioners are required to provide patients prompt access to their records upon written request. A failure to do so constitutes unprofessional conduct. Vermont law also requires that copies of medical records be provided to a patient's representative or succeeding health care practitioner upon the patient's written request, and that providers notify patients about how to obtain their records when a practice closes. <u>3 V.S.A. § 129a(a)(8)</u> and <u>26 V.S.A.</u> § 1354(a)(10).

Federal Law

The HIPAA Privacy and Security Rules also require that medical records (except for psychotherapy notes) or copies thereof be made available to patients upon request. Providers may require that the request for records be in writing but the provider must inform the patient of this requirement. The HIPAA Privacy and Security Rules require a health care provider to respond to a patient's request to inspect or obtain a copy of their medical record within thirty (30) days. This response time may be extended for a second thirty-day period. <u>45 C.F.R. § 164.524</u>. Under the HIPAA Privacy Rule, a provider may deny an individual's request for access in particular circumstances.

A provider may deny an individual access without providing the individual an opportunity review in the following circumstances:

- The protected health information is excepted from the right of access as (a) psychotherapy notes or (b) information compiled in reasonable action of, or for use in, a civil, criminal, or administrative action or proceeding;
- A correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate;
- An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research;
- An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law; or
- An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

See <u>45 C.F.R. § 164.524(a)(2)</u>

A provider may deny an individual access, but that individual had the right to request a review of the denial, in the following circumstances:

- A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
- (The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined,

in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

• The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

See <u>45 C.F.R. § 164.524(a)(3)</u>

Electronic Health Information Requests

The Information Blocking Rule prohibits actors from engaging in practices that are likely to interfere with the access, exchange, or use of electronic health information ("EHI"), unless required by law or covered by an exception. The Rule does not require actors to disclose EHI if doing so would violate state or federal law (e.g., HIPAA). EHI is the electronic protected health information (ePHI) in a Designated Record Set, which typically includes medical records and billing records about individuals and other records used, in whole or in part, by providers to make decisions about individuals. The Information Blocking Rule does not apply to paper records.

Under the Information Blocking Rules, a provider must respond to EHI requests without unreasonable delay and in the manner requested. If an individual patient requests EHI through a third-party application programming interface (API), the provider may advise the individual on potential security risks of using third-party health IT, but may not deny the request.

The provider may respond to an EHI request in an alternative manner from the one requested when certain circumstances set forth in the rule are met. *See* <u>45 C.F.R. Part 171</u>.

Access, Use, or Disclosure

May access to a patient's medical record ever be denied to the patient or their representative? Vermont professional conduct laws require the prompt disclosure of a patient's medical information to that patient, their representative or succeeding health care professionals. <u>3 V.S.A.</u> \S 129a(a)(8) and 26 V.S.A. \S 1354(a)(10).

Unlike the Vermont statutes pertaining to unprofessional conduct, the HIPAA Privacy and Security Rules specify the following limited circumstances under which a practitioner may deny access to an individual's health information:

- When the portion of the medical record requested contains:
 - Psychotherapy notes; or
 - Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding;
- When a health care provider acting under the direction of the Department of Corrections determines that permitting an inmate to obtain a copy of their medical record would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate;
- Under limited circumstances, when the protected health information is created or obtained by the health care provider in the course of research that includes treatment, an individual's

access to the protected health information may be temporarily suspended for as long as the research is in progress;

- When an individual's protected health information is contained in records that are subject to the Privacy Act, an act granting privacy to government-held records, if the denial of access under the Privacy Act would meet the requirements of that law;
- When the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information;
- When a provider has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
- When the protected health information makes reference to another person (unless such other person is a health care provider) and a provider has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or
- When the request for access is made by the individual's personal representative and a provider has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

<u>45 C.F.R. § 164.524(a)</u>.

The provider must provide the patient with a written denial of access detailing the basis for the denial of medical records. If the provider is relying on one of the last three bullets as the basis for denying access to the medical record, the patient has a right to seek review of the decision to deny access. The provider must, to the extent possible, give the patient access to any other protected health information requested, after excluding the protected health information as to which the provider has a ground to deny access. 45 C.F.R. & 164.524(a).

As noted above, Vermont professional licensing law contains no similar exceptions permitting providers to deny access to medical information. Because Vermont law would be considered to be more beneficial to a patient, it is likely to govern and to preempt any contrary federal provision allowing for providers to deny access to records. Thus, before denying a patient access to their medical records based on the HIPAA Privacy and Security Rules set forth above, a provider should consult counsel.

Must health care providers release to a patient records received from another provider?

Yes. The patient has a right to all of their medical information in the possession or under the control of a health care provider regardless of who generated the original documentation. <u>3 V.S.A. §</u> <u>129a</u>(a)(8) and <u>26 V.S.A. § 1354</u>(a)(10).

Must health care providers release to a patient a record that has been labeled "Do Not Rerelease"?

Yes. Under Vermont law, a patient has access to all medical records in the possession or under the control of a health care provider. Generally, records labeled "Do Not Rerelease" are related to substance use disorder diagnosis or treatment. Records of such treatment are subject to federal regulations that require the provider to obtain specific consent from the patient before the provider

further releases the record of substance use disorder diagnosis or treatment to a third party. $\underline{42}$ <u>C.F.R. Part 2</u>. These regulations, however, do not prohibit a patient from obtaining access to their own substance use disorder records. $\underline{42 \text{ C.F.R. § 2.23}}$.

Who may authorize the disclosure of the medical record of a deceased individual?

For disclosures outside of a judicial proceeding, the HIPAA Privacy and Security Rules disclosure requirements should be followed. (As noted elsewhere, Vermont law has specifically adopted them for disclosures of protected health information. <u>18 V.S.A. § 1881</u>.) If an executor, administrator or other person has the authority to act on behalf of the deceased individual under applicable state law, then that person, as the decedent's personal representative, must be treated as having the same rights as the deceased individual. <u>45 C.F.R. § 164.502(g)(1)</u> and (4).

The Vermont patient privilege statute requires health care providers to disclose information regarding the mental or physical condition of a deceased patient (except for information that "would tend to disgrace the memory of the decedent"), if the privilege of confidentiality is waived:

- by the decedent's personal representative, the surviving spouse or the next of kin of the decedent
- by any party in interest if, in any litigation, the interests of the personal representative are deemed by a trial judge to be adverse to those of the estate of the decedent or
- by the executor named in the will, or the surviving spouse or any heir-at-law or any of the next of kin or any other party in interest if the validity of the will of the decedent is in question.

<u>12 V.S.A. § 1612(c)</u>.

"Next of kin" is often synonymous with "heirs". Under Vermont law, next of kin would follow this hierarchy in order of priority:

- Surviving spouse;
- Children or descendants;
- Parents;
- Sibling(s); and
- Grandparents or descendants of grandparents.

<u>14 V.S.A. § 314</u>.

What procedures should be followed if a health care provider seeks to amend a medical record previously created?

If it is necessary to correct an entry in a medical record, health care providers must make the correction without erasing, obliterating or deleting the original medical record entry. Alterations to or deletions of original records may raise the suspicion of an attempt to conceal the truth. Whether the correction is made in an electronic record or a paper record, the original entry should not be changed. The amendment should include the date and time of the amendment, a notation that the entry is an amendment (to distinguish it from the original record), and the reason for the amendment. Health care facilities and professionals should develop policies on correcting medical records and delegate authority to make corrections to specific identified individuals.

What rights does a patient have to amend their medical record?

Patients have the right under HIPAA Privacy and Security Rules to seek to amend or supplement their own medical records for as long as the covered entity maintains the information. <u>45 C.F.R. §</u> Vermont Guide to Health Care Law Page 36
<u>164.526(b)(1)</u>. The provider may require patients to make requests for amendment in writing and to provide a reason to support a requested amendment, provided patients are informed in advance of such requirements. The provider must act on a patient's request for amendment no later than 60 days after it receives the request. <u>45 C.F.R. § 164.526(b)(2)</u>. The deadline may be extended up to 30 days.

If a request to amend is accepted, the covered entity must make the appropriate amendment and inform the patient that the amendment is being made. The provider must also obtain consent from the patient for the provider to share the amended protected health information with other relevant persons, including the following individuals:

- Persons identified by the patient as having received protected health information about the patient and needing the amendment; and
- Persons, including business associates, that the provider knows
 - Have the protected health information subject to the amendment, and
- May have relied, or could rely, on such information to the detriment of the patient. 45 C.F.R. § 164.526(c).

<u>45 C.F.R. § 104.520(</u>C).

A request to amend may be denied if the health care professional or facility determines that the information or record:

- Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of the protected health information is no longer available to make the amendment;
- Is not part of the designated record;
- Would not be available for inspection under the patient's right of access; or
- Is accurate and complete.

<u>45 C.F.R. § 164.526(a)(2).</u>

When a provider denies the patient's request for an amendment, the provider must give the patient written notice of its decision that describes:

- The basis for the denial;
- The patient's right to submit a written statement disagreeing with the denial and how to do so;
- A statement that the patient can request the health care professional or facility to include the patient's request and the denial with any future disclosures of the information (if the patient does not file a statement of disagreement); and

• How the individual can file a complaint with the covered entity or the secretary of HHS. <u>45 C.F.R. § 164.526(d)</u>.

A health care provider that is informed by another provider of an amendment to a patient's protected health information must amend the protected health information in their own records for the patient. 45 C.F.R. & 164.526(e).

May a Vermont provider disclose health information or medical records without a patient's consent or authorization to report abuse or neglect?

Under Vermont law, a health care provider may disclose health information or medical records without a patient's consent or authorization only where there are "express provisions of law" or a court order. Disclosures required by "express provisions of law" include the following:

<u>Mandatory Reporting of Suspected Child Abuse or Neglect</u>. Health care providers are obligated to contact the Department of Children and Families ("DCF") when they have reasonable cause to believe that any child has been abused or neglected. The health care provider must file a report with DCF within 24-hours of the time information regarding the suspected abuse or neglect was first received or observed. <u>33 V.S.A. §§ 4911</u> et seq.

<u>Mandatory Reporting of Suspected Abuse, Neglect or Exploitation of Vulnerable Adults</u>. Health care providers must report to the Department of Aging and Independent Living when they have reasonable cause to believe that a disabled adult or an adult suffering from infirmities of age or an adult receiving personal care services at home or at a licensed facility has been abused, neglected or exploited. <u>33 V.S.A. §§ 6901</u> et seq. Note, however, that under the HIPAA Privacy and Security Rules, the victim must be notified of such a report or disclosure unless it is believed that such notification might place the individual at risk of serious harm. If the health care provider would be informing a personal representative of the victim, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual, the health care provider may use professional judgment in determining whether to inform the personal representative. <u>45 C.F.R.</u> § 164.512(c)(2).

See the *Vermont Guide to Health Care Law* Chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

May a Vermont provider disclose health information or medical records without a patient's consent or authorization to report possible criminal activity or potential harm to a third party? Crime Victim Under Age of Sixteen. Health care providers are required to disclose information indicating that a patient under the age of sixteen (16) has been a victim of a crime. <u>12 V.S.A.</u> § 1612(b).

<u>Firearm-Related Injuries</u>. Health care providers treating bullet wounds, gunshot wounds, powder burns or other injuries caused by the discharge of a gun, pistol, or other firearm must report such cases to local law enforcement officials or to the state police. <u>13 V.S.A. § 4012</u>.

<u>Suspicious Deaths</u>. When a person dies from violence, or suddenly when in apparent good health or when unattended by a physician or a recognized practitioner of a well-established church, or by casualty, or by suicide or as a result of injury or when in jail or prison, or any psychiatric hospital, or in any unusual, unnatural, or suspicious manner, or in circumstances involving a hazard to public health, welfare, or safety, a physician notified of the death must report it to a medical examiner. 18 V.S.A. § 5205(a).

<u>Requests by Chief Medical Examiner</u>. Information regarding the mental or physical condition of a deceased patient must be released by a physician, dentist, chiropractor, mental health provider, or nurse upon request from the chief medical examiner. <u>12 V.S.A. § 1612</u>(c)(2).

<u>Blood Alcohol Level Reporting</u>. If a health care provider who is providing health services to a person in the emergency room of a health care facility as a result of a motor vehicle accident becomes aware as a result of any blood test performed in the health care facility that the person's blood alcohol level meets or exceeds the level prohibited by law, the health care provider shall report that fact, as soon as is reasonably possible, to a law enforcement agency having jurisdiction over the location where the accident occurred. 23 V.S.A. § 1203b.

<u>Duty to Warn</u>. Mental health professionals who know or should know that a patient poses a serious risk of danger to an identifiable individual have a duty to exercise reasonable care to protect the identifiable victim from that danger even if it requires the disclosure of confidential patient information. <u>18 V.S.A. § 1882</u>. (A "mental health professional" is defined under state law as physicians, psychologists, social workers, mental health counselors, nurses, and other qualified persons so designated by the Commissioner of Mental Health "with professional training, experience, and demonstrated competence in the treatment of mental illness…". <u>18 V.S.A.</u> § 7101(13).) For further discussion, see "When must a mental health provider disclose confidential patient information to warn about a patient who may present a serious risk of harm?"

Bioterrorism. Health care providers must report all cases of patients who exhibit any illness, disease, injury or death identified by the Department of Health as likely to be caused by a weapon of mass destruction, including illnesses, diseases, injuries or deaths which can result from bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins, and that might pose a risk of a significant number of human fatalities or incidents of permanent or long-term disability; or which can be caused by biological agents identified under federal law. A pharmacist must report any unusual or increased prescription requests, unusual types of prescriptions, or unusual trends in pharmacy visits that may result from bioterrorist acts, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins, and might pose a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability. Prescription-related events that require a report include an unusual increase in the number of prescriptions to treat fever, respiratory or gastrointestinal complaints, an unusual increase in the number of prescriptions for antibiotics, an unusual increase in the number of requests for information on over-the-counter pharmaceuticals to treat fever, respiratory or gastrointestinal complaints, and any prescription that treats a disease that is relatively uncommon and may be the result of bioterrorism. 13 V.S.A. § 3504.

See the *Vermont Guide to Health Care Law* Chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

May a Vermont provider disclose health information or medical records without a patient's consent or authorization to report specific health conditions or treatments for public health and other purposes?

<u>Communicable Diseases</u>. If a health care provider has reason to believe that a person is sick or has died of a diagnosed or suspected communicable disease, identified by the Department of Health

as a reportable disease and dangerous to the public health, they shall transmit a report thereof within 24 hours and identify the name and address of the patient and the name of the patient's physician to the Commissioner of Health. A list of reportable communicable diseases, including tuberculosis and venereal diseases, can be found at: https://www.healthvermont.gov/sites/default/files/documents/2016/12/REG_reportable-and-communicable-diseases.pdf (last visited August 16, 2021). 18 V.S.A. §§ 1001, 1004, 1007, 1041-1048, 1091-1106.

<u>Animal Bites</u>. A physician is required to report to a local health officer the name, age and address of any person who has been bitten by an animal of a species subject to rabies within 24 hours of actual or constructive notice of the bite. <u>Vermont Department of Health Reportable and Communicable Diseases Rule 7.0 - 7.1.2.</u>

<u>Childhood Immunizations.</u> A health care provider must report to the Department of Health all data regarding immunizations of children under the age of eighteen (18) within seven (7) days of the immunization. <u>18 V.S.A. § 1129</u>.

<u>Fetal Deaths</u>. Health care providers are obligated by statute to report fetal deaths of certain gestational age or size and all therapeutic or induced abortions to the Department of Health within seven (7) days after delivery. A physician who is treating a woman as a result of miscarriage and does not know if a report of fetal death has been made to the State shall file such a report. If there is evidence of violence or other unusual or suspicious circumstances surrounding the fetal death, the physician must report the death to the medical examiner immediately. <u>18 V.S.A. § 5222</u>.

<u>Cancer</u>. Providers are required to report each case of cancer to the Department of Health within 180 days of diagnosis, unless the patient has been previously diagnosed or admitted for cancer treatment at a hospital facility in Vermont. All health care facilities and health care providers who provide diagnostic or treatment services to patients with cancer shall report to the Department of Health any further demographic, diagnostic, or treatment information requested by the Commissioner concerning any person now or formerly receiving services, diagnosed as having or having had a malignant tumor. Additionally, the Commissioner or their authorized representative shall have physical access to all records that would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient with cancer. <u>18 V.S.A. §§ 151</u> et seq. Additionally, Vermont law permits the good faith submission of mammography and pathology data relating to breast cancer to the Vermont Mammography Registry. <u>18 V.S.A. § 157</u>.

<u>Lead Poisoning</u>. All health care providers who analyze blood samples for lead levels or who use laboratories outside Vermont to analyze blood samples for lead levels shall report all information required by the Department of Health to the Department immediately by telephone if the result of any analysis is 45 micrograms or more of lead per deciliter of blood, or by electronic means within 14 days of analysis if the result of the analysis is less than 45 micrograms of lead per deciliter of blood. Any laboratory in Vermont that analyzes blood samples of Vermont residents for lead levels shall make reports as required by the Department. <u>18 V.S.A. § 1755(d)</u>.

<u>Involuntary Hospitalizations</u>. The head of the hospital must immediately provide notice to the parents, legal guardian, nearest known relative or interested party (if known), or spouse of an individual who has been involuntarily hospitalized due to a mental health related condition. If the hospital admission was not pursuant to court order, the head of the hospital must also notify the district court judge for the district where the hospital is located. If the hospital admission was pursuant to court order, the head of the hospital admission was pursuant to court order, the head of the hospital must immediately notify the court and the Commissioner of Mental Health of the admission and also of discharge. 18 V.S.A. § 7106.

See the *Vermont Guide to Health Care Law* Chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

May a Vermont provider disclose health information or medical records without a patient's consent or authorization to report a patient's condition to the Department of Motor Vehicles?

Vermont law does not require providers to report drivers to the Department of Motor Vehicles. Federal HIPAA Privacy and Security Rules permit, but do not require, disclosure of a serious and imminent threat to the health or safety of a person or the public without authorization from the patient. <u>45 C.F.R. § 164.512(j)</u>. The American Medical Association ("AMA") provides physicians with ethical guidance about reporting patients who may be impaired drivers. See <u>AMA Code of Medical Ethical Opinion 8.2: Impaired Drivers and Their Physicians</u>.

See the *Vermont Guide to Health Care Law* Chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

May a Vermont provider disclose health information or medical records without a patient's consent or authorization to identify patients?

Dentists are obligated to disclose information necessary for the identification of patients. It is presumed that the disclosure would be made to law enforcement or to a medical examiner or other entity authorized to request or receive the information. <u>12 V.S.A. § 1612(b)</u>.

See the *Vermont Guide to Health Care Law* Chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

May a Vermont provider disclose health information or medical records without a patient's consent or authorization to disclose information related to deceased patients?

Physicians, nurses, and chiropractors are required to disclose information as to the mental or physical condition of deceased patients in certain circumstances (e.g., a will contest) unless the information would be considered "to disgrace the memory of the decedent." In such circumstances, the privilege must be waived by either the decedent's personal representative, the surviving spouse of the decedent, or the next of kin of the decedent. In addition, physicians, dentists, chiropractors, mental health professionals, and nurses are required to produce information as to the mental or physical condition of a deceased patient if requested to do so by the chief medical examiner. 12 V.S.A. \S 1612(c).

See the *Vermont Guide to Health Care Law* Chapter entitled, "<u>Reporting & Disclosure</u> <u>Requirements</u>" for more information.

Can a hospital or health care provider inform visitors or callers about a patient's location in the facility and general condition?

Yes, the HIPAA Privacy and Security Rules permit a hospital or other health care provider to maintain a directory of certain information about patients and to use this facility directory to inform visitors or callers about a patient's location in the facility and general condition if they ask for the patient by name. <u>45 C.F.R. § 164.510(a)</u>. A patient must be informed about the information to be included in the directory, and to whom the information may be released, and the patient must have the opportunity to restrict the information or to whom it is disclosed, or opt out of being included in the directory. The patient may be informed, and make their preferences known, orally or in writing.

The directory can include the following information:

- The patient's name;
- The individual's location in the healthcare provider's facility. Providers should not disclose the location in the facility if it would effectively disclose the nature of the patient's treatment, e.g., the psychiatric unit, labor and delivery, or a drug and alcohol treatment facility; and
- The individual's condition described in general terms that do not communicate specific medical information about the individual or religious affiliation.

The <u>American Hospital Association</u> has recommended the following one-word descriptions of a patient's condition.

- Undetermined: Patient awaiting physician and assessment.
- Good: Vital signs are stable and within normal limits. Patient is conscious and comfortable. Indicators are excellent.
- Fair: Vital signs are stable and within normal limits. Patient is conscious but may be uncomfortable. Indicators are favorable.
- Serious: Vital signs may be unstable and not within normal limits. Patient is acutely ill. Indicators are questionable.
- Critical: Vital signs are unstable and not within normal limits. Patient may be unconscious. Indicators are unfavorable.
- Treated and Released: Patient received treatment but was not admitted.
- Treated and Transferred: Received treatment. Transferred to a different facility. (Although a hospital may disclose that a patient was treated and released, it may not release information regarding the date of release or where the patient went upon release without patient authorization.)

The facility or health care provider may provide the appropriate directory information – except for religious affiliation – to anyone who asks for the patient by name unless the patient has restricted the information or opted out of the directory. Religious affiliation may be disclosed to members of the clergy so long as the patient has been informed of this use and disclosure and does not object. <u>45 C.F.R. § 164.510</u>. When, due to emergency treatment circumstances or incapacity, the patient has not had an opportunity to express their preference about how, or if, the information may be disclosed, directory information about the patient may still be made available if doing so is in the individual's best interest as determined in the professional judgment of the provider, and would not be inconsistent with any known preference previously expressed by the individual. In these cases, as soon as practicable, the health care provider must inform the patient about the directory and provide the patient an opportunity to express their preference about how, or if, the information may be disclosed. 45 C.F.R. \$ 164.510.

What rights do the media or press have to patient information?

The HIPAA Privacy and Security Rules generally prohibit providers from disclosing patient PHI to the media unless the patient or their personal representative authorizes disclosure. 45 C.F.R. § 164.502.

The media may inquire about a patient by name to gain information from the facility directory, but information that can be shared is very limited. <u>45 C.F.R. § 164.510</u>. For more information on what information can be disclosed from the facility directory see question: "*Can a hospital or health care provider inform visitors or callers about a patient's location in the facility and general condition?*"

What obligation does a provider have to notify a patient of an unauthorized use, disclosure, or access of medical information of a Vermont patient?

Vermont and Federal law require providers to notify a patient of unauthorized use, disclosure, or access of protected health and consumer information. For breaches of health data, the HIPAA Privacy and Security Rule has specific requirements for how patients must be notified; for breaches of consumer data, Vermont law requires consumer notification. In some circumstances, the notice required by the HIPAA Privacy and Security Rule will satisfy state requirements, but in the event of a data breach we recommend consulting with outside counsel and/or your cybersecurity insurance provider.

Under the HIPAA Privacy and Security Rule, "breach" means the acquisition, access, use, or disclosure of protected health information in a manner not permitted by the HIPAA Privacy and Security Rule, which compromises the security or privacy of the protected health information. <u>45</u> <u>C.F.R. § 164.402</u>. A breach does not include limited disclosures to and access by workforce members or other individuals authorized to access protected health information under the authority of the provider or through a business associate agreement.

Providers are required to notify a patient whose protected health information has been or is reasonably believed to have been breached without unreasonable delay and no later than 60 days after the discovery of the breach. <u>45 C.F.R. § 164.404</u>. The content and methodology for a notification of a breach are set forth in federal regulations. If the breach of unsecured protected health information involves 500 patients or more, a provider must notify media outlets as well as the individual patients. <u>45 C.F.R. § 164.406</u>. Providers are required to keep a log of any breaches involving fewer than 500 patients and provide the log to the U.S. Department of Health and Human Services not later than 60 days after the end of each calendar year. <u>45 C.F.R. § 164.408</u>.

Providers who comply with the HIPAA Privacy, Security, and Breach Notification rules do not have additional reporting requirements under Vermont law regarding a breach of protected health information. Under Vermont law, meeting the requirements of the HIPAA Breach Notification rule is sufficient. However, providers are required to report data breaches involving personally identifiable information that is not considered protected health information—see list below. <u>9</u> V.S.A. § 2435(e).

What obligation does a provider have to notify a patient of an unauthorized use, disclosure, or access of non-medical personally identifiable information of a Vermont patient?

Under Vermont's Security Breach Notice Act (amended July 1, 2020), a security breach of personally identifiable information must be reported to the Vermont Attorney General within 14 days of discovery, which may be preliminary and is kept confidential by the State. The Security Breach Notice Act defines a "security breach" as the "unauthorized acquisition or a reasonable belief of an unauthorized acquisition of electronic data that compromises the security, confidentiality, or integrity of the personal information maintained by the [provider]". Consumer notification must be sent as soon as possible, and no later than 45 days after discovery or notice of the breach. 9 V.S.A. § 2435.

For the purposes of this statute, "personally identifiable information" includes a consumer's first name or first initial and last name with any of the following data elements:

- Social Security number;
- a drivers license or nondriver State identification card number, individual taxpayer identification number, passport number, military identification card number, or other identification number that originates from a government identification document that is commonly used to verify identity for a commercial transaction;
- a financial account number or credit or debit card number, if the number could be used without additional identifying information, access codes, or passwords;
- a password, personal identification number, or other access code for a financial account;
- unique biometric data generated from measurements or technical analysis of human body characteristics used by the owner or licensee of the data to identify or authenticate the consumer, such as a fingerprint, retina or iris image, or other unique physical representation or digital representation of biometric data;
- genetic information; and
- health records or records of a wellness program or similar program of health promotion or disease prevention;
 - o a health care professional's medical diagnosis or treatment of the consumer; or
 - a health insurance policy number.

For more information and guidance on the Vermont Security Breach Notice Act, visit the Vermont Attorney General's informative site here: <u>https://ago.vermont.gov/privacy-data-security/</u> (last accessed August 17, 2021).

What liability or penalties could be imposed on a provider who wrongfully discloses the medical information of a Vermont patient?

Under the HIPAA Privacy and Security Rules, a civil penalty may be imposed by the U.S. Department of Health and Human Services Office of Civil Rights (OCR) ranging from \$100 to a

maximum of \$1,500,000. <u>45 C.F.R. § 160.404</u>. The Vermont Attorney General's office, along with all states attorney generals, is authorized to enforce the HIPAA Privacy and Security Rules through injunction or civil penalties ranging from \$100 up to a maximum of \$25,000 per calendar year. <u>42</u> <u>U.S.C. § 1320d-5(d)</u>. Criminal penalties for certain egregious wrongful disclosures may be pursued by the U.S. Department of Justice, as well. <u>42 U.S.C. § 1320d</u>-6.

There is no Vermont-specific penalty for the wrongful release of confidential medical information. However, Vermont law does prohibit the disclosure of protected health information in violation of the HIPAA Privacy and Security Rules. 18 V.S.A. § 1881. Additionally, there is a \$2,000 fine or up to one year of imprisonment or both for the wrongful disclosure of information related to treatment or hospitalization for mental illness. <u>18 V.S.A. § 7103(c)</u>.

Although in other states a person harmed by a wrongful disclosure of medical information may have a cause of action for invasion of privacy, defamation or breach of contract or fiduciary trust, Vermont law has long been silent on any remedy until the 2019 case, *Lawson v. Halpern-Reiss and Central Vermont Medical Center.* In *Lawson,* the Vermont Supreme Court determined that while Vermont patient privacy law (<u>18 V.S.A. § 1881</u>) does not expressly provide a private right of action, that does not preclude an individual from seeking a civil right of action for negligent or wrongful disclosure of patient medical records by a health care provider. Essentially, *Lawson* allows patients to sue a provider for unlawful disclosure of their protected health information based on a breach of the duty of confidentiality. *Lawson v. Halpern-Reiss,* 210 Vt. 224 (2019).

Procedural Issues

What are health care providers allowed to charge patients or others, such as lawyers and insurance companies, for providing copies of a patient's health care record?

A provider may charge fees for paper copies of a patient's health care record or electronic copies that require manual effort such as collating or assembling records from multiple systems.

Where fees are permitted for copies of health care records, a provider may charge a reasonable, cost-based fee, not to exceed a \$5.00 flat fee or \$.50 per page, whichever is greater. <u>18 V.S.A.</u> <u>§ 9419</u> and <u>45 C.F.R. § 164.524</u>(c)(4). The fees may only include costs for the following:

- Labor for copying the protected health information requested by the individual, whether in paper or electronic form;
- Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;
- Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
- Preparing an explanation or summary of the protected health information requested (if the patient agrees to receive the summary in lieu of providing access to the full record and to pay for the costs of preparing the summary).

45 C.F.R. § 164.524(c)(4).

Practitioners and health care facilities are required to provide an itemized bill to the recipient of the records copied. <u>18 V.S.A. § 9419</u>.

Vermont law prohibits any charge for copies of records needed to support a claim or an appeal for public benefits such as welfare, Social Security, Medicare or Medicaid. <u>18 V.S.A. § 9419</u>. The HIPAA Privacy and Security Rules do not override this provision.

Under the Information Blocking Rules, a provider may not charge any fees that are based in any part on the electronic access to an individual's electronic health information ("EHI") by the individual, their personal representative, or another person or entity designated by the individual. The Information Blocking Rules define "electronic access" as "an internet-based method that makes EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request". <u>45 C.F.R. § 171.302.</u>

For requestors other than an individual or personal representative, the provider may—but is not required to—impose a fee on the access, exchange or use of EHI, so long as the fee is based on the following:

- Objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests;
- Reasonably related to provider's costs of providing the type of access, exchange or use of EHI to, or at the request of, the person or entity to whom the fee is charged;
- Reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and
- Costs not otherwise recovered for the same instance of service to a provider and third party.

Any fees charged must **not** be based on any of the following (if applicable):

- Whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with provider;
- Sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange or use of the EHI;
- Costs provider incurred due to the health IT being designed or implemented in a nonstandard way, unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange or use the EHI;
- Costs associated with intangible assets other than the actual development or acquisition costs of such assets;
- Opportunity costs unrelated to the access, exchange or use of EHI;
- Any costs that led to the creation of intellectual property, if provider charged a royalty for that intellectual property under the Licensing Safe Harbor and that royalty included the development costs for the creation of the intellectual property; or
- Fees to perform an export of EHI via certified health IT for the purposes of switching health IT or to provide patients their EHI, or a fee to export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.

What is the difference between the federal regulation and state law on medical record copy charges?

Both Vermont law and the HIPAA Privacy and Security Rules address the amount that may be charged for providing copies of a patient's health care record. The two provisions provide as follows:

• Vermont law permits a health care provider or custodian of health records to charge a fee that is no more than a flat \$5.00 fee or \$0.50 per page, whichever is greater. No charges

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may be imposed when the records are requested to support a claim or an appeal for public benefits, such as welfare, Social Security, Medicare or Medicaid. <u>18 V.S.A. § 9419</u>.

- The federal HIPAA Privacy and Security Rules permit health care providers to charge a reasonable, cost-based fee for copying a patient's medical records, based only on the cost of labor, supplies, postage and, where applicable, the drafting of an explanation or summary of the protected health information. <u>45 C.F.R. § 164.524(c)(4)</u>.
- The federal Information Blocking Rules prohibit a provider from charging any fees that are based in any part on the electronic access of an individual's electronic health information ("EHI") by the individual, their personal representative, or another person or entity designated by the individual. <u>45 C.F.R. § 171.302.</u>

A health care provider must follow the provision above that results in the lower copying fee, if any. For example, if your office's reasonable cost-based fee of copying the records is less than the Vermont allowance of \$.50 per page or \$5.00 fee, you must charge the reasonable cost-based fee for the copies, unless it is to support a public benefits claim or appeal in which case no copy charge may be imposed. On the other hand, if the actual cost of providing copies exceeds the amount permitted by Vermont law, you are capped by the Vermont statutory allowance and can charge no more than \$.50 per page or a \$5.00 fee.

A provider is permitted to charge for the preparation of an explanation or summary of a record, in lieu of the full record, if the recipient has agreed in advance to receive an explanation or summary and if they have agreed in advance to the fees. <u>45 C.F.R. § 164.524(c)(2)(iii)</u>. A provider may also charge a fee for mailing, if the patient agrees in advance. <u>45 C.F.R. § 164.524(c)(4)</u>. A provider should document in the patient's record whether they have requested that the record be mailed to them or have agreed to have the record summarized.

What am I allowed to charge patients for providing copies of images?

Consistent with the HIPAA Privacy and Security Rules, Vermont law allows health care provider offices to charge a cost-based fee for providing copies of x-rays, films, models, disks, tapes or health information maintained in other formats. <u>18 V.S.A. § 9419</u>. However, under Information Blocking Rules, no fee may be charged if images are available through electronic access (e.g., patient portal) that makes EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request. 45 C.F.R. § 171.302.

How long must a provider retain medical records?

Hospitals are required to retain medical records for a minimum of ten (10) years as part of their state licensure obligations. <u>18 V.S.A. § 1905</u>(8). Vermont law does not specify how long other providers should retain medical records. Based on the statutes of limitation for certain causes of action under Vermont and federal law, all health care providers are advised to retain medical records for at least ten (10) years after the patient was last treated by the provider.

Here is a list of relevant statutes of limitations that might impact medical record retention time:

- The Vermont statute of limitations on medical malpractice actions:
 - Allows a cause of action to be brought within three (3) years of the date of the incident, or two (2) years of the discovery of the injury, but not later than seven (7) years from the date of the incident. <u>12 V.S.A. § 521</u>.

- Where fraudulent concealment has prevented the patient from discovering the injury, there is no time limit on when the patient can commence an action against the provider.
- Where the action is based on the discovery of a foreign object in the patient's body, discovered later than seven (7) years after the incident, the patient may commence an action within two (2) years of the discovery of the object.
- Actions against health care providers brought under the federal or state False Claims Acts have a six-year statute of limitation, or up to ten (10) years if the facts could not be reasonably discovered. <u>31 U.S.C. § 3731</u>; <u>32 V.S.A. § 639</u>.

Children's records should be retained until at least three (3) years following their eighteenth (18th) birthday because the statute of limitations for a minor to sue for a cause of action does not begin until the minor reaches the age of majority. <u>12 V.S.A. § 551(a)</u>.

Hospitals and other health care providers should establish medical record retention and disposal policies and procedures and manage all medical records accordingly.

What period of time is recommended for retaining the records of a deceased patient?

As a general rule, it is recommended that a provider retain records of deceased patients for no less than three (3) years after the patient's death or ten (10) years after care was provided, whichever is longer. The wrongful death statute requires court actions to be commenced two (2) years from the discovery of the death unless the death was deemed murder, in which case the cause of action must be commenced within seven (7) years of the discovery of the death. 14 V.S.A. § 1492. The survival of actions law permits court actions to be commenced two (2) years after the date of issuance of letters testamentary or administration (i.e., if a person, by or against whom an action may be brought, dies before such action may be commenced) by the probate court. 12 V.S.A. § 557(a). Letters testamentary or administration can be issued some time after the death. Physicians should check with the court with respect to the timing of the issuance of letters testamentary.

Pharmacists and Prescription Records

Are prescription records given the same confidentiality protection as other medical records?

Under the federal HIPAA Privacy and Security Rules, prescription records are treated the same as other health records and are subject to the same confidentiality provisions. Vermont law allows inspection of prescriptions, orders and prescription records only by federal or state officers or their specifically authorized agent whose duty it is to enforce the federal and state drug laws, or to the authorized agents of professional licensing boards or the Board of Medical Practice. <u>18 V.S.A. §§</u> <u>4211</u> and <u>4218</u>.

The law also specifies that no privilege of confidentiality shall apply to information communicated to a physician in an effort to unlawfully procure a regulated drug or the administration of any such drug. <u>18 V.S.A. § 4223(b)</u>. Such unlawful means include fraud, deceit, misrepresentation, subterfuge, forgery, concealment, or other unlawful or deceitful means. <u>18 V.S.A. § 4223(a)</u>. Examples of such unlawful behavior may include failing to disclose that the patient is receiving regulated drugs from another prescriber, pretending to be an established patient of another

physician to a covering physician, altering a prescription for 10 pills to be a prescription for 100 by adding a zero, or a patient saying they are taking a drug when a screen shows they are not.

When are pharmacists and providers required to <u>report</u> prescription records regarding dispensing of Schedule II, III and IV controlled substances?

Pharmacies and prescribers (licensed health care professionals licensed to prescribe controlled substances) that dispense Schedules II, III or IV controlled substances ("Controlled Substances") to their patients are required to report to the Vermont Prescription Monitoring System ("VPMS") each dispensed prescription for a Controlled Substance within twenty-four (24) hours or one (1) business day of dispensing the prescription. Pharmacies and prescribers that dispense Controlled Substances must submit a "zero controlled substances report" on any day that no controlled substances are dispensed. See <u>Vermont Prescription Monitoring System Rule</u> 4.0.

Reports to the VPMS must include information related to the patient, prescription, dispenser and prescriber. See <u>Vermont Prescription Monitoring System Rule</u> 4.2.

Each pharmacy shall provide to every customer to whom a controlled substance is dispensed an advisory notice informing the customer that all prescriptions for Controlled Substances are entered into a statewide VPMS database in order to protect patients and the public. The notice, available on the <u>Department of Health's website</u>, must either be posted by the pharmacy in a prominent manner readily accessible to customers or duplicated in its entirety on a written insert for delivery to the patient. See <u>Vermont Prescription Monitoring System Rule</u> 4.3.

Reporting to VPMS is not required when a drug is administered directly to a patient or dispensed by a health care provider at a facility licensed by the Department of Health, provided that the quantity dispensed at the facility is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours. A pharmacy that does not stock or dispense Controlled Substances may request an exemption from reporting from the VPMS program office. The exemption shall terminate when the pharmacy dispenses any controlled substance. See <u>Vermont Prescription Monitoring System Rule</u> 5.0.

When are pharmacists and providers required to <u>access</u> prescription records of other providers regarding dispensing of Schedule II, III and IV controlled substances?

Prescribers and pharmacists registered with the VPMS are permitted to access the prescription records in the VPMS when the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient. <u>18 V.S.A. § 4284(b)(1)</u>.

Pharmacists and prescribers are required to query the VPMS in several circumstances, with the exception of hospital-based dispensers using controlled substances to treat a patient for fewer than forty-eight (48) hours.

Prescribers must query the VPMS in the following circumstances (See <u>Vermont Prescription</u> <u>Monitoring System Rule</u> 6.2 and <u>18 V.S.A. § 4289</u>):

• The first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat pain when such a prescription exceeds ten (10) pills or the equivalent;

- When starting a patient on a Schedule II, III, or IV controlled substance for nonpalliative long-term pain therapy of ninety (90) days or more;
- Prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance;
- At least annually for patients who are receiving ongoing treatment (treatment without meaningful interruption) with an opioid Schedule II, III, or IV controlled substance;
- The first time a provider prescribes a benzodiazepine;
- When a patient requests an opioid prescription or a renewal of an existing prescription for pain from an Emergency Department or Urgent Care prescriber if the prescriber intends to write a prescription for an opioid;
- Except for prescriptions written from an Opioid Treatment Program ("OTP"), prior to prescribing buprenorphine or a drug containing buprenorphine to a Vermont patient for the first time and:
 - At regular intervals thereafter, but no less than twice annually;
 - No fewer than two (2) times annually thereafter; and
 - Prior to writing a replacement prescription;
- In the case of prescriptions written from an Opioid Treatment Program, prior to prescribing buprenorphine or a drug containing buprenorphine to a Vermont patient for the first time, and:
 - o Annually thereafter; and
 - Any other time that is clinically warranted.
- Prior to prescribing buprenorphine or a drug containing buprenorphine that exceeds the dosage threshold approved by the Vermont Medicaid Drug Utilization Review Board and published in its Preferred Drug List, prescribers must receive prior approval from the Chief Medical Officer or Medical Director of the Department of Vermont Health Access or designee.
- Prior to the first prescription of an extended release hydrocodone or oxycodone that is not an abuse deterrent opioid for the first time:
 - During the initial query, the prescriber must conduct a review of the other controlled substances prescribed to the patient prior to the first prescription of an extended release hydrocodone or oxycodone that is not an abuse deterrent opioid;
 - a query no less frequently than once every one hundred twenty (120) days for any patient prescribed forty (40) mg or greater of hydrocodone or thirty (30) mg or greater of oxycodone per day of an extended release hydrocodone or oxycodone that is not an abuse deterrent opioid; and
 - A query no less frequently than described in the Vermont Prescription Monitoring System Rule.
 - See <u>Rule Governing the Prescribing of Opioids for Pain</u>, Rule 8.1.7.

All dispensers (with the exception of hospital-based dispensers dispensing a quantity of a Schedule II, III, or IV opioid controlled substance that is sufficient to treat a patient for fewer than forty-eight (48) hours) will also be required to query the VPMS in the following circumstances (See <u>Vermont Prescription Monitoring System Rule</u> 5.2 and <u>18 V.S.A. § 4289</u>):

- Prior to dispensing a prescription for a Schedule II, III, or IV opioid controlled substance to a patient who is new to the pharmacy;
- When an individual pays cash for a prescription for a Schedule II, III, or IV opioid controlled substance and the individual has prescription drug coverage on file;

- When a patient requests a refill of a prescription for a Schedule II, III, or IV opioid controlled substance substantially in advance of when a refill would ordinarily be due; and
- When the dispenser is aware that the patient is being prescribed Schedule II, III, or IV opioid controlled substances by more than one prescriber.

Substance Use Disorder Diagnosis and Treatment Records

What rules apply to the confidentiality of substance use disorder treatment records?

Federal law affords separate protections for the confidentiality of patient information relating to substance use disorders maintained by a "Part 2 Program." 42 U.S.C. § 290dd-2 and <u>42 CFR Part</u> <u>2</u>. A Part 2 Program is defined in the regulation as independent entities or individuals, or staff or subunits within a general medical facility that (a) receive federal assistance, (b) hold themselves out as providing diagnosis, treatment or referral for treatment for a substance use disorder, and (c) actually provide such services. <u>42 C.F.R. § 2.11</u>.

The Part 2 rules prohibit, absent written patient consent, a Part 2 Program or other lawful holder of Part 2 patient information (e.g., payers, health information exchanges) from disclosing any information that would identify a patient as having or having had a substance use disorder, either directly, by reference to publicly available information, or through verification of such identification by another person. <u>42 C.F.R. § 2.12(a)(1)(i)</u>. The rules also prohibit recipients of Part 2 information from re-disclosing Part 2 information absent a patient's express, written consent for such a re-disclosure.

What is needed to support a disclosure of substance use disorder treatment records?

Before a Part 2 Program or lawful holder of Part 2 information discloses any Part 2 information, the federal rules require the execution of a specific consent or authorization form (distinct from the form required by the HIPAA Privacy and Security Rules) by a patient or, if the patient lacks capacity to provide informed consent, from the patient's legal representative. The patient's written consent may be paper or electronic and must include the following information:

- The name of the patient;
- The specific name(s) or general designation(s) of the program(s), entity(ies), or individual(s) permitted to make the disclosure;
- The purpose of the disclosure;
- How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed;
 - The Part 2 Program may provide options on the form by including free text space or choices based on generally accepted architecture or document requirements, such as diagnostic information, medications and dosages, lab tests, allergies, substance use history summaries, trauma history summary, elements of a medical record such as clinical notes and discharge summary, employment information, living situation and social supports and claims/encounters data. It is also permissible to include "all my substance use disorder information" as long as more granular options are also included on the form.
- The name of the individual(s) or entity(ies) to whom a disclosure is to be made (see additional information below regarding disclosure to an entity without a treatment relationship with the patient). Multiple individuals or entities may be named on one form;

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- The purpose of the disclosure;
- A statement that the consent is subject to revocation at any time except to the extent that the Part 2 Program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it;
- The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given;
- The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign in lieu of the patient. Electronic signatures are permitted to the extent they are not prohibited by any applicable law;
- The date on which the consent is signed; and
- The following written statements:
 - "This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided in Sections 2.12(c)(5) and 2.65 of 42 CFR part 2."
 - "If you have consented to the disclosure of your Part 2 Information to an entity with whom you do not have a current treatment relationship and you have not named an individual or a treating entity within that entity to receive your information, you are entitled to a list of entities to whom your information has been disclosed."

45 C.F.R. §§ <u>2.31-2.32</u>.

If the patient consents to the disclosure of Part 2 information to an entity with whom the patient does *not* have a treatment relationship other than a third-party payer (e.g., VHIE or a research institution), the consent form must include the name of the entity and:

- The name of an individual participant in the entity (e.g., Jane Doe, MD or John Doe);
- The name of entity participants with whom the patient has a treating provider relationship (e.g., Lakeview County Hospital); or
- A general designation of individual or entity participant(s) or a class of participants who have a treatment relationship with the patient (e.g., my current and future treating providers).

The written consent from the patient only permits the disclosure of the substance use disorder records to the specified individual or entity, and only for the purposes specified on the form. Only information that is necessary to carry out the specified purpose may be disclosed. Health care providers who receive Part 2 Information from a Part 2 Program or other lawful holder and who are notified of the prohibition on re-disclosure of the Part 2 information may not further disclose or re-release the information absent the patient's express, written consent. <u>42 C.F.R. §2.32</u>.

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In 2021, the Department of Health and Human Services ("DHHS"), Office of Civil Rights ("OCR") released a notice of proposed rulemaking introducing proposed updates to HIPAA and shortly after, the DHHS, Substance Abuse and Mental Health Services Administration ("SAMHSA") announced that they would be working with OCR to update Part 2 to more closely align with HIPAA requirements. As this is an area of evolving law, it is advisable to seek out the most up-to-date legal and medical resources.

Mental Health Treatment Records

What additional protection is given to mental health treatment records in Vermont?

Information and records pertaining to the treatment of mental illness and developmental disability or to involuntary hospitalization must be kept confidential, including information which directly or indirectly identifies the patient, unless either one of a very limited list of exceptions applies (e.g., the mental health provider has a duty to warn or is required to file a report with the National Instant Criminal Background Check System), the patient or legal guardian consents in writing to the disclosure, or a court orders the disclosure. <u>18 V.S.A. § 7103</u> (a).

Under the HIPAA Privacy and Security Rules, psychotherapy notes require specific authorization from an individual in order to be disclosed except when disclosure is required by law or when disclosure is to a person reasonably able to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. $45 \text{ C.F.R.} \\ 164.512(j)(1)(i)$. Psychotherapy notes refer to notes recorded by a mental health professional and documenting or analyzing a conversation during a private, group, joint, or family counseling session and are kept separate from the rest of an individual health record. $45 \text{ C.F.R.} \\ \frac{164.501}{64.501} \\ \frac{164.508}{60}(a)(2)$. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. $45 \text{ C.F.R.} \\ \frac{164.501}{64.501}$.

When must a mental health professional disclose confidential patient information to warn about a patient who may present a serious risk of harm?

When a mental health professional knows or, based on the standards of the mental health profession, should know that a patient poses a serious risk of danger to an identifiable individual, the professional has a duty to exercise reasonable care to protect the identifiable victim from that danger even if it requires the disclosure of confidential patient information. <u>18 V.S.A. § 1882</u>. (A "mental health professional" is defined under state law as physicians, psychologists, social workers, mental health counselors, nurses, and other qualified persons so designated by the Commissioner of Mental Health "with professional training, experience, and demonstrated competence in the treatment of mental illness…" <u>18 V.S.A. § 7101(13)</u>.) This "duty to warn", which has evolved in case law in Vermont and other states, is an exception to the patient privilege of confidentiality.

The duty to warn exception originated in California with the case of *Tarasoff v. Regents of the University of California*, 551 P.2d 334 (1976). In *Tarasoff*, a university hospital psychologist was told by his patient that the patient intended to kill a woman, Tatiana Tarasoff. Two months later, he did so. The Supreme Court of California ruled that the "public policy favoring protection of

patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert danger to others." 551 P.2d at 347.

In *Peck v. Counseling Service of Addison County*, the Vermont Supreme Court adopted the *Tarasoff* ruling in a situation where a patient receiving mental health services threatened to burn his father's barn down. 146 Vt. 61 (1985). The Court held that if a mental health professional knows or should know that their patient poses a serious risk of danger to an identified person, the professional has a duty to take whatever steps are reasonably necessary to protect the identifiable victim from that danger, which could include reporting confidential patient information. The mental health professional has a duty to exercise due care in determining what steps may be necessary to protect the identifiable victim of a patient's threat of harm and what confidential information must be disclosed. *Id.* at 68. Mental health professional must report confidential information discretely, and in a fashion that would preserve the privacy of the patient to the fullest extent compatible with the prevention of the threatened danger, ensuring that only that information which is necessary to protect the potential victim is revealed. *Peck*, 146 Vt. at 67-68, *citing Tarasoff*, 7 Cal.3d at 441. The Vermont legislature has adopted the mental health professional's duty to warn as described in *Peck*. <u>18 V.S.A. § 1882</u>.

Although to date the Vermont courts have not had occasion to extend the duty to warn beyond mental health professionals, other states have done so when a patient is incapacitated as a result of medical treatment or disease and the person poses an obvious risk of serious harm to others (e.g., the patient is taking medication that makes him/her drowsy and, consequently, poses a danger to other drivers). In these situations, a health care provider may have a duty to warn reasonably identifiable potential victims or a duty to take action to avoid the harm.

In almost all instances, consultation with a colleague is advised to determine the most appropriate course of action given the conflicting duties imposed on the mental health professional.

How does the duty to warn relate to HIPAA Privacy and Security Rule requirements?

The HIPAA Privacy and Security Rules do not create a duty to warn or mandate disclosure. Rather, under the HIPAA Privacy and Security Rules, a covered entity is permitted to use and disclose protected health information – including psychotherapy notes – if the covered entity believes, in good faith, that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and the disclosure is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat. <u>45 C.F.R.</u> § <u>164.512(j)</u>. A covered entity may also disclose protected health if the covered entity believes, in good faith, that the use or disclosure is necessary for law enforcement to identify or apprehend an individual because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim, or where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody. <u>45 C.F.R.</u> § <u>164.512</u>.

In the above situations, medical records and psychotherapy notes may be disclosed without authorization or consent of the patient. The disclosure must be made to a person or persons reasonably able to prevent or lessen the threat or to the target of the threat. The disclosure must be limited to the minimum amount of information necessary to prevent the harm from occurring.

LAW ENFORCEMENT

Patient Consent

Must a patient provide informed consent for non-medical purposes such as a blood draw for a law enforcement purpose?

A patient's broad consent for medical treatment is distinct from consent for a blood draw for *non-medical, law enforcement* purposes. A health care provider may be liable for failure to obtain informed consent if they draw blood for law enforcement purposes from a conscious patient who has refused requests from law enforcement to submit to a blood alcohol test. This is the case even if the health care provider is acting in reliance on an order from law enforcement. The health care provider would not be subject to liability for battery, however, if law enforcement provided a warrant for the blood draw. *See O'Brien v. Synnott*, 193 Vt. 546, 553 (2013).

Of note is that many states place restrictions on when a law enforcement officer may obtain a blood sample from a patient without that patient's consent, even with a warrant. *See Commonwealth v. Bohigian*, 486 Mass. 209 (2020) (holding that Massachusetts statutes make it clear that blood alcohol level testing shall not be done absent consent); *see also McNeely v. Missouri*, 569 U.S. 141 (2013) ("a majority of States either place significant restrictions on when police officers may obtain a blood sample despite a suspect's refusal ... or prohibit nonconsensual blood tests altogether").

Patient Privacy and Medical Records

If there is no signed patient authorization, may a health care or mental health provider in Vermont release medical records or disclose medical information in response to court ordered warrants or summonses?

Providers shall release PHI and other listed information or items in response to a warrant or summons issued or ordered by a court or a summons issued by a judicial officer (judge, administrative judge, magistrate). The provider may disclose only that information specifically described in the warrant or summons. 45 C.F.R. \$ 164.512(f).

If there is no signed patient authorization, may a health care or mental health provider in Vermont release medical records or disclose medical information in response to a court-issued subpoena?

Providers should establish procedures for aiding staff in determining whether a document labeled "subpoena," "warrant" or "summons" has been issued by a court or, instead, a judicial officer.

Providers shall not release PHI in response to a subpoena unless there is a court order or an express provision of law. However, a subpoena should never be ignored because failing to respond in some manner may result in contempt of court. The provider should respond stating that under the HIPAA Privacy and Security Rules and Vermont's patient privilege law, patient authorization or a court order is needed for release of the requested PHI. <u>45 C.F.R. § 164.512(f)</u>.

If there is no signed patient authorization, may a health care or mental health provider in Vermont release medical records or disclose medical information in response to an inquest subpoena?

Providers shall release PHI in response to an inquest subpoena if a judge signs it. 45 C.F.R.\$ 164.512(f).

May a health care or mental health provider in Vermont release medical records or disclose medical information in response to a grand jury subpoena?

Providers shall disclose PHI in response to a subpoena issued by a grand jury. Only information specifically described in the subpoena may be disclosed. 45 C.F.R. \$ 164.512(f).

If there is no signed patient authorization, may a health care or mental health provider in Vermont release medical records or disclose medical information in response to an Administrative (Non-Judicial) Request, Administrative Subpoena, or Summons?

An administrative request, subpoena, or summons is one that is issued by a federal or state agency or law enforcement rather than a court of law (for example, a subpoena issued by the attorney general). If a provider receives an administrative request, subpoena, or summons, a civil or authorized investigative demand, or other similar process authorized by law, patient information shall be disclosed only if all of the following requirements are met:

- Relevance
 - The information requested must be relevant and material to a legitimate law enforcement inquiry.
- Specificity
 - The request must be specific and limited in scope to the extent possible in light of the law enforcement purpose for which the information is requested.
- Identifiable Information Necessary
 - De-identified information could not reasonably be used.

Providers may rely on statements in the administrative request, subpoena, or summons or other document in deciding that this test is satisfied. The provider should not release the information if the provider believes the three-part test is not met. 45 C.F.R. \$ 164.512(f)(1)(ii)(C).

What should a provider do if they are served a subpoena for medical records or to testify about medical information?

The following steps are recommended:

- Determine whether there is a proper legal basis for releasing the patient's records. For instance, a patient authorization may be attached to the subpoena. If so, the provider is authorized to release patient information in response to the subpoena.
- If no proper legal basis appears for releasing the records, contact the party issuing the subpoena to seek a voluntary resolution. Explain that the subpoenaed documents or information cannot be released without the patient's authorization and that none appears. Often, a subpoena will be withdrawn on this basis or authorization will be obtained. If the former occurs, document the withdrawal of the subpoena in writing by a follow-up letter.
- Under appropriate circumstances, it may be desirable to contact a patient in response to a subpoena to determine whether the patient will consent to the release of the requested documents or records.

- If the subpoena is not voluntarily withdrawn, and there remains no evident legal basis for releasing the records or information sought, determine whether the subpoena has been validly issued. Note that a subpoena issued by another state court is not valid in Vermont and requires no response. There may be other technical defects in the subpoena as well. (Check with your attorney.)
- If the subpoena is valid, a response must be made before the return date. Counsel should be contacted to make an appropriate response, either by written objection, a motion to quash, or by a motion for protective order.

Some special comments are in order regarding responding to investigative or criminal subpoenas issued by prosecutors and law enforcement agencies. Subpoenas in this context may be seeking information about a criminal defendant or suspect or about a victim (as in a rape case). Resistance from practitioners to release information may sometimes be interpreted by law enforcement agencies as lack of cooperation in criminal enforcement. These situations must be handled delicately and diplomatically, and may require meetings with local law enforcement agencies to explain the practitioner's obligations to protect patient records and communications. At a minimum, law enforcement officials could be asked to obtain a district court order in support of a criminal subpoena. Such an order would ensure that due consideration is accorded the confidentiality rights of the patient whose records are being sought.

What should a practitioner do if an officer has a search warrant for medical records?

The practitioner must comply with the warrant as a search warrant is a court order issued after prior judicial approval and a showing of probable cause. The practitioner should call legal counsel as soon as possible.

Search warrants have a distinctly different purpose than a subpoena. Search warrants are limited to criminal proceedings to obtain evidence against a defendant suspected of a criminal violation. The defendant may be a health care provider or facility or a patient. Because a search warrant is only issued after a showing of probable cause, they are executed immediately and there is no time between issuance and execution for the person subject to the warrant to challenge its legal validity. Therefore, challenges to search warrants are always made after the warrant has been issued and executed and prior to the introduction of the documents or objects in evidence.

A copy of the search warrant will be served on the person from whom or from whose premises the property was taken. In addition, the officer executing the warrant must provide a receipt for the property taken. The basic requirements for state search warrants are set forth in the <u>Vermont Rules</u> of Criminal Procedure, Rule 41 (V.R.Cr.P. Rule 41).

What can a practitioner share with law enforcement to report a crime?

A provider may report a death caused by criminal conduct. If the provider suspects that the death may have been caused by criminal conduct, the provider may disclose information about the individual who died to law enforcement.

If a provider believes in good faith that criminal conduct occurred on its premises, the provider may disclose to law enforcement information related to such suspected criminal conduct. $\underline{45}$ C.F.R. § 164.512(f)(5).

If the provider is providing emergency health care services at a location other than on the hospital's premises, the hospital may disclose information as necessary to alert enforcement to any or all of the following (45 C.F.R. \$ 164.512(f)(6)):

- The commission and nature of a crime;
- The location of such crime or of the victim(s) of such crime;
- The identity, description, and location of the perpetrator of such crime.

If the provider believes the crime is the result of abuse, neglect, or domestic violence, it is subject to other disclosure requirements under HIPAA and state laws.

The provider may disclose PHI to law enforcement authorities if the provider believes, in good faith, that the disclosure is necessary for identification or apprehension of an individual. The provider's good faith belief may be based on one of the following (See <u>45 C.F.R. § 164.512(j)</u>):

- If it appears from all circumstances that the individual escaped from a correctional institution or from lawful custody; or
- If an individual makes a statement, admitting participation in a violent crime that the provider reasonably believes may have caused serious physical harm to the victim. In this case, the provider may release only the individual's statement and those items of information that may be disclosed when assisting in the identification and location of a person, as discussed above.
- Providers may not disclose patient information to avert a serious threat to health or safety if the information was obtained in the course of treatment to affect the propensity to commit criminal conduct; in counseling or therapy; or through the individual's request for such treatment, counseling or therapy

What can a practitioner share with law enforcement to report a victim of a crime?

Hospitals may disclose information about a patient who may have been the victim of a crime, if the patient agrees to the disclosure. Such agreement may be oral, but must be documented. If the patient is incapacitated or some other emergency circumstance prevents the hospital from obtaining the individual's agreement, the hospital may disclose information to law enforcement only if all of the following requirements are met (See 45 C.F.R. § 164.512(f)(3)):

- Not to be Used Against Victim: Law enforcement represents that such information is needed to determine whether a violation of law by a person other than the victim occurred and such information is not intended to be used against the victim;
- Necessary for Immediate Enforcement Activity: Law enforcement represents that immediate law enforcement activity depends upon the disclosure of information and such law enforcement activity would be materially and adversely affected by waiting until the individual is able to agree to the release of information; and
- Best Interests of Individual: The provider, in their exercise of professional judgment, believes that the release of information to law enforcement is in the best interests of the individual.

What can a practitioner share with law enforcement to identify or locate a suspect, fugitive, material witness, or missing person?

At the request of law enforcement, a provider may release limited information for purposes of identification and location of a suspect, fugitive, material witness, or missing person (See 45 C.F.R. § 164.512(f)(2)):

- Name and address;
- Date and place of birth;
- Social security number;
- ABO blood type and rh factor;
- Type of injury;
- Date and time of treatment;
- Date and time of death, if applicable; and
- A description of any distinguishing physical characteristics (e.g., height, weight, gender, race, hair and eye color and presence or absence of facial hair, scars, and tattoos).

In responding to a request to help locate or identify a person, hospitals shall not disclose any information related to the individual's DNA, DNA analysis, dental records, or typing, samples, or analysis of body fluids or tissues. 45 C.F.R. & 164.512(f)(2).

What can a practitioner share with a correctional institution or law enforcement agency having lawful custody of an individual?

A provider can share PHI for an individual in custody if the institution or official represents that such information is necessary for any of the following (See 45 C.F.R. 164.512(k)(5)):

- The provision of health care to such individual;
- The health and safety of such individual, other inmates, officers, employees or others at the institution or involved in transport of the individual;
- Law enforcement purposes on the premises of the correctional institution; or
- The administration and maintenance of the safety, security, and good order of the correctional institution.

How should a provider respond if a law enforcement officer requests a patient's personal belongings without a search warrant?

Search warrants are not the only manner in which law enforcement may seize personal property belonging to a patient. They may also seize property under the "plain view" doctrine. Objects falling in the "plain view" of an officer are subject to seizure without a warrant, and providers should hand over the items requested.

MINORS

Minor Consent

What is the legal age of consent in Vermont?

Eighteen (18) is the legal age of consent in Vermont. Individuals under the age of eighteen are minors under Vermont law. <u>1 V.S.A. § 173</u>. With a few specific exceptions that are listed below and discussed in more detail throughout this section, generally a minor's parent or guardian must provide informed consent for the minor to undergo medical treatment or a procedure.

Who can give informed consent to health care for a minor?

Generally, only the following individuals may give informed consent to health care for a minor:

- A guardian or representative who has been appointed by a judge to make health care decisions for the minor;
- A parent (adopted or biological).

For inmates who are minors, the State (Commissioner of Corrections, officer, or designated employee) shall stand in the relationship of parent legal guardian of a minor needing medical assistance.

Can an emancipated minor give informed consent for their own health care?

Yes, minors who are married or have ever been married and minors on active U.S. military duty may give informed consent to their own health care. <u>12 V.S.A. § 7151</u> and <u>12 V.S.A. § 7156</u>. Minors emancipated by a court order may also give informed consent to their own health care. If a minor states that they are emancipated by court order and are thus authorized to provide informed consent for a medical procedure, the health care provider should obtain a copy of the court order regarding emancipation and retain the court order in the patient's medical record.

To become emancipated, a probate court must determine that a minor: (1) is at least sixteen (16) years of age; (2) has lived separate and apart from their parents, custodian, or legal guardians for at least three (3) months; (3) manages their own financial affairs; (4) demonstrates the ability to be self-sufficient in financial and personal affairs, including proof of employment or other means of support; (5) holds a high school diploma or its equivalent or is earning passing grades in an educational program approved by the court and directed toward the earning of a high school diploma or its equivalent; (6) is not under a legal guardianship or in the custody of the Commissioner for Children and Families; and (7) is not under the supervision or in the custody of the Commissioner of Corrections. <u>12 V.S.A. § 7151</u>(b).

Are there any special situations where an unemancipated minor may give informed consent to their own health care?

Yes, minors may give informed consent to their own health care under the following circumstances:

- An individual of any age may be treated without informed consent in an emergency, <u>12</u> <u>V.S.A. § 1909</u> (b);
- Minors of any age may give informed consent to:
 - Medical treatment associated with rape, incest, or sexual abuse. Health care providers are required to report such incidents to the Department of Children and Families ("DCF") within 24 hours, <u>33 V.S.A. § 4911</u> et seq.;
 - Outpatient mental health treatment including psychotherapy and counseling services, but not prescription drugs. <u>18 V.S.A. § 8350</u>;
 - Reproductive care including: contraceptive devices, termination of pregnancy, prenatal, delivery and other pregnancy care. <u>18 V.S.A. § 9493</u>.
- Minors who are twelve (12) years or older may give informed consent to testing and treatment for sexually transmitted diseases including HIV and AIDS, substance use, or substance use disorder. <u>18 V.S.A. § 4226(a)</u>. But if a minor requires immediate

hospitalization for treatment of any of these conditions, the parents shall be notified of the hospitalization. <u>18 V.S.A. § 4226(b)</u>.

- Minors who are fourteen (14) years or older may also apply for voluntary admission to a designated hospital for mental health related evaluation and treatment. Informed consent must be in writing and must include a representation that the person (a) understands that treatment will involve inpatient status, (b) that they desire to be admitted to the hospital, and (c) they consent to voluntary admission without coercion or duress. Minors under 14 may admit themselves to a hospital for mental health related treatment by providing their own written informed consent and a written application from a parent or guardian. <u>18</u> <u>V.S.A. § 7503</u>.
- Minors sixteen (16) or older may consent to donate blood to a voluntary blood donation program where no compensation is received. <u>18 V.S.A. § 9</u>.

What disclosures must be made to the parent or guardian of an unemancipated minor when they provide consent for a minor to receive a vaccination?

Informed consent from a parent or guardian should be obtained prior to administering a vaccine to a minor. If present, the parent or guardian must be provided the Vaccination Information Sheet ("VIS"); if not present, the VIS must be provided to the parent or guardian in advance of the minor's vaccination. Per the federal <u>National Childhood Vaccine Injury Act</u> ("NCVIA"), if the parent or legal representative is *not* present at the time of the vaccination (e.g., the minor has driven to the appointment independently), the provider must provide the parent or legal representative with a VIS prior to vaccination (i.e., before the minor arrives to receive the vaccination) and the VIS must be coupled with a method to acknowledge receipt and review of the VIS (e.g., adding a written statement that the parent or legal representative received and reviewed the current edition of the VIS, with the edition date specified, on the medical consent form authorizing vaccination).

Health care providers must give the parents or legal representatives of a child a separate VIS prior to administering *every dose* of the vaccine. <u>42 U.S.C. § 300aa-26</u>(d) (Emphasis added); *see also* Centers for Disease Control and Prevention ("CDC"), *Vaccine Information Statements: Frequently Asked Questions*, <u>https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html</u> (last visited August 14, 2021) and *CDC*, *Facts about VISs*, https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html (last visited August 16, 2021).

Must a parent give informed consent for an unemancipated minor to receive the COVID-19 vaccine in a public health emergency?

The COVID-19 global pandemic and subsequent authorization of COVID-19 vaccines for adolescents raise the question of whether an unemancipated minor should be able to consent to vaccination during a federal or state public health emergency. Vermont still requires parent consent for a minor to get the COVID-19 vaccine, but some jurisdictions outside of Vermont imposed emergency provisions allowing a minor to consent to the vaccine without parent permission. As this is an area of evolving law, it is advisable to seek out the most up-to-date legal and medical resources.

Must a parent or guardian provide informed consent for an unemancipated minor to receive the HPV vaccination?

Informed consent from a parent or guardian should be obtained before administering an HPV vaccine to a minor. Although HPV is a sexually transmitted disease ("STD"), it is unclear whether the vaccine for HPV is considered a "treatment" for an STD. Thus, it is unlikely that the HPV vaccine falls within the Vermont statutory exception permitting minors 12 years or older to give informed consent to treatment for STDs. *See "Are there any special situations where an unemancipated minor may give informed consent to their own health care?*", above, and <u>18</u> V.S.A. § 4226. Further, in addition to obtaining informed consent from a parent or legal guardian for the vaccination, health care providers must give the parents or legal representatives of a child a separate VIS prior to administering *every dose* of the HPV vaccine.

Who can give informed consent to health care when the minor's parents are divorced?

In general, both parents can make health care decisions for the child. If the parents are divorced, the informed consent of either parent may be assumed to be sufficient. That said, every divorce decree is different and there are situations where a judge has entered an order in which one or both of the parents is no longer authorized to make health care decisions for their child. In those situations, health care professionals are obligated to follow the judge's order. If one parent claims that they have exclusive control of medical decision-making, that parent should be asked to present relevant family court documents.

Can a parent or guardian delegate authority for giving informed consent to medical treatment for a minor?

Vermont law is silent on this question. It is reasonable to assume that where the parent(s) or guardian(s) will not be reasonably available to give informed consent to medical treatment (e.g., vacations, illness, etc.), they may delegate this authority to a selected adult. Because there are no clear guidelines for determining the legality of an apparent delegation of this parental authority, providers should make reasonable efforts to obtain parental informed consent and should use their professional judgment and exercise greater caution in providing services involving any increased risk. If the office has a written consent on file that has been signed by the parent authorizing the health care provider and their staff to provide medical care to the minor, there is little or no risk in providing the minor with routine medical care. In situations where the treatment is non-routine or poses some degree of risk to the minor, it is always advisable to consult with the parent before proceeding. Asking parents ahead of time to document authorization for medical treatment in their absence is recommended.

When faced with a situation where the minor has been brought to the office by a grandparent or adult sibling, should a provider refuse treatment until informed consent from the parent or guardian has been obtained?

No. As long as the health care provider has exercised due care and made a good faith determination that the grandparent or adult sibling has been authorized by the child's parent or guardian to act as the agent in obtaining medical care for the minor, liability is unlikely if the parent later claims that the grandparent or sibling lacked authorization. That said, if the medical care will involve anything more than routine, low-risk procedures, the health care provider should make every effort to obtain the parent's specific informed consent before providing this type of care. Health care providers are expected to use good judgment in determining which procedures require specific parental informed consent.

Vermont Guide to Health Care Law

Is parental informed consent required before a minor can terminate a pregnancy?

Vermont state law recognizes the fundamental right of every individual to choose to continue a pregnancy or have an abortion and thereby permits unemancipated minors to give informed consent to abortions and related medical treatment. In determining whether the minor's informed consent is sufficient, health care providers should carefully assess whether the minor understands the nature and risks of the proposed treatment and is capable of making an informed, rational choice. The following factors should be considered when making such an assessment: age of the minor, ability, experience, education, maturity level, conduct and demeanor. If the provider determines that notifying the parent or guardian is in the best interests of the minor, this should be discussed with the minor. It is always important to document decisions and the basis for the decision. *See* <u>18 V.S.A. § 9493</u>, et seq.

Private insurance may or may not cover abortions and related medical treatment. If private insurance is used, there is a risk that the person who holds the insurance policy, which may be a parent or guardian, will receive an explanation of the services provided. Vermont Medicaid is required by court order to cover abortions. *See Doe v. Celani,* No. S81-84CnC (Vt. Super. Ct. May 26, 1986). Further, programs that are funded by federal <u>Title X</u> family planning service grants provide individuals of all ages with family planning and related preventive health services.

Is parental informed consent required before a minor can receive contraceptive devices or medications?

Vermont state law recognizes the fundamental right of every individual to choose or refuse contraception and thereby permits unemancipated minors to give informed consent to medical treatment necessary to obtain contraceptive devices and medications. In determining whether the minor's informed consent is sufficient, health care providers should carefully assess whether the minor understands the nature and risks of the proposed treatment and is capable of making an informed, rational choice. The following factors should be considered when making such an assessment: age of the minor, ability, experience, education, maturity level, conduct and demeanor. If the provider determines that notifying the parent or guardian is in the best interests of the child, this should be discussed with the minor. It is always important to document decisions and the basis for the decision. *See* <u>18 V.S.A. § 9493</u>, et seq.

Vermont law requires that insurance providers, including Medicaid and other state public health care assistance programs, cover contraceptive services. <u>8 V.S.A. § 4099c</u>. There is a risk that if a minor consents to contraceptive care and uses private insurance to pay, that the person who holds the insurance policy, which may be a parent or guardian, will receive an explanation of the services provided. Programs that are funded by federal <u>Title X</u> family planning service grants provide individuals of all ages with family planning and related preventive health services.

Is parental informed consent required before minors are provided pregnancy, prenatal and delivery care?

Vermont law, <u>18 V.S.A. § 9493</u>, et seq., provides "individuals" the fundamental right to choose or refuse contraception or sterilization or to carry a pregnancy to term and give birth or to have an abortion and thereby unemancipated minors can give informed consent to reproductive services. Nonetheless, health care providers should evaluate whether the minor's informed

consent is sufficient considering the following factors: age of the minor, ability, experience, education, maturity level, conduct and demeanor.

Are there any situations where providers need not obtain informed consent from anyone before providing the minor with health care?

Yes. When dealing with an emergency – a situation in which immediate treatment is needed to save the patient's life or health – where informed consent cannot be obtained, treatment may be provided without obtaining informed consent. <u>12 V.S.A. § 1909(b)</u>. It is good practice to try and obtain informed consent as soon as possible even in an emergency situation.

If adolescents drive themselves to their appointments, should providers obtain parental informed consent before treating the minor?

In such a situation, the health care provider is expected to exercise sound judgment as to whether the parent must be contacted before treating an unemancipated minor. If the office has a written consent on file that has been signed by the parent authorizing the health care provider and their staff to provide medical care to the minor, there is little or no risk in providing the minor with routine medical care. In situations where the treatment is non-routine or poses some degree of risk to the minor, it is always advisable to consult with the parent before proceeding.

In situations where it is not required to obtain the parent or guardian's informed consent (e.g., treatment for sexually transmitted infection/disease or substance use), is the parent or guardian responsible for the costs of this medical care?

Yes. Generally, a parent or guardian is responsible for support of their unemancipated minor if the treatment is medically necessary.

There is a risk and providers should discuss with a minor patient, that if a minor consents to a medical treatment or procedure and uses private insurance to pay, that the person who holds the insurance policy, which may be a parent or guardian, will receive an explanation of the services provided.

Under Vermont law if the minor requires immediate hospitalization for treatment of substance use or sexually transmitted disease or infection, the parents shall be notified of the hospitalization. <u>18 V.S.A. § 4226</u> (b)

Note, if a minor patient over the age of twelve (12) is seeking treatment for substance use or substance use disorder from a clinic or provider subject to 42 C.F.R. Part 2 provisions, federal law prohibits disclosure of patient identifying information to parents for the purposes of seeking reimbursement. <u>42 C.F.R. § 2.14.</u> Thus, providers must obtain the minor's consent before seeking reimbursement for these services from the minor's parent or guardian. If a minor seeking treatment for substance use or substance use disorder lacks capacity to make medical decisions—due to extreme youth or mental or physical condition—the provider may disclose information to the parent or guardian to reduce a substantial threat to the life or physical well-being of the minor or any other individual. 42 C.F.R. § 2.14.

In situations where it is not required to obtain the parent or guardian's informed consent, may the health care provider inform the minor's parents of the medical treatment?

Under Vermont law if the minor requires immediate hospitalization for treatment of substance use or sexually transmitted disease or infection, the parents shall be notified of the hospitalization. <u>18 V.S.A. § 4226</u> (b)

In other circumstances where the law is silent, ethical and medical concerns control the decision about whether providers should inform parents when there is no requirement to obtain their informed consent. In circumstances where disclosure is in the best interest of the minor or prevents threat to life or physical well-being, the legal risk of informing a parent or guardian is low. Note that parents may become aware of the visit if their insurance is used to pay for care through the explanation of benefits.

In the case of substance use disorder, federal regulations prohibit a health care provider or clinic subject to 42 C.F.R. Part 2 provisions from disclosing this treatment to the parent or guardian unless the minor lacks the capacity to make rational decisions, the situation poses a substantial threat to the minor's life or well-being, and the health care provider determines that this threat may be reduced by communicating the treatment to the parents. 42 C.F.R. & 2.14(d).

In addition to obtaining informed consent from the parent or guardian, must providers also obtain informed consent from the minor?

No, if the parent or guardian is authorized to provide informed consent, health care providers are not also required to obtain the informed consent of the minor. That said, depending on the age and maturity level of the child, it is good practice to explain the procedure to the child and attempt to obtain their informed consent and cooperation.

A minor who is under fourteen (14) years of age may apply for voluntary admission to a designated hospital for mental health related evaluation and treatment with a written application from the minor's parent or guardian accompanied by the minor's written informed consent. <u>18</u> V.S.A. § 7503.

Is parental informed consent required for an unemancipated minor to obtain transgender care? Unemancipated transgender minors may consent to treatment as outlined in the section titled: "Are there any special situations where an unemancipated minor may give informed consent to their own health care?"

While this is an area of evolving law, Vermont does not permit an unemancipated minor to give informed consent to undergo hormone replacement therapy ("HRT"), gender affirmation surgery, or similar treatment without a parent or guardian's consent.

Can unemancipated minors who are victims of sexual assault or human trafficking consent to their own medical care?

Unemancipated minors who are victims of sexual assault or human trafficking may consent to treatment as outlined in the section titled: "*Are there any special situations where an unemancipated minor may give informed consent to their own health care?*"

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In situations where an unemancipated minor has a child of their own, who is authorized to give informed consent for care of the minor's child?

A child's parent, regardless of age, is authorized to make decisions for their own minor child. This may lead to the anomalous situation where the parent is not legally capable of giving informed consent to their own health care, but can make decisions on behalf of their infant.

Minors in State Custody (DCF or DOC)

When minors are in the state's custody, who is authorized to provide informed consent for their health care?

When a minor is in the custody of the State, the Commissioner of the Department of Children and Families ("DCF") has authority to provide informed consent for a minor's health care just as a parent would as outlined above. The Commissioner has additional authority to delegate this responsibility to other members of DCF. Vermont DCF Family Services Policy Manual: Working with Youth and Families, Medical Care for Children and Youth in DCF Custody No. 77, February 27, 2020, <u>https://dcf.vermont.gov/sites/dcf/files/FSD/Policies/77.pdf</u> (last visited August 16, 2021).

Are minors in DCF custody able to receive contraceptive services?

According to the policies of the DCF, caseworkers will ensure that appropriate supportive counseling and contraceptive services are available to teens in custody. Vermont DCF Family Services Policy Manual: Working with Families, Pregnant or Parenting Teens in Custody No. 74, October 27, 1999, <u>https://dcf.vermont.gov/sites/dcf/files/FSD/Policies/74.pdf</u> (last visited August 16, 2021).

May minors in DCF custody receive pregnancy-related services without informing their parents?

In Vermont, a pregnant minor is not required to inform their parent(s) of their pregnancy or any choices that they make concerning pregnancy. DCF staff may or may not inform parents of teens in custody about their pregnancy-related care, depending upon the DCF's determination of what is in the best interest of the minor. Factors for this decision include physical health, past history of abuse and neglect, etc. Vermont DCF Family Services Policy Manual: Working with Families, Pregnant or Parenting Teens in Custody No. 74, October 27, 1999, https://dcf.vermont.gov/sites/dcf/files/FSD/Policies/74.pdf (last visited August 16, 2021).

Who is authorized to consent to treatment when a child is in custody of the Department of Corrections?

The State of Vermont, through the Commissioner of the Department of Corrections ("DOC"), has exclusive authority to consent to medical treatment for children in the custody of the DOC. The Commissioner or any other officer or employee shall represent the State in this relationship. 28 V.S.A. § 1104. The DOC may try to involve the child's parents to obtain their input and background information.

When minors are in custody of the Commissioner of Corrections, who has access to their medical records or health care information?

The following individuals have access to health care information about a minor in custody of the Department of Corrections:

- The Commissioner, Deputy Commissioner, Director of Correctional Services, clinical director, medical director and their designees on an as-needed basis;
- Health care providers designated by the Department of Corrections;
- Non-health staff employed by the Department of Corrections have access as determined by health services staff.

Persons in custody are entitled to reasonable opportunities to discuss their medical care with health care providers. Guardians, including parents, have the same type of access to discuss care that the person in custody has so long as the person in custody has signed a written release approved by the DOC health care provider or a court has approved the guardian to act on behalf of the minor in custody.

Department of Corrections Directive, Access to Health Care Records, 254.02, June 11, 1999, <u>https://doc.vermont.gov/sites/correct/files/documents/policy/administrative/254.02-Access-To-Health-Care-Records.pdf</u> (last visited August 16, 2021).

Minor Privacy and Medical Records

Can a parent access the medical records of their unemancipated minor child?

Generally, parents or guardians may access their unemancipated minor child's medical records unless the records are for services that a minor may consent to without parent or guardian consent or when parent or guardian access is not in the best interest of the minor (e.g., suspected abuse or situations that might endanger the minor or another person).

When may a parent or guardian access their unemancipated minor's patient portal account?

Parents may access their minor child's patient portal account as the minor's "authorized representative." Issues arise when the minor reaches an age or level of maturity where the minor may seek care without parental consent in some circumstances. While there are no specific regulations in Vermont, a provider must restrict the parents' access to medical information available through a patient portal if it is for treatment that the minor may consent to without a parent. Many providers choose to seek a minor patient's consent to allow their parent to access their patient portal when they reach the age of 12 or 14.

Under what circumstances may a minor restrict parent access to the minor's medical record? Minors may restrict access to protected health information for health care that minors may consent to without a parent or guardian. See the Sub-Chapter on Minor Consent for further detail.

Under what circumstances may a provider disclose an unemancipated minor's alcohol or drug use to the minor's parent or guardian?

If a provider is not subject to 42 C.F.R. Part 2 provisions that restrict the disclosure of substance use disorder treatment or diagnosis, the provider must consider the basis under which they

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learned about the minor's alcohol or drug use. If the minor sought treatment related to substance use, the minor (over the age of 12 per Vermont Law) may consent to treatment without parental involvement and records cannot be released—paper or electronic including patient portal access—without the minor's authorization. <u>18 V.S.A. § 4226(1)(A) and 45 C.F.R.</u> <u>§ 164.502(g)(3)</u>.

If the provider believes that the disclosure of this PHI to the parents is needed to prevent or lessen a serious and imminent threat to the minor's health, a minimum necessary disclosure of the minor's PHI is permitted without minor's consent under the HIPAA Privacy Rule. <u>45 C.F.R.</u> § <u>164.512(j)</u>. Also, Vermont law permits a provider to notify the parent(s)/guardian, without minor consent, if a minor requires immediate hospitalization as a result of alcohol or drug use. <u>18 V.S.A. § 4226(b)</u>.

Federal regulations prohibit a health care provider or clinic subject to 42 C.F.R. Part 2 provisions from disclosing this treatment to the parent or guardian unless the minor lacks the capacity to make rational decisions, the situation poses a substantial threat to the minor's life or well-being, and the health care provider determines that this threat may be reduced by communicating the treatment to the parents. 42 C.F.R. § 2.14(d).

May a provider disclose to an unemancipated minor's parent or guardian that the minor is seeking mental health treatment?

In Vermont, a minor of any age may seek outpatient mental health treatment including psychotherapy and counseling services, but not prescription drugs (<u>18 V.S.A. § 8350</u>) and minors who are fourteen (14) years or older may voluntarily admit themselves to a designated hospital for mental health related evaluation and treatment (<u>18 V.S.A. § 7503</u>). When the minor lawfully consents to treatment without a parent or guardian, the provider may not notify a parent or guardian that their minor is starting treatment without the consent of the minor.

When may a parent or guardian access an unemancipated minor's school health records?

Parents or guardians are able to access the education records of their minor children. School health records that are part of a minor's education record, including records from a school nurse or similar, are protected under the Family Educational Rights and Privacy Act ("FERPA") which protects the confidentiality of educational records. Once a student reaches the age of majority, eighteen (18), parents must have the student's authorization to access school records. Note that the records maintained by health clinics or health centers on a school campus (e.g., university health clinic) are considered medical records and governed by health privacy laws including HIPAA and <u>18 V.S.A. § 1881</u>.

Can a parent without parental rights and responsibilities request or access their minor child's medical records?

Parent access to medical records for their minor child shall not be denied based solely on the fact that the parent has not been awarded parental rights and responsibilities. The court may deny the non-custodial parent access to all or portions of the minor's records if access is not in the best interest of the child or if access may cause detriment to the other parent including, but not limited to, abuse. <u>15 V.S.A. § 670</u>.

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EMPLOYMENT CONTRACTS – PHYSICIAN

Topics Covered in this Chapter: <u>Physician Employment Contract Overview</u> <u>Ethical Considerations</u> <u>Compensation</u> <u>Arbitration</u> <u>Additional Resources</u> About the Author

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PHYSICIAN EMPLOYMENT CONTRACT OVERVIEW

Do physicians typically have employment contracts? Why?

Yes, physicians employed by hospitals and medical centers (or in any other setting) almost always are parties to contracts governing the terms and conditions of their employment. This is because the physician employment relationship is a complex and variable one, and a good deal of work needs to be put into defining the terms of that relationship to ensure the most positive outcomes for both the physician and the employer.

What does an employment contract typically look like?

Although a written document is not necessary – at least in the legal sense – to form an employment contract, physician contracts are almost always reduced to writing, and physicians should insist that any agreement be put in writing. Forms vary widely, but a physician employment contract should set forth the correct legal names of all relevant parties (i.e., the physician and the legal entity employing the physician) and, at a minimum, address the following topics:

- The nature of the employment relationship;
- Physician disclosures and representations;
- The physician's obligations;
- The employer's obligations;
- Compensation and benefits;
- Professional liability insurance;
- Term (length) of the agreement and contract termination;
- Any restrictive covenants (e.g., non-solicitation & non-compete clauses); and
- Terms related to enforcement of the agreement.

Each of these topics is discussed in greater detail below.

What are the common topics addressed in physician employment contracts?

Nature of the Employment Relationship

The contract should describe the employer-employee relationship intended to be created by the contract. For instance, the contract should specify that the physician will be an employee of the employer (and not an independent contractor), and whether the employment will be full or part-time. The contract should also spell out the physician's specialty, and define any prerequisites

that need to be fulfilled before employment is to begin (e.g., necessary documentation, background/drug test contingencies, etc.).

Physician Disclosures and Representations

Generally, physician employment contracts include what are sometimes called "covenants," "representations," or "warranties" that are designed to ensure that the physician is at all times, properly authorized to practice medicine or receive payments from payors. For example, the physician is typically required to "warrant" that he or she is authorized to practice medicine in a particular jurisdiction, and is registered to prescribe controlled substances. For employment at a hospital, the physician will typically be required to maintain staff membership and privileges.

The disclosures section will also commonly require the physician to promise to tell the employer about any disciplinary issues, legal (malpractice) complaints, investigations, or other factors that might affect the physician's ability to practice. Theses provisions should be reviewed carefully, as failure to make a disclosure required by the contract could lead to significant consequences if the employment relationship sours.

The Physician's Obligations

In addition to the basic outline of hours requirements and physician responsibilities (which should be outlined in detail, usually as an exhibit to the contract), this section may also cover a variety of other issues. For example, the physician may be required in this part to comply with the employer's billing practices and/or to appoint the employer as the physician's agent for payor contracting. The section may also cover the creation and ownership of medical records (more on this below), the ability of the physician to conduct outside activities (such as teaching, writing, or acting as an expert witness), and the degree of control the physician is anticipated to be able to exercise over the employer's operations.

The Employer's Obligations

Here, the contract will set out the employer's commitments. These commitments generally include providing appropriate staffing, equipment, medical supplies, and facilities for the physician to perform his or her obligations.

Compensation and Benefits

Importantly, the employment contract should also clearly set forth the compensation and benefits due to the physician. Compensation may take a variety of forms, but most commonly, will be paid as some combination of a set salary plus bonus. In any case, the contract should clearly specify the amount of the salary and how the salary and any bonuses are computed. This section should also explain how taxes are to be withheld.

The compensation may also include a provision under which the physician and the employer agree that the physician will not be compensated at a level considered "unreasonable" or beyond "fair market value" under state and federal law. Such terms are intended to protect the employer from problems under certain federal and state laws that prohibit excessive payments to providers, and should be reviewed carefully because they can sometimes operate to impose a cap on earnings under the contract.

Finally, this section should list the employer-paid benefits and discuss the terms of those benefits, which might include:

- Vacation/sick time;
- Payment for continuing medical education (CME) and conferences;
- Educational benefits;
- Employer-sponsored insurance (health, life, disability, etc.); and
- Retirement plans or programs.

Professional Liability Insurance

Physician employment agreements also commonly include some provision as to who will pay the premiums for professional liability (malpractice) insurance. Typically, the employer will cover the professional liability premiums and will set forth the policy limits for the insurance. However, if the insurance is a "claims made" policy, the contract will normally have to spell out who is responsible for securing "tail" insurance, which covers claims made after the physician has left the practice. Sometimes the employer pays for this coverage as a benefit of employment, and sometimes the physician is responsible for securing the coverage. The contract should clearly specify which party will cover this obligation.

Contract Term and Termination

Perhaps the most important part of any employment contract is the section setting the term of the contract and governing how the contract can be terminated early. Typically, the contract will set a fixed term (e.g., 3 years) during which it will be valid, followed by a renewable provision that allows the parties to renew it for additional terms. If the contract does not specify a term, the contract may be terminated by any party, at any time, for almost any reason. Where the contract specifies a term, however, it may be terminated during that period of time only under the conditions specified. Thus, careful attention must be paid by both the physician and the employer to the termination provisions.

Typically, physician employment contracts contain both "for cause" and "without cause" termination provisions. Under a "for cause" provision, the physician gives the employer the right to terminate the agreement immediately upon the finding of misconduct or some occurrence that would significantly undermine the purposes of the agreement. Common "for cause" termination clauses provide that a physician may be terminated immediately for serious misconduct such as criminal acts, egregious failures to follow the employer's policies, or failure to maintain a medical license, while for less serious deficiencies such as performance issues, the clause might give the physician an opportunity to correct the problem before the employer may terminate the agreement. Again, though, physicians should pay close attention to the "for cause" termination provisions because these provisions will be critical should issues arise – physicians will want to ensure that the provisions are drawn with sufficient particularity to ensure that the terms under which termination can occur are clear.

Under "without cause" provisions, both parties to the contract typically are given the opportunity to terminate for any reason upon sufficient notice (usually 60-90 days, but sometimes longer in the case of highly specialized or skilled positions). In many cases, contracts restrict without cause terminations within the first year or two to avoid disruption to the employer's practice and to ensure that an any initial investment in attracting and training new physicians is not immediately lost.
Restrictive Covenants

A restrictive covenant is a promise by a party to forgo some action in the future. In the context of physician employment contracts, restrictive covenants usually operate to restrict a physician's ability to do certain things once he or she is no longer an employee. Physician employment contracts commonly include three types of restrictive covenants: non-compete agreements, non-disclosure (or "confidentiality") agreements, and non-solicitation agreements. Each type is discussed briefly below.

1. Non-Compete Agreements

A non-compete agreement (or "covenant not to compete") typically prohibits a physician from practicing medicine (or some particular specialty) within a particular geographic area during a specified period of time. For example, an employment contract may provide that after leaving the employer's employment a departing physician may not practice his or her specialty within 25 miles of the employer's practice for 3 years following his or her departure.

Covenants not to compete are frequently challenged in court and are looked upon unfavorably as restraints of trade. In Vermont and most other states, however, such covenants will be enforced so long as they are reasonably tailored to protect the employer's legitimate interests, which primarily takes the form of an investment in the physician's practice. Ultimately, the enforceability of a non-compete agreement will depend on a number of factors, including the size of the market in which the physician is practicing, the nature of the physician's practice, and the scope of the restriction.

Because they restrict a physician's ability to secure gainful employment after the end of the employment relationship, non-compete clauses should be carefully reviewed to ensure that any confusion is clarified at the beginning of the employment relationship.

2. Non-Disclosure Agreements

It should come as no surprise that medical practices deal in large volumes of confidential information. That information may include confidential medical information (the type of information also protected by HIPAA and discussed elsewhere in this guide), and confidential *business* information, such as patient lists, utilization review and management data, and employee information. A non-disclosure, or confidentiality, agreement typically restricts a physician's access and use of such confidential information both during and after employment. Usually, these agreements make clear that the physician is permitted to access and use confidential information only as necessary to do his or her job, and may not keep copies of such information once the employment relationship has ended.

3. Non-Solicitation Agreements

Non-solicitation agreements are designed to protect the employer from the "poaching" of employees or patients after a physician leaves the practice. Such agreements usually involve a commitment on the part of the physician not to solicit former patients or recruit employees of the practice after the employment relationship has ended.

Non-solicitation agreements should be reviewed carefully to the extent they might have the effect of prohibiting patients from seeing a particular doctor. In the medical profession, ethics

rules generally prohibit the abandonment of patients, and the American Medical Association has recommended that physicians not enter into agreements that would prohibit their patients from following them to a new practice if it is the patients' desire to do so (more below on how this issue is sometimes addressed in employment contracts).

Enforcement Provisions

In addition to the substantive terms governing the employment relationship, physician employment contracts will also typically include a variety of provisions addressing the manner in which the agreement will be enforced. Such provisions include fairly "boilerplate" legal provisions selecting which state's laws will govern the agreement, the procedures for amending the agreement, how notices provided for in the agreement are to be given, and what happens in the event one party breaches the agreement.

Perhaps the most important "enforcement" provisions are those specifying the remedies for violations of particular parts of the agreement. Such provisions are commonly attached to restrictive covenants (see above), and frequently allow an employer to obtain injunctive relief (essentially a court order directing a physician to do something or refrain from doing something) against a departing physician who fails to honor the covenant. These provisions may also require a physician who violates the agreement to pay the employer's costs and attorney's fees in pursuing an injunction.

Another important provision sometimes found in physician employment contracts is known as an "arbitration clause." Arbitration clauses restrict both parties' ability to go to court to cure a violation of the agreement, and will be addressed separately below.

ETHICAL CONSIDERATIONS

What are some common ethical concerns that should be addressed in a physician employment contract?

Medical ethics rules discourage physicians from entering into agreements that would compromise their independent medical judgment. Moreover, as discussed above, employment agreements sometimes contain provisions (such as non-compete and non-solicitation agreements) that have the potential to implicate rules prohibiting patient abandonment.

Independent Medical Judgment

With respect to the first concern relating to independent medical judgment, physician contracts should make clear that while the employer might have the final say with respect to certain *operational* issues related to the running of the practice, the physician should maintain the independence to make medical decisions (perhaps in conjunction with a medical director) free of interference or improper influence from the employer.

Practice Transition - Patient Abandonment

Contracts should also be carefully reviewed to ensure that patients are not prevented from continuing to see a departing physician (because, for example, a non-solicitation agreement prohibits the doctor from communicating with patients after leaving). This does not mean that a non-compete agreement cannot prevent a physician from practicing in the local area, so long as there is no other restriction that would prohibit the physician from seeing former patients at the patients' request.

One area in which dispute sometimes arise at the end of an employment relationship – particularly in the context of family practitioners or primary care doctors – has to do with how patients are notified of their physician's departure. As discussed above, employment agreements commonly include a non-solicitation clause prohibiting a physician from improperly using patient lists, etc. to "poach" patients from the employer. However, ethics restrictions prevent physicians from abandoning patients, and therefore, a non-solicitation clause cannot be used to prevent patients from continuing to see a departing physician if it is their choice to do so.

Thus, it is very useful to specify in the employment contract how the parties will notify patients that a physician has left the practice. The agreement could provide, for example, for either the physician or the employer to send a notice to the physician's patients informing them of the departure and providing them with the option to continue with the same practice with another physician, or to move with the departing physician. The notice should also inform patients how to request and transfer their medical records to the new practice.

COMPENSATION

What are the limits on physician compensation?

As mentioned above, physician employment contracts frequently contain a provision limiting compensation to an amount considered consistent with the "reasonable" value of the physician's services, or "fair market value." These provisions are intended to ensure compliance with federal health care fraud statutes such as the Stark Law, the Anti-Kickback Statute, and the False Claims Act (these laws are discussed separately in another section of this Guide). For present purposes, it is important to understand that each of these laws includes important limitations on how much physicians who work for recipients of federal payors (including Medicare and Medicaid) can lawfully make, and those limitations typically are based on the concept of "fair market value." If an employer pays physicians substantially more than "fair market value" for their services, the employer could potentially be found liable under one or more of those statutes.

The Stark Law, in particular, prohibits Medicare and Medicaid recipients from paying physicians for their "referrals." Thus, if any part of a compensation scheme in a physician employment agreement appears to be based on what might be considered a "referral" of a patient for a separate "designated health service" (including lab services, physical therapy, radiology, etc.), the agreement might raise concerns under the Stark Law. For instance, a compensation structure that provides a significant monetary bonus to a physician based on how many patients the physician refers to the employer's radiology services likely would violate the Stark Law.

These federal statutes get very complicated, and the penalties for violations can be severe, so it important to closely scrutinize any payment terms in a physician employment contract that appear to base compensation on something other than the reasonable value of the services provided by the physician.

ARBITRATION

What is an arbitration agreement?

Many physician employment contracts contain "arbitration" clauses, which require the parties to the contract to resolve disputes under the contract in front of a private arbitrator rather than a court. Such clauses generally are enforceable, provided they comply with state and federal laws

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governing arbitration. The primary benefit of an arbitration clause is that arbitration is a substantially less complicated process than a lawsuit, and therefore both sides may save significant resources by presenting disputes to an arbitrator rather than a court. On the other hand, arbitration is seen as more favorable to employers, because the opportunity to obtain information from the other side in the dispute is more limited, and employers generally have custody of most of the information relevant to any dispute. Moreover, arbitration is a more informal process that involves fewer procedural protections than a lawsuit, and adverse arbitration decisions may be more difficult to appeal. Finally, remedies in arbitration may be somewhat more limited than the remedies a party could obtain in a formal court proceeding.

ADDITIONAL RESOURCES

Where can I get further guidance on physician employment contracts?

Every situation is different, and it is therefore advisable to consult with an attorney before signing an employment contract. For additional general guidance, however, the American Medical Association <u>website</u> (for those with membership privileges) provides additional information and includes an Annotated Model contract that includes examples of some of the common provisions in physician employment contracts.

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EMPLOYMENT LAW

Topics Covered in this Chapter: <u>The Employment Relationship</u> <u>Hiring</u> <u>Employee Benefits</u> <u>Documents and Record-Keeping</u> <u>On the Job</u> <u>Problems and End of Employment</u> <u>About the Author</u>

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This Employment Law Chapter is for informational purposes only and is not for the purpose of providing legal or professional advice. Employers facing a specific issue or problem should seek the assistance of an attorney. Please note that the information in this Chapter assumes a non-unionized workforce. Please also note that due to the rapidly changing nature of the law, information contained in this Chapter may become outdated and is subject to change without notice.

THE EMPLOYMENT RELATIONSHIP

After an employer determines that a staff person is needed but before advertising or hiring, there are several decisions to be made. These include whether the worker will be classified as an employee or independent contractor, whether the person will have a contract or not, what wages can or must be paid, and what duties will be performed.

When can/should a health care professional or facility hire an independent contractor rather than an employee?

Some organizations may prefer to retain an independent contractor to save money on employment taxes and to avoid the cost of benefits, workers' compensation, and unemployment. Some workers would rather be treated as independent contractors to avoid withholding from their paychecks and other reasons. However, the decision is not up to the individuals involved; different federal and state laws dictate whether a worker can be classified as an independent contractor rather than an employee. To make it even more complicated, the test is not the same under all laws applicable to the employment relationship. For example, a worker may be an independent contractor under the IRS test for purposes of federal tax withholdings, but be considered an employee for Vermont workers' compensation and unemployment purposes, although some of the tests are similar. The following is a summary of these three tests.

(1) IRS Independent Contractor Test

For purposes of distinguishing between employees and independent contractors for federal tax withholding purposes, the IRS cares primarily about the degree of control exercised by the employer and the degree of independence experienced by the worker. More detail on the IRS's independent contractor test can be found in <u>IRS Publication 15-A</u>, Employer's Supplemental Tax

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Guide. The IRS test is grouped into three categories—behavioral control, financial control, and type of relationship. For example, under behavioral control, the IRS looks at the degree to which the person is generally subject to the organization's instructions about when, where, and how to work. If the organization directs when and where to do the work, provides tools and equipment to the worker, purchases or tells the worker where to purchase supplies, informs the worker what order or sequence to follow, and/or similarly has significant control over how the work is performed, the worker will generally be considered an employee for federal tax withholding purposes.

Within the issue of financial control, the IRS expects that an independent contractor will often perform the same work for other organizations, receive a flat fee rather than an hourly wage, have an opportunity for profit or loss, have unreimbursed expenses, or otherwise have a significant investment in the work. Finally, the type of relationship also helps determine the classification. An employee is less likely to have a written contract, is more likely to receive employee benefits, usually is not hired for a specific project or period, and performs work that is a key aspect of the organization's business. For example, a physician or nurse hired by a physician's office would generally be an employee, not an independent contractor under the IRS test, as either professional would be performing work essential to the operations of the organization. In contrast, the person who mows the lawn or cleans the office performs peripheral duties and is more likely to be performing work under their own business, have other customers, bring their own supplies, etc, and could be an independent contractor under the IRS test.

(2) Vermont Unemployment Insurance "ABC" Test

The tests for distinguishing between employees and independent contractors for Vermont unemployment insurance and workers' compensation coverage are narrower. For purposes of Vermont unemployment insurance, all persons who perform services for wages are presumed to be employees, entitled to unemployment benefits. To rebut this presumption, an employer must show that a worker meets <u>all three</u> elements of the "ABC" test:

(A) such individual has been and will continue to be free from control or direction over the performance of such services, both under his or her contract of service and in fact;(B) such service is either outside the usual course of the business for which such service is performed, or that such service is performed outside of all the places of business of the enterprise for which such service is performed; and

(C) such individual is customarily engaged in an independently established trade, occupation, profession or business.

21 V.S.A. § 341(a).

Unless all three elements of the ABC test are met, the worker must be classified as an employee for purposes of unemployment compensation, even if the worker is classified as an independent contractor for federal tax withholding purposes. The Vermont Department of Labor's website summarizes the test for unemployment insurance at:

https://labor.vermont.gov/sites/labor/files/doc_library/Who%20is%20an%20Employee%20vs.% 20Independent%20Contractor.pdf

(3) Vermont Workers' Compensation "Nature of Business" Test

To determine whether an employee-employer relationship exists for purposes of Vermont workers' compensation law, a "right to control," then a "nature of the business test" is used, i.e., whether the work that the owner contracted for is part of, or process in, the trade, business or occupation of the owner. If the right to control test demonstrates that an employer controls the worker, the inquiry ends, and the worker must be classified as an employee. If the "right to control" test shows the employer does not "control" the worker, the next test is the "nature of the business test". Under this test, an individual is an employee for Vermont workers' compensation purposes if they are hired to carry out some phase of the hiring entity's business. The Vermont Department of Labor's provides more detail on this test at: https://labor.vermont.gov/workers%E2%80%99-compensation/misclassification

The state tests for unemployment insurance and workers' compensation are more inclusive than the IRS tests, so it is possible that a worker could be classified as an employee for certain purposes and an independent contractor for others. For example, a temporary replacement physician is not performing services outside the usual business of a physician's office and therefore will be considered an employee for unemployment insurance and workers' compensation, even though it may be possible to classify the physician as an independent contractor under the IRS test, depending on the nature and extent of their services.

Proper classification is important because misclassifying a worker as an independent contractor could lead to substantial liability for back taxes, overtime pay, benefits, and other liabilities.

What is employment at-will?

An employer must next decide whether to hire an employee on an at-will basis, or some other defined basis. Vermont law presumes that an employee who is hired for an indefinite period is an employee "at-will." This means that the employee remains employed only as long as both the employer and employee agree. An at-will employee may leave employment at any time, and there is no law requiring that the employee give any notice. Similarly, an at-will employee can be terminated from employment with or without cause and with or without notice, as long as the employee is <u>not</u> terminated for an unlawful reason. Unlawful reasons for employment termination are discussed below in other sections.

An employer can modify the at-will relationship by hiring an employee for a definite period, making promises about job security, entering into a contract with the employee, or taking other steps that a court would deem sufficient to change the presumption. Creating personnel policies or practices that assure employees that they will have continued employment or that certain procedures will be followed before the employee is terminated is a common way the at-will relationship can be modified (sometimes inadvertently). If an employer wishes to preserve at-will status, all employment-related documents, including handbooks, policies, and offer letters, should reaffirm employees' at-will status.

How is an employment contract formed?

An employment contract is formed similarly to other contracts — an offer is made, it is accepted, and consideration is given for it. It does not have to be in writing to be binding on the parties. Generally, if an offer of employment (which usually states or at least implies a promise of payment) is made and then is accepted by the employee, an employment contract is formed. Thus, virtually every employee is working under some form of contract; the important issue is

what the terms of the contract are. Remember, if the contract did not specify a length of time or a term, it is generally considered an at-will contract and may be terminated at any time by either party. If the contract is at all ambiguous, it is generally construed against the drafter. Therefore, if an employer sends an offer letter or prepares personnel policies or makes oral promises to an employee or applicant and the contents are at all unclear, they will be interpreted to favor the employee. Thus, any communications with employees should be made clearly and carefully. The organization should determine before hiring whether it intends to hire its employees on an at-will or other contractual basis and craft its offer letter, personnel policies, and practices accordingly.

What laws govern how an employee is paid?

The federal Fair Labor Standards Act (FLSA) and Vermont wage and hour laws govern certain aspects of how an employee must be paid. The federal law does not apply to all employers, so an organization must first determine whether it is covered by the FLSA or only by state law. The FLSA applies to enterprises with annual gross volume of sales made or business done of \$500,000 or more; the FLSA applies to all hospitals, businesses providing medical or nursing care for residents, schools and public agencies are covered regardless of the dollar amount of business; in addition, the FLSA applies to any employee who engages in interstate commerce (this includes activities such as ordering supplies from another state over the telephone or Internet).

Under both federal and Vermont law, an employer must pay employees at least the applicable minimum wage and must pay time-and-a-half for any time worked over 40 hours in a workweek, unless the employee is specifically exempted from such overtime provisions. Both the FLSA and Vermont law require employers to keep accurate records of the hours worked by non-exempt employees and the wages paid to all employees. 21 V.S.A. § 393.

In Vermont, the minimum wage for employees is \$12.55 an hour, as of January 1, 2022. Vermont law provides that its minimum wage will continue to increase each year thereafter. 21 V.S.A. § 384(a). Employers should consult the Vermont Department of Labor's website for the applicable minimum wage to be effective January 1, 2023.

Non-exempt employees of hospitals, public health centers, nursing homes, therapeutic community residences, maternity homes, and residential care homes must be paid overtime under Vermont law for any time worked over 40 hours in a workweek, unless the employer files an election and instead pays them time and a half for any hours more than eight in any day and 80 in a two week pay period. *See* 21 V.S.A. §384(b)(4); 29 C.F.R. § 778.601.

Vermont law requires that employers pay employees weekly unless they notify the employees in writing that they will be paid bi-weekly or semi-monthly, and payment must be made no more than six days after the end of the pay period. 21 V.S.A. §342(a). An employee who is terminated must be paid within 72 hours of discharge. 21 V.S.A. §342(b)(2). An employee who voluntarily leaves his/her employment must be paid on the next regular payday. 21 V.S.A. §342(b)(1).

How does overtime work?

If an employer is covered by the FLSA, every employee is presumed to be entitled to overtime pay for any time worked over 40 hours in a workweek (not 80 hours in a pay period). When an

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employee is eligible for overtime and minimum wage, it is referred to as "non-exempt". Some positions are "exempt" from these requirements, but the exemptions are intended to be quite narrow and are construed against the employer. An employee must specifically meet an exemption or she/he is entitled to overtime pay.

The three primary exemptions applicable to physician's offices are the executive, administrative, and professional exemptions. The first requirement for all three is that the employee be paid on a salary basis of at least \$684* for each week in which the employee performs any work (with a few exceptions). Effective January 1, 2020 the U.S. Department of Labor revised regulations located at 29 C.F.R. part 541, amount of salary required. In addition to this "salary basis" test, the employee must also satisfy a "job duties" test to be exempt. The executive employee's primary duty must be to manage a department, direct the work of two or more other full time employees, and have the authority to hire and terminate (or at least have his/her recommendations carry particular weight). The administrative employee must perform office work directly related to the organization's general business operations, and the employee's primary duty must include the exercise of discretion and independent judgment with respect to matters of significance. The professional employee must have advanced, specialized knowledge in a recognized field of science or learning (such as an MD or an RN) customarily acquired from a prolonged course of specialized intellectual instruction. Generally, a Licensed Practical Nurse does not fit the "professional" exemption. Unless an employee meets the test to be exempt under the FLSA, the employee must be classified as non-exempt. Determining whether or not an exemption applies to a particular position or employee can be complicated and may require consultation with an attorney or other human resource professional. It is prudent to seek legal guidance with any questions about employee classification.

An employer must pay a non-exempt employee one and a half times the employee's regular rate of pay for any time worked over 40 hours in any workweek, even if the employer has not authorized or expressly permitted the overtime. The employee may not waive the overtime pay, and an employer may not offer compensatory time in a different workweek in lieu of the overtime pay. If an employee works unauthorized overtime, the employer may take disciplinary action, including termination, against the employee (consistent with its policies and/or any contract of employment),, although the employee must be paid for the time worked.

Why should an employer have job descriptions?

Written job descriptions help define the expectations an employer has for its employees, reduce the risk for disagreements about the scope of job requirements, and provide a basis for evaluation of employee performance and appropriate compensation. In addition, job descriptions identify the essential functions of a job for purposes of engaging in the interactive process and providing reasonable accommodations for qualified individuals with disabilities. Ideally, a job description should identify those functions the employer deems essential before the employee is even hired.

HIRING

Like other employers, physicians may wish to use a range of measures to choose employees, including advertisements, background checks, applications, interviews, and references.

What should be in a job advertisement?

The content of a job advertisement varies by the nature of the job and extent of the search. It is unlawful for an employer to publish a job advertisement that shows a preference for or discourages someone from applying based on a category protected by law (e.g., their age, race, color, religion, sex, gender identity, sexual orientation, pregnancy, national origin, disability, genetic information, crime victim status, past, present or prospective military service, or any other legally protected category). The advertisement must be truthful and not misleading, although it need not include all of the particulars of the job. Many advertisements include an equal employment opportunity statement.

What should be included in an EEO policy?

An equal employment opportunity ("EEO") policy in Vermont should include the statement that an employer provides equal employment opportunities to all employees and applicants and that it will not discriminate on the basis of race, color, religion, ancestry, national origin, place of birth, sex, gender, sexual orientation, gender identity, age, pregnancy, HIV-positive status, veteran status, military service or obligation, genetic information, or against a qualified individual with a disability, citizenship, immigration status, crime victim status, or any other characteristic protected by law. In addition, an employer must ensure that there is no retaliation against an individual who has opposed any alleged discrimination, has lodged a complaint of discrimination, has cooperated with a state investigation into a discrimination complaint, or who the employer believes may be about to lodge such a complaint. Some employers voluntarily choose to add protection in their policies for categories that may not be protected by law, but are particular to the employer's clientele or mission.

Though there are different thresholds for coverage under each of these laws, the following is a non-inclusive list of laws that prohibit discrimination in employment based on protected categories: Title VII of the Civil Rights Act of 1964, Age Discrimination in Employment Act, Americans with Disabilities Act, Rehabilitation Act, Pregnancy Discrimination Act, Equal Pay Act, Family and Medical Leave Act, Immigration Reform and Control Act of 1986, Title II of the Genetic Information Nondiscrimination Act, Vermont's Fair Employment Practices Act, Vermont's Parental and Family Leave law, Vermont's Healthcare Whistleblower's Protection Act, and Vermont's Sexual Harassment law.

What questions are allowed or prohibited in an application or interview?

An employer should not ask questions that elicit information about protected characteristics, which include, but are not limited to, age, sex, race, religion, national origin, sexual orientation, gender identity, disability, crime victim status, etc., as the question alone may be evidence supportive of a discrimination claim. Employers should also not ask an applicant about their workers' compensation history, birthplace, dates of attendance at school, arrest record, or marital status. Effective July 1, 2018, employers were prohibited from asking a prospective employee or their past/current employer about current or past compensation (salary history). 21 V.S.A. §495m. Employers also must not ask about criminal history on an initial job application. 21 V.S.A. §495j. Instead, a job application or interview should focus on assessing the applicant's skill set, ability, and possession of qualifications necessary to perform the job – licensing, education, employment history, performance of expected duties. If the applicant will be driving a car, inquiries about a driver's license may be appropriate. As to compensation, employers are permitted to ask a prospective employee about their salary expectations or requirements.

State and federal laws require that employers provide reasonable accommodations to both employees and job applicants with a disability, unless doing so would cause undue hardship (significant difficulty or expense for the employer). Vermont law also requires that employers provide reasonable accommodation(s) for an employee's pregnancy-related condition, unless it would impose an undue hardship. 21 V.S.A. § 495k.

There are also strict limits on when employers can ask applicants or employees about medical issues, disabilities or require a medical examination. Under the Americans with Disabilities Act ("ADA"), a disability is defined in one of three ways: (i) a physical or mental impairment that substantially limits one or more major life activities; (ii) a record or past history of impairment; or (iii) being regarding as having an impairment. 29 C.F.R. § 1630.2(g)(1). Under the law, the definition of disability must be construed in favor of broad coverage of individuals. The ADA does not contain a list of all conditions which constitute disabilities, but impairments such as epilepsy, diabetes, cancer, HIV infection, and bipolar disorder nearly always meet the definition of a disability.

An employer cannot ask a job applicant if they have a disability (or about the nature of an obvious disability), to answer medical questions, or take a medical exam before extending a job offer. At the application and interview stage, employers may only ask job applicants whether they can perform the job and how they would perform the job (but an employer cannot ask the applicant if they needs a reasonable accommodation to do the job). Thus, an applicant who is blind or visually impaired may be asked specifics of how they would perform the duties of the job but cannot be asked whether they have any sight or how they became blind or whether their vision is expected to improve in the future. After a conditional job offer has been made, the law allows the employer to ask disability-related questions or require a medical examination, but only if they are required of all entering employees within a job classification. To withdraw a job offer following such inquiries, the employer must demonstrate the reason was job-related and consistent with business necessity and that no reasonable accommodation would enable the applicant to perform the essential functions of the job.

Once an employee has started working, an employer generally can only ask medical questions or require a medical exam if the employer needs medical documentation to support an employee's request for an accommodation or if, based on current, objective evidence, the employer believes that an employee is not able to perform a job successfully or safely because of a medical condition, i.e., when it is job related and consistent with business necessity. Employers must treat any medical information obtained from a compliant inquiry or disclosed by the employee as a confidential medical record and maintain it separately from the employee's personnel file.

Can I ask about criminal histories on job applications?

Effective July 1, 2017, most Vermont employers were prohibited from asking about an individual's criminal history record on initial employment applications. 21 VSA § 495j. Now, employers can still ask about a prospective employee's criminal history record during a job interview or once the applicant has been deemed otherwise qualified for the position. Under the law, if an applicant divulges criminal history in response to an employer inquiry, the employer is required to offer that applicant the opportunity to explain the circumstances, including any post-conviction rehabilitation, if the criminal history record does not disqualify the applicant under

federal or state law. An employer will only be able to ask about criminal offenses on an initial application if it is subject to an obligation imposed by federal or state law or regulation that prohibits it from employing an individual who has been convicted of certain criminal offences. In such case, the question(s) on the application must be limited only to the types of criminal offenses that create the legal disqualification.

What kind of background checking may or should an employer do before hiring an employee? The extent of background checking to be done before hiring an employee depends on the nature of the position and duties to be performed and must be performed in compliance with the law. Some employers have a legal requirement to conduct background checks.

When can an employer do a criminal background check on an applicant?

Effective July 1, 2017, an employer must not perform a background check on an applicant until after a job interview or the applicant has been deemed otherwise qualified for the position. 21 VSA § 495j.

Under Vermont law, any employer may obtain criminal records directly from the Vermont Criminal Information Center (VCIC) if the requirements of 20 V.S.A. § 2056c are met.

When an employer uses a third party (i.e., not the employer's own employee) to conduct a background check or to obtain reports from outside agencies, such reports are subject to the federal Fair Credit Reporting Act ("FCRA"). Background information is either classified as a "consumer report" or an "*investigative* consumer report." The third party company performing the background check is called a "consumer reporting agency." A "consumer report" is defined as any communication that contains information about an individual's credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics or mode of living. A "consumer report" includes reports on criminal history, driving records, verification of education, etc., not just credit reports. Generally, the following notices are required when an employer is obtaining a "consumer report" that is covered by the FCRA:

- 1. Written disclosure to the applicant/employee;
- 2. Written authorization from the applicant/employee;
- 3. Certification to the reporting agency that it will comply with the FCRA;
- 4. Before taking adverse action based on the consumer report, provide the person with a copy of the report, and a statement of his/her rights from the FCRA; and
- 5. Providing notice of the adverse action. This must include (a) a statement that adverse action was taken based on the consumer report; (b) contact information for the consumer reporting agency; (c) a statement that the consumer reporting agency did not make the adverse decision and cannot explain why that decision was made; (d) an explanation of the applicant's or employee's rights under the FCRA to obtain a free copy of the consumer report from the reporting agency and to dispute with the agency the accuracy or completeness of the report.

An "*investigative* consumer report" is when the <u>third party</u> consumer reporting agency obtains information about character, etc. from *personal interviews*. Employers must ensure they are following the FCRA's additional disclosure requirements if they decide to have a background check company or private investigator obtain an "investigative consumer report." The FCRA does not cover an employer's own background investigation conducted by the employer's own staff; the FCRA applies to background reports from private investigators or other consumer reporting firms.

The Equal Employment Opportunity Commission emphasizes that in all cases with background checks, employers treat everyone equally. It is unlawful, for example to only check backgrounds for individuals based on a protected characteristic (e.g., race, national origin, age, etc.) or to use a background check in a manner that discriminates disproportionately against individuals in protected categories. Employers should have a business necessity to justify using a conviction record (and should generally never ask about arrest records) taking into account the nature and gravity of the offense(s), the time that has passed since the conviction, and the nature of the job.

When can an employer do a credit check?

In addition to limitations under the FCRA set forth above, Vermont law (21 V.S.A. § 495i) prohibits employers from inquiring into an applicant or employee's credit report or credit history except if certain conditions are met. Under Vermont law, a credit history (which includes a credit report) may only be required if the position involves access to confidential financial information, a financial fiduciary duty to the employer, access to payroll information, or the employer can demonstrate the information is a "valid and reliable predictor of employee performance in the specific position of employment." If an employer will obtain a credit history or act on a credit history, it must obtain written consent each time, disclose in writing the reasons for accessing the credit history, disclose in writing the reason for adverse action, if any, not charge the employee for the cost associated with obtaining a credit history, keep the information confidential, and if the applicant is not hired, either destroy the credit history in a secure manner or give it to the applicant.

What about social media and employee privacy?

Effective January 1, 2018, employers were prohibited from requiring, requesting or coercing an applicant or employee to: (i) disclose a social media username, password, or turn over unlocked device so the employer may access the employee or applicant's social media account; (ii) access a social media account in presence of employer; (iii) divulge or present the employee or applicant's social media account content; (iv) change privacy settings to increase third-party access; or (v) add anyone to their list of contacts. 21 V.S.A. § 4951. Social media accounts are defined broadly to include any account with an electronic medium or service through which users create, share and interact with content, such as videos, photographs, blogs, podcasts, instant or text messaging, email, and online profiles.

Under the law, employers are permitted to request an employee share specifically identified social media content to: (i) comply with employer's legal and regulatory obligations; (ii) investigate alleged unauthorized disclosure of proprietary, confidential or financial information; or (iii) investigate allegation of unlawful harassment, threats of violence or discriminatory or disparaging content concerning another employee. In addition, the above prohibitions do not apply to a social media account that is provided by or intended to be used primarily on behalf of the employer. The law contains other exceptions for law enforcement agencies; it permits access to employer-issued devices and does not prevent an employer from complying with requirements of other state or federal laws.

Retaliation against employees who exercise their rights under this law is also prohibited, and employees may not waive their rights under the law.

When can an employer conduct drug or alcohol testing?

Vermont has a strict drug testing laws. An employer may only require an applicant to submit to a drug test if:

- the applicant has already been offered the job conditioned on a negative test result;
- the applicant receives written notice of the employer's policy, the procedure, and list of drugs to be tested;
- the employer follows the specific procedures required by the law, which includes a strict chain of custody, use of designated state labs, an appointed medical review officers and collector, etc.; and
- the employee is given an opportunity to retest any positive result.

No random or company-wide drug tests are permitted unless federal law requires it (i.e., for certain transportation employees). To test an employee, the employer must:

- have probable cause to believe the employee is using or under the influence of a drug on the job;
- have an employee assistance/rehabilitation program (EAP);
- not terminate the employee if the employee agrees to complete the EAP; and
- follow the specific testing process in the act.

More information is available at Vermont's Drug Testing Act, 21 V.S.A. §§511-520.

What about marijuana and the workplace?

Effective July 1, 2018, Vermont legalized recreational use of marijuana. Vermont's law, among other things, eliminated penalties for possession of one ounce or less of marijuana and two mature and four immature marijuana plants for a person who is 21 years of age or older. Under the law, employers are not required to permit or accommodate the use, consumption, possession, transfer, display, transportation, sale, or growing of marijuana in the workplace and can prohibit or regulate the use of marijuana on their premises. The law also specifically states it does not create a cause of action against an employer that discharges an employee for violating a policy that restricts or prohibits the use of marijuana by employees. Employers can and should adopt or revise their policies to prohibit marijuana use in the workplace.

Vermont also has a law on the Therapeutic Use of Cannabis, but employers do not have to accommodate an employee's request to use marijuana at work, even if it is being used to treat a disability. Provided, if an employer becomes aware that an employee is using marijuana for a medical purpose, the employer should engage in the "interactive process" with the employee to determine if he or she can perform essential job functions, with a reasonable accommodation. An employer should consult with employment counsel prior to taking adverse action against an employee in these situations.

Marijuana remains illegal under federal law, meaning federal authorities retain the ability to enforce federal drug laws.

Separately, Vermont employers must prohibit smoking in the workplace. Vermont Guide to Health Care Law

When can/must an employer check an applicant's licensing or professional status?

An employer can check an applicant's (or employee's) licensing or professional status at any time. The National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB) allow certain entities, including a "health care entity," to obtain information about medical malpractice or similar claims. 45 C.F.R. Part 60. A "health care entity" is a hospital or an organization that provides health care services and follows a formal peer review process for the purpose of furthering quality health care, or a committee of that entity, including a professional society, HMO, or medical or dental group practices following a formal peer review process. A health care entity can check a health care practitioner's licensing or professional status when the health care entity is employing, affiliated with or granting privileges to the health care practitioner. The health care entity may check the health care practitioner's status at any time. Only an authorized entity may obtain information from the databanks, and there are requirements about registration, fees, and other criteria available from the NPDB website. Authorized entities include state licensing and professional agencies, law enforcement, other state and federal agencies, utilization and quality peer review organizations, health plans and, in limited circumstances, attorneys or individuals pursuing medical malpractice claims. For more information, see the National Practitioner Databank section in the Professional Liability chapter.

The Vermont Board of Medical Practice maintains a database of licensed physicians. (http://healthvermont.gov/health-professionals-systems/board-medical-practice/look-license; see also 26 VSA § 1368). The Vermont Secretary of State's Office of Professional Regulation licenses most other health care professionals, including nurses, pharmacists, radiologic technologists, occupational therapists, physical therapists, and many others. Its website includes a searchable database of professionals and their licenses. (https://sos.vermont.gov/opr/find-a-professional/) Licenses and specific information regarding the discipline of a licensee are public records, although ongoing investigations or prior complaints that did not result in discipline are not. 3 VSA § 131. Given the easy availability of the information, an employer would be hard-pressed to explain why it did not check to ensure that an employee was properly licensed.

May an employer require an employee to sign a covenant not to compete before beginning work? Yes. As of the date of this Guide, Vermont law does not prohibit an employer from requiring that an employee sign a restrictive covenant agreement not to compete with the employer, as long as the restraint is narrowly tailored in geographical, temporal, and subject matter restrictions to protect the employer's legitimate interests.

EMPLOYEE BENEFITS

Earned Sick Leave

Vermont passed earned sick leave legislation in 2016. 21 V.S.A. §§ 481-486. Effective January 1, 2018, the earned sick leave law covered all Vermont employers.

Generally, all employees who work on average at least 18 hours per week must receive earned sick time. The law contains several classifications of employees who may be <u>excluded</u> from eligibility for earned sick time, including: individuals under 18 years of age, seasonal employees (employees who work 20 or fewer weeks in a 12-month period in a job that is scheduled to last

20 weeks or fewer), and per diem employees of health care facilities. Employees can use earned sick time for any of the reasons listed in 21 V.S.A. § 483(a):

- (1) The employee is ill or injured.
- (2) The employee obtains professional diagnostic, preventive, routine, or therapeutic health care.
- (3) The employee cares for a sick or injured parent, grandparent, spouse, child, brother, sister, parent-in-law, grandchild, or foster child, including helping that individual obtain diagnostic, preventive, routine, or therapeutic health treatment, or accompanying the employee's parent, grandparent, spouse, or parent-in-law to an appointment related to his or her long-term care.
- (4) The employee is arranging for social or legal services or obtaining medical care or counseling for the employee or for the employee's parent, grandparent, spouse, child, brother, sister, parent-in-law, grandchild, or foster child, who is a victim of domestic violence, sexual assault, or stalking or who is relocating as the result of domestic violence, sexual assault, or stalking. As used in this section, "domestic violence," "sexual assault," and "stalking" shall have the same meanings as in 15 V.S.A. § 1151.
- (5) The employee cares for a parent, grandparent, spouse, child, brother, sister, parent-in-law, grandchild, or foster child, because the school or business where that individual is normally located during the employee's workday is closed for public health or safety reasons.

Covered employees must accrue one hour of earned sick time for every 52 hours worked. All hours actually worked by non-exempt employees will count towards the accrual of earned sick time. However, an employer can limit the number of hours in a workweek that will count towards the accrual of earned sick time for exempt employees to 40 hours. Employers can limit the total amount of earned sick time an employee can accrue to 40 hours in a 12-month period.

Employers can impose a waiting period of up to one year during which an employee must accrue earned sick time, but can be prohibited from using the earned sick time until after they have completed the waiting period.

All earned sick time that remains unused at the end of every annual period must generally carry over to the next annual period. However, carry-over is not required if an employer offers a paid time off policy and provides the employee with access to their full accrual of earned sick time at the beginning of each annual period (i.e, the time is "front loaded"). Also, an employer, at its discretion, can pay out accrued but unused earned sick time at the end of an annual period, and then the amount of earned time for which the employee was compensated would not carry over.

Employers do not have to pay out earned sick time at separation from employment.

An employer's existing paid time off policy will comply with Vermont law if the paid time off accrues at a rate that is greater than or equal to the rate in Vermont's law and may be used for the same purposes and with at least the same rights as they would be able to use earned sick time under Vermont's law. Employers can offer paid time off benefits that are more generous than the provisions under Vermont law, if they choose to. Employers who already offer paid time off

should review and revise existing policies for compliance with the provisions of Vermont's earned sick time law.

All employers must post a poster on earned sick leave issued by the Vermont Department of Labor. Employers are also required to notify employees about earned sick leave benefits at the time of hire.

For more information, including a link to the poster, frequently asked questions and the Department of Labor's final rules on earned sick time, see the Department of Labor's website.

Paid Vacation or Holidays

Employers are not required to provide employees with paid vacation or paid holidays. However, if an employer and employee have an oral or written agreement providing specific benefits to the employee and the employer fails to provide the benefits, the employer is liable for actual damages caused by failure to pay the benefits. 21 V.S.A. § 345(b).

Breaks

Vermont law does not require an employer to provide employees with any specific break or lunch periods but requires that employers provide "reasonable opportunities during work periods to eat and to use toilet facilities in order to protect the health and hygiene of the employee." 21 V.S.A. §304.

Nursing Mothers

Vermont law requires employers to provide nursing mothers, for three years after the birth of a child, with reasonable time (paid or unpaid) throughout the day to express breast milk and to provide accommodations, including appropriate private space to express milk that is not a bathroom stall. 21 V.S.A. §305.

The federal Fair Labor Standards Act also requires employers to provide reasonable break time for an employee to express breast milk for her nursing child for one year after the child's birth, each time such employee has the need to express milk. 29 U.S.C. \$ 207(r). Under the FLSA, employers are required to provide a place for the employee to express breast milk, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public.

Employers are not required under state or federal law to compensate nursing mothers for breaks taken for the purpose of expressing milk. However, where employers already provide compensated breaks, an employee who uses that break time to express milk must be compensated in the same way that other employees are compensated for break time. In addition, employers must follow the FLSA's general requirement that the employee must be completely relieved from duty or else the time must be compensated as work time applies. Employers should treat breaks taken by nursing mothers to express milk consistently with the way other break time is compensated.

Flexible Working Arrangements

All Vermont employers are required by law to consider employee requests for flexible working arrangements. 21 V.S.A. § 309. "Flexible working arrangements" mean intermediate or long-term changes in the employee's regular working arrangements, including changes in the number Vermont Guide to Health Care Law Page 89

of days or hours worked, changes in the time the employee arrives at or departs from work, work from home, or job-sharing. Under the law, employers must engage in good faith discussions concerning employee requests for flexible working arrangements. Employers are obligated to respond to employee requests at least twice per calendar year. An employer has discretion to deny a request when it is inconsistent with business operations. Vermont law lists eight possible reasons denial may be appropriate, including situations where a request: imposes additional costs, has a detrimental effect on aggregate employee morale or the ability to meet consumer demand, or there is an inability to reorganize work among existing staff. It is important to note that if an employee requests a flexible work arrangement in writing and the employer denies any part of the request, the employer must provide a written denial. Retaliation against employees who exercise their rights under this law is also prohibited. Employers should implement internal procedures to document employee requests and efforts taken to evaluate and respond to requests.

Group Health or Retirement Benefits

If an employer does choose to offer group health or retirement benefits, the Employee Retirement Income Security Act of 1974 ("ERISA"), the Internal Revenue Code, and the Affordable Care Act (group health only) are the principal laws that affect such plans. Employers should consult with an employee benefits advisor, a human resources professional or an attorney concerning an employer's obligations in connection with offering group health or retirement benefits.

Workers' Compensation and Unemployment Insurance

Employers are required to provide workers' compensation and unemployment compensation coverage for all employees. Under Vermont's workers' compensation law, an employee is entitled to compensation if the worker "receives a personal injury by accident arising out of and in the course of his employment." Generally, any employer who employs at least ten employees for more than 15 hours per week must reinstate to the first available, suitable job, any employee if the employee recovers within two years of the onset of the work related injury. Recovery is determined if the employee can "reasonably be expected to perform safely the duties of his or her prior position or an alternative suitable position." 21 V.S.A. § 643b(a)(2).

The employer need not reinstate the employee to the same job, but must reinstate them to "the first available position suitable for the worker given the position the worker held at the time of the injury." 21 V.S.A. § 643b(b). The employee also regains seniority and unused leave time that had been earned up to the date of the injury. Reinstatement is not required if the employee had prior notice or had already given notice before the injury that his/her employment would end, if the employer about his/her interest in reinstatement, status of recovery, and current mailing address. 21 V.S.A. § 643b(d). Under Vermont's workers' compensation law, an employer need not hold a job open for an employee who is out on workers' compensation leave, unless the employee's leave also qualifies for job-protected leave, such as leave under the FMLA or VPFLA. While an employee is on workers' compensation leave and the employee's prior job or a similar job is open when the employee recovers (and less than two years has passed since the employee was injured), the employer must reinstate the employee. Vermont employers are not required to establish light duty positions, but may do so.

For more information on Unemployment Insurance, see the section below, <u>What is</u> <u>Unemployment Compensation</u>.

Family and Medical Leave

In addition to Earned Sick Leave requirements under Vermont law, many employers are required to provide unpaid, job-protected leave for qualifying family, medical and parental reasons. Depending on their size, employers may be covered by the federal Family and Medical Leave Act ("FMLA") and/or Vermont's Parental and Family Leave Act ("VPFLA").

Who must comply with the FMLA and VPFLA?

The FMLA allows eligible employees to take reasonable unpaid leave for medical reasons, for the birth or adoption of a child, to care for a child, spouse, or parent who has a serious health condition, or for qualifying exigencies related to the foreign deployment of a military member. It applies to all private employers who employ fifty (50) or more employees. Vermont has enacted a family leave law as well, which requires any employer that employs fifteen (15) or more eligible employees to provide medical leave and any employer with at least ten (10) eligible employees to provide parental and short-term leave. If an employee is covered by both federal and state leave law, the employee must receive the more favorable benefits so that the leave of absence will run concurrently under the FMLA and VPFLA.

Which employees are covered?

To be eligible under the FMLA, an employee must have been employed for at least twelve months (not needing to be consecutive) with at least 1,250 hours of service during the previous twelve months and work at a worksite that has at least fifty (50) employees within seventy-five (75) miles. The VPFLA applies to any employee who has been continuously employed by the same employer for at least one year, who has worked an average of at least thirty (30) hours per week during the previous year.

May an employer require advance notice and medical certification?

An employer may require an employee to give at least thirty (30) days' notice of their intent to take leave when the need for leave is foreseeable. When the need for leave is unforeseeable, notice must be provided as soon as practicable. If the leave is for a serious illness, the employer may require certification from a health care provider of the condition and the need for the leave. The federal Department of Labor has created specific FMLA forms for employers to use, including certifications for health conditions which include only the information to which an employer is entitled. The FMLA requires that an employer notify the employee if medical certification will be required and allow the employee 15 days to return the form; it also limits the information the employer can ask. For example, the employer generally cannot call the employee's physician and ask questions, except where it is within limited circumstances permitted by FMLA regulations.

A covered employer must notify the employee requesting leave whether or not they are eligible under the FMLA. If the employee is eligible for FMLA leave, and once the employer has enough information to determine that leave is being taken for a FMLA-qualifying reason, the employer must notify the employee that the leave is designated and will be counted as FMLA leave, and the amount of leave counted against the employee's leave entitlement. The employer must also notify the employee if the leave is not FMLA-protected. The federal Department of Labor has also created FMLA forms for Eligibility and Designation Notices.

How much leave time must be given and for what reasons?

The FMLA and VPFLA allow covered employees to take up to twelve weeks of unpaid leave in a twelve-month period for their own serious health condition, the serious health condition of an immediate family member, the birth and care of the employee's newborn child, or for the adoption or foster care placement of a child. The VPFLA law uses the term serious illness and defines it as any condition that poses an imminent danger of death, requires inpatient care in a hospital, or requires continuing in-home care under direction of a physician. The VPFLA also limits parental leave to the initial placement of a child 16 years of age or younger for adoption. Vermont law defines immediate family members as the employee's child, stepchild or ward who lives with the employee, foster child, parent, spouse (including civil union partner), or parent of the employee's spouse or civil union partner. The employee may use any earned, accrued paid time during the 12 weeks leave, but they cannot use the paid leave to take the entire 12 weeks. The employee can cap the total amount of paid time off an employee can use during VPFLA leave to 6 weeks.

Employees do not need to use their leave entitlement in one block. If medically necessary, FMLA/VPFLA leave for a serious health condition may be taken intermittently (in separate blocks of time due to a serious health condition) or on a reduced leave schedule (reducing the usual number of hours you work per workweek or workday). FMLA leave may also be taken intermittently or on a reduced leave schedule for a qualifying exigency relating to covered military service.

The FMLA also includes a special leave entitlement that permits eligible employees to take up to 26 weeks of leave to care for a covered service member during a single 12-month period.

What happens when the employee returns from leave?

At the conclusion of FMLA or VPFLA leave, an employee must generally be reinstated to the same or an equivalent position with equivalent benefits, pay, and other terms and conditions of employment. In other words, an employee generally cannot be permanently replaced while on VPFLA or FMLA leave. Also, during the leave, the employer must continue the employee's group health insurance as if the employee remained continuously employed, and leave cannot result in the loss of an employment benefit that accrued prior to the start of the employee's leave.

What is short-term family leave?

Vermont law also entitles eligible employees to an additional 24 hours of leave in any 12-month period, but limited to four hours in any 30-day period, for short-term family leave which can be used to participate in academic activities at their child's school, attend routine medical appointments with their child or parent, or similar matters that might not qualify for FMLA. The employee is expected to make a reasonable attempt to schedule the appointments outside of work time and to give the earliest possible notice of the need for leave.

Legislative Leave

This law covers employers who have at least six employees immediately before the covered employee's first day of legislative leave. 21 V.S.A. § 496(e). To be eligible for this leave, an employee must: work full-time and serve as a member of the Vermont General Assembly. 21 V.S.A. § 496(a). An eligible employee may take leave to perform the employee's official duties in the Vermont General Assembly. The statute does not specify an amount of leave that may be taken each year.

Jury Duty and Witness Leave

Vermont law prohibits an employer from discharging, penalizing or depriving an employee of any right or benefit of employment because the employee has been called for jury duty. 21 V.S.A. § 499. To be eligible for this leave, an employee must: (i) serve as a juror; or (ii) act as a witness in response to a court summons. The statute does not specify an amount of leave that may be taken each year.

Town Meeting Leave

All employees in Vermont are eligible to take unpaid leave to attend an annual town meeting. 21 V.S.A. § 472b. The law does not specify an amount of leave that may be taken each year.

Military Reserve and National Guard Members' Leave

All employees in Vermont are eligible for Military Reserve and National Guard Member leave. 21 V.S.A. §§ 491-493. To be eligible for this leave, an employee must be in either: (i) the reserve components of the armed forces; or (ii) an organized unit of the National Guard. An eligible employee may take leave to participate in military drills, training, or other temporary duties under military authority. 21 V.S.A. § 491(a). An eligible employee may take up to 15 days' leave under this law each calendar year. 21 V.S.A. § 491(a). For members of the Vermont National Guard who have been ordered into state active duty, the law provides for continued coverage of the employer-sponsored insurance coverage at the same levels of employer and employee contributions:

- For up to 30 days, the employer must contributions.
- If more than 30 days, the state of Vermont must cover the employer's share of contributions if the employer chooses not to continue its contributions.

21 V.S.A. § 492(c)(1), (2).

Crime Victim Status Leave

Effective July 1, 2018, all employers in Vermont were required to provide unpaid leave for employees who are "crime victims" so the employee can attend a deposition or court proceeding related to:

- 1. a criminal proceeding, when the employee is a victim as defined in 13 V.S.A. § 5301, and the employee has a right or obligation to appear at the proceeding;
- 2. a relief from abuse hearing pursuant to 15 V.S.A. § 1103, when the employee seeks the order as plaintiff;
- 3. a hearing concerning an order against stalking or sexual assault pursuant to 12 V.S.A. § 5133, when the employee seeks the order as plaintiff; or
- 4. a relief from abuse, neglect, or exploitation hearing pursuant to 33 V.S.A. chapter 69, when the employee is the plaintiff.

21 V.S.A. § 472c.

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"Crime victim" has a specific definition under the law and means: someone who has obtained under Vermont law a relief from abuse order, an order against stalking or sexual assault, or an order against abuse of a vulnerable adult; or is a victim as defined in <u>13 V.S.A. § 5301</u>, if the victim is identified as a crime victim in an affidavit filed by law enforcement with a prosecuting attorney of competent state or federal jurisdiction (and in such case "victim" shall also include the victim's child, foster child, parent, spouse, stepchild or ward of the victim who lives with the victim, or a parent of the victim's spouse, provided the person is not identified in the affidavit as the defendant). 21 V.S.A. § 495d(15)

Crime victim leave is separate and in addition to any leave available under Vermont's Family and Parental Leave law. The law contains no limit on how much leave may be utilized. To be eligible for crime victim leave, the employee must meet the definition of "crime victim" and must have been continuously employed by the same employer for a period of six months, for an average of at least 20 hours per week. It must be the employee's option whether to utilize accrued paid leave during this absence.

Employers must hold the employee's position open and continue employment benefits for the duration of crime victim leave, similar to provisions under Vermont's Parental and Family Leave law. The only exception for providing crime victim leave is for "an employer that provides goods or services to the general public if the employee's absence would require the employer to suspend all business operations at a location that is open to the general public." 21 V.S.A. § 472c(h).

Employers are required to post a notice informing employees of the provisions of this law, in a form to be provided by the Vermont Commissioner of Labor.

DOCUMENTS AND RECORD-KEEPING

What documents must a new employee complete?

After an employee is hired (but not before), the employee must complete a form I-9 (https://www.uscis.gov/i-9), and the employer must examine evidence of the employee's identity and employment eligibility, as specified on the form I-9, on the employee's first day of employment. The employee must also fill out Form W-4 (https://www.irs.gov/pub/irs-pdf/fw4.pdf) for federal income tax withholding. Any insurance forms should also be completed, as well as emergency notification information. In Vermont, new hire reporting is mandatory, and more information is available at the Vermont Department of Labor's website. (https://labor.vermont.gov/unemployment-insurance/unemployment-information-employers/employer-online-services/new-hire-0)

In addition to documents that must be completed by an employee, all employers have workplace posting requirements. Many state and federal laws require employers to notify employees of their rights under such laws through the conspicuous display of posters in the worksite.

What records should be in an employee's personnel file?

The following types of documents are generally maintained in an employee's personnel file: employee contact and emergency contact information, employment application, resume, offer or hiring letter, salary or other compensation information, including information confirming pay changes, records related to promotion, demotion, transfer, or reporting structure, performance reviews, documentation of disciplinary action, signed acknowledgment(s) of receipt of: the employee handbook or other company policies or procedures, job descriptions, any other signed agreements with the employee, including non-competes, non-disclosure (confidentiality), non-solicitation agreements, if any. Some employers also choose to keep other documents with sensitive employee information, such as the employee's social security number, separate from the employee's main personnel file.

Any information concerning an employee's health or medical conditions must be kept in confidential files, separate from other personnel documents. Otherwise, as of the date of this Chapter, Vermont does not have a law governing what documents must be or may not be in an employee's personnel file. Additionally, there is currently no Vermont law requiring a private employer to provide an employee with access to their personnel file.

What records must be kept and for how long?

Numerous state and federal laws require retention of specific employment records, but the length of retention varies. Most financial records, particularly those to support federal income tax filings, should be kept for at least seven years after the relevant return is filed. Employee benefits documents under ERISA must be kept for at least six years after the plan ends. Vermont's unemployment law requires payroll and work hour records to be kept for four years, and various employment laws, including the FLSA, require retention for at least three years after an employee leaves (or as long as any legal proceeding involving them continues). OSHA requires that documents related to certain toxic exposures be kept for the duration of employment plus thirty years. Applications, even of unsuccessful candidates, must be kept for at least one year after the hiring decision is made.

Generally, employers should consider keeping all employee personnel records (except records relating to exposure to toxic substances) for seven years after termination of employment. At the end of whatever compliant timeframe that is chosen, records should be destroyed pursuant to an established document-destruction plan.

Must an employer have an employee handbook?

Vermont law requires that every Vermont employer have a sexual harassment policy. A sexual harassment policy must include at least all information required under Vermont law. 21 V.S.A. \S 495h. The policy does not have to be in a handbook per se, but it does have to be written and disseminated (and the sexual harassment policy must be posted). For more information, see the section in this chapter on <u>Unlawful Harassment</u>.

There are pros and cons to having a handbook with more than these policies. However, every employer has policies, even if they are not written down. Those policies should be applied consistently and fairly, and putting them in writing may make it easier to do so. If an employer has a handbook, it should be clear and simple. It should say what the employer means, and the employer should really mean everything it says. Which policies to include and the extent of detail in them should reflect the employer's values, style, and culture. The contents of a handbook must be compliant with state and federal law and may be used to argue a contractual obligation has been created on the part of the employer, so any handbook should be reviewed by the organization's attorney.

What policies should an employer consider including in a handbook?

Policies should address the employer's expectations for employees - behavior, attendance, meal and rest breaks, personal use of equipment, drugs and alcohol, anti-discrimination/harassment/ retaliation, etc. They should also provide information employees need to know about administrative matters - benefits information, payroll practices, filing harassment complaints, overtime rules, expense reimbursement policies, etc. Consequences for an employee's breach of policy or failure to perform their job are often addressed. Leave time, particularly vacation, Earned Sick Leave, and unpaid family leave issues, are important topics, as there are certain choices an employer can make on such policies. Although a confidentiality provision is often included in a personnel handbook, most operational issues (how to do proper billing, what to put in a client's chart, how to answer the phone, etc.) belong elsewhere.

Vermont law requires that all employers with employees who deliver direct social or mental health services maintain a written workplace violence prevention and crisis response policy that contains elements specifically set forth in the law. 33 VSA § 8201.

ON THE JOB

What should an employer do to supervise and evaluate employees?

Each workplace has its own culture about how supervision and evaluation is carried out, ranging from formal to informal. When a problem arises, however, it is important that the employer have documentation of all corrective action it has taken or attempts it has made to improve the employee's performance. Best practice suggests that employers provide informal supervision on an ongoing basis but that formal supervision or evaluations occur at least annually. Evaluations should be as objective as possible and based on the employee's job description. If an employee has worked for an employee for several years, there is no documentation that any problems were ever discussed, and the employee is then terminated, the employer may have difficulty defending the performance-based reasons for its decision if the employee asserts the firing was for an unlawful reason. Documentation can be as simple as handwritten notes in a file, or as formal as a typed evaluation form. Above all, evaluations and supervision should be honest and not ignore or minimize problems or concerns.

What must an employer do to protect an employee's privacy?

As an employer, a physician practice may be subject to the privacy requirements of HIPAA, if it provides any health services to the employee (e.g., free screenings to employees), if it is self-insured (even partially) for health care, if it offers a medical reimbursement plan, or if it receives an employee's protected health information (PHI) for any insurance-related purpose. An employer is not subject to HIPAA merely because it has information about an employee's health for employment purposes, such as determining sick leave, family leave, workers' compensation, or disability accommodations. Therefore, each employer must determine if it is subject to the HIPAA privacy regulations related to records created or maintained for employment-related purposes. If it is, the employer must have a HIPAA policy (for employee records), must enact appropriate procedures to ensure that none of the PHI is used for employment purposes, must appoint a privacy officer, and take other steps to comply with the regulations.

Employees also have a common law right to expect privacy in certain areas, such as on their person, in bathrooms, and in changing areas. The extent of the privacy right depends on the

situation and circumstances, and employers can take steps to limit the expectation. For example, a private employer may notify employees that it will monitor workplace email or Internet use, monitor telephone calls, or search employees' workstations or handbags, as long as the notification is clear and the practice is limited to business-related matters.

When and how can an employer monitor an employee's electronic communications?

The Federal Wiretapping Act, as amended by the Electronic Communications Privacy Act, generally makes it criminal for anyone to intercept anyone else's telephone or electronic communications. The Act contains an exception that allows employers to intercept and monitor the communications of employees on its premises for work-related purposes. An employer may monitor an employee's personal call only so long as needed to determine the call is personal, or if the employee consents. Additionally, anyone may record or intercept any communication if one party to the communication consents (i.e., a person may record a conversation they are involved in, even without notice to the other parties). Some states prohibit this kind of interception without consent (so interstate calls may raise problems), but Vermont does not. A written policy clearly stating what communications will be monitored and obtaining employee acknowledgment or consent is advisable before an employee's electronic communications are monitored.

The Stored Communications Act covers stored communications, such as employee websites or emails stored on a server. (18 U.S.C. §§ 2701-12). The Stored Communications Act does not prevent an employer from reviewing communications stored on employer-provided wire or electronic communications services, if the review is authorized by the employer's policies.

There are certain circumstances where employers are prohibited from surveillance. For example, under the federal National Labor Relations Act, which applies to all employers, employers must not conduct surveillance of employees engaging in union organizing activities. Employers also must not target employees for surveillance in an unlawfully discriminatory manner.

What is an employer's obligation to employee health and safety?

Both federal and state laws require that employers maintain a safe and healthful working environment. To that end, VOSHA provides technical assistance or has the right to inspect a workplace to ensure that employers are following state and federal regulations.

When is an employer liable for an employee's acts?

Generally, an employer can be held liable by a third party for negligent acts committed by its employees within the scope of their employment. Sometimes employers are even liable for the intentional or reckless acts of employees, but usually only if the employer was aware of the potential that the employee would act as they did and the scope of the employee's employment allowed the employee to engage in that act. Employers generally are not liable for the acts of their employees outside the scope of their employment.

What must an employer do to accommodate an employee with a disability?

The federal Americans with Disabilities Act of 1990 (ADA), as amended by the ADA Amendments Act of 2008 and the Vermont Fair Employment Practices Act both require an employer to refrain from discriminating against qualified individuals because of a disability and provide qualified individuals with a disability a reasonable accommodation, unless doing so

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would cause an undue hardship. All employers are covered by Vermont's FEPA and a private employer is covered under the ADA if it has 15 or more employees on its payroll for 20 or more calendar workweeks (which do not need to be consecutive) in either the current or preceding calendar year. 29 C.F.R. § 1630.2(e).

A reasonable accommodation is a change in the work, workplace, or application process that helps make it possible for an individual with a disability to perform the duties of or apply for a job, or enjoy the benefits and privileges of employment. An employer does not have to provide the exact accommodation the employee or applicant wants, if more than one accommodation would be effective.

Under the ADA, the term "qualified," with respect to an individual with a disability, means that the individual satisfies the requisite skill, experience, education and other job-related requirements of the employment position such individual holds or desires and, with or without reasonable accommodation, can perform the essential functions of such position. 29 C.F.R. § 1630.2(m).

An undue hardship means the accommodation would cause significant difficulty or expense for an employer, in light of the employer's size, financial resources, and the needs of the business. It is not an undue hardship just because an accommodation request involves some cost to the employer.

When does an employee have a disability?

According to the Americans with Disabilities Act and the Vermont Fair Employment Practices Act (VT FEPA), a disability is a physical or mental impairment that substantially limits one or more major life activities (such as walking, talking, seeing, hearing, learning, or working). 42 U.S.C. § 12102(1); 29 C.F.R. § 1630.2(g); 21 V.S.A. § 495d(5). The ADA and VT FEPA also prohibit discrimination against individuals who have a history or record of a disability (e.g., cancer that is in remission) or who are regarded as having a disability (e.g., the employer believes the employee is disabled). The ADA further prohibits discrimination against individuals who have a relationship with or are associated with a person with a disability.

A physical impairment is further defined as:

any physiological disorder, or condition, cosmetic disfigurement or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic, lymphatic, skin, endocrine, immune, or circulatory. 29 C.F.R. § 1630.2(h)(1).

A mental impairment is defined as "any mental or psychological disorder, such as intellectual disability, organic brain syndrome, emotional or mental illness, and specific learning disabilities." 29 C.F.R. § 1630.2(h)(2).

Under the ADA, the definition of disability is to be interpreted in favor of broad coverage. Nonetheless, not every impairment will constitute a disability within the meaning of the ADA. However, the term "substantially limits" shall be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of the ADA. "Substantially limits" is not meant to be a demanding standard. 29 C.F.R. § 1630.2(j)(1)(i). An impairment is a disability within the meaning of the ADA if it substantially limits the ability of an individual to perform a major life activity as compared to most people in the general population. An impairment does not need to prevent, or significantly or severely restrict, an individual from performing a major life activity in order to be considered substantially limiting. 29 C.F.R. § 1630.2(j)(1)(i).

Under ADA regulations, the following (non-exhaustive) list includes impairments that should be "easily" be found to be disabilities: deafness, blindness, an intellectual disability, partially or completely missing limbs or mobility impairments requiring the use of a wheelchair, autism, cancer, cerebral palsy, diabetes, epilepsy, human immunodeficiency virus (HIV), multiple sclerosis, muscular dystrophy, major depressive disorder, bipolar disorder, post-traumatic stress disorder, obsessive compulsive disorder, and schizophrenia. 29 C.F.R. § 1630.2(j)(3)(iii). Mitigating or corrective measures (such as hearing aids or medications) must not be considered in the analysis of whether an individual has a disability.

Alcoholism may meet the definition of a disability, but the ADA specifically provides that employers may prohibit the use of alcohol in the workplace and may require an employee who is an alcoholic or who engages in the illegal use of drugs to meet the same performance and behavior standards of other employees. 42 U.S.C. § 12114 (c)(4). The ADA does not protect an individual who currently engages in the illegal use of drugs, but it may protect a recovered drug addict who is no longer engaging in the illegal use of drugs, who is qualified and can meet the definition of disability under the ADA. 42 U.S.C. § 12210.

<u>What documentation can an employer require to determine if an employee has a disability?</u> After a request for a reasonable accommodation has been made, and whether the need for accommodation is not obvious, an employer may request that the employee provide reasonable documentation from a health care provider confirming the existence of a disability, the employee's job-related functional limitations, and the need for a reasonable accommodation. An employer must be careful to avoid seeking more information than is necessary to make those determinations. For example, an employer can only seek documentation pertaining to the disability that requires a reasonable accommodation.

What must an employer do if an employee requests an accommodation?

Generally, a request for an accommodation comes from the disabled individual. Alternatively, a request may come from a third party asking for an accommodation on behalf of the covered individual. Requests can be made verbally or in writing, and the individual does not specifically have to say the word "accommodation." An employer cannot obligate that an employee's request take a certain form before considering it. EEOC guidance also suggest that employers should be offered or provided without request in situations where the employer knows the employee has a disability and is experiencing workplace problems because of the disability.

When an individual requests a reasonable accommodation for a disability, the employer must promptly engage in an "interactive process" in good faith to determine what limitation are created by the disability and to explore potential, appropriate and reasonable accommodation(s). When engaging in the interactive process, an employer should do the following:

• Document the individual's accommodation request;

- Determine (if not known or obvious) that the individual has a disability;
- Ask the individual to provide relevant information, if necessary;
- Meet with the individual to discuss job-related limitations, the accommodation request, and possible alternatives; and
- Document the discussion about the accommodation and the determination on the request.

The ADA and Vermont law require an employer to provide a reasonable accommodation if the employee (or applicant) is otherwise qualified for the job and if the employee needs the accommodation to perform the essential functions of their job. A reasonable accommodation means any modification or adjustment to the job or work environment. The essential functions of a job are key to any reasonable accommodation analysis under the ADA. If an employee cannot perform one or more of the essential functions of the job they were hired to do, and there is no reasonable accommodation that can enable them to perform that function, the employee is not qualified to do the job. In such cases, an employer must examine whether the employee can be reassigned to a vacant position as a reasonable accommodation.

An employee may request that marginal or non-essential duties of a position (for example, a function that can be performed by another employee or a function that is only occasional) be reallocated or redistributed as a reasonable accommodation.

The laws do not define, in relation to any particular job, what is reasonable and what is not. That determination is made on a case-by-case basis, although employers do not have to change the essential functions or nature of the job to accommodate an employee. Also, the duty to provide an accommodation is ongoing - an individual can make more than one accommodation request and may modify a request if circumstances change.

What are examples of reasonable accommodations?

Examples of reasonable accommodation include: making existing facilities used by employees readily accessible to and usable by an individual with a disability; restructuring a job; modifying work schedules; acquiring or modifying equipment; providing qualified readers or interpreters; or appropriately modifying examinations, training, or other programs; providing a leave of absence; allowing the use of reserved parking spaces, etc. Reassigning an employee to a vacant position may be a reasonable accommodation if it is requested or there are no accommodations that would keep the employee in their current position.

An employer is not required to provide personal use items such as glasses, wheelchairs, or hearing aids unless the employee only needs them to perform a specific function at work and in no other situation. It is not a reasonable accommodation to eliminate or reassign an essential function of the job.

What can an employer do if an employee presents a health or safety risk?

An employer does not have an obligation to accommodate an employee who poses a direct threat to the safety of themself or others. A "direct threat" means "a significant risk of substantial harm" that cannot be reduced or eliminated by any reasonable accommodation. The risk of harm must not be speculative but must be reasonable and based on current, objective medical knowledge and/or evidence.

What must an employer do to accommodate an employee with a pregnancy-related condition? Vermont law requires that employers provide reasonable accommodation(s) for an employee's pregnancy-related condition, unless it would impose an undue hardship. 21 V.S.A. § 495k. A pregnancy-related condition is a limitation of an employee's ability to perform the functions of a job caused by pregnancy, childbirth, or a related medical condition. An employee with a pregnancy-related condition has the same rights to reasonable accommodations that a qualified individual with a disability has under the law.

PROBLEMS AND END OF EMPLOYMENT

When can an employee be disciplined or terminated?

In Vermont, an at-will employee may be disciplined or terminated at any time, with or without notice, and for any reason or for no reason at all, as long as it is not an unlawful reason. Having said that, there are several specific laws that define unlawful reasons for termination or that govern an employer's behavior towards an employee, many of which have been addressed in this Guide. For example, common law may provide an employee with a civil remedy if an employer denies an employee any protection or benefit the employer has promised and on which the employee has detrimentally relied, defames an employee or former employee, intentionally inflicts emotional distress on him/her, or intentionally interferes with the employee's contractual relations with others.

What are unlawful reasons to discipline or terminate an employee?

There are numerous unlawful reasons to terminate an employee, but some of the most common follow (this list is not all-inclusive):

- because of the employee's race, color, sex, gender, gender identity, age, religion, national origin, ancestry, place of birth, ethnicity, pregnancy, sexual orientation, disability, physical or mental condition, genetic information, HIV-positive status, military service or obligation, veteran status, crime victim status, citizenship, or immigration status;
- because the employee has disclosed the amount of his/her wages or inquired about or discussed the wages of other employees;
- because the employee has complained about discrimination, filed a charge of discrimination, or cooperated in an employment discrimination investigation or lawsuit or because the employer believes that the employee may lodge a complaint or cooperate with officials in an employee discrimination investigation;
- because the employee filed a workers' compensation or VOSHA claim;
- because the employee has exercised or attempted to exercise his/her rights to medical, parental, family or other leave under the law, if applicable;
- because the employee missed work to serve on a jury;
- because the employee reported a health or safety violation;
- because the employee attempted to unionize other employees or engaged in other protected concerted activities for employees' mutual aid or protection;
- because the employee refuses to take a polygraph test (except where permitted by law); or
- because the employee engaged in activities protected by public policy.

Employees of hospitals and nursing homes also have whistleblower protection. 21 V.S.A. §507.

What is discrimination?

Discrimination is an action that adversely affects an employee in any aspect of the terms, conditions, or privileges of employment, such as hiring, firing, compensation, transfer, promotion, testing, recruiting, or receipt of benefits. Treating one employee or one class of employees differently from others because of one or more legally protected characteristics is unlawful discrimination.

What kind of discrimination is prohibited?

The Vermont Fair Employment Practices Act (21 V.S.A. § 495) applies to all Vermont employers, regardless of size, and prohibits discrimination on the basis of race, color, religion, national origin, sex, sexual orientation, gender identity, ancestry, place of birth, age (18 and up), physical or mental condition, crime victim status, or HIV-positive status.

There are many state and federal laws that prohibit discrimination in employment based on various additional protected characteristics, each of which has a different threshold level of employees for coverage (some of these characteristics are included under the unlawful reasons to terminate an employee, set forth above).

What is unlawful harassment?

Harassment is a form of unlawful employment discrimination. Harassment is unwelcome conduct based on a legally protected characteristic, where 1) enduring the offensive conduct becomes a condition of continued employment; or 2) the conduct is severe or pervasive enough to create a work environment that a reasonable person would consider intimidating, hostile, or abusive. Employers should take appropriate steps to correct and prevent unlawful harassment of its employees. Any employee who is affected by the offensive conduct can be the victim of harassment, even if he or she is not the person being harassed.

Vermont law specifically defines sexual harassment as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when:

- submission to that conduct is made either explicitly or implicitly a term or condition of employment; or
- submission to or rejection of such conduct by an individual is used as a component of the basis for employment decisions affecting that individual; or
- the conduct has the purpose or effect of substantially interfering with an individual's work performance or creating an intimidating, hostile or offensive work environment. 21 V.S.A. § 495d(13).

Beginning on July 1, 2018, every person who engages someone to perform work or services is obligated to ensure the working relationship with that person will be free from sexual harassment, not just employees.

Vermont law requires every employer to have a sexual harassment policy, which shall include:

- a statement that sexual harassment in the workplace is unlawful;
- a statement that it is unlawful to retaliate against an employee for filing a complaint of sexual harassment or for cooperating in an investigation of sexual harassment;

- a description and examples of sexual harassment;
- a statement of the range of consequences for employees who commit sexual harassment;
- if the employer has more than five employees, a description of the process for filing internal complaints about sexual harassment and the names, addresses, and telephone numbers of the person or persons to whom complaints should be made; and
- the complaint process of the appropriate state and federal employment discrimination enforcement agencies, and directions as to how to contact such agencies. 21 V.S.A. § 495h(b).

If an employer changes their sexual harassment policy, it must provide written notice of the updated policy to all employees.

A poster containing at a minimum, the required elements of a sexual harassment policy must be prominently displayed in every workplace, and each employee must receive an individual written copy.

In addition, both federal and Vermont law require an employer to take prompt, remedial action reasonably calculated to end the harassment whenever the employer receives a report of unlawful harassment. The first step in any response is to investigate and document the allegations. What other action to take will depend on the nature of the conduct at issue and the relationship of the perpetrator to the victim. An employer will be held liable for a supervisor's sexual harassment, where that supervisor has taken a tangible employment action against the victim. Conduct by a co-worker may involve liability to the employer if the employer has knowledge of the harassment and fails to take appropriate and prompt remedial action.

What can an employer do to reduce exposure to claims for harassment or discrimination?

First, all changes in an employee's terms and conditions of employment should be based on legitimate performance reasons or be consistent with the business needs and mission of the organization. Second, employee performance problems should be addressed promptly and honestly, rather than being tolerated, downplayed, or ignored. Third, if an employer learns that an employee feels they are being discriminated against or harassed, the employer should document the concerns, immediately investigate them, and take prompt action to try to end the behavior. An employer must promptly investigate allegations of unlawful discrimination or harassment, even if the employee or witness refuses to submit a complaint in writing or the employee asks that the matter be kept confidential. While an employer should keep employee complaints as confidential as possible, complete confidentiality should never be promised because some information must be disclosed when investigating a complaint in order to gather relevant information. Fourth, the employer should conduct periodic training of employees to ensure that they are aware of the laws affecting the workplace and that their conduct conforms with them. Fifth, employment policies should be clear and consistently followed.

What laws govern reductions in force or mass layoffs of employees?

The federal law specifically governing layoffs is the Worker Adjustment and Retraining Act (the "WARN Act"), which applies to organizations with 100 or more employees. The WARN Act requires notification 60 days before a facility or operating unit of a business is closed or a mass layoff is held that involves employment loss for 50 or more employees.

Vermont also has the Notice of Potential Layoffs Act (or "NPLA") 21 V.S.A. §§ 411-418, which applies to employers with 50 or more employees. The NPLA generally requires employers to provide 45 days' notice to the State government and 30 days' notice to employees and local government in advance of covered mass layoffs. Notice obligations are triggered when there is to be a mass layoff or business closing that will result in the permanent employment loss of at least 50 employees at one or more worksites in Vermont during any 90-day period. An employer who fails to provide required notice may be liable for administrative penalties as well as severance pay and health benefit continuation for affected employees.

To ensure compliance with both the state and federal layoff notification laws, potentially covered employers should consult with counsel in advance of implementing any layoffs, reductions in force or plant closings.

What is unemployment compensation?

Under Vermont and federal laws, employees who lose their jobs, generally through no fault of their own, are entitled to unemployment compensation during periods between jobs. The unemployment compensation fund is funded entirely by employer taxes, and the amount of tax is based on the employer's experience rating - that is, the number of claims attributable to it within the relevant period. Non-profit 501(c)(3) organizations may elect not to contribute (and pay any claims directly themselves).

A former employee will generally be eligible for unemployment benefits if the separation is through no fault of their own and they are willing and able to work. There are certain circumstances where a claimant may be partially or totally disqualified from unemployment benefits in circumstances of misconduct or gross misconduct, as these terms are narrowly defined by Vermont unemployment compensation law. The Vermont Department of Labor's unemployment office particularly looks to find out if the employee has received notice and warning about the consequences of their behavior, as well as its severity, before denying benefits. A claimant may also be denied benefits if the employee quits (leaves voluntarily without good cause attributable to the employer). For more information, see the Vermont Department of Labor's unemployment of Labor's unemployment insurance webpage.

What can/should an employer say in giving a reference?

Employers must be careful in giving references for former employees, as defamation, retaliation and tortious interference with contract claims have been made against employers for making false statements that damage a person's reputation or ability to find another job. On the other hand, employers have been sued by a person's new employer because they have given a falsely positive reference that fraudulently misrepresented the former employee in an overly positive light. Many of the legal cases have involved extreme situations, such as accusing an employee of stealing when the employer had no evidence the employee stole (and particularly if the employee is later able to prove that she/he did not) or giving a glowing reference for an employee who was terminated for sexual assault. To minimize exposure to claims, many employers refuse to give references for anyone (there is no legal requirement to provide a reference) or choose to give only limited information (e.g., to confirm solely dates of employment, positions held). Still others give a reference only after receiving a written release from the former employee to do so. Whatever the approach, employers should consistently follow the same practice when providing references.

What are the requirements for continuation of health benefits for employees who leave employment?

The Consolidated Omnibus Budget Reconciliation Act (COBRA) requires group health plans offered by employers with 20 or more employees to offer continuation coverage for employees or their dependents who experience a "qualifying event" and requires employers to give notice of COBRA rights. A qualifying event may be termination of employment, a reduction in hours, divorce, or similar acts that result in a loss of group health benefit coverage. The continuation of coverage may require that the employee pay the cost of the coverage and may continue for up to 18 months (36 months for certain qualifying events) from the date the health plan would have ended. If the beneficiary does not pay the premium, the employer ceases to offer any group health plan, or the employee becomes eligible for another health insurance plan or Medicare, the continuation coverage ends. When the employee leaves employment, the employer or insurer must send the employee a notice to elect continuation coverage.

Vermont law requires all group health insurance plans, even those for employers with fewer than 20 employees, to provide 18 months of continuation coverage. 8 V.S.A. § 4090a, et. seq. The standards are similar to COBRA, and an employer must sent notice of the right to elect continuation of coverage to the employee (or former employee) within 30 days following the occurrence of any qualifying event. 8 V.S.A. § 4090a(e).

COVID-19 AND EMPLOYEE SAFETY

At the time of this chapter's most recent update, the Occupational Health and Safety Administration, as well as the Centers for Medicare and Medicaid had attempted to implement vaccine mandates for employers. Under these mandates, employers may be subject to vaccination requirements and a requirement to provide paid time off to receive and recover from the vaccine. However, these mandates are the subject of litigation, and given the rapidly changing nature of the law, these mandates are not addressed in this Guide. Employers should consult with a human resources professional or an experienced employment or health care attorney concerning an employer's obligations in connection with COVID-19 vaccination and workplace safety requirements.

ABOUT THE AUTHOR

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END OF LIFE CONSIDERATIONS

Topics Covered in this Chapter: <u>Autopsy & Death Certificates</u> (unedited by C. Bruzzese) <u>Advance Care Planning</u> <u>Patient Self-Determination</u> <u>Advance Directives for Health Care</u> <u>Do-Not-Resuscitate (DNR) & Clinician Orders for Life Sustaining Treatment (COLST) Orders</u> <u>Surrogate Consent for Hospice</u> <u>Patient Bill of Rights for Palliative Care and Pain Management</u> <u>Required Policies and Procedures</u> <u>Organ Donation</u> (also called Anatomical Gifts) <u>Medical Aid in Dying (Vermont's Act 39)</u> <u>About the Author</u>

By: Cindy Bruzzese, MPA, MSB, HEC-C Executive Director & Clinical Ethicist, Vermont Ethics Network Clinical Ethicist, University of Vermont Medical Center

AUTOPSY & DEATH CERTIFICATES

Note: Sub-section on Autopsies and Death Certificates Not Written by C. Bruzzese and Last Updated for 2018 Edition

Who must sign a death certificate?

The physician who last attended the deceased person during his or her last illness must immediately fill out a death certificate, in a form established by the commissioner of health. If this physician is unable to state the cause of death, he or she must immediately notify the physician, if any, in charge of the patient's care, who should then fill out the certificate. If neither physician is able to state the cause of death, then the autopsy provisions discussed below apply.

A physician who fails to furnish a death certificate within 24 hours of death shall be fined not more than \$100.00.

Beginning on Jan. 1, 2012, a law passed by the legislature in 2009 will allow licensed health care professionals (physician assistants and advance practice registered nurses, as stipulated by the law), in addition to physicians, to sign death certificates. If a physician assistant or advance nurse practitioner is unable to determine the cause of death, he or she must notify a physician.

What role does the funeral director play in completing a death certificate?

The physician, or other health care professional as stipulated above after Jan. 1, 2012, may, with the consent of the funeral director, delegate the responsibility of gathering data and filling out all items on the death certificate, except the medical certification of cause of death.

What happens if the attending physician at a hospital death is unavailable?

When an admitted patient in a hospital dies and it is impossible to obtain a death certificate from an attending physician before burial or transportation, any physician (or health care professional after Jan. 1, 2012) who has access to the facts and can certify that the death is not subject to the autopsy provisions (set out below) may complete and sign a preliminary death report. The town clerk or deputy shall accept this report and issue a burial-transit permit. This preliminary report does not relieve the attending physician from the responsibility of completing a death certificate and delivering it to the funeral director within 24 hours after death.

When is a health care professional required to notify the medical examiner of a death?

A health care professional must notify the medical examiner when he or she learns that a person has died:

- From violence; or
- Suddenly, when in apparent good health; or
- When unattended by a physician or a recognized practitioner of a well-established church; or
- By casualty; or
- By suicide; or
- As a result of injury; or
- When in jail or prison, or any mental institution; or
- In any unusual, unnatural or suspicious manner; or
- In circumstances involving a hazard to public health.

The medical examiner who resides nearest the town where the death occurred should be notified. The medical examiner must then notify the state's attorney of the county in which the death occurred.

Does a physician have to share any potentially privileged information with the medical examiner?

Yes. Upon a medical examiner's request, physicians are required to disclose any information as to the mental or physical condition of a deceased patient privileged under subsection (C)(2) of 12 V.S.A. § 1612.

Who can order an autopsy?

If the chief medical examiner or investigating state's attorney deems it necessary and in the interest of public health, welfare and safety, he or she may order an autopsy. When it is completed, the chief medical examiner must submit a report to the appropriate state's attorney and the attorney general, and then complete and sign a certificate of death.

ADVANCE CARE PLANNING

Advance care planning (ACP) is an ongoing process of discussing, planning, and documenting an individual's goals, values and wishes for future health care in the event they are unable to make their own decisions. Designed to help people prepare for unexpected events due to medical emergency or an acute, chronic, or terminal illness, the aim of ACP is to improve quality care and reduce the burden of decision-making for family members called upon to make decisions should a patient become incapacitated. In addition to improving quality of care through the clarification of complex and often complicated medical options, effective advance care planning seeks to ensure that the care and treatment that patients desire ultimately aligns with the care and treatment that is provided.

PATIENT SELF-DETERMINATION

In 1990, Congress passed the Patient Self-Determination Act, which required hospitals, skilled nursing facilities, and home health and hospice organizations to (1) inform patients of their rights under state law to make decisions concerning their medical care; (2) periodically inquire as to whether a patient had executed an advance directive and document their wishes regarding medical care; (3) not discriminate against people who have completed an advance directive; (4) provide educational programs for staff, patients and community on self-determination and advance directives; and (5) ensure that valid advance directives and documents surrounding patient preferences are implemented to the extent permitted by law.

The State of Vermont recognizes this fundamental right of patient self-determination and has promulgated laws that allow decisional adults to determine the extent of health care that they will receive, including treatment provided during periods of incapacity and at the end of life. The right to self-determine allows adults to retain control over their own medical and mental health care through legal documents called advance directives. Self-determination further dictates that when adults lack decisional capacity, decisions that are made by their appointed decision-maker (aka *health care agent, durable power of attorney for health care, health care proxy*) shall be based on the express instructions, values, and goals of the individual, if known (*substituted judgement*), and if unknown, by what is in the individual's health-related *best interest*.

ADVANCE DIRECTIVE FOR HEALTH CARE

Prior to 2005, Vermont utilized the *durable power of attorney for health care (DPOA-HC)* as the recognized legal tool to appoint a health care decision-maker and the *living will* (or terminal care document) as the legal tool for expressing treatment wishes at the end of life. In 2005, Vermont updated its laws to better reflect the complex nature of medical decision-making throughout the adult lifespan, not just at end-of-life. In so doing, they combined the former *DPOA-HC* and *living will* into one comprehensive document called an advance directive.

An advance directive is a legal document that allows an adult with decision-making capacity to appoint a surrogate decision maker (*health care agent*) and to provide specific information regarding their values and preferences for medical and mental health treatment in the event that they are unable to speak for themselves.
Completing an Advance Directive

In Vermont, an adult with capacity can execute a legally binding advance directive by signing their completed document in the presence of two or more adult witnesses. Witnesses must sign and affirm that the individual appeared to understand the nature of the document and was free from duress or undue influence at the time the document was signed. Neither the appointed agent nor the individual's spouse, parent, adult sibling, adult child, or adult grandchild may serve as a witness to their advance directive. A health care provider may serve as a witness to an advance directive. There is no notary requirement in Vermont, nor can a notary be used in lieu of the two required adult witnesses.

If the individual is being admitted to or is a resident of a nursing home, residential care facility or is being admitted to or is a patient in a hospital at the time the advance directive is completed, Vermont requires that a <u>designated explainer</u> [see 9703(d) and (e)] to explain the nature and effect of the advance directive to the individual and sign the document attesting to that fact. The individual who serves as the explainer may also serve as one of the two required witnesses.

Nursing homes and residential care facilities that choose to use volunteers to explain advance directives per subsection 9703(d) of the advance directive statute must ensure that volunteers receive appropriate training.

Every hospital must designate and adequate number of individuals to explain advance directives to patients who are being admitted or already admitted and completing advance directive while in the hospital.

The Purpose of Advance Directives

Advance directives are a legal tool used to appoint a surrogate decision maker called a *health care agent* to speak on an individual's behalf if they become unable or unwilling to communicate for themselves. Individuals can list the people they would like informed about their care or involved in decision-making, including their primary care physician. Advance directives can also be used to identify any people that the individual does not want involved with or consulted about their health care decisions.

In addition to identifying who is and is not authorized to make medical decisions, advance directives allow individuals to communicate a wide range of health care goals and priorities, including the kind of treatment they do or do not want if they become incapacitated, seriously ill or are dying. In general, individuals can use advance directives to express their overarching goals of care; their preferences surrounding the use of cardiopulmonary resuscitation, intubation, feeding tubes, etc.; their preferred setting for care and treatment; as well as their specific wishes regarding organ donation, spiritual beliefs, funeral, burial, and disposition of remains.

There are a number of advance directive forms available in Vermont to assist individuals with their advance care planning needs. Individuals are encouraged to seek out and utilize the form that best promotes them to document what matters most and what they believe their health care clinicians need to know in order to take the best possible care of them. The most frequently used advance directive forms in Vermont can be found on the <u>forms page</u> of the Vermont Ethics Network website.

Psychiatric Advance Directives

Advance care planning (ACP) and advance directives are most frequently considered in the context of serious medical illness or end-of-life situations. Yet, there is great utility for advance care planning for individuals living with mental illness or psychiatric conditions. The ACP process can help clarify preferences for mental health treatment and develop a plan in advance of a crisis. The conversation around developing a psychiatric advance directive enhances the process of informed consent, improves continuity of care, and provides a mechanism for family or close friends to be involved in treatment officially, without having to go through a complicated and often protracted guardianship proceeding.

The process of creating a psychiatric advance directive helps an individual think through what to do to prevent a crisis, what to do during a crisis, and how best to recover from a crisis. Psychiatric advance directives can also be a great help to clinicians trying to make decisions in a system where treatments are complicated, information sharing is fragmented, and friends/families may not be immediately available.

Similar to their counterparts in the medical environment, psychiatric advance directives are legal documents completed by individuals to document preferences for future treatment in advance of a mental health or psychiatric crisis. While there is no *special* advance directive form for psychiatric care in Vermont, the *Long Form Advance Directive* or *Disability Rights Vermont Form* are recommended for documenting what to do if a person loses capacity to give or withhold consent for treatment during an acute episode of a psychiatric illness.

When an Advance Directive Becomes Effective

In general, an advance directive becomes effective when a clinician determines that an individual lacks capacity for the specific medical decision at hand. However, an individual may specify a circumstance or condition, unrelated to their capacity, which when met, makes the authority of their health care agent effective. Individuals can also specify a date when they want their advance directive to go into effect and can also have the document go into effect immediately upon execution. Should an individual choose to have their advance directive and the authority of their health care agent go into effect in advance of losing capacity, the individual with capacity retains concurrent authority with their agent to make health care decisions. Should the individual disagree with the decision of their designated agent, the decision of the capacitated individual is controlling.

Decision-Making Capacity

Decision-making capacity (DMC) is not synonymous with *competence*. Legal competence is a global determination made by a court, whereas decision-making capacity is decision-specific and is determined by a clinician—physician, nurse practitioner or physician assistant. DMC is directly related to informed consent and requires a patient to be able to understand and appreciate their medical situation, reason through risks, benefits and alternatives and make choices freely and voluntarily. Having decisional capacity also includes having the ability to engage in what a stated decision requires.

Patients with decision-making capacity have the right to accept or decline medical intervention consistent with their goals, values, and priorities, even if decisions may result in a poor outcome—including death. Clinicians are obligated to respect the decisions of capacitated individuals, even if those decisions are contrary to medical recommendations. Clinicians are also required to support patients to make as many decisions as their capacity allows and to do so in the least restrictive manner possible.

All adults are presumed to have decision-making capacity. To protect the autonomous rights of patients the threshold for decision-making capacity is set low and the burden of proof for establishing impaired decision-making capacity is therefore high. Uncertainty is managed in the direction of the presumption and not in the direction of the impairment.

When capacity is impaired or lacking, patients retain the right to have their values respected via surrogate decision makers – health care agents, medical guardians, or other persons with a known close relationship to the patient who can give context to contemporary health issues and apply the patient's goals and values. It is incumbent on all surrogate decision-makers to utilize substituted judgment (knowledge of the patient's goals and values, statements and/or instructions in advance directives, etc.) when making decisions for the patient (if possible). This means that they are responsible to voice what the patient would say if they were able. When DMC is impaired or absent (and the patient cannot provide informed consent), clinicians are still responsible to seek the patient's assent – their agreement, or at least their lack of refusal. **Patients who lack decisional capacity retain the fundamental right to refuse recommended treatment.**

Documentation by Clinician of Impaired DMC: When a patient is assessed as lacking capacity for a specific medical decision, the clinician must document the cause, nature, and projected duration of the incapacity in the patient's medical record. At the same time, autonomy-based obligations require that clinicians work to restore a patient's capacity, if possible, and while so doing to make reasonable efforts to notify the patient's health care agent, medical guardian, or appropriate surrogate decision-maker of the patient's decision-making status.

Request for Reevaluation of a Patient's Capacity: The patient, agent, guardian, surrogate, ombudsman, health care provider, or treating clinician, may request that the patient be reexamined to determine whether the patient has regained capacity.

Responsibilities of Clinician Who Reassesses Patient's Capacity: The clinician must document the results of the reexamination in the patient's medical record and make reasonable efforts to notify the patient, agent, guardian, or surrogate of the results. Consistent with HIPAA's privacy requirements, the clinician must also notify the person who requested the reexamination.

Impact of Restored Capacity on Medical Decision-Making: Generally, when capacity has been restored, medical decision-making reverts to the patient to make decisions for themself. If an advance directive had been activated, it would no longer be in effect and the agent's authority to make medical decisions would also cease.

Authority & Obligations of Health Care Providers and Health Care Facilities Regarding Advance Directives

Absent an emergency, health care providers, facilities and residential care facilities are obligated to determine if an advance directive is in effect before providing treatment to an incapacitated individual. Having knowledge that an advance directive is in effect, health care clinicians, facilities and residential care facilities must follow the instructions of the person who has the authority to make medical decisions or the instructions in the advance directive unless: the instructions by the decision-maker are inconsistent with the individual's advance directive or contrary to the individual's known goals and values; the instruction would cause the clinician to violate Vermont advance directive law or other laws, established standards of care, or standards of professional conduct; or because of moral, ethical or other conscience-related conflicts.

In instances where clinicians are unable to honor an advance directive or the instructions of the authorized decision-maker, the clinician shall inform the patient (if possible) and the authorized decision maker (health care agent, guardian, surrogate) of the reasons for the refusal and document in the patient's medical record their refusal, the reason for the refusal, who was notified, and any other steps take to resolve the issue.

In the event that the reason for not honoring the advance directive or instruction by an authorized decision-maker pertains to moral, ethical or other conscience-related conflicts, the clinician shall promptly inform the patient (if possible) and their decision-maker of the conflict, assist in transfer of care to another provider willing to honor the instruction, provide ongoing care until a new provider has been found to provide the services and document in the medical record the nature of the conflict, steps taken to resolve the conflict and the resolution of the conflict.

There may be instances where an individual has appointed more than one person to serve as their health care agent (i.e. co-agents). In this circumstance, the individual's clinician, health care provider or residential care provider may rely on the decision of one of the agents as long as they document in the medical record that the agent confirms that:

- 1. all agents agree on the specific health care decision; or
- 2. all agents agree that this agent can make the decision; or
- 3. the other agents are not reasonably available.

Failure to Follow Advance Directives

Health care providers and facilities are subject to review and disciplinary action by the appropriate licensing entity for failing to act in accordance with a known advance directive or instruction of a health care agent or guardian, and for unauthorized accessing of the Vermont Advance Directive Registry.

Health Care Agent Authority and Obligations

A health care agent must be an adult (18 years of age or older) that the individual trusts to make decisions on their behalf and will advocate for care and treatment that aligns with the individual's values, goals and health care priorities. The individual's health care provider may not serve as their health care agent. Unless related to the individual by blood, marriage, civil

union or adoption, a health care agent may not be the owner, operator, employee, agent or contractor of a residential care facility, a health care facility, or a correctional facility in which the individual resides at the time of execution of an advance directive. (18 VSA § 9702)

Health care agents have the authority to make all health care decisions that the individual could make if they had capacity. This includes the right to accept or decline medical treatment consistent with the individual's preferences and goals. Health care agents also have the same rights as the individual would have to request, review, and receive oral or written information regarding the patient's physical or mental health, including medical records; to participate in meetings concerning the patient; to consent to the disclosure of information; and to file a complaint on behalf of the patient.

Agents are obligated to make health care decisions by first attempting to determine what the individual would have wanted under the circumstances (substituted judgment). In so doing, the health care agent must consider specific instructions contained in an advance directive (to the extent applicable), wishes expressed since or prior to the execution of the advance directive, and knowledge of the individual's values, goals or religious or moral beliefs. If the health care agent cannot determine what the individual would have said under the circumstances, they are obligation to make decisions based on what is in the individual's best interests. When making best interest decisions, health care shall not be provided or withheld based on economic status, or pre-existing, long-term mental or physical disability. Moreover, the agent shall not consider their own interests, wishes, values or beliefs when making decisions for an in incapacitated individual.

If a designated health care agent is unable or unwilling to make medical decisions in accordance with requirements, they must recuse themselves from the decision or resign from serving as the health care agent. They must also notify the patient (if possible), the alternate agent (if there is one) and the health care provider and residential care provider of their recusal or resignation.

For more information about serving as a health care agent and making medical decisions for someone else, download the <u>Vermont Handbook on Making Medical Decisions for Someone Else.</u>

Frequently Asked Questions about Advance Directives

The Vermont Ethics Network has compiled a comprehensive listing of frequently asked questions that address a range of topics related to completing advance directives, what to do after a document has been completed, updating, amending, or revoking existing documents, reciprocity with other states, how decisions are made when an individual lacks capacity but has not completed an advance directive and myriad other questions. To review the complete listing of frequently asked questions, go <u>here</u>.

Right to Refuse Treatment & The Ulysses Clause

It is well established in medicine, ethics and law that patients with decision-making capacity have the right to decline medical intervention as an expression of their autonomy, even when so doing may result in a poor outcome, including death. This right of refusal is considered a negative right—the right to noninterference and to be free of unwanted medical interventions and

bodily invasions. Individuals who lack decisional capacity retain the right to refuse. Health care agents, medical guardians and informal surrogates do not have authority to consent for treatment over objection when an individual lacks capacity and is refusing.

In the medical environment, the law provides guidance and a framework for when it is permissible to treat a person who lacks capacity and is refusing. Per 18 VSA § 9707, individuals who lack decisional capacity cannot be treated over their objection unless:

- 1. the individual's advance directive contains a Ulysses Clause provision which permits their health care agent to authorize or withhold treatment over objection and the agent authorizes providing or withholding the treatment; or
- 2. the individual lacks capacity and will suffer serious and irreversible bodily injury or death if the health care cannot be provided within 24 hours and:
 - a. there is no health care agent or Ulysses Clause provision in an advance directive or the agent is not reasonably available; or

b. the agent or advance directive authorizes providing or withholding the treatment. The intent of the law is to permit physicians to emergently treat incapacitated persons when time does not permit for judicial review. When treatments are not emergent, the law requires judicial oversight for the patient to be declared incompetent (the legal determination based on the medical assessment of lacking capacity) and a guardian appointed through the Probate Court with permission to treat over objection.

The Ulysses Clause: A specific provision in an advance directive that permits a health care agent, in the event the individual lacks capacity, to authorize or withhold consent to treatment over objection. A Ulysses Clause allows an individual to bind themselves to a course of treatment in advance of needing it for the purpose of overcoming an illness-induced refusal. Individuals who are vulnerable to having an acute mental health crisis who have benefited from a particular course of treatment in the past may be appropriate to consider use of a Ulysses Clause to expedite access to treatment and shorten a psychiatric crisis. Such a provision in an advance directive becomes effective when the individual's clinician and a second clinician have determined that the individual lacks capacity. A clinician shall follow the instructions of the agent authorizing or withholding treatment over the patient's objection in accordance with the provision.

In general, individuals with and without decision-making capacity may suspend or revoke all or part of their advance directive, including the designation of their health care agent. However, only individuals with capacity can suspend or revoke a Ulysses Clause provision in their advance directive.

Required elements of a valid Ulysses Clause:

- \circ The individual must name an agent for the clause to be effective.
- The agent must accept in writing the responsibility to enforce the Ulysses Clause over the individual's objection.
- The clinician must sign the Ulysses Clause and affirm that the individual understands the risks, benefits, and alternatives to the treatment specified in the Ulysses Clause.
- An attorney licensed in Vermont, ombudsman, mental health patient representative, or probate court designee, must explain the clause to the patient

and affirm that the patient appeared to understand the provision and be free from duress or undue influence. If the patient is in a hospital when the Ulysses Clause is executed, the ombudsman, attorney, mental health patient representative or probate court designee must be independent of the hospital and not an interested individual.

- The Ulysses Clause must specify the treatments that it covers and include an explicit statement that the individual desires or does not desire the specified treatments, even if they object in the future.
- The clause may authorize the agent to consent to voluntary hospitalization.
- The clause must include an acknowledgment that the individual is knowingly and voluntarily waiving the right to refuse or receive treatment at a time of incapacitation.

The Vermont Advance Directive Registry

Vermont provides a registry for residents to submit their advance directive documents free of charge. Vermont's Advance Directive Registry (VADR) is part of the national US Living Will Registry. It is a secure online database where Vermonters can submit copies of their completed advance directive forms to be accessed by authorized health care facilities and providers.

Every health care provider, health care facility, and residential care facility shall develop protocols to ensure that the provider or facility checks the VADR at the time any individual without capacity is admitted or provided services to determine whether they have an advance directive on file. (18 VSA § 9709)

For more information about the Vermont Advance Directive Registry, instructions for submitting advance directive documents, and answers to frequently asked questions visit the Vermont Ethics Network website <u>here</u>.

Probate Court Review of Advance Directives

Probate courts can consider whether to revoke an advance directive on grounds that at the time the individual signed the advance directive, they did not have capacity to understand its nature, were under duress, or were the subject of fraud or undue influence. Probate courts can also consider whether to reinstate an advance directive on the grounds that the individual was under duress or the subject of undue influence or fraud at the time of a suspension or revocation.

Probate courts can make declaratory judgements regarding the construction of an advance directive or the rights, legal status, or legal relationship of the parties with respect to an AD or for disposition of remains.

Probate courts may limit the frequency of capacity redeterminations if they find that there have been multiple requests that have been frivolous or in bad faith.

If an advance directive is in effect, either because a condition has been triggered or a determination of incapacity has been made, it remains in effect until the probate court orders

otherwise. Probate judges can issue emergency orders on request when there is a risk of harm occurring before notice and a full hearing can take place.

DO-NOT -RESUSCITATE (DNR) AND CLINICIAN ORDERS FOR LIFE SUSTAINING TREATMENT (COLST)

Some seriously ill or dying people do not want certain medical procedures or interventions at the end of life. Others do not want to be taken to the hospital if a medical issue arises or be given aggressive treatment. An advance directive alone may not be sufficient to ensure that wishes to limit treatment will be honored because advance directives are not recognized by emergency medical personnel and first responders. A do-not-resuscitate (DNR)/clinician orders for life-sustaining treatment (COLST) may be necessary to ensure that a preference to limit treatment will be honored across all care settings – particularly in an emergency.

DNR/COLST orders are the outcome of a shared decision-making process between a patient (or the agent, guardian or surrogate, if the patient lacks <u>decision-making capacity</u>) and their clinician (physician, physician assistant or nurse practitioner). These orders should be based on the individual's current medical condition and their goals and values.

The Vermont DNR/COLST form address the following medical treatments:

- Cardiopulmonary resuscitation (CPR)
- Breathing machines (intubation and ventilation)
- Medical intervention guidelines
- Artificial nutrition and hydration
- Transfer to hospital
- Use of antibiotics
- Other medical treatments

If an individual is certain that they would not want one or more of these treatments regardless of the clinical circumstance or medical situation, it is important to have a discussion with their clinician to see if a DNR/COLST order is appropriate.

A DNR order may be written on the basis of either informed consent or medical non-benefit (i.e. futility). If the order is based on informed consent, it must include the name of person giving informed consent and their relationship to the patient. An order based on medical non-benefit must include a certification by the clinician and a second clinician that resuscitation would not prevent the imminent death of the patient should they experience cardiopulmonary arrest. (18 VSA § 9708)

Patients (or their surrogates) are free to request any medical intervention to further their goals, however it is the responsibility of the clinician to determine the appropriateness of the intervention relative to the problem at hand. Treatments that will not achieve their intended short- or long-term physiological goal, or have no realistic chance of returning the patient to a level of physical health that permits survival outside of the hospital setting are considered non-beneficial. (Am J Respir Crit Care Med. 2015 Jun 1;191(11):1318-30). It is ethically problematic to escalate medical interventions that offer no achievable goal, are outside of the recommended standard of care and result in disproportionate burdens/harms. Doing everything for the patient

includes recognizing when the limits of medical intervention have been reached. Providing excellent care <u>for</u> the patient avoids doing things that are inappropriate <u>to</u> the patient.

When completing DNR/COLST orders clinicians should be aware of the following:

- A DNR/COLST must be issued on the Department of Health's "<u>Vermont DNR/COLST</u> form" as designated by rule.
- The order must be completed and signed by a health care clinician (MD, DO, APRN, or PA) based on patient's medical condition, goals and values.
- Verbal orders are acceptable with follow-up signature by the clinician in accordance with facility/agency policy.
- Photocopies and faxes of signed DNR/COLST order are legal and valid.
- By signing, clinician is certifying that they have consulted or made an attempt to consult with the patient, the patient's agent, guardian or surrogate.
- Clinician signature on a DNR/COLST form serves as issuance of a DNR Identification
- If the patient is in a health care facility or residential care facility, the DNR order must certify that it meets the facility's DNR protocol.
- Prior orders completed on previously approved Vermont DNR/COLST forms remain legal and valid and shall be honored.

For a comprehensive comparison of advance directives and DNR/COLST orders, as well as answers to many frequently asked questions regarding DNR/COLST orders, visit the Vermont Ethics Network website <u>here.</u>

Surrogate Consent for DNR/COLST

Vermont does not have a comprehensive surrogacy statute to provide guidance surrounding who will make decisions for a patient who lacks capacity but does not have a health care agent or medical guardian. In these situations, health care providers and facilities look to individuals who have a known close relationship to the patient (family, close friends, etc.) in an effort to obtain a substituted judgement-based decision. That is, to determine what the patient would likely say about their current health situation and their options if they were able.

Given the high stakes of DNR/COLST decisions, the Vermont legislature created a legal framework for surrogate consent for DNR/COLST which went into effect in January of 2018. (18 VSA § 9731)

Specifically, this subchapter of the advance directive statute outlines a process for determining who can give informed consent for a DNR/COLST order when a patient lacks capacity, has not appointed a health care agent, and does not have a guardian authorized to make medical decisions. It also ensures that medical decision-making standard of substituted judgement is prioritized over best interest decisions across all care settings. The process outlined in this subchapter only applies to decisions to either consent or withhold consent for DNR/COLST.

> New Definitions (§ 9701)

• **Surrogate:** an *interested individual* who provides or withholds informed for consent for DNR/COLST order.

• Interested Individual:

- The individual's or patient's spouse, adult child, parent, adult sibling, adult grandchild or clergy person; or
- Any adult who has exhibited special care and concern for the individual or patient and who is personally familiar with the patient and their values.

Interested Individuals cannot be the patient's health care provider; or the owner, operator, employee of a residential care facility or correctional facility where patient resides -- unless related to the patient by blood, marriage, civil union or adoption.

Identification of the Surrogate

- **Oral designation**. A patient can designate a surrogate orally by personally informing the clinician. The clinician shall document the designation in the medical record at the time it is made.
- If no oral designation (or if that person designated is unwilling or unable to serve) the clinician shall:
 - Make a *reasonable* attempt to notify *all reasonably available* interested individuals of the need for a decision regarding a DNR/COLST order.
- Eligible surrogates: Must be an interested individual who:
 - is willing to consent/withhold consent in accordance with patient's wishes (if known); and
 - \circ $\;$ is willing and available to consult with the patient's clinician
- Only one surrogate can act at a time
- An individual shall not serve as a surrogate over the patient's objection even if the patient lacks decision-making capacity
- Consensus Model No Hierarchy: Clinician can rely on the decision of the surrogate as long as it is documented that one of the following applies:
 - All interested individuals agree on the decision surrounding the DNR/COLST order. One surrogate will be identified, as well as an alternate if available, and that person's name will be identified on the DNR/COLST form and in the patient's medical record. <u>OR</u>
 - All interested individuals agree on the person who should be identified as the surrogate to make the decision surrounding the DNR/COLST order. That person shall be identified on the form and in the patient's medical record.
 - If consensus cannot be reached a petition for guardianship may be necessary.
- Immunity surrogates are immune from civil or criminal liability for acting in good faith.

SURROGATE CONSENT FOR HOSPICE

A family member of a patient or a person with a known close relationship to the patient may elect hospice care on behalf of the patient if the patient does not have a health care agent or guardian or the patient's agent or guardian, or both, are unavailable.

PATIENT BILL OF RIGHTS FOR PALLIATIVE CARE AND PAIN MANAGEMENT

Patients have the right to be informed of all evidenced-based options for care and treatment including palliative care, in order to make fully informed choices. Patients with a terminal illness have the right to be informed of all options related to terminal care (including the availability of hospice services and the eligibility criteria for those services) [18 V.S.A. § 1852], and to request any, all or none of these options. Patients with pain have the right to request or reject the use of any or all treatments in order to relieve their pain and to have competent and compassionate assistance in managing physical and emotional symptoms.

Pediatric patients with serious or life-limiting conditions have the right to receive palliative care while seeking and undergoing potentially curative or disease modifying therapies.

REQUIRED POLICIES AND PROCEDURES

All health care providers, health care facilities, and residential care facilities must develop protocols to ensure that:

- advance directives and DNR/COLST orders are available when services are provided;
- a process exists for maintaining advance directives received from individuals who are not yet patients of that facility/provider;
- the existence of an advance directive and/or DNR/COLST order prominently in the patient's medical record;
- the Vermont Advance Directive Registry is checked at the time an individual without capacity is admitted or provide services;
- health care agents and guardians have the same rights as a patient with capacity would have to access the patient's records, participate in discussions about treatment and decisions, and file complaints.

Every health care facility and residential care facility must also develop protocols to ensure that:

- Patients are asked if they have an advance directive before or as soon as possible after admission and periodically while at the facility;
- Vermont patients with advance directives are encouraged and supported to submit their document to the Vermont Advance Directive Registry
- Advance directives are reviewed to determine whether the facility is able to follow the patient's stated wishes and instructions;
- If the facility is unable to follow the instruction, steps are taken to notify the patient and agent, and to assist the patient to transfer to another facility that has the ability to follow the instruction;
- the facility has a consistent process and standards for all patients regarding the issuance, revocation and general handling of DNR/COLST orders;
- current copies of advance directives and/or DNR/COLST orders are transferred from one facility to another to ensure continuity of care;
- DNR/COLST orders that are to be continued upon discharge, during transport, or in another setting are properly documented on the Vermont DNR/COLST form or on the requisite form for the patient's state of residence.

ORGAN DONATION (UNIFORM ANATOMICAL GIFT ACT)

An individual who has sustained either irreversible cessation of all functions of the entire brain, including the brain stem, or irreversible cessation of circulatory and respiratory function is considered dead under Vermont law. (18 VSA §5218)

Anatomical gifts are the voluntary donation of all or part of a human body **to take effect after the donor's death**. A donor (i.e. adult, emancipated minor, or individual at least 16 years of age), an individual's health care agent (unless the individual's advance directive prohibits making an anatomical gift), the parent of an unemancipated minor, or an individual's guardian can make an anatomical gift during the life of the donor for the purpose of transplantation, therapy, research or education after the donor has died.

An individual can indicate their desire to be an organ donor by registering with the organ donor registry (online for through Vermont DMV), by indicating that preference in their advance directive or will, or by any form of communication to at least two adults, one of whom is a disinterested witness. Individuals can refuse to make an anatomical gift and can also amend or revoke an anatomical gift.

To register to become an organ donor in Vermont, a person must do so online at **Donate Life New England** or enroll at the <u>Department of Motor Vehicles</u> (DMV). By registering the person is giving legal consent for organ and tissue donation.

If an individual signed up to be a donor while at the Vermont DMV after January 2013, they are automatically enrolled in the Donate Life New England Registry. Prior to January 2013, the Donate Life New England registry was not linked to the Vermont DMV and the individual will need to register.

Vermont law also allows for individuals to consent to organ donation after a person has died. Individuals who can do this, in order of priority, include the decedent's:

- health care agent
- spouse
- adult children
- parents
- adult siblings
- adult grandchildren
- an adult who has exhibited special care and concern for the decedent
- guardian(s) at the time of decedent's death
- any other person having authority to dispose of the decedent's body

For more information about becoming an organ donor and the process of organ donation in Vermont visit <u>Donate Life New England</u>, <u>New England Donor Services</u>, or <u>Center for Donation</u> <u>& Transplant</u>.

MEDICAL AID IN DYING – VERMONT'S ACT 39

In May of 2013 Vermont became the fourth state to legalize Medical Aid in Dying. Vermont's law (Act 39) permits a terminally ill, capable adult to request and obtain a lethal prescription of medication to self-administer for the purpose of hastening their own death. There are currently <u>12 states</u> in the United States where medical aid in dying is permitted.

Qualifying Criteria for Medical Aid in Dying under Vermont's Act 39

A patient must:

- Be a Vermont resident
- Be at least 18 year of age or older
- Have a terminal illness with a prognosis of six months or less to live,
- Be capable of making their own health care decisions,
- Be able to make an informed and voluntary request to your physician
- Be able to self-administer the medication

Participation in Vermont's Act 39 is voluntary—for patients and health care providers. Only a patient (not their health care agent or medical guardian) can request a prescription under Vermont's medical aid in dying law. Patients seeking this end-of-life option can change their mind at any time.

While many Vermont physicians, facilities and hospice organizations now have experience with Act 39, their participation is also voluntary. There is no public list of participating prescribers.

Process for Medical Aid in Dying under Vermont's Act 39

The patient must:

- Make two oral requests not less than 15 days apart to the physician who will be writing the prescription. Oral requests may be made in the physician's physical presence or by telemedicine if the physician determines use of telemedicine is clinically appropriate.
- <u>Make a written request.</u> The written request must be signed in the presence of two (2) witnesses who are at least 18 years of age and who sign and affirm that the patient appeared to understand the nature of the document and to be free from duress or undue influence at the time the request was signed.
 - Witnesses cannot be:
 - the patient's physician;
 - a patient's relative by blood, civil marriage, civil union or adoption;
 - a person who knows that s/he would be entitled, upon the patient's death, to any portion of the estate or assets of the patient under any will or trust, by operation of law, or by contract; or
 - an owner, operator, or employee of a health care facility, nursing home, or residential care facility where the patient is receiving medical treatment or is a resident.
- Have a second physician confirm that the patient meets the required qualifying criteria

Once a prescription is written, instructions will be provided on where the prescription can be filled and how to take the medication. Even after a prescription is filled, the patient can still decide whether or not they wish to take it.

Facts for Participating Physicians

Participation is voluntary. Per section 5285 of 18 VSA Chapter 113, a physician, nurse, pharmacist, or other person shall not be under any duty, by law or contract, to participate in the provision of a lethal dose of medication to a patient. Further, a health care facility or health care provider shall not subject a physician, nurse, pharmacist, or other person to discipline, suspension loss of license, loss of privileges or other penalty for participation or refusal to participate in Vermont's Patient Choice at the End-of-Life law.

A health care facility may prohibit a physician from writing a prescription for a lethal dose of medication when all 3 of the following conditions exist:

- 1. The patient is a resident in the facility;
- 2. The patient intends to use the medication on that facility's premises; and
- 3. The facility has notified the physician in writing of its policy in regard to prescribing medications pursuant to the new law.

Prescribing Physician Process

A physician must:

- Determine that the patient is suffering from a terminal condition based on the review of the patient's relevant medical records and a physician's physical examination of the patient.
- Determine that the patient is capable.
- Determine that the patient is making an informed decision.
- Determine that the patient is a Vermont resident.
- Determine that the patient is making a voluntary request for medication to hasten his or her death.
- Determine that the patient is able to self-administer the medication requested to hasten death.
- Inform the patient in person or by telemedicine, both verbally and in writing of the following:
 - The medical diagnosis.
 - The prognosis, including an acknowledgment that this is a prediction of life expectancy and an estimate based on the physician's best medical judgment, is not a guarantee of the actual time remaining in the patient's life and that the patient could live longer than the time predicted.
 - The range of treatment options appropriate for the patient's diagnosis. If the patient is not enrolled in hospice care, all feasible end-of-life services, including palliative care, comfort care, hospice care and pain control.
 - The range of possible results, including potential risks associated with taking the prescribed medication.
 - The probable result of taking the prescribed medication.
- Refer the patient to a second physician for medical confirmation of the diagnosis, prognosis, and a determination that the patient is capable, is acting voluntarily, and is making an informed decision.
- Either verify that the patient did not have impaired judgment or refer the patient for an evaluation by a psychiatrist, psychologist, or clinical social worker licensed

in Vermont for confirmation that the patient is capable and does not have impaired judgment.

- Consult with the patient's primary care physician, with the patient's consent, if applicable.
- Inform the patient of their right to rescind their request at the time that the second oral request is made (which can be no fewer than 15 days after the first oral request).
- Ensure that all the required steps were carried out in accordance with the law and confirm, immediately prior to writing the prescription, that the patient was making an informed decision.
- Write the prescription after the last of the following events:
 - The patient's written request for medication to hasten death,
 - The patient's second oral request (which can be no fewer than 15 days after the first oral request); and
 - The physician offering the patient an opportunity to rescind the request.
- Dispense the medication directly (if they are licensed to dispense medication in Vermont); or contact a pharmacist (with the patient's consent) and inform the pharmacist of the prescription, and deliver the written prescription personally, by mail or by fax to the pharmacist.
- Promptly file a report, after writing the prescription, with the Department of Health documenting completion of all of the requirements under this statute.

Documentation

The physician must record and file the following in the patient's medical record:

- The date, time and wording of all oral requests of the patient for medication to hasten death.
- All written requests by the patient for medication to hasten death.
- The physician's diagnosis, prognosis, and the basis for the determination that the patient was capable, and was acting voluntarily and had made an informed decision.
- The second physician's diagnosis, prognosis and verification that the patient was capable, and was acting voluntarily and had made an informed decision.
- The physician's attestation that the patient was enrolled in hospice care at the time of the oral and written requests for medication, or that the physician informed the patient of all feasible end-of-life care services.
- The physician's verification that the patient either did not have impaired judgment or that the physician referred the patient for an evaluation and the person conducting the evaluation determined that the patient did not have impaired judgment.
- A report of the outcome and determinations made during any evaluation which the patient may have received.
- The date, time and wording of the physician's offer to the patient to rescind their request at the time of the patient's second oral request.
- A note by the physician indicating that all requirements under the statute were satisfied, describing the steps taken to carry out the request and including a notation of the medication prescribed.

Reporting

After writing the prescription, promptly file a report with the Department of Health documenting completion of all of the requirements under this statute.

- <u>Physician Reporting Form</u>
- Consulting Physician Reporting Form
- Follow-Up Reporting Form After Death

Other Statutory Obligations

Physicians have an obligation to inform patients of all available options related to terminal care pursuant to 18 V.S.A. § 1871. Patient Choice at the End of Life as outlined in 18 V.S.A. Chapter 113 is now an available option related to terminal care. In addition, pursuant to 12 V.S.A. §1909(d), a patient is entitled to a reasonable answer to any specific question about foreseeable risks and benefits of treatment.

Immunity

Physicians shall not be subjected to any civil or criminal liability or professional disciplinary action if the physician prescribes to a patient with a terminal condition medication to be self-administered for the purpose of hastening the patient's death and affirms by documenting in the patient's medical record that the necessary steps were followed. (18 VSA Chapter 113 §5283 (a))

Limitations on Actions

No physician, nurse, pharmacist, or other person licensed, certified, or otherwise authorized by law to deliver health care services in this State shall be subject to civil or criminal liability or professional disciplinary action for acting in good faith compliance with the provisions of this chapter.

Facts for Non-Participating Physicians

Participation in Act 39 is voluntary. Per § 5285 of 18 VSA Chapter 113, a physician, nurse, pharmacist, or other person shall not be under any duty, by law or contract, to participate in the provision of a lethal dose of medication to a patient. Further, a health care facility or health care provider may not penalize a physician, nurse, pharmacist, or other person based on their participation or refusal to participate in the law.

Act 39 does not alter the rights and duties existing under Vermont's Patient's Bill of Rights, 18 V.S.A. § 1871, or under 12 V.S.A. § 1909 regarding informed consent.

Legal References

18 V.S.A. § 5282 Right to Information

"The rights of a patient under Section 1871 of this title to be informed of all available options related to terminal care and under 12 V.S.A. § 1909(d) to receive answers to any specific question about the foreseeable risks and benefits of medication without the physician's withholding any requested information exist regardless of the purpose of the inquiry or the nature of the information. A physician who engages in discussions with a patient related to such risks

and benefits in the circumstances described in this chapter shall not be construed to be assisting in or contributing to a patient's independent decision to self-administer a lethal dose of medication...."

18 V.S.A. § 1871.

Patient's bill of rights for palliative care and pain management:

- A patient has the right to be informed of all evidence-based options for care and treatment, including palliative care, in order to make a fully informed patient choice.
- A patient with a terminal illness has the right to be informed by a clinician of all available options related to terminal care; to be able to request any, all, or none of these options; and to expect and receive supportive care for the specific option or options available.
- A patient suffering from pain has the right to request or reject the use of any or all treatments in order to relieve his or her pain.

12 V.S.A. § 1909.

Limitation of medical malpractice action based on lack of informed consent:

• A patient shall be entitled to a reasonable answer to any specific question about foreseeable risks and benefits, and a medical practitioner shall not withhold any requested information.

Facts for Vermont Facilities

Participation in Act 39 is voluntary. Per §5285 of 18 VSA Chapter 113, a health care facility shall not subject a physician, nurse, pharmacist, or other person to discipline, suspension, loss of license, loss of privileges or other penalty for participating in or refusing to participate in Vermont's Patient Choice at the End-of-Life law.

Definition

Health care facility is defined as all persons or institutions, including mobile facilities, whether public or private, proprietary or not for profit, which offer diagnosis, treatment, inpatient, or ambulatory care to two or more unrelated persons, and the buildings in which those services are offered. The term shall not apply to any institution operated by religious groups relying solely on spiritual means through prayer for healing, but shall include but is not limited to:

- hospitals, including general hospitals, mental hospitals, chronic disease facilities, birthing centers, maternity hospitals, and psychiatric facilities including any hospital conducted, maintained, or operated by the state of Vermont, or its subdivisions, or a duly authorized agency thereof;
- nursing homes, health maintenance organizations, home health agencies, outpatient diagnostic or therapy programs, kidney disease treatment centers, mental health agencies or centers, diagnostic imaging facilities, independent diagnostic laboratories, cardiac catheterization laboratories, radiation therapy facilities, or any inpatient or ambulatory surgical, diagnostic, or treatment center.

Health Care Facility Exemption (§5286)

Under the new law, a health care facility may prohibit a physician from writing a prescription for a lethal dose of medication when all 3 of the following conditions exist:

- 1. The patient is a resident in the facility;
- 2. The patient intends to use the medication on that facility's premises; and
- 3. The facility has notified the physician in writing of its policy in regard to prescribing medications pursuant to the new law.

Additional Information

The Vermont Department of Health maintains a list of frequently asked questions: <u>https://www.healthvermont.gov/sites/default/files/documents/pdf/Act39_faq.pdf</u> Patient Choices Vermont (PCV) the advocacy organization for Medical Aid in Dying in Vermont also has many resources that can help:

- PCV MAID brochure page <u>https://www.patientchoices.org/guide-to-medical-aid-in-dying-and-end-of-life-decision-making.html</u> for a simple explanation.
- PCV guidance for talking to your doctor <u>https://www.patientchoices.org/how-to-talk-to-your-doctor-about-act-39.html</u>
- PCV Frequently Asked Questions: <u>https://www.patientchoices.org/frequently-asked-questions.html</u>

Vermont Statute/Acts

- 2013 Act 39: Patient Choice and Control at End of Life
- 2022 <u>Act 97: Relating to Modifications to Vermont's Patient Choice at End of Life</u> Laws

For more resources and annual legislative reports you can visit the Vermont Ethics Network website <u>here</u>.

ABOUT THE AUTHOR

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FRAUD AND ABUSE COMPLIANCE

- Topics Covered in this Chapter: <u>Introduction</u> <u>The Federal False Claims Act</u> <u>The Anti-Kickback Statute</u> <u>The Physician Self-Referral Ban (The Stark law)</u> <u>Other Federal Laws</u> <u>Vermont Laws</u> <u>Preventative Action Compliance Programs</u> <u>Conclusion</u> <u>About the Authors</u>
- By: Eileen Elliott, Drew Kervick and Jonathan Rose Dunkiel Saunders Elliott Raubvogel & Hand, PLLC

INTRODUCTION

The regulatory enforcement atmosphere for health care providers has been steadily intensifying since the early 1990s, roughly paralleling the growth in the nation's government-funded health care programs. Indeed, passage of major health care reform initiatives in 2009 and 2010 brought with it expanded liabilities and penalties for fraud, enhanced screening of providers and suppliers, and additional funding for regulatory enforcement.

Under the best circumstances, it is sometimes difficult for providers (and even regulatory professionals!) to predict what types of arrangements and practices might constitute fraud or unlawful conduct under the various enforcement statutes. And penalties for unlawful conduct can be substantial, including criminal fines (or even imprisonment), civil monetary penalties, and exclusion from Medicare, Medicaid, and other federal programs.

All this means that providers are finding it absolutely essential to become familiar with the basic tenants of fraud and abuse laws to understand the potential pitfalls associated with their business activities. This section briefly outlines the primary enforcement tools used to root out and combat fraud in the health care system, including the federal False Claims Act, the federal health care program "Anti-Kickback law," the physician self-referral or "Stark law", the Vermont False Claims Act and the state Medicaid fraud law. In addition to these primary enforcement mechanisms, this section also discusses a number of other statutes that may be implicated by conduct triggering the primary fraud and abuse laws.

THE FEDERAL FALSE CLAIMS ACT

The federal False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, was first enacted in 1863 to combat defense procurement fraud during the Civil War. Since then, the FCA has been amended a number of times, and in 1986, as the federal government continued to take on more responsibility for health care, Congress made changes that shifted the primary focus of the law from the defense industry to health care. In 2009, the statute was substantially amended by the Fraud Enforcement and Recovery Act (FERA) as a part of broader health care reform efforts.

Today, the federal government recovers billions of dollars each year from companies and individuals in the health care industry through FCA enforcement actions and settlements. In 2021, legislation was introduced to further strengthen the FCA in response to claims of widespread fraud on the government during the COVID-19 pandemic. As of this writing, however, it is not clear whether that legislation—which would generally make it easier in several ways for the government to prove a false claim—will be enacted by Congress.

In the most general terms, the FCA creates stiff penalties for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government. In a provision commonly known as the "reverse" false claims section, the law also prohibits actions to improperly avoid paying money owed to the government.

In the health care industry, FCA liability arises most commonly out of the miscoding of or misrepresentation in ICD codes, improper billing for tests not performed, or misrepresentations involving places or providers of services. And importantly, certain conduct that violates the anti-kickback and Stark laws (see below for more on these laws) may also violate the FCA.

Key Elements of the FCA

Under the FCA as amended by the FERA, a "claim" is "any request or demand, whether under a contract or otherwise, for money or property" made to the U.S. government or certain government contractors (including contractors implementing Medicare Part C and D plans). A claim must be "false" to be covered by the FCA, and falsity may take the form of an express claim that is false, or an express or implied certification that is false. False claims must also be "material," which means the claim must have had a "natural tendency to influence, or [must have been] capable of influencing, the payment or receipt of money or property."

The FCA primarily prohibits a person from "knowingly" presenting (or causing someone else to present) a false or fraudulent "claim" for payment to the U.S. government. The statute itself defines "knowingly" as (1) having actual knowledge of the falsity of the claim; (2) deliberate ignorance of the truth or falsity of the claim; or (3) reckless disregard of the truth or falsity of the claim. That means that a person need not specifically intend to defraud the government in order to be held liable; rather the FCA prohibits all claims that a person knows *or should know* are false.

In determining whether a claim is submitted "knowingly," courts and the U.S. Department of Justice (which is responsible for enforcing the FCA) may ask the following questions:

- Did the provider have either actual or constructive knowledge of the rules or policies governing the submission of the particular claim? Were there Medicare or Medicaid bulletins or advisories on point?
- How clear is the policy that was violated? Is there room for reasonable mistake?
- How many false claims were submitted? Reckless indifference can be inferred from a large number of claims.
- Does the practitioner or provider have a compliance plan, and is it being followed?
- Does the practitioner have a record of reporting suspected compliance problems and attempting to fix them?
- Did the provider seek guidance on billing issues from CMS or a third-party carrier, and was any guidance given clear?

Penalties and Damages

Penalties and damages in a successful FCA case can be severe. As of August 1, 2016, civil penalties under the FCA dramatically increased from up to \$11,000 (\$5,500 minimum) per claim to a maximum of \$21,563 (and at least \$10,781) *for every false claim*. Those penalties have increased further in recent years to a range of \$11,665 to \$23,331 per false claim.

The civil penalties apply whether or not the government actually suffered a financial loss. If the government did suffer such a loss, it is also entitled to up to three times the amount of damages it suffered, or twice the amount if the provider self-reported and was cooperative during the enforcement action.

Finally, in the event a successful FCA case is brought by a private whistleblower, the provider may also be responsible for paying the whistleblower's costs and attorneys' fees.

Whistleblowers and "Qui Tam" Actions

A qui tam action is a mechanism through which a private party may sue in the name of the government to enforce its rights. In the context of the FCA, this means that a private party – frequently a whistleblower – may sue a provider on behalf of the federal government and receive a portion of any judgment or settlement that results. In such cases, the private party bringing suit is known as the "relator."

By design, relators are provided with a substantial financial incentive to bring FCA cases. If the government decides not to participate in the suit (in every case, the United States Attorney General must be given notice and an opportunity to take over the case), the relator is entitled to 25-30 percent of any amount recovered. And even if the government *does* decide to handle the case, the relator is still entitled to 15-25 percent.

In a qui tam action, a health care whistleblower may include a count alleging retaliation by the provider. If successful, the whistleblower may be entitled to reinstatement (if he or she was fired as a result of his or her whistleblowing activity), awarded twice his or her backpay plus interest, compensation for any special damages, attorney's fees, and the costs of bringing suit.

Health care whistleblowers are also protected by Vermont's Healthcare Whistleblower's Protection Act, 21 V.S.A. §§ 507-509, and can also pursue claims under Vermont's False Claims Act, 32 V.S.A. §§ 630 *et seq.*, both of which are discussed later on in these materials.

Steps to Reduce Risk of FCA Violations

The primary way for providers to reduce FCA risk is to ensure that employees and business colleagues understand the law's basic requirements and know that the provider takes FCA and fraud and abuse issues seriously. The following are a few additional, specific steps providers can take to help minimize FCA risk:

- Ensure that corporate policies clearly spell out FCA compliance and reporting requirements. Make sure that the consequences of failing to report fraud are clearly communicated and understood. Policies should also protect those who come forward with billing questions, complaints or concerns.
- Conduct periodic trainings on FCA compliance.

- Maintain clear personnel policies and meticulous personnel records. This is important as a means to identify and prevent employees from committing health care fraud, and to help defend against claims of retaliation.
- Have a system of review in place for claims and invoices submitted to the government. Try to spot billing errors or regulatory compliance issues before they are submitted.
- Regularly engage employees in areas of potential FCA problems. Solicit open communication about potential problems, and again, make sure that those who come forward are adequately protected.
- Have a plan in place to deal with allegations of fraud. Ensure prompt investigatory and remedial action.
- Consider self-reporting any problems to potentially avoid larger exposure. Always consult with an attorney first, though.

THE ANTI-KICKBACK STATUTE

The Federal Health Care Program Anti-Kickback Statute (its full name), 42 U.C.S. § 1320a-7b, creates *criminal* liability for individuals and entities that "knowingly and willfully" solicit, receive, offer or pay anything of value to induce referrals of items or services paid for by a federal health care program (including Medicare and Medicaid). The statute is designed primarily to prevent kickbacks, bribes and rebates, as well as similar arrangements with a potential to improperly increases costs or decrease efficiencies in the federal health care benefit programs.

"Knowing and Willful"

To be held liable under the Anti-Kickback Statute, an individual or entity must "knowingly and willfully" enter into a prohibited arrangement. The precise meaning of "knowingly and willfully" has been the subject of some debate, but in general, it must be established that at least one purpose of the challenged arrangement must have been to unlawfully induce referrals of items or services paid for by a federal program.

In a 2010 amendment to the Anti-Kickback law, Congress clarified that a person or entity need not have actual knowledge of the law or specific intent to violate it – a construction some courts had previously placed on the law that had made it difficult for criminal prosecutions to be successful. Rather, the prosecution must show only that the person or entity knew that its conduct was generally illegal.

Exceptions to the Anti-Kickback law

Congress has expressly recognized that the Anti-Kickback law's language is quite broad and that the potential for confusion and unfair application of the statute is great. Therefore, the law and its regulations include a set of statutory exceptions and regulatory "safe harbors" for a variety of business arrangements. If a particular arrangement meets the requirements of one of the safe harbors, it will be presumed not to violate the statute and will not be subject to an enforcement action by the agency responsible for administering the law, the U.S. Department of Health & Human Services.

It is difficult to provide a concise description of all the specific requirements for an arrangement to fall within an exception or safe harbor. In general, though, the exceptions and safe harbors encompass the following types of arrangements:

Statutory Exceptions

- Payments to bona fide employees
- Discounts
- Payments to purchasing agents
- Some types of risk-sharing arrangements
- Prescription drug discounts for certain beneficiaries in the Medicare coverage gap (or "donut hole")

Safe Harbors

- Investment interests in certain entities
- Certain space, equipment, personal services and management contracts
- Sale of a practice
- Legitimate referral services
- Warranties (so long as certain reporting requirements are met)
- Group purchasing organizations
- Certain Medicare Part A waivers of coinsurance and deductibles
- Beneficiary incentives offered by group health plans and price reductions offered to such plans
- Certain efforts to recruit physicians to underserved areas
- Investment interests in group practices by physicians
- Obstetrical malpractice insurance subsidies
- Investment interests in surgeon-owned ambulatory surgical centers
- Cooperative hospital service organizations
- Referral agreements for specialty services
- Ambulance replenishing arrangements
- Certain arrangements involving electronic prescribing and electronic medical records
- Certain transfers of goods and services in the context of federally qualified health centers

Notably, in late 2020, as part of the Department of Health and Human Services' "Regulatory Sprint to Coordinated Care" initiative, the Office of the Inspector General issued a set of new rules that established new safe harbors under the Anti-KickBack Statute for the certain "value-based compensation" arrangements, broadly including:

- Care coordination arrangements to improve quality, health outcomes, and efficiency
- Value-based arrangements with substantial downside financial risk
- Value-based arrangements with full financial risks

The 2020 rule also modified specific requirements of some of the previous safe harbors discussed above. And like the traditional Anti-Kickback Statute safe harbors, rules related to these new safe harbors are complex. Great care should be taken in the design of value-based arrangements intended to fall within their protection.

To fit within any of the Anti-Kickback safe harbors, a person must satisfy certain specific criteria that are set forth in the applicable statutory or regulatory provisions. Notably, a business arrangement that does not fall within a safe harbor is not automatically illegal. Rather, such arrangements will be evaluated on a case by case basis by the Office of Inspector General.

Penalties

Violation of the Anti-Kickback law is a federal felony, punishable by up to five years of imprisonment and/or fines up to \$25,000. Moreover, a violation of the law can result in exclusion from participation in the federal health care programs. Discipline imposed under the law may also be a basis for state unprofessional conduct charges and license suspension.

Relationship of Anti-Kickback law with the False Claims Act

As part of health care reform efforts in 2010, Congress made clear that a violation of the Anti-Kickback law is also a violation of the federal False Claims Act. Thus, although the Anti-Kickback law does not itself provide for a private cause of action for its violation, civil liability still could be established through either a direct or qui tam action under the FCA.

Additional Guidance for Anti-Kickback Statute Compliance

Under the Anti-Kickback statute, OIG is authorized to issue advisory opinions assessing proposed business arrangements for compliance with the law. 42 C.F.R. §§ 1008.5(a)(1)-(3). The opinions may address (1) whether the arrangement constitutes a prohibited referral and/or (2) whether the arrangement fits within a safe harbor.

Previous advisory opinions are available to the public on OIG's website and are helpful for understanding how OIG might view a particular arrangement. However, only parties to a particular advisory opinion can rely on it as evidence in an enforcement action.

Anyone may request an advisory opinion from OIG, but the decision to request an opinion should be made only after careful consideration of the costs, benefits and risks. For example, though the process for obtaining an advisory opinion is far less costly than an enforcement action, it might still be considered somewhat expensive, and it could result in either an adverse decision or a decision based on a set of facts that might no longer exist once the opinion is issued.

OIG also issues more generalized Special Fraud Alerts, Special Advisory Bulletins and other guidance, all available on its website. If it appears that no helpful advisory opinion is available, one of these other resources may include useful information.

THE PHYSICIAN SELF-REFERRAL BAN (THE STARK LAW)

The physician self-referral statute, 42 U.S.C. § 1395nn, was first introduced by Representative Pete Stark, and therefore became known as the Stark law. As originally enacted in 1992, it prevented physicians from referring Medicare beneficiaries to clinical laboratories in which the physician (or a member of his or her immediate family) has a financial interest. In 1995, however, the law was expanded to cover referrals for a much wider range of health services that were considered to be particularly susceptible to over-utilization. The statute as originally

passed is commonly referred to as "Stark I," while the 1995 expansion is referred to as "Stark II" and a 2007 series of regulations is known as "Stark III."

Broadly speaking, the Stark law now prohibits a physician from (i) making a "referral" of a patient; (ii) for the furnishing of "designated health services" payable by Medicare (or possibly Medicaid – see discussion below); (iii) to an entity with whom the physician (or the physician's family) has a "financial interest."

Key Elements of the Stark law

"Referral" by a Physician

The application of the Stark law is triggered by a referral by a physician. The law's definition of "referral" contains two components. In the case of referrals for which payment is to be made under Medicare Part B, a "referral" encompasses a request by the physician for designated health services, the "ordering of" any such services or the "certifying or recertifying" of the need for such services. For all other referrals the definition also includes the "establishment of a plan of care" by a physician that includes provision of designated health services.

The key point is that this is a broad definition. Indeed, under the Stark law, it is not necessary for a physician to expressly "refer" a patient to a particular service provider – all that is required is an "order" from the physician and use of the services by the patient.

"Designated Health Services"

Furthermore, for the Stark law to apply, the referral must be for "designated health services" (DHS). Those DHS include:

- Clinical laboratory services
- Physical therapy, occupational therapy, and speech language pathology services
- Radiology/imaging services and radiation therapy services
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

"Financial Relationship"

The Stark law prohibits referrals to DHS providers with whom a physician, or an immediate family member of the physician, has a "financial relationship." A "financial relationship" is a "direct or indirect ownership interest or compensation arrangement."

An "ownership interest" includes stock, partnership interests, limited liability company memberships, loans, bonds or other financial interests secured by an entity's property or revenue. The law also includes ownership interests in any third-party entity that has an ownership interest in the DHS provider. Interests in retirement plans, stock options or unsecured loans are not included.

For purposes of the Stark law, "immediate family members" include the physician's:

- Husband or wife
- Birth or adoptive parent, child or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law
- Grandparent or grandchild and spouse of grandparent or grandchild

Payable by Medicare (or Medicaid?)

As discussed above, the Stark law originally applied only in the context of DHS payable by Medicare, and still, no express language provides for direct application of the Stark law to self-referrals of Medicaid patients. But that, unfortunately, is not the end of the story.

Under Stark II (the 1995 expansion), a provision was added that prohibits the federal government from reimbursing state Medicaid claims that would violate Stark law prohibitions. Recently, based on that provision, courts have held that physicians and DHS providers may be held liable under the False Claims Act if they cause a state to submit a Medicaid reimbursement claim that would have violated the Stark law in the context of Medicare.

In other words, the Stark law does not expressly apply to referrals of Medicaid patients, but it is likely that referrals of Medicaid patients that would violate the Stark law if made in the context of Medicare patients could also serve as a basis for liability under the False Claims Act. Thus, providers should *not* assume that the Stark law has no application in the context of Medicaid.

Exceptions

The Stark law contains a number of exceptions permitting referrals in the case of certain specified "financial relationships." Generally, most of these exceptions require that the financial relationship be established in advance through a written agreement and that any interest or compensation be made at fair market value and not depend on the amount or value of any referral business.

Unlike the safe harbor provisions in the Anti-Kickback law, the exceptions in the Stark law are the only way an otherwise unlawful referral will be protected. If a referral does not satisfy all of the requirements of an exception, the referral will be deemed to be unlawful.

The Stark law exceptions are grouped into three separate categories: those relevant to both ownership interests and compensation arrangements; those relevant only to ownership interests; and those relevant only to compensation arrangements.

Exceptions to Prohibited Ownership Interests and Compensation Arrangements

- Physician services within the same group practice
- In-office ancillary services (in some case, so long as the physician provides a list of alternative suppliers of such services in the area)
- Services furnished by certain organizations and health plans to enrollees in the organization
- Services provided by academic medical centers

- Implants furnished by an ambulatory surgical center
- EPO and other dialysis related drugs
- Preventative screening tests, immunizations and vaccines
- Eyeglasses and contact lenses following cataract surgery
- Intra-family rural referrals

Ownership Interest Exceptions

- Publicly traded securities and mutual funds
- Hospitals in Puerto Rico
- Ownership in hospitals (under certain, very limited conditions)

Compensation Arrangement Exceptions

- Rental of office space and equipment
- Bona fide employment relationships
- Fair market value personal service arrangements
- Payments unrelated to the provision of DHS
- Physician recruitment and retention
- Isolated financial transactions
- Certain group practice arrangements with a hospital
- Payments by physicians for items or services
- Non-monetary compensation up to \$392 (2016 figure adjusted each year for inflation)
- Certain fair market value transactions
- Medical staff incidental benefits (parking, meals, free internet, etc.)
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Referral services that meet anti-kickback safe harbor rules
- Obstetrical malpractice insurance subsidies that meet anti-kickback safe harbor rules
- Professional courtesy
- Retention payments in underserved areas
- Community-wide health information systems
- Charitable donations made by physicians
- Electronic prescribing and health record items and services

In November 2020, the Center for Medicare and Medicaid Services (CMS) issued a new set of rules intended to modernize the Stark Law to accommodate a policy shift toward value-based delivery and payment arrangements. In issuing the new rules, CMS recognized that traditional Stark Law restrictions could prohibit some arrangements that are designed to enhance care coordination, improve quality, and reduce waste. To that end, CMS added a new series of exceptions for value-based arrangements, including:

- Remuneration paid under a value-based arrangement
- Value-based arrangements with meaningful downside risk to the physician
- Value-based arrangements with full financial risk

• Special rule for indirect compensation arrangements involving value-based arrangements.

The new rule also provided guidance on several other requirements for meeting the Stark Law's exceptions, including, for example, new guidance on determining whether a compensation arrangement meets "fair market value" requirements, and new definitions of "commercial reasonableness" and "volume or value of referrals."

Again, Stark Law regulations are complex, and providers looking to take advantage of exceptions should carefully assess proposed arrangements to ensure compliance with those regulations.

Penalties

Violations of the Stark law are punishable with civil monetary penalties up to \$15,000 for each bill or claim presented for a service that a person knew or should have known violates the Stark prohibition, and up to \$100,000 for "circumvention schemes" where physicians or entities enter into arrangements that have the principal purpose of assuring referrals in violation of the Stark prohibition.

Claims will not be paid for any DHS provided in violation of the law, and reimbursement is required for any payments already collected. Violations may also result in exclusion from Medicare, Medicaid and any other federal health care program, and as discussed above, may serve as the basis for liability under the False Claims Act.

Exclusion from Participation in the Federal Health Care Programs

Physicians and other providers who are excluded from participation in the federal health care programs may no longer submit claims, either directly or through an entity by which they are employed, to those programs. In fact, health care providers face civil monetary penalties for submitting claims for items or services provided, directly or indirectly, by excluded persons or entities.

Health care providers have an affirmative duty to check the Department of Health & Human Services' Office of Inspector General's "List of Excluded Individuals" before hiring or contracting with anyone. This list is available on OIG's website, <u>www.oig.hhs.gov</u>. If a provider contracts with or hires and excluded individual, it faces penalties of up to \$10,000 for each item or service furnished by the excluded individual and submitted in a claim for federal program reimbursement, plus three times the amount claimed, and program exclusion.

OTHER FEDERAL LAWS

In addition to the federal False Claims Act, Anti-Kickback law and Stark law, there are a number of additional pertinent federal laws that pose a threat of criminal liability relating to fraud and abuse. Although several are specific to health care claims, there are also general federal criminal statutes that punish false or fraudulent conduct that deprives the federal government of money or property.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) contains certain provisions aimed at preventing health care fraud and abuse. The first provision prohibits health care fraud, which consists of knowingly and willfully executing or attempting to execute a scheme:

- to defraud any public or private health care benefit program; or
- to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned or controlled by a health care benefit program in connection with the delivery of or the payment for health care benefits, items or services. 18 U.S.C. § 1347.

Any such health care fraud violations are punishable by fines or imprisonment of up to 10 years, or both, provided that a violation resulting in serious bodily injury or death may result in longer prison sentences.

HIPAA also prohibits theft or embezzlement in connection with health care. 18 U.S.C. § 669. This provision prohibits embezzling, stealing or otherwise, without authority, converting to the benefit of any other person, or intentionally misapplying money, funds, securities, premiums, credits, property, or other assets of a health care benefit program.

HIPAA substantially strengthened health care enforcement authority and established a Fraud and Abuse Control Program to coordinate federal, state, and local health care anti-fraud investigation and enforcement, which is jointly administered by the U.S. Attorney General and the U.S. Department of Health and Human Services Office of the Inspector General. It also authorized the Fraud and Abuse Data Collection Program, a nationwide database reporting final adverse actions taken against health care providers, practitioners, and suppliers by federal and state enforcement authorities. Finally, HIPAA prohibits the concealment of a material fact or the knowing and willful making of a material false statement in connection with the delivery of or payment for benefits, items or services pursuant to a health care program. 18 U.S.C. § 1035.

Additional Criminal Provisions under the Social Security Act

The Social Security Act (SSA), 42 U.S.C. § 1320a-7b(a), makes it a felony to knowingly and willfully make or cause to be made any false statement of a material fact in any application for payment, or for use in determining rights to payments, under a federal health care program. It also makes it unlawful to conceal or fail to disclose an improper payment with an intent to fraudulently secure such benefit or payment.

Further, the SSA makes it unlawful for a person to knowingly and willfully make or cause to be made any false statement of a material fact about the operation of any institution, facility or entity to qualify for certification or recertification (if certification is required) or when responding to any required disclosure of information. It additionally makes a misdemeanor the accepting of an assignment of benefits or agreeing to be a participating physician or supplier and knowingly, willfully and repeatedly violating the term of such assignment or agreement. Any claim under the provisions of the SSA described in this section also constitutes a false claim under the False Claims Act.

Mail and Wire Fraud

The mail and wire fraud statute, 18 U.S.C. §§ 1341, 1343, prohibits using the mail or a wire to execute a scheme or artifice to defraud or obtain money or property by means of false or fraudulent representation. Mail or wire fraud is a felony punishable by fines and/or up to twenty years imprisonment.

False Statements

The making false statements statute, 18 U.S.C. § 1001, subjects a person to a fine and/or imprisonment of up to five years when the person, in any matter involving a health care program, knowingly and willfully falsifies, conceals or covers up any trick, scheme or device of material fact, or makes any materially false, fictitious, or fraudulent statement, or makes or uses any materially false document or writing, knowing that the document contains a materially false statement or entry.

Conspiracy Statutes

The conspiracy to defraud the government with respect to claims statute, 18 U.S.C. § 286, prohibits conspiring to defraud any federal agency by obtaining or helping someone else to obtain payment from any false, fraudulent or fictitious claim.

The conspiracy to commit offense or to defraud the United States statute, 18 U.S.C. § 371, applies when two or more persons conspire to commit any offense against, or defraud the federal government or any of its agencies, and at least one of the persons acts in furtherance of the conspiracy.

Theft of Government Property

The theft of government property statute, 18 U.S.C. § 641, prohibits a person from embezzling, stealing, or knowingly converting to his/her use or the use of another, or selling, conveying, or disposing of anything of value to the United States or any of its agencies. Anyone who receives, conceals or retains any such thing of value, intending to use it to his or her gain, and knowing it to have been embezzled or stolen, is subject to fines or imprisonment or both.

RICO

The Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § § 1961 *et seq.*, the application of which is not limited to organized crime, prohibits a person from receiving income, directly or indirectly, from a pattern of racketeering activity. A pattern is two or more occurrences of a "predicate act" over a 10-year period. RICO contains a private right of action for persons injured in their business or property.

Money Laundering

The criminal statute governing money laundering, 18 U.S.C. §§ 1956, 1957, prohibits knowingly engaging or attempting to engage in a "monetary transaction in criminally derived property" valued over \$10,000 and derived from "specified unlawful activity."

Obstruction

The obstruction of criminal investigation statute, 18 U.S.C. § 1510, prohibits willfully bribing someone to obstruct, delay or prevent communication of information relating to violation of any criminal statute to a criminal investigator.

The obstruction of criminal investigations of health care offenses statute, 18 U.S.C. § 1518, prohibits preventing, obstructing, misleading, delaying or attempting to do any of those things with respect to communicating information or records relating to a violation of a federal health care offense to a criminal investigator.

Aiding and Abetting

People who aid or abet in the commission of an offense are punishable as if they were principals. 18 U.S.C. § 2. In addition, people who, knowing that an offense against the United States has been committed, assists the offender in order to hinder his or her apprehension or punishment is an accessory after the fact. 18 U.S.C. § 3.

VERMONT LAWS

In addition to the federal laws on health care fraud and abuse, health care practitioners should also become familiar with Vermont's fraud and abuse laws. Of particular importance are (i) the State False Claims Act (the State FCA), (ii) the criminal false representation law, (iii) the Medicaid fraud statute, and (iv) the Healthcare Whistleblower's Protection Act.

State False Claims Act

In 2015, Vermont became the thirtieth state to adopt a civil false claims act modeled on the federal FCA (see discussion in Part A above on the federal FCA). The State FCA, 32 V.S.A. §§ 630 *et seq.*, authorizes civil enforcement for any false or fraudulent claims made for State funds. Vermont's definition for the term "claim" under the State FCA tracks the federal definition: a claim is "any request or demand, whether under a contract or otherwise, for money or property" made to the State of Vermont or certain government contractors. The act is broad and prohibits any person from, among other things:

- knowingly submitting, or causing to be submitted, a false claim;
- knowingly making or using any false record or statement material to a false claim or to an obligation to pay the State;
- knowingly submitting a claim that violates the State's criminal false claims act (see below) or the federal false claims act, anti-kickback statute or Stark law (see above for a discussion of these federal fraud and abuse laws);
- knowingly and improperly avoiding or decreasing an obligation to pay the State;
- entering into a written agreement with the State knowing the agreement contains false information;
- if the person discovers after submission that a false claim has been made resulting in overpayment, failing to timely disclose the false claim or receipt of overpayment to the State; and
- conspiring to submit a false claim.

General Categories of False Claims

The above-listed prohibitions of the State FCA can be summarized as prohibiting five general types of behaviors:

- <u>Mischarge</u>. The act prohibits a person from billing the State for goods or services that are not actually provided. This category of prohibited acts includes overcharging for goods and services, such as upcoding for health care services.
- <u>Fraud-in-the-inducement</u>. The act prohibits a person from making false statements or taking illegal actions during the formation of an agreement with the State. Examples include making false representations and warranties in a contract with the State or making an increased number of claims due to a kickback arrangement.
- <u>False certification</u>. Under the act, a person may not falsely certify that he or she qualifies for a State program, that he or she is eligible for a State benefit, or that his or her claims are complaint with the State program's requirements.
- <u>Substandard service or product</u>. The act prohibits a person from providing a substandard service or product under a State contract. For example, a false claims action could be brought against a physician for failing to meet applicable quality of care standards under a State contract.
- <u>Reverse false claim</u>. Finally, the act prohibits so-called "reverse false claims." A reverse false claim occurs when a person has an obligation to pay the government and tries to avoid that obligation. In other words, it is the government that is owed the payment, as opposed to the traditional false claim that involves the government paying a person. One such reverse false claim arises when a person keeps what the State has given him or her, as the beneficiary of an inadvertent false claim or overpayment, if that person fails to disclose the claim or overpayment within the later of (i) 120 days after discovery of the false claim or overpayment, or (ii) the date of a corresponding cost report. Another type of reverse false claim arises if a person knowingly uses a false record or statement to avoid paying or reducing the amount owed to the State.

Investigation and Enforcement.

Similar to the federal FCA, the State FCA may be enforced either by the State attorney general or by a private citizen who is aware of the false claim(s), called a "relator." A suit by a relator under the State FCA is filed in the name of the State and under seal, pending review by the State attorney general's office. When the suit is under seal, it means that the filing of the case is not public record and is confidential; the named defendant is not notified of the suit until the court issues an unsealing order. The attorney general has an initial 60-day period during which to determine whether to intervene in the suit or to decline the case, though the attorney general may seek an extension of the seal period.

If the attorney general elects to intervene, then it generally has full control over the suit and may move to dismiss or settle the case. If the attorney general declines to intervene, then the relator has the right to conduct the action. Even if the attorney general declines to intervene, the office retains the right to receive all pleadings and transcripts, and may choose to intervene at a later date by showing good cause. And even in declined cases, the State typically will be involved in settlement negotiations, either by intervening or by working with the relator's attorney.

Like the federal FCA, the State FCA provides a financial incentive for relators. If the attorney general intervenes in the suit, the relator is entitled to 15-25 percent of any recovery, based upon the relator's contribution to the suit. If the attorney general declines to intervene, then the relator

is entitled to receive 25-30 percent of any recovery, again based on the relator's contribution. Successful relators are also entitled to receive reasonable attorney's fees and expenses from the defendant.

In investigating potential violations of the State FCA, the attorney general has the authority to issue a civil investigative demand (CID). A CID may be issued when there is reason to believe that a person may be in possession of any information relevant to a false claims investigation, and it includes the power to seek documents, interrogatories, or oral testimony. Any CID must state the nature of the conduct that constitutes the alleged violation, as well as the applicable provision of law that has been allegedly violated. Materials obtained by the attorney general from a CID may be used for any lawful purpose in investigating or prosecuting a claim under the act, and may be shared with a relator as necessary as part of the investigation.

Damages and Penalties.

State FCA violations carry stiff penalties and damages. The act provides for the following mandatory penalties upon a finding of liability:

- A civil penalty of not less than \$5,500 and not more than \$11,000 per false claim;
- Three times the amount of damages that the State sustained in connection with the false claim(s); and
- The costs of investigation and prosecution of the false claims(s).

A person can limit his or her exposure to damages and penalties under the State FCA by self-reporting. A person who self-reports a false claim prior to the commencement of any action regarding the violation will not be subject to civil penalties under the law and will be subject to reduced damages of two times the amount of damages sustained by the State in connection with the false claims(s).

The Criminal False Representation Law.

In addition to the State FCA, which is a civil law, Vermont also has a criminal false representation law, 33 V.S.A. § 141, that prohibits a person from making any false or fraudulent material statements, or falsifying, concealing, or covering up with any trick, scheme or device, any material facts, or falsifying any documents or writings knowing they contain a material fact, regarding any matter within the jurisdiction of a state or local government body.

The penalty for a violation depends on the amount of the loss sustained by the government entity and the benefit gained by the person. If there is no loss to the government or gain to the person, or if the loss or gain is less than \$500, the violator can be imprisoned for up to two years and fined up to \$5,000, or both. If the government's loss or the person's gain exceeds \$500, the person can be imprisoned for up to five years, fined up to \$10,000, or both.

A provider may be subject to both the State FCA and criminal false representation law, as well as the federal FCA. However, a provider who commits an act punishable under the Medicaid fraud statute discussed below may not be prosecuted under the state criminal false representation law.

The Medicaid Fraud Statute

Medicaid fraud is committed when a provider is untruthful regarding services provided to Medicaid beneficiaries to obtain improper payment. A provider may commit Medicaid fraud, for

instance, by submitting false claims and records for services or supplies that were not provided, billing twice or more for the same services or supplies, or billing for services or supplies that were not medically necessary. The Medicaid fraud statute, 33 V.S.A. § 14, specifically defines fraudulent conduct as:

- knowingly filing, attempting to file, or aiding and abetting in filing a claim for services to a Medicaid beneficiary that were not rendered; or
- knowingly filing a false claim, or a claim for unauthorized items or services under the Medicaid program; or
- knowingly billing the Medicaid recipient or family for amounts in excess of the amount allowable by law; or
- failing to credit the State for amounts received from Social Security, insurance or other sources; or
- in any way knowingly receiving, attempting to receive, or helping to receive unauthorized payments from Medicaid.

Investigation and Enforcement.

Medicaid is a joint federal-state program, and states administer their own Medicaid programs within the context of minimum federal requirements. Congress enacted the Medicare and Medicaid Fraud and Anti-abuse Amendments in 1977 to authorize and substantially fund Medicaid Fraud Control Units in the states.

The Medicaid Fraud and Residential Abuse Unit of the Vermont attorney general's office is responsible for investigating and prosecuting providers who commit fraud against the Medicaid program. It also is responsible for investigating and prosecuting instances of residential patient abuse and neglect.

Penalties.

Medicaid fraud is a felony and conviction can lead to substantial penalties including but not limited to imprisonment for up to 10 years, a fine of up to \$1,000 or an amount equal to twice the amount of the assistance or benefits wrongfully obtained, or both a fine and imprisonment. Additionally, individuals convicted of Medicaid fraud will be excluded from participating in Medicaid for four years unless the state secretary of human services waives the suspension after finding that the recipients the provider serves would suffer a substantial hardship by being denied medical services that cannot reasonably be obtained through another provider. 33 V.S.A. § 143a.

There is also a provision that allows the attorney general to bring a civil action against a provider who knowingly violates the fraud statute. 13 V.S.A. § 3016. The penalties for civil violations include restitution of any amounts wrongfully obtained plus interest, and a penalty of up to three times the amount wrongfully obtained, or \$500 per false claim, or \$500 for each false document submitted in support of a false claim, whichever is greatest.

Healthcare Whistleblower's Protection Act.

The act, 21 V.S.A. § 507 - 509, makes it illegal for a hospital or nursing home to fire, threaten, or take any adverse employment action (such as demotion, suspension, failure to make a promotion, discrimination) against an employee because the employee:

• Discloses or threatens to disclose what he or she reasonably believes is a violation of law or improper quality of patient care by the employer or by an agent of the employer;

- Testifies or provides information to a public body that is investigating whether the employer violated any law or engaged in behavior constituting improper patient care; or
- Objects to or refuses to participate in any activity, policy, or practice of the employer's that the employee reasonably believes is a violation of law or constitutes improper quality of patient care.

To receive protection under the act (other than protection for testimony), the employee must first report the alleged violation of law or improper care to the employer, supervisor or other person designated by the employer to address such reports, unless the employee reasonably believes that doing so would be futile. After receiving the employee's report, the employer must then have a reasonable opportunity to address the violation. Any violation must be addressed under the employer's compliance plan, if it has one.

The law gives aggrieved employees the right to bring an action in superior court seeking such relief as reinstatement, back pay, lost wages and benefits, punitive and compensatory damages, and attorney's fees.

Hospitals are required to have internal processes that reflect the Magnet Recognition Program quality care and professional standards developed by the American Nurses Credentialing Center. Hospitals and nursing homes are also required to post a notice about the Healthcare Whistleblower Protection Act. The notice is available on the Vermont Department of Labor's website, <u>labor.vermont.gov</u>. An employer's willful failure to post the notice can lead to a fine of up to \$100 per day.

PREVENTATIVE ACTION COMPLIANCE PROGRAMS

Every office should voluntarily adopt and scrupulously adhere to a compliance program. In October 2000, OIG issued a document entitled "Compliance Program Guidance for Individual and Small Group Physician Practices." OIG has issued a number of such compliance program guidelines for different segments of the health care industry, including clinical laboratories, hospitals, home health agencies, third-party medical billing companies, durable medical equipment suppliers, hospices, pharmaceutical manufacturers, ambulance suppliers, Medicare+Choice organizations, and nursing facilities. The most recent guideline issued is a "Supplemental Compliance Program Guidance for Nursing Facilities," which was published in September 2008. OIG's compliance program guidance documents are posted on its website at https://oig.hhs.gov/compliance/compliance-guidance/index.asp.

OIG's motive in issuing compliance program guidance is to engage the industry in avoiding the submission of erroneous claims and ferreting out fraudulent conduct through internal controls that monitor adherence to the laws and program requirements. Having a compliance program in place is one of the factors that enforcement authorities will take into account when assessing some violations.

It is important, however, that the compliance policy not be simply a volume on a shelf, but a discernible good faith attitude and set of procedures that are integrated into the fabric of the practice.

Basic Recommendations for Individual and Small Group Physician Practices.

The OIG Compliance Program for Individual and Small Group Physician Practice guidance sets forth seven basic elements that should be addressed in every compliance program. OIG acknowledges that small and solo practices have limited resources to devote to a compliance program. Therefore, the fundamental principle in adopting a compliance program is showing a good faith commitment to compliance, best exhibited by taking reasonable steps to address each of the following seven elements.

- 1. Establish written practice standards and procedures after doing an initial audit to understand risk areas.
- 2. Audit and monitor periodically review the office's standards and procedures and audit the claims submission process.
- 3. Designate a compliance officer or compliance contacts.
- 4. Conduct appropriate training and education in coding, billing and compliance.
- 5. Respond to detected offenses and develop corrective action initiatives.
- 6. Develop open lines of communication.
- 7. Enforce disciplinary standards through well-publicized guidelines.

Other Useful Materials for Compliance with Fraud and Abuse Issues.

OIG publishes a Work Plan for each fiscal year that lists the areas it intends to focus on during the year to protect the integrity of all of the Department of Health and Human Services programs, including Medicaid and Medicare. The Work Plan can serve as an annual guide for practitioners for purposes of reviewing compliance issues and risks. Each year, starting in early October, practitioners can review the compliance areas of interest to OIG for the coming year with respect to hospitals, physician practices, home health agencies, and other health care providers. The current and past Work Plans can be found at https://oig.hhs.gov/reports-and-publications/workplan/index.asp#current.

In addition, OIG issues special fraud alerts and special advisory bulletins to inform the health care industry of particular practices that it deems suspect. As mentioned earlier, OIG responds to requests for formal advisory opinions on the application of the anti-kickback statute and other fraud and abuse statutes to particular business arrangements. All of these materials are found on OIG's website, <u>http://oig.hhs.gov</u>.

Finally, OIG provides compliance education resources and materials aimed at a fairly basic level at its "Compliance 101" website at <u>https://oig.hhs.gov/compliance/101/index.asp</u>. In addition to links to the compliance guidance documents described above, the website features a variety of educational materials aimed at providers including videos, podcasts, bulletins, transcripts and more.

CONCLUSION

As you can see, there are many laws regulating fraud and abuse in the health care field, many of which are quite complex. Moreover, violations of these laws can lead to substantial penalties. Accordingly, if someone alleges that you or your practice has committed fraud or abuse, or if you discover potential fraud or abuse, you should contact competent fraud and abuse counsel right away.
ABOUT THE AUTHORS

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MARIJUANA FOR THERAPEUTIC USE

Topics Covered in this Chapter: <u>The Vermont Medical Cannabis Registry Program</u> <u>Legal and Regulatory Considerations for Clinicians</u> <u>About the Authors</u>

By Lindsey Wells, B.S & Meredith Bullock, Cannabis Control Board Updated by VMS Staff for 2022 Edition

In 2004, the Vermont Legislature passed Act 135, "An Act Relating to Marijuana Use by Persons with Severe Illness." The Department of Public Safety was designated to administer the Vermont Marijuana Registry (VMR). There have been various amendments passed since 2004, the most notable being Act 164 of 2019, which were part of the statue legalizing sales of cannabis to adults and moved the cannabis for symptom relief program from the Department of Public Safety to the Cannabis Control Board (CCB), recodified the statutes and authorized rewriting the rules of the program. It is now referred to as the Medical Cannabis Program and information can be found on the CCB Website: https://ccb.vermont.gov/medical

The rules governing the program can be found in <u>Rule 3 of the Cannabis Control Board</u> and statutes governing the program are found in 7 VSA \$\$ 951 - 956.

THE VERMONT MEDICAL CANNABIS REGISTRY PROGRAM

What is the Vermont Medical Cannabis Registry?

The Cannabis Control Board is directed by statute to establish and manage the Vermont Medical Cannabis Registry for the purpose of allowing persons with qualifying medical conditions and their caregivers to obtain privileges regarding cannabis and cannabis product possession, use, cultivation, and purchase. A person who is a registered patient or a registered caregiver on behalf of a patient may: (1) Cultivate not more than two mature and seven immature cannabis plants. (2) Possess not more than two ounces of cannabis. (3) Purchase cannabis and cannabis products at a licensed medical cannabis dispensary.

Who is eligible to register with the Medical Cannabis Registry?

To become a registered patient, a person must be diagnosed with a debilitating medical condition by a health care professional in the course of a bona fide health care professional-patient relationship. A registered patient must also be a resident of Vermont and issued a registry identification card. "Resident of Vermont" means a person whose domicile is Vermont. A "debilitating medical condition" is defined in statute at 7 V.S.A. § 951 and means:

 (A) cancer, multiple sclerosis, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, glaucoma, Crohn's disease, Parkinson's disease, or the treatment of these conditions, if the disease or the treatment results in severe, persistent, and intractable symptoms;

- (B) post-traumatic stress disorder, provided the VMR confirms the applicant is undergoing psychotherapy or counseling with a licensed mental health care provider; or
- (C) a disease or medical condition or its treatment that is chronic, debilitating, and produces one or more of the following intractable symptoms: cachexia or wasting syndrome; chronic pain; severe nausea; or seizures.

How does an individual apply for a registry identification card with the Vermont Marijuana Registry?

To register a patient must submit:

- A completed patient application;
- A Health Care Professional Verification Form completed by a health care professional;
- The required \$50 non-refundable fee; and,
- An electronic color photo of themselves from the shoulders up.
- Patients diagnosed with post-traumatic stress disorder must submit a completed Mental Health Care Provider Form to confirm the applicants is undergoing psychotherapy or counseling with a licensed mental health care provider.

Forms and instructions may all be found at: https://ccb.vermont.gov/med-forms

The CCB must approve or deny an application in writing within 30 days of receipt of a completed application. If the application is approved, the CCB will issue the applicant a registry identification card.

A registered patient may designate a caregiver to assist with marijuana for symptom relief. A caregiver is a person who may obtain the benefits of participating in the Cannabis Registry Program on behalf of a registered patient, for example, obtaining cannabis from a dispensary or assisting with the cultivation of cannabis. A registered caregiver must be a person who is a resident of Vermont, at least 21 years of age, and has met the criminal history record requirements contained in the Rules for Medical Cannabis.

Do patients need to renew their Registry Cards?

A registry identification card expires one year after its issue date and may be renewed by completing and submitting the required forms and fees, found on the CCB website. According to current CCB rules, the renewal must contain a new Health Care Professional Verification Form with a certification that is dated less than 6 months prior to the submission of the renewal application, provided that the Health Care Professional Verification Form and electronic photo will only be required every second renewal application

What is the definition of a Health Care Professional?

A health care professional is an individual licensed as a:

- Doctor of Medicine (M.D.);
- Osteopathic Physician (D.O.);
- Naturopathic Physician (N.P);
- Physician Assistant (P.A.); or,

• Advanced Practice Registered Nurse (APRN).

This definition includes individuals licensed in Vermont and under substantially equivalent provisions in New York, New Hampshire and Massachusetts.

What is the definition of a Mental Health Care Provider?

A mental health care provider is a person licensed in Vermont as a:

- Psychiatrist;
- Psychologist;
- Psychologist-doctorate;
- Psychologist-master;
- Clinical social worker; or
- Clinical mental health counselor.

What are the responsibilities of the patient's Health Care Professional?

A health care professional electing to the complete a verification form for a patient must do so truthfully and accurately to the best of his/her knowledge. The verification form is not considered a prescription and the only purpose of the form is to confirm the patient has a debilitating medical condition and existence of a bona fide health care professional-patient relationship.

What is a bona fide heath care professional-patient relationship?

The phrase "bona fide health care professional-patient relationship" means a treating or consulting relationship of not less than three months' duration, in the course of which the health care professional has completed a full assessment of the registered patient's medical history and current medical condition, including a personal physical examination.

See the Medical Verification Form available at: <u>https://ccb.vermont.gov/sites/ccb/files/2022-02/Health%20Care%20Professional%20Form%202022.pdf</u>

The three-month requirement does not apply if:

- 1. A patient has been diagnosed with:
 - a. A terminal illness;
 - b. Cancer; or
 - c. Acquired immune deficiency syndrome.
- 2. Is currently under hospice care.
- 3. A patient had been diagnosed with a debilitating medical condition in another state and has moved to Vermont within the past 3 months. The new health care professional must have completed a full assessment of the patient's medical history and current medical condition, including a personal physical examination.
- 4. A renewal patient changes health care professionals three months or less prior to renewing their registration, provided the new health care professional has completed a full assessment of the patient's medical history and current medical condition, including a personal physical examination.

- 5. A patient is referred by his or her health care professional to another health care professional who has completed advanced education and clinical training in specific debilitating medical conditions, and that health care professional conducts a full assessment of the patient's medical history and current medical condition, including a personal physical examination.
- 6. When a patient's debilitating medical condition is of recent or sudden onset.

What are the responsibilities of the patient's Mental Health Care Provider?

A person registering as a patient with only a post-traumatic stress disorder diagnosis confirmed on the Health Care Professional Verification Form must additionally submit a completed Mental Health Care Provider Form. A Mental Health Care Provider completing the Mental Health Care Provider Form is confirming he or she is providing psychotherapy or counseling to the patient identified in section 1 of the form.

The Mental Health Care Provider Form can be found at the end of the full Patient Application packet, available at: <u>https://ccb.vermont.gov/sites/ccb/files/2022-</u>02/2022%20Registration%20Packet.pdf

Can a Health Care Professional inactivate a patient's registry identification card?

Yes, a registered patient's verifying health care professional may void a registered patient's registry identification card by submitting to the Board a signed statement to that effect. This shall have the effect of canceling a Patient's registration. A Patient who has been deregistered in this manner may submit an application to the Board at any time, provided that the Patient must submit a new and timely Health Care Professional Verification Form. See CCB Medical Cannabis Rules Section 3.7.

Where can I obtain information about the dispensaries and the types of products they offer? The CCB website has information available regarding the current dispensaries at: <u>https://ccb.vermont.gov/med-dispensaries</u>. Additional information may be obtained from the individual dispensaries. There are currently five registered dispensaries in the State of Vermont.

What protections are there for Health Care Professionals?

Vermont statue previously stated that a health care professional who participated in a patient's application process under the statute, rules, policies or procedures of the registry would not be subject to arrest, prosecution, or disciplinary action under 26 V.S.A. Chapter 23, penalized in any manner, or denied any right or privilege under state law, except for giving false information, pursuant to 18 V.S.A. § 4474c(f). 18 VSA § 4474b (b). This statute was removed from law with Act 164 of 2019 and is no longer in effect.

Have questions about the Vermont Marijuana Registry?

You can learn more about the Vermont Medical Cannabis Program at <u>https://ccb.vermont.gov/med-FAQ</u>. To contact the Medical Cannabis Program, please email <u>CCB.Med@vermont.gov</u> or call 802-828-1010 ext. 2

OTHER LEGAL AND REGULATORY CONSIDERATIONS FOR CLINICIANS

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This section has been prepared by the Vermont Medical Society to provide additional information to clinicians considering whether to participate in a patient's application under Vermont law. For further information, contact the Vermont Medical Society at 802-223-7898.

Despite state laws legalizing marijuana for therapeutic and recreational use, the federal government continues to classify marijuana as a Schedule I drug with no currently accepted medical use and a high potential for abuse. Federal law prohibits knowingly or intentionally distributing, dispensing, or possessing marijuana. 21 U.S.C. §§841–44. Additionally, a person who aids and abets another in violating federal law or engages in a conspiracy to purchase, cultivate, or possess marijuana may be punished to the same extent as the individual who commits the crime. 18 U.S.C. §2, 21 U.S.C. §846. Other federal sanctions for prescribers who violate federal law are also possible, such as revocation of a prescriber's DEA registration or exclusion from participation in the Medicare and Medicaid programs.

Based on the increasing number of states legalizing marijuana for therapeutic and recreational use, the U.S. Department of Justice has issued several memoranda regarding its marijuana enforcement policy – and depending on the Presidential Administration has issued various statements regarding whether or not to prioritize cannabis investigations and convictions. (See, for example, discussion at: <u>https://www.jdsupra.com/legalnews/merrick-garland-signals-new-stance-on-8828319/</u>)

Participating in a patient's application process under a state medical marijuana law is generally considered low risk for federal enforcement or other disciplinary or legal action. However, the continuing inconsistency between federal and state law, and lack of clarity in case law around the country regarding the extent to which clinicians are protected from federal prosecution when discussing marijuana with patients, raises questions for medical professionals. The Vermont Medical Society recommends that physicians and other clinicians consider the following:

- If you assist a patient with the application process, you should comply with all state statutory requirements for establishing a bona fide professional-patient relationship under the Vermont program and meet the same standard of care as in other types of patient encounters. Disciplinary actions from other states that have been reported in the press relate to issues such as physicians completing a high number of forms without establishing the required physician-patient relationship, not performing required medical exams and/or maintaining inadequate patient records. See the model guidelines created by the Federation of State Medical Boards discussing best practices regarding patient evaluations, medical record keeping, informed decision making and written treatment agreements.
- Limit the information provided to the Cannabis Control Board to that required to complete and confirm the accuracy of the information contained on the Health Care Professional Verification Form. Do not prescribe, and avoid "recommending," marijuana to patients. While health care professionals may discuss relevant information regarding possible health risks and therapeutic benefits of cannabis with patients, "recommending" marijuana may be seen as akin to "prescribing" and abetting the patient in obtaining an illegal substance in violation of federal law. (See e.g. *Conant v. Walters* (9th Cir. 2002) 309 F.3d 629, affirming *Conant v. McCaffrey* (N.D.Cal. Sept. 7, 2000) 2000 WL 1281174). Also, avoid offering individualized patient advice concerning appropriate

cannabis strains, dosage, timing, amount and route of administration as this may also be interpreted as prescribing.

- Do not dispense or otherwise provide marijuana to patients.
- Discuss your participation with your liability carrier to ensure that you would have coverage for any harms resulting from medications, including cannabis, that are not approved by the FDA.
- Discuss your participation with any employer or facility for which you work. Health care facilities and employers may have to comply with additional federal regulations that impact the ability of a physician to participate in the application process.
- The statute does not require a health care professional to participate in the application process.

ABOUT THE AUTHORS

Lindsey Wells, B.S., received her Bachelor of Science Degree in Business Administration in 2005 from Norwich University. She has an extensive work history with state and federal regulations. She was employed by the Department of Public Safety as the Marijuana Program Administrator for the Vermont Marijuana Registry since 2012 and is now the Marijuana Program Administrator for the Medical Marijuana Program within the Cannabis Control Board.

Meredith Bullock was employed by the Department of Public Safety as a Program Technician for the Vermont Marijuana Registry (VMR) since August 2013 and now serves as the Program Technician for the Medical Marijuana Program within the Cannabis Control Board.

MENTAL HEALTH AND SUBSTANCE ABUSE TREATMENT ISSUES

- Topics Covered in this Chapter: <u>Admission</u> <u>Treatment Over Patient's Objection</u> <u>Rights of Admitted Patients</u> <u>Minor Consent to Mental Health Treatment</u> <u>Substance Use Disorder Provisions</u> <u>Sterilization</u> <u>Confidentiality and Privacy of Information</u> <u>Duty to Warn</u> <u>Any Willing Provider</u> <u>Patient Suicides and Liability</u> <u>Forms And Crisis Numbers</u> <u>About the Author</u>
- By Elizabeth Wohl, Esq. Downs Rachlin Martin PLLC

In the State of Vermont mental health and addiction treatment services are delivered by a wide range of providers. The Vermont Department of Mental Health oversees community mental health centers known as "designated agencies" (DAs) each of which has a "catchment area" in which the DA is required to provide services. The state also oversees a number of hospitals approved to care for patients hospitalized against their will known as "designated hospitals" and a quasi-state hospital system comprising the Vermont Psychiatric Care Center (operated by the State of Vermont) and two private non-profit hospitals, the Brattleboro Retreat and Rutland Regional Medical Center. In addition, many therapists, psychologists and psychiatrist provide services privately though their own practices or in group practice outside the designated agencies and hospitals.

Similarly, the Division of Alcohol and Drug Abuse Programs oversees a wide variety of residential, intensive outpatient and outpatient substance abuse treatment programs. Vermont also pioneered an innovative "Hub-and-Spoke" approach to opioid treatment (described in more detail below.) Providers are encouraged to review the sections of this guide on licensure and regulation relevant to their specialty.

ADMISSION

In Vermont, Act 79 of 2012 governs the legal requirements for voluntary, involuntary and emergency admissions to designated hospitals. The relevant portions of this act are codified in Title 18. No. 79 (Adj. Sess.) eff. April 4, 2012.

What are the requirements for a voluntary admission?

Title 18 allows any person 14 years of age or older to apply for voluntary admission to a designated hospital for examination and treatment. 18 V.S.A. § 7503. Each person voluntarily admitted to a designated hospital must provide written consent on a form approved by the Department of Mental Health. The consent must include a representation that the person understands the inpatient nature of her treatment and consents to that admission voluntarily and

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without coercion. If the person is under 14 years old, then they must consent, as provided in §7503(b), and a parent or guardian makes written application. 18 V.S.A. § 7503(c).

Patients may only be voluntarily admitted in instances in which they have the capacity to give informed consent to treatment. *Zinermon v.Burch*, 494 U.S. 113, 139 (1990). It remains the clinician's role to evaluation whether patients have the capacity to provide informed consent, and to begin an application for involuntary treatment if they do not.

What are the requirements for involuntary admission?

There are three steps in every involuntary admission.

- 1. An interested party must seek (through application or warrant) an emergency examination. A physician must support the *application* for an emergency examination with a physician's certificate. 18 V.S.A. § 7504. If no physician is readily available, a law enforcement officer or a mental health professional may seek a *warrant* for emergency examination from a superior court judge. 18 V.S.A. § 7505. If the judge issues a warrant, the person must be taken immediately to a hospital where a physician may examine the person and either certify that the person is a "person in need of treatment" or release that person.
- 2. An emergency examination must be conducted within 24 hours of the initial certification. The emergency examination must be conducted by a psychiatrist, and it may not be the same physician who signed the first certification. The emergency examination is evidenced by a second certification signed by the examining psychiatrist. If the psychiatrist determines that the person is not a person in need of treatment, then the person must be returned to the place from which he was taken or so some other place that the person requests. Id. § 7508.
- 3. If the psychiatrist issues a second certification, the person may be held for involuntary treatment for an additional 72 hours. At the end of 72 hours the Commissioner of the Department of Mental Health must file an application for involuntary treatment pursuant to section 7612. Id. The application must be filed in the family division of the superior court in the county in which the hospital is located.

At any time during the involuntary process, the person may agree to a voluntary admission, or may be discharged from the hospital if his or her mental health condition has improved sufficiently that he or she is no longer a "person in need of treatment."

TREATMENT OVER PATIENT'S OBJECTION

What must an application for involuntary treatment contain?

- 1. The name and address of the applicant.
- 2. A statement of the current and relevant facts upon which the allegation of mental illness and need for treatment is based. The application shall be signed by the applicant under penalty of perjury.

The application must be accompanied by:

1. a certificate of a licensed physician, which shall be executed under penalty of perjury stating that he or she has examined the proposed patient within five days of the date the petition is filed, and is of the opinion that the proposed patient is a person in need of treatment, including the current and relevant facts and circumstances upon which the physician's opinion is based; or

2. a written statement by the applicant that the proposed patient refused to submit to an examination by a licensed physician.

Before an examining physician completes the certificate of examination, he or she shall consider available alternative forms of care and treatment that might be adequate to provide for the person's needs, without requiring hospitalization. The examining physician shall document on the certificate the specific alternative forms of care and treatment that he or she considered and why those alternatives were deemed inappropriate, including information on the availability of any appropriate alternatives.

Within three days after an application for involuntary treatment is filed, the family division of the superior court must conduct a review of the documentation to determine whether there is "probable cause" to believe that the person was a person in need of treatment at the time of his or her admission. 18 V.S.A. § 7612a. If the court finds there is no probable cause then the person must be released from the hospital and returned to the place from which he or she was transported or to such other place as he or she may reasonably direct.

How do hearings on petitions for involuntary treatment proceed?

Hearings on applications for involuntary treatment are supposed to be set within 10 days of receipt of the application, unless a psychiatric evaluation is ordered. In reality, these hearings are often continued based on an agreement of both parties or simply because there is not enough court time to set the hearing within the 10 day time limit.

The applicant and the patient both have the right to attend the hearing and testify. The patient is entitled to have a support person present. The court generally excludes all other persons not necessary to the conduct of the hearing. Id. §7615. 18 V.S.A. § 7615.

The Attorney for the Commissioner of the Department of Mental Health must prove that the person is a person in need of treatment at the time of the application and the time of the hearing by clear and convincing evidence. Id. § 7616.

If the court finds that the person was not a person in need of treatment at the time of the application or is no longer a person in need of treatment at the time of the hearing, the court shall dismiss the application and the patient must be discharged. Id. § 7617.

If the court finds that the person is a person in need of treatment, the court will order that the person be hospitalized or, if appropriate, undergo a treatment program other than hospitalization by issuing an order of non-hospitalization. Id. §§ 7617-7619.

An initial order of hospitalization may not last more than 90 days from the date of the hearing. Id. § 7619.

What can the Commissioner do if the patient does not respond to treatment within 90 days?

The Commissioner may apply for an application for continued treatment. Once the application is filed, the initial order will not expire until the Court issues a decision on continued treatment. Id. § 7620. An order for continued treatment may last no longer than one year. Id. § 7621.

When can the Commissioner administer medication to a patient who refuses medication?

The Commissioner may also seek an application for involuntary medication. As a general matter the commissioner may not seek an application for involuntary medication unless the patient has been involuntarily committed. There are a few specific circumstances in which medication applications can be combined with applications for involuntary treatment.

Even where a patient has been involuntarily committed, the court must determine, as a threshold matter, in a medication application, whether the person is competent to make the medication decision. If the person is competent, then the court must deny the application for involuntary medication. Id. § 7627; *In re L.A.*, 2007 VT 119.

In no instance shall a court order involuntary medication if the patient has validly executed advanced directive that addresses the decision regarding the proposed treatment. Id. § 7626. Challenges to the validity of an advanced directive may generally be heard in the probate court, but may also be made in an application for involuntary medication in the family division of the Vermont Superior Court. In re G.G., 2019 VT 83, ¶¶ 17-18.

RIGHTS OF ADMITTED PATIENTS

What rights to admitted patients have?

Persons admitted to the care and custody of the commissioner of the Department of Mental Health, whether they are in a designated hospital or not, shall receive treatment in the least restrictive manner necessary to protect the safety of the person and the public. Id. § 7617-19. They shall receive care that respects their privacy and prevents physical and psychological trauma. They must be provided with a notice of rights which includes contact information for Vermont Legal Aid, the Office of the Mental Health Care Ombudsman and the mental health patient representative. Id.

All patients must be treated with dignity and respect and shall be given the medical and psychiatric treatment indicated. Patients have the right to know what their rights are by having relevant portions of statutes provided to them and posted in convenient places. Id. §7701. Patients have the right to communicate with others, to have a peer-support person present at treatment team meetings and all other meetings the patient is entitled to attend, and to have reasonable use of the telephone, electronic mail and the internet. The patient is entitled to have the hospital communicate with people that he or she wants notified of his or her hospitalization. Id.§ 7509.

When an application for involuntary treatment is filed, the person shall have a right to an attorney. The Court will appoint an attorney for the person. Id. § 7613. The person is entitled to an independent psychiatric evaluation paid for by the state of Vermont. Id. § 7614.

A patient has the right to file an application for discharge no sooner than 90 days after an order of continued treatment has issued, and no sooner than six months after a previously filed application for discharge. Id. § 7801.

The commissioner is responsible for ensuring that all reasonable and appropriate measures consistent with public safety are made to transport or escort a person subject to this chapter to and from any inpatient setting, including escorts within a designated hospital or the Vermont

State Hospital or its successor in interest or otherwise being transported under the jurisdiction of the commissioner in any manner which:

- 1. prevents physical and psychological trauma;
- 2. respects the privacy of the individual; and
- 3. represents the least restrictive means necessary for the safety of the patient.

The commissioner designates the professionals or law enforcement officers who may authorize the method of transport of patients under the commissioner's care and custody. When a professional or law enforcement officer decides an individual is in need of secure transport with mechanical restraints, the reasons for such determination shall be documented in writing. It is the policy of the state of Vermont that mechanical restraints are not routinely used on persons in the custody of the commissioner of the department of mental health unless circumstances dictate that such methods are necessary. Id. § 7511.

MINOR CONSENT TO MENTAL HEALTH TREATMENT

Can minors consent to mental health treatment without the consent of their parents?

Yes. The admission procedure allows any person 14 years or older to voluntarily consent to inpatient psychiatric treatment. Id. § 7503. In addition, minors may consent to receive outpatient treatment from a mental health professional, as that term is defined in statute. Consent of the parent or guardian is not necessary to authorize outpatient treatment including counseling or psychotherapy, but excluding prescription drugs. Id. § 8350.

In both of these instances, the provider must have an upfront conversation with the minor to determine the minor's capacity to consent to treatment under the general rules of informed consent, as well as to discuss payment options. Providers are advised to consult the Guide's chapter on Informed Consent.

SUBSTANCE USE DISORDER PROVISIONS

The Vermont Division of Alcohol and Drug Abuse Programs (ADAP) oversees network of community partners to promote and deliver a wide range of substance abuse information, prevention, intervention treatment and recovery programs. As of July 1, 2015, the Department of Vermont Health Access determined that inpatient treatment was not necessary for most people suffering from substance use disorder. Thus, Vermont Medicaid now only pays for inpatient substance abuse treatment when there is a co-occurring medical or mental health diagnosis. As with all treatment, providers would do well to seek prior authorization from the patient's insurer before beginning a course of treatment.

Most recently, the State has launched the Care Alliance for Opioid Addiction, "hub and spoke" model of treatment. This statewide partnership of clinicians and treatment centers provide medication assisted treatment to Vermonters recovering from opioid addiction. Patients begin with daily doses of methadone, buprenorphine or suboxone in a "hub" setting, and then as their recovery progresses may transition to receiving care closer to their homes in a "spoke" clinic. Rules governing "hubs" and "spokes" and further resources can be found here: http://www.healthvermont.gov/alcohol-drugs/professionals/medication-assisted-treatment-resources

The statutes governing substance abuse treatment have not been amended since 1977 and do not reflect the changing models of substance abuse treatment and recovery. 18 V.S.A. §§ 8401-8405.

Therefore, before relying on those statutes, it would be wise to consult with counsel knowledgeable in the current substance use treatment landscape.

STERILIZATION

Vermont allows for voluntary and involuntary sterilization of adults with an intellectual disability under circumstances that protect the best interest and rights of that person. Involuntary sterilization may only be performed after a hearing at which the respondent is entitled to counsel and other procedural safeguards. 18 V.S.A. §§ 8705-8716.

CONFIDENTIALITY AND PRIVACY OF INFORMATION

In Vermont, providers of mental health treatment are governed by the same privacy and confidentiality rules that all providers must abide by. There are additional rules for providers of involuntary mental health treatment, 18 V.S.A. § 7103, and for providers of substance abuse treatment, 42 C.F.R. Part 2. For more detail, please refer to the <u>Privacy and Medical Information</u> chapter herein.

DUTY TO WARN

Since 1976, Courts and legislatures have struggled to define the duty that a mental health professional has to warn a third party of dangers that their patient may pose. *Tarasoff v. Regents of the University of California*, 551 P.2d 334 (1976). Fundamentally, this struggle demonstrates the tension between a patient's right to privacy and confidentiality in her conversations with her provider, and an unrelated third party's need to have information necessary to protect himself from a threat that the mental health professional knows exists.

While nearly everyone recognizes that a mental health professional has an obligation to act to prevent harm to third parties, determining when that obligation arises is extremely challenging.

In 1985, the Vermont Supreme Court determined that when a mental health provider knows or should know that his patient poses a serious risk of danger to an identified individual, then the provider must take whatever steps are "reasonably necessary" to protect the identifiable victim from danger. *Peck v. Counseling Service of Addison County*, 146 V.t 61, 67 (1985).

In 2016, the Vermont Supreme Court added an additional duty to inform certain individuals in certain circumstances even when there was no identifiable victim. *Kuligoski v. Brattleboro Retreat, et al.*, 2016 VT 54A.

Providers and legislators determined the Court's new standard to be unworkable, and in 2017, the legislature passed Act 51, which negated the Kuligoski decision, and "limit[ed] mental health professionals' duty to that established in common law by *Peck v. Counseling Service of Addison County*, 146 Vt. 61 (1985)." 18 V.S.A. § 1882.

The General Assembly also found that the "overwhelming majority of people diagnosed with mental illness are not more likely to be violent than any other person" and that "the majority of interpersonal violence in the United States is committed by people with no diagnosable mental illness." 2017, Act 51 § 1.

ANY WILLING PROVIDER

Vermont Guide to Health Care Law

What is the any willing provider law?

Vermont, like many states requires that insurers provide the same benefits for mental health conditions that they do for medical conditions. In addition, the law requires insurers to include in their networks any licensed mental health or substance abuse provider located within the geographic coverage area of the health benefit plan, if the provider is willing to meet the terms and conditions for participation established by the health insurer. 8 V.S.A. §4089b.

PATIENT SUICIDES AND PROVIDER LIABILITY

Can health care providers be sued over patient suicides?

Yes. Increasingly, families of patients who have committed suicide sue health care providers alleging a failure to follow the standard of care when treating a suicidal patient. Plaintiffs typically allege that the health care provider was negligent in failing to diagnose and treat the patient and that this failure was the proximate cause of the suicide. While these cases can pose significant problems of proof, health care providers should be mindful of this trend and take all necessary steps including conducting and documenting an appropriate assessment, and making appropriate referrals based on the outcome of that assessment. Practitioners are advised to consult the chapter on Medical Malpractice for additional information.

FORMS AND CRISIS NUMBERS

Where can I obtain mental health services information?

Mental health services forms may be obtained by downloading them from the Vermont Agency of Human Services Department of Mental Health website at <u>http://mentalhealth.vermont.gov/contact</u> or by mail from Vermont Department of Mental Health, 280 State Drive, NOB 2 North, Waterbury, VT 05671-2010. Information is also available by calling the following numbers: Adult Mental Health - (802) 241-0090 Child, Adolescent & Family MH - (802) 241-0090 Vermont Psychiatric Care Hospital - (802) 828-3300 TTY Relay Service - 1-800-253-0191

Vermont Crisis Numbers

Patients can access the Crisis Text Line serves for any type of crisis, providing access to free, 24/7 support and information via the medium people already use and trust: text. Text "VT" to 741741 from anywhere in the USA, anytime, about any type of crisis.

Practices can also find the crisis line for the Designated Agency (DA) in each geographic region of the state here: <u>How to Get Help | Department of Mental Health (vermont.gov)</u>

ABOUT THE AUTHOR

Elizabeth Wohl practices health law at the prominent New England law firm Downs Rachlin Marin PLLC. She served as in-house General Counsel and Chief Compliance Officer at the Brattleboro Retreat for four years and continues in that role as outside counsel. Before joining the Retreat, she practiced health law for nine years at firm Downs Rachlin Martin PLLC completing an accelerated track from associate to director. She chaired DRM's health law practice group and provided advice to hospitals, health systems, nursing homes, assisted living facilities, designated agencies, and individual providers. Her experiences in both in-house and

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private practice settings have given Elizabeth rare and valuable insights into the many pressures and tensions affecting the varied parts of the health care system in the region. She particularly enjoys teasing out the complex legal issues that arise in the course of providing high-quality mental and physical health care for Vermonters.

NON-DISCRIMINATION IN HEALTH CARE

Topics Covered in this Chapter: General Non-Discrimination Requirements/Section 1557 Disability Discrimination & ADA Accommodations Limited English Proficiency & Interpreter Requirements About the Author

By Jessa Barnard, Esq. Vermont Medical Society

GENERAL NON-DISCRIMINATION REQUIREMENTS/SECTION 1557

Long-standing Federal civil rights laws regarding non-discrimination apply to most health care practices. For example, Title VI of the Civil Rights Act of 1964 (requiring, among other things, access for those with limited English proficiency) and the Americans with Disabilities Act. In May 2016, the US Department of Health and Human Services (HHS) issued a Final Rule implementing a prohibition of discrimination by health care services found in Section 1557 of the Affordable Care Act (ACA). On June 12, 2020, HHS OCR announced a revision to the final rule. Litigation continued through Spring 2021 regarding some sections of the rule, especially the protections for sex discrimination. Section 1557 builds on many of the earlier civil rights laws and while many of the provisions of the Final Rule are not new to physicians, there are several new procedural requirements and clarifications of existing requirements.

Please note: As of publication of this edition of the Guide, HHS has also issued a proposed rule to revise the implementing regulations for Section 1557. While these are not in effect as of the time of publication, please monitor the <u>HHS Section 1557 website</u> for updates. Changes included in the propose rule would:

- Require covered entities to have Section 1557 policies and staff training
- Require covered entities to provide notice of the availability of language assistance services and auxiliary aids and services
- Codify protections against discrimination on the basis of sex as including discrimination on the basis of sexual orientation and gender identity

Generally, Section 1557 and the Final Rule prohibit "discrimination on the basis of race, color, national origin, sex, age or disability [by] any health program or activity, any part of which is receiving Federal financial assistance."

Does Section 1557 apply to me?

The Final Rule applies to "every health program or activity, any part of which receives Federal financial assistance." HHS expects that this **applies to almost all physician practices** in the nation as Federal financial assistance includes, but is not limited to: state Medicaid payments, "meaningful use" payments, National Health Service Corp funding, NIH research funding and CMS gain-sharing payments. Physician practices that exclusively receive Medicare Part B payments are not included, but practices should conduct a thorough review of their funding sources and consult an attorney before deciding they are exempt.

When did Section 1557 go into effect?

Section 1557 has been in effect since the passage of the ACA and the Final Rules went into effect in 2016, with an update in 2020.

What does the law require?

The law clarifies and extends discrimination protections on the basis of national origin, sex, and disability.

The 2016 final rule included a number of procedural requirements, which were removed in the revised 2020 rule and so are no longer in effect. The provisions no longer in effect include designating a compliance coordinator, adopting grievance procedures, posting a notice of non-discrimination, and including tag lines in non-English languages about non-discrimination in significant communications. (*Please note that updates to the Section 1557 Rules proposed by HHS in July 2022 but not finalized as of the publication of this edition of the Guide would reinstate some of these requirements such as requiring covered entities to provide notice of the availability of language assistance services and auxiliary aids and services and requiring covered entities to have Section 1557 policies and staff training. These have not yet been finalized but please monitor <u>https://www.hhs.gov/civil-rights/for-individuals/section-1557/</u> for updates.)*

What should I know about what 1557 means for non-discrimination/Language Access Laws

The Final Rule clarified and strengthened various non-discrimination protections that apply in the health care setting. Among other things, the law addresses:

- Limited English Proficiency/Requirements for Interpretation Services. Most health care providers have already been required to provide language access services to patients or prospective patients with limited English proficiency. Under this Final Rule, all covered practices are required to "take reasonable steps to provide meaningful access to...activities by limited English proficient individuals." See more details in the section on Limited English Proficiency, below.
- **Disability Discrimination:** The final rule reiterates the requirement that physician practices not discriminate on the basis of disability. See more details in the <u>Disability</u> <u>Discrimination</u> section, below.
- Sex Discrimination
 - The final rule establishes that individuals cannot be denied health care or services based on their sex. Sex-specific health programs are permissible only if the entity can demonstrate an exceedingly persuasive justification (e.g. most sex-specific clinical trials would still be considered appropriate.)
 - Consistent with the Supreme Court's decision in Bonstock v Clayton County and subsequent litigation, beginning May 10, 2021, OCR will also interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. For example, providers may not deny or limit services ordinarily available to individual of one gender based on the fact that a person seeking such services identifies as belonging to another gender. (E.g. a provider may not deny treatment for ovarian cancer to an individual who identifies as a transgender male where the treatment is medically indicated).

Where can I find more information?

HHS has a website dedicated to Section 1557, available <u>here</u>, that includes a summary of the rule, fact sheets and an FAQ page.

DISABILITY DISCRIMINATION & ADA ACCOMMODATIONS

Accessibility of doctors' offices, clinics, and other health care providers is essential in providing medical care to people with disabilities. Due to barriers, individuals with disabilities are less likely to get routine preventative medical care than people without disabilities. Accessibility is not only legally required, it is important medically so that minor problems can be detected and treated before turning into major and possibly life-threatening problems.

What laws address providing health care services to those with disabilities?

The <u>Americans with Disabilities Act of 1990 (ADA)</u> is a federal civil rights law that prohibits discrimination against individuals with disabilities in every-day activities, including medical services. Private hospitals or medical offices are covered by <u>Title III of the ADA</u> as places of public accommodation. <u>Section 504 of the Rehabilitation Act of 1973</u> (Section 504) is a civil rights law that prohibits discrimination against individuals with disabilities on the basis of their disability in programs or activities that receive federal financial assistance, including health programs and services that receive federal financial assistance, which can include Medicare and Medicaid reimbursements. <u>Section 1557</u> of the Affordable Care Act, and accompanying <u>regulations</u>, reiterate the requirement that physician practices not discriminate on the basis of disability. These statutes require medical care providers to make their services available in an accessible manner.

Vermont public accommodation law, <u>9 VSA §4502</u>, contains substantially the same requirements as the ADA and Section 504 and requires that places of public accommodation, including medical practices, provide an individual with a disability the opportunity to participate in its services, facilities, privileges, advantages, benefits and accommodations. Failure to comply may result in an action for civil penalties either through the Vermont Human Rights Commission or a private court action

What accommodations must be provided?

Federal and State public accommodations law require that medical care providers provide individuals with disabilities:

- Full and equal access to their health care services and facilities; and
- Reasonable modifications to policies, practices, and procedures when necessary to make health care services fully available to individuals with disabilities, unless the modifications would fundamentally alter the nature of the services or create an undue burden.

Regarding physical modifications/accommodations for those with mobility disabilities, the ADA sets <u>requirements</u> for new construction of and alterations to buildings and facilities, including health care facilities. Most physician practices have already been required to meet this standard. For those few that did not, under <u>Section 1557</u>, facilities or programs that are constructed or altered after January 18, 2018 must comply with the <u>2010 ADA Standards for Accessible Design</u>.

In addition, all buildings, including those built before the ADA went into effect, are subject to accessibility requirements for existing facilities. Under Title III and Vermont Public Accommodations law, existing facilities are required to remove architectural barriers where such removal is readily achievable. Examples of architectural barriers include inaccessible parking spaces, entrances, door handles and registration counters. Barrier removal is readily achievable when it is easily accomplishable and able to be carried out without much difficulty or expense. If barrier removal is not readily achievable, the entity must make its services available through alternative methods, if those methods are readily achievable. This same program accessibility standard generally also applies under Section 504 and Vermont public accommodations law.

Under <u>Section 1557</u>, online services must also be accessible, unless doing so would result in an undue financial burden. This means that patient portals, online forms, online appointment systems, electronic billing and other online services must be accessible to individuals with disabilities, such as vision impairments, unless doing so would impose an undue financial burden to the practice. See <u>Section 1557 Summary</u>, Ensuring Effective Communication with and Accessibility for Individuals with Disabilities.

For more information, See the <u>ADA Guidance Access to Medical Care for Individuals with</u> <u>Mobility Disabilities</u>. This technical assistance publication provides guidance for medical care providers on the requirements of the ADA in medical settings with respect to people with mobility disabilities, which include, for example, those who use wheelchairs, scooters, walkers, crutches, or no mobility devices at all. See also the <u>ADA Guide for Small Businesses</u> for more information about making parking lots, entrances and other structures accessible.

LIMITED ENGLISH PROFICIENCY & INTERPRETER REQUIREMENTS

Vermont physician practices are required under federal and state laws to provide interpreters for patients with limited English proficiency and for those who are deaf or hard of hearing. There are very limited exceptions, discussed below. Use of interpreters or translation services may be necessary to ensure that patients can give informed consent. There are several sources for interpreters that physicians can use, including phone-based interpreters, in-person interpreters and online translation services. Vermont's Medicaid program does reimburse physicians for the cost of providing an interpreter to patients.

What are the legal requirements for a physician practice to provide language interpretation services for patients with limited English proficiency (LEP)?

The following is a summary of applicable federal and state laws.

Civil Rights Act/Affordable Care Act

<u>Title VI of the Civil Rights Act of 1964</u> states that no person shall be subjected to discrimination on the basis of race, color or national origin under any program or activity that receives federal financial assistance. 42 U.S.C.A. § 2000d. In 2003 the Department of Health and Human Services issued <u>Guidance to Federal Financial Assistance Recipients</u> Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons to clarify the responsibilities of health care providers under Title VI. In June 2020, the US Department of Health and Human Services (HHS) issued a <u>Final Rule</u> implementing a prohibition on discrimination by health care services found in <u>Section 1557</u> of the Affordable Care Act (ACA). Section 1557 builds on long-standing Federal civil rights laws that have already applied to most health care practices, such as Title VI of the Civil Rights Act. The requirements of the Section 1557 Final Rule and Title VI are consistent and should generally be reviewed together – though Section 1557 provides further detail in several areas.

The Section 1557 Final Rule applies to "every health program or activity, any part of which receives Federal financial assistance." HHS expects that this **applies to almost all physician practices** in the nation as Federal financial assistance includes, but is not limited to: state Medicaid payments, "meaningful use" payments, National Health Service Corp funding, NIH research funding and CMS gain-sharing payments. Physician practices that exclusively receive Medicare Part B payments are not included, but practices should conduct a thorough review of their funding sources and consult an attorney before deciding they are exempt.

Under Title VI and Section 1557, practices must ensure that they take reasonable steps to provide meaningful access to individuals with limited English proficiency.

There is no one-size-fits all solution for the type of interpretation (verbal) or translation (written) services that must be provided by the practice and HHS acknowledges that the services provided by a large facility may not be appropriate for a small practice. For verbal interpretation, practices can consider options including hiring bilingual staff, using in-person interpreters or contracting with phone or video interpretation services. Written translation can range from translation of an entire document to translation of a short description of the document to an oral translation by an interpreter. Practices should conduct a review to determine if specific "vital" documents or portions of documents should be translated into the language of any frequently-encountered LEP groups.

Language access services must be provided **free** of charge, be **accurate** and **timely**, and **protect the privacy and independence** of the patient; a patient cannot be required to provide his or her own interpreter.

Interpreters and translators must also be qualified. Bilingual staff, interpreters and translators must all adhere to ethical principles, including confidentiality, demonstrate proficiency in the appropriate languages and be effective, accurate and impartial. **Adult family** can **only** be used in **emergencies** involving an imminent threat to health or safety and when no other interpreter is available OR if the patients specifically requests the family member and it is appropriate under the circumstances. In many circumstances family members are NOT competent to provide quality, accurate interpretation. **Minor children** can only be relied on if there is an imminent threat to safety or health. Remote interpretation must be capable of providing high quality audio.

In examining compliance on a case-by-case basis, the **Office of Civil Rights will examine a number of factors** to determine if reasonable steps are being taken to ensure meaningful access to LEP patients. The factors may include: the frequency with which LEP individuals come in contact with the program; the nature of the service; and the resources available to the practice and costs.

Enforcement by the Office of Civil Rights is carried out through compliance reviews, complaint investigations and providing technical assistance and guidance.

To help understand how to comply with the Title IV Guidance, HHS published a Summary, Fact Sheet and FAQs <u>here</u>. For more information about Section 1557, see the OCR website <u>here</u>.

Vermont Patients' Bill of Rights

In a hospital inpatient setting, "a patient who does not speak or understand English has a right to an interpreter if the language barrier presents a continuing problem to patient understanding of care and treatment." Failure to comply with any provision of the Patients' Bill of Rights may constitute a basis for disciplinary action against a physician by the Board of Medicine. <u>18 VSA § 1852 (a)(15)</u>.

Vermont Public Accommodations

Vermont law states that "An owner or operator of a place of public accommodation or an agent or employee of such owner or operator shall not, because of the race, creed, color, national origin...of any person, refuse, withhold from or deny to that person any of the accommodations, advantages, facilities and privileges of the place of public accommodation." Public accommodations include any facility in which services are offered to the general public. Failure to comply may result in an action for civil penalties either through the Vermont Human Rights Commission or a private court action. <u>9 VSA § 4502</u>.

What are the legal requirements for a physician practice to provide language interpretation services for patients who are deaf of hard of hearing? The following is a summary of applicable federal and state laws.

Americans with Disabilities Act (42 USC §§ 12131-12134)/Affordable Care Act

The ADA prohibits public accommodations from discriminating against people with disabilities. This entails furnishing auxiliary aids and services when necessary to ensure effective communication with individuals with hearing impairments, including in certain situations, providing an interpreter who is able to interpret sign language effectively, accurately, and impartially.

The ADA provides an exception for services that would impose an undue burden or would fundamentally alter your offered services. The fact that an interpreter's charge exceeds the fee for the visit is not alone considered an undue burden.

Private individuals may bring lawsuits in which they can obtain court orders to stop discrimination. Individuals may also file complaints with the attorney general, who is authorized to bring lawsuits in cases of general public importance or where a pattern or practice of discrimination is alleged. In these cases, the attorney general may seek monetary damages and civil penalties.

For a helpful summary of physician practice obligations under the ADA, see the National Association for the Deaf <u>Questions and Answers</u> for health care providers.

<u>Section 1557</u> of the Affordable Care Act, and accompanying <u>regulations</u>, reiterate the requirement that physician practices ensure that communications with individuals with disabilities are as effective as communications with others. In addition, physician practices covered by the law must ensure that any online services available to patients are accessible to individuals with disabilities. For more information, see the section on Non-Discrimination/Section 1557, above.

Vermont Patients' Bill of Rights

In a hospital inpatient setting, "a patient who is hearing impaired has a right to an interpreter if the impairment presents a continuing problem to patient understanding of care and treatment." Failure to comply with any provision of the Patients' Bill of Rights may constitute a basis for disciplinary action against a physician by the Board of Medicine. <u>18 VSA § 1852 (a)(15)</u>.

Vermont Public Accommodations

The law says that, "A public accommodation shall provide an individual with a disability the opportunity to participate in its services, facilities, privileges, advantages, benefits and accommodations [and] shall make reasonable modifications in policies, practices, or procedures when those modifications are necessary to offer goods, services, facilities, privileges, advantages, or accommodations to individuals with disabilities...." <u>9 VSA § 4502 (c)(1), (c)(5)</u> Failure to comply may result in an action for civil penalties either through the Vermont Human Rights Commission or a private court action.

Do the interpretation requirements affect the requirement to provide informed consent to patients?

The Vermont Patients' Bill of Rights provides that "the patient has the right to receive from the patients' physician information necessary to give informed consent prior to the start of any procedure or treatment." <u>18 VSA §1852 (a)(4)</u>.

Additionally, failing to obtain informed consent may be a factor in medical malpractice litigation, although there are some exceptions. For the purposes of medical malpractice actions, "lack of informed consent" is defined as a failure to disclose to the patient reasonably foreseeable risks, benefits, and alternatives to the proposed treatment, in a manner permitting the patient to make a knowledgeable evaluation. In addition, patients are entitled to reasonable answers to specific questions about foreseeable risks and benefits. <u>12 V.S.A. §1909</u>.

Using interpreters, translation services or other communication aids and services may be necessary to ensure that patients with limited English proficiency (LEP), deaf, or hard-of-hearing patients receive appropriate information about the proposed treatment to enable them to give informed consent to treatment.

Is a written authorization required to disclose health information to interpreters?

An interpreter/interpreter service or a bilingual employee is covered under the health care operations exception for purposes of HIPAA, and the patient's written authorization to disclose protected health information is not required. Providers who utilize a private company for interpretation or translation on an ongoing contractual basis should put in place a HIPAA Privacy Rule business associate agreement.

In other situations, with disclosures to family members, friends, or other persons identified by an individual as involved in his or her care, when the individual is present, the health care professional or facility may obtain the individual's agreement or reasonably infer, based on the exercise of professional judgment, that the individual does not object to the disclosure of protected health information to the interpreter.

Authorization is also not required when using a TRS phone service for an individual who has a hearing impairment.

For more information, see the HHS FAQs on disclosing protected health information to an <u>interpreter</u> or when using a <u>TRS service</u>.

Is there a need for language interpretation services in the Vermont population?

According to the 2020 American Community Survey, conducted by the US Census Bureau,, Vermont had roughly 33,000 people over the age of 5 in Vermont listed as speaking a language other than English and close to 8,300 who spoke English "less than very well." The top 15 languages spoken "less than very well" as of 2019 were: French (1,491 speakers); Spanish (1,251); Nepali or other Indic Languages (1,121); Chinese (Mandarin/Cantonese) (1,076); "Other Slavic Languages" (516); Arabic (434); Swahili or related language (303); Amharic, Somali or other Afro-Asiatic (316); "Other Languages of Asia" (312); Russian (280); Vietnamese (244); Punjabi (156); Japanese (136), German (132) and Korean (115).

Is there a need for interpretation services for patients who are deaf or hard of hearing in Vermont?

According to the 2020 <u>American Community Survey estimates</u>, conducted by the US Census Bureau, of the approximately 617,000 people living in Vermont, 27,000 identify as having a hearing difficulty.

Where can I find more information about working with interpreters?

There are a number of resources available for practices seeking more information about working with interpreters, including:

- AMA Office Guide to Communicating With Limited English Proficient Patients [PDF]
- Agency of Human Services Division of Vocational Rehabilitation <u>resources</u> for hiring and working with sign language interpreters.
- AAFP, Family Practice Management article, <u>Getting the Most from Language</u> <u>Interpreters</u> and American Family Physician article, <u>Appropriate Use of Medical</u> <u>Interpreters</u>

Where can I find interpreter services?

Below is a non-exclusive list of service providers and contact information. Please note that the Vermont Medical Society does not endorse any of these services and this information is subject to change.

Limited English Proficiency

Organization: Language Line Services Phone: 1-877-866-3885 Vermont Guide to Health Care Law Web: <u>www.languageline.com</u> Fee Structure: Per minute charges Type of Service: Over-the-phone interpretation, online document translation

Organization: Cryacom Language Solutions Phone: 1-800-481-3289 Web: <u>http://www.cyracom.com/</u> Fee Structure: Per minute charges Type of Service: Over-the-phone interpretation, online document translation (Discounts available for VMS members here: <u>https://start.cyracom.com/vermont-signup</u>)

Organization: Vermont Refugee Resettlement Program Phone: 1-802-655-1963 Web: https://www.facebook.com/USCRIVT/ Fee Structure: Varies based on services provided Type of Service: In-person interpretation, phone/audio, translation services

Sign Language Specific

Organization: Vermont Relay Service Phone: 1-866-931-9028 Web: <u>http://www.vermontrelay.com/</u> Fee Structure: no charge Vermont Relay is a free service that enables people who are Deaf, Hard of Hearing, DeafBlind or those with a Speech Disability to place and receive phone calls.

Organization: Vancro Integrated Interpreting Services Website: <u>https://vancroiis.com</u> Phone: 802-271-0103 Email: interpretingservices@vancro.com Fee Structure: Finder fee for each interpreter in addition to negotiated interpreter fee Type of Service: In-person interpretation

Can I charge patients for the cost of using an interpreter?

No, the patient cannot be held responsible for the additional cost of using an interpreter to access services.

Do insurers reimburse for interpreter services?

To our knowledge, only Medicaid reimburses for interpreter services at this time. A provider who pays for interpreter services for Vermont Medicaid members may bill procedure code T1013 for each 15 minutes of paid interpreter services provided, on site or via telephone. The rate on file for the billing code is \$15 per 15-minute increment. This may include interpreter service outside of the actual healthcare provider encounter in order to fill out forms or review information/instructions. The provider may not bill Vermont Medicaid or the member for a missed appointment per federal policy. Claims are submitted using the CMS 1500 claim form with HCPCS code T1013.

Is there any way to bill for the extra time spent with a patient in the office when a translator is involved?

The only way to account for this extra time is to submit one of the prolonged services codes (99354-99357), which requires that the face-to-face time spent with the patient extend at least 30 minutes beyond the typical time associated with the appropriate CPT services. Note that Medicare and most other payers will not pay for the services of the translator even if they are willing to pay for the extra visit time associated with using a translator.

ABOUT THE AUTHOR

Jessa Barnard is the Vermont Medical Society's Executive Director. She is a native of Bennington and holds a Bachelor's degree from Dartmouth College and a law degree from Stanford University School of Law. She served as VMS' policy specialist from 2002 to 2005. Following her graduation from law school, she founded a program in San Jose, California to address the legal barriers to health stability facing low-income individuals living with diabetes. She then spent four years with the Maine Medical Association representing physicians in Augusta and addressing their legal and regulatory concerns. From 2016 to 2017 she served as the VMS' General Counsel and Vice President for Policy before being named Executive Director in 2017. Jessa has extensive experience in health care policy and regulation and is a frequent speaker on topics including health reform, advocacy, and issues in health law.

PATIENT-PHYSICIAN RELATIONSHIPS

Topics Covered in this Chapter: <u>Initiation & Termination of The Patient-Physician Relationship</u> <u>Treating Self or Family</u> <u>Patients' Rights: Residents in Long-Term Care Setting</u> <u>Patients' Rights: Hospital Setting</u> <u>Patients' Rights: Palliative Care and Pain Management</u> <u>About the Author</u>

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INITIATION AND TERMINATION OF THE PATIENT-PHYSICIAN RELATIONSHIP

What constitutes the beginning of a patient-physician relationship?

Vermont law does not specify what constitutes the beginning of a patient-physician relationship. The CPT Manual defines a new patient as a patient who has not received any professional services from the physician/non-physician practitioner or another physician of the same specialty who belongs to the same group practice within the past three years. Professional services are defined as face-to-face professional services or evaluation and management services. See <u>CMS</u> <u>Evaluation and Management Services Guide</u>. The AMA Code of Ethics states that a "patient-physician relationship exists when a physician serves a patient's medical needs." <u>Opinion 1.1.1</u>.

As a general precaution, a physician should consider that the relationship has begun at any point when the physician or a member of the physician's practice has offered to provide a medical service, unless it has been explicitly stated in writing to the patient that the physician is providing care only on an interim or emergency basis and that the patient should continue looking for another physician. If, after offering to provide services to a patient, the physician decides that he or she does not want to or is unable to serve that patient, the physician should follow the process for discharging a patient as described below.

May physicians refuse to see a specific patient even if the practice is accepting other new patients?

Yes, according to AMA <u>Ethics Opinion 1.1.2</u>, regarding prospective patients, physicians have the prerogative to choose whether to enter into a patient-physician relationship with any individual. However, a physician must respond in cases of emergency and cannot discriminate based on race, gender, sexual orientation or gender identity, or other personal or social characteristics that are not clinically relevant to the individual's care. See <u>Chapter on Non-Discrimination</u>, above. The physician should also be aware of any contractual relationship - for example, a participation agreement with an insurer - that requires him or her to treat certain patients.

As a general guideline, when considering his or her ability to accept additional patients, the physician should balance a prospective new patient's medical needs with the physician's skills

and capacity and the needs of the physician's other patients. According to the AMA's Code of Medical Ethics, "greater medical necessity of a service engenders a greater obligation to treat."

Potential reasons to refuse to initiate treatment may include:

- the treatment request is beyond the physician's competence;
- the treatment request is scientifically or medically invalid or cannot reasonably be expected to achieve the intended clinical benefit;
- the treatment request is incompatible with the physician's personal, religious, or moral beliefs, in keeping with ethical guidelines on exercise of conscience;
- the physician lacks the resources to provide safe, competent, respectful care for the individual, though cannot decline for reasons that would constitute discrimination;
- Meeting the medical needs of the prospective patient could seriously compromise the physician's ability to provide the care needed by his or her other patients; or
- the individual is abusive or threatens the physician, staff or other patients and it is not an emergency situation.

See <u>AMA Ethics Opinion 1.1.2</u>.

A practice should consider developing an office policy on acceptance of patients, including examples of reasons for refusing to accept a patient, the process for informing the patient that they will not be accepted into the practice and a statement of nondiscrimination.

May physicians discharge patients from their care?

Yes, physicians are allowed to end the physician-patient relationship if it is the best option. Such situations may include a patient who is consistently noncompliant, unreasonably demanding, or threatening to you or your staff. It may also be necessary to transition a patient due to the relocation or retirement of a health care professional.

A 1999 Vermont Board of Medical Practice <u>advisory</u> states that the Board recognizes that the physician-patient relationship may be terminated by either party and that a physician "has the right to terminate the relationship when he or she believes it is best to do so. However, termination. . . must be done in compliance with the physician's obligation to support continuity of care for the patient."

What are the risks of discharging a patient from care?

If not done properly, a patient can claim that a physician has abandoned his or her care. Abandonment means the termination of a professional relationship between physician and patient at an unreasonable time and without giving the patient the chance to find an equally qualified replacement. Under Vermont law abandoning a patient is considered unprofessional conduct, 26 VSA § 1354 (a)(4), and if reported to the Vermont Board of Medical Practice can trigger an investigation. The Board has the authority to issue warnings, impose fines, or condition, suspend or revoke licenses to practice medicine. A physician may also be at risk for medical malpractice claims if the termination of care occurs at a critical state of treatment and an injury results.

Are there guidelines to follow when discharging a patient from the care of a practice?

The Vermont Board of Medical Practice and the American Medical Association offer guidance on the appropriate process physicians should follow when discharging a patient from their practice.

In assessing whether a physician has abandoned a patient, the Board <u>will consider the following</u> <u>factors</u>:

- Whether the physician gave the patient at least 30-days notice in writing if ending a treatment relationship. The physician does not have to state a reason for ending the relationship. The notice should also state clearly whether termination involves only an individual physician or an entire group practices and written notice of termination should be "presented to the patient by a method to ensure that the patient received the notice." (For example, via certified, return receipt mail).
- Whether the physician provided necessary ongoing and/or emergency treatment during the transition period to a new physician at least 30 days; and
- Whether the physician promptly transferred records to a new physician, as chosen by the patient, regardless of whether the patient had any outstanding bills with the practice. (It is best practice to provide resources and/or recommendations to help a patient locate another physician of appropriate specialty.)

Note that while 30 days is the minimum transition period advised by the Board of Medical Practice, more time may be necessary based on patient circumstances, such as the complexity of the patient's ongoing medical needs. AMA <u>Ethics Opinion 1.1.5</u>, states that physicians "must notify the patient (or authorized decision maker) long enough in advance to permit the patient to secure another physician [and] must facilitate transfer of care when appropriate." See also <u>Ethics Opinion 1.1.3</u>: "the physician will not discontinue treating [a patient] when further treatment is medically indicated without giving them sufficient notice and reasonable assistance in making alternative arrangements for care."

A practice should consider developing an office policy on termination of patients. The policy should include examples of reasons for terminating a patient such as:

- The patient is displaying hostility or inappropriate behavior to staff, physicians or other patients;
- The patient is refusing to cooperate with staff in diagnosis or treatment, or refusing to follow treatment instructions; or
- The patient is making unreasonable demands on staff or physicians.

The policy should clarify the process for providing notice of termination to patients and should also clarify that the practice will continue to comply with ethical and legal requirements including:

- Providing care in an emergency;
- Continuity of care; and
- Prohibition of discrimination on the basis of race, color, national origin, sex (including sexual orientation or gender identity), age, disability or other personal or social characteristics that are not clinically relevant to the individual's care. See more information in the Chapter on Non-Discrimination.

For more practical guidance on terminating the physician-patient relationship, including a sample termination policy, see Medical Mutual Insurance Company of Maine's <u>Practice Tip on</u> <u>Termination of the Physician/Patient Relationship</u>.

What immediate and longer-term steps can a practice take when a patient is dangerous, threatening or inappropriate for the practice?

If a patient is dangerous or threatening to staff or other patients you can ask him or her to leave your office immediately, and call law enforcement if the patient refuses. If necessary, you may obtain a court order such as a "no trespass" order or a restraining order that will bar the patient from your practice. The practice can also initiate steps to terminate the patient from the practice, as discussed above. During the notice period while the patient finds another physician, you may need to make arrangements to see the patient at a safe location such as an emergency room, should he or she require treatment.

If the patient is served by a mental health agency or other social support agency, you can request that the patient not come to your office without one or more staff persons from the agency accompanying the patient.

Also see AMA Code of Ethics <u>Opinion 1.2.2</u>, Discrimination and Disruptive Behavior by Patients.

TREATING SELF OR FAMILY

AMA Ethical Opinion 1.2.1 advises physicians *generally not to treat themselves or family members* as it "poses several challenges for physicians, including concerns about professional objectivity, patient autonomy and informed consent." It may be acceptable in limited circumstances, such as emergency situations or isolated settings when there is no other qualified physician available or for short-term, minor problems. When treating self or family members, physicians have an obligation to document treatment and care and convey information to the patient's primary care physician, avoid providing sensitive or intimate care, especially to a minor, and recognize that family may be reluctant to state a preference for another physician. See <u>Opinion 1.2.1</u> for further guidance.

Under <u>Vermont Board of Medical Practice rules</u> section 13.0, it also is unacceptable medical practice and unprofessional conduct for a licensee to prescribe Schedule II, III, and IV controlled substances to him or herself or to a member of his or her immediate family. There is an exception to allow prescribing to family members in a bona fide emergency, of short-term and unforeseeable character. "Immediate family" includes the following: a spouse (or spousal equivalent), parent, grandparent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or any other person who is permanently residing in the same residence as the licensee. It is also discouraged for a licensee to prescribe or dispense non-controlled prescription substances for the licensee's own use or to a member of the licensee's immediate family. Licensees who do prescribe non-controlled substances for their own use or that of a family member are required to meet all standards of appropriate care, including proper establishment of a professional relationship with the patient and maintenance of appropriate patient records.

Additionally, it is unprofessional conduct for a physician assistant to prescribe or dispense controlled substances to a physician who is the PA's participating physician, and it is discouraged for a PA to prescribe or dispense non-controlled prescription substances to a physician who is the PA's participating physician. See Board Rules Section 29.1 & 29.2.

PATIENTS' RIGHTS: RESIDENTS IN LONG-TERM CARE SETTING

Both the federal and Vermont governments have adopted certain regulations to promote quality care in nursing facilities. Under these regulations, all nursing facilities are required by law to have written policies called the Nursing Home Residents' Bill of Rights. These rights were implemented to protect the resident from abuse and neglect and to provide the resident with an opportunity to participate in his or her care.

What are some of the individual rights specific to a long-term care setting?

Vermont's Nursing Home Residents' Bill of Rights is found at <u>33 VSA § 7301</u>. Further detail can be found in the Department of Disabilities, Aging and Independent Living <u>Licensing and</u> <u>Operating Rules for Nursing Homes</u>. Patients' rights include, but are not limited to:

- The right to be fully informed, prior to or upon admission and during the stay, of the rules of the facility, his or her rights as a resident in the facility, the services with related charges available in the facility, about Medicare and Medicaid eligibility and about eligibility for hospice services.
- The right to choose one's own personal physician, be fully informed about his or her care and treatment, to participate in planning or changing the care or treatment, and to refuse to participate in experimental research.
- The right to refuse care or treatment, including the right to discharge him or herself from the facility.
- The right to be transferred or discharged only for medical reasons or for the resident's welfare or that of other residents or for nonpayment.
- The right to return to the first available bed after hospitalization if the facility is able to meet his or her needs, and to retain his or her bed in the facility while absent due to hospitalization not exceeding ten successive days.
- The right to professional assessment and management of pain.
- The right to be free from mental and physical abuse and free from chemical and physical restraints except as authorized in writing by a physician.
- The right to confidentiality of personal and clinical information, and to approve or refuse their release to any individual outside the facility, except, in case of his or her transfer to another health care institution, or as required by law or third-party payment contract.
- The right to send and receive mail unopened, to have access to a private use of a telephone, to receive visitors, to voice grievances, to vote, to participate in council meetings, and to manage his or her personal financial affairs.
- The right to review current and past state and federal survey and inspection reports of the facility.

Examples of violations include, but are not limited to:

• Failure to provide the resident with a copy of his or her rights and responsibilities or any changes made to such rights.

- Failure to disclose all cost and charges to the resident.
- Not permitting the resident to manage his or her finances. Restraining a resident, except in an emergency, without an order from a physician.
- Discussing a resident's medical condition with someone who is not involved with the resident's care.
- Not providing the resident an opportunity to review the latest inspection report.

These State-established rights generally follow the rights established in the Federal 1987 Nursing Home Reform Act (42 USC 1396r(c) and 42 USC §1395i-5(c)) and federal regulations for skilled nursing facilities, 42 CFR Part 483. Federal law includes: the right to freedom from abuse, mistreatment, and neglect; the right to freedom from physical restraints; the right to privacy and confidentiality; the right to reasonable accommodation of medical, physical, psychological, and social needs; the right to participate in resident and family groups; the right to be treated with dignity; the right to exercise self-determination; the right to communicate freely; the right to participate in the review of one's care plan, and to be fully informed in advance about any changes in care, treatment, or change of status in the facility; and the right to voice grievances without discrimination or reprisal.

How are these rights implemented?

The governing body of the facility establishes written policies regarding these rights and responsibilities of residents and, through the administrator, is responsible for the development of and adherence to procedures implementing such policies. All staff of the facility ensures compliance with these rights. <u>33 VSA § 7301 (1)</u>.

How are these rights communicated to the residents?

The facility is required to post a summary of the obligations of the facility to residents in clear language, in easily readable print and posted conspicuously in a public place on each floor of the facility. The notice shall summarize the facility's grievance procedure and directions for contacting the ombudsman program. A readable copy of the notice shall be presented to each resident on admission together with an oral explanation of the rights, grievance procedure, and directions for contacting the ombudsman program. <u>33 VSA § 7303</u>. (Under the federal <u>Older Americans Act</u>, every state is required to have an Ombudsman Program that addresses complaints and advocates for improvements in the long term care system.)

What if a right is violated?

Every nursing home must establish a grievance mechanism that allows for residents to file a grievance. Complaints that cannot be resolved by the facility grievance procedure within 7 days must be referred to the Long-Term Care Ombudsman program. <u>33 VSA § 7302</u>.

A resident can also file complaints with a variety of state and federal agencies, including the <u>Vermont Department of Disabilities, Aging and Independent Living</u>, which regulates and surveys nursing homes: 1-800-564-1612 or 280 State Drive HC 2 South Waterbury, Vermont 05671-2060. Residents can also contact the <u>Vermont Long Term Care Ombudsman's Project</u> at 1-800-889-2047.

To establish compliance with the 1987 Nursing Home Reform Act, the law established a statebased certification and survey process. If found in violation of the law, nursing homes, their Vermont Guide to Health Care Law Page 175 owners, and administrators can be fined, have their licenses suspended or revoked, and lose their right to payment by Medicaid or Medicare.

If the resident in not capable of understanding these rights, who may exercise these rights on his or her behalf?

Under <u>33 VSA §7306</u>, the rights and obligations under the Nursing Home Residents' Bill of Rights devolve to a resident's reciprocal beneficiary, guardian, next of kin, sponsoring agency, or representative payee (except when the facility itself is a representative payee) if the resident:

- has been adjudicated incompetent;
- has been found by his or her physician to be medically incapable of understanding or exercising the right; or
- exhibits a communication barrier.

The facility however will make every reasonable effort to communicate the rights and obligations directly to the resident.

PATIENTS' RIGHTS: HOSPITAL SETTING

Vermont has adopted a Bill of Rights for Hospital Patients that establishes certain rights for an individual who is an inpatient at a Vermont hospital. See <u>18 VSA §1852</u>.

What are some of these rights?

These include, but are not limited to, the right to:

- Considerate and respectful care.
- Obtain current and understandable information about his or her diagnosis, treatment and prognosis.
- Be informed of the name and position of the doctor in charge of the care.
- Receive all the information necessary to give informed consent for any proposed procedure or treatment, including risks and alternative options.
- Refuse treatment and be told what effect this may have on the patient's health.
- Privacy while in the hospital and confidentiality of all information and records regarding the care.
- Receive all reasonable medical services provided by the hospital, at the request of the physician.
- Know the identity and professional status of individuals providing services.
- Whenever possible, parents/guardians of children and family members of terminally ill patients have the right to remain with the patient 24 hours per day.
- Receive an itemized bill and explanation of all charges.
- Know what hospital rules and regulations apply to his or her conduct as a patient.
- Professional assessment and management of pain.
- Written information about availability of and eligibility for hospice services.
- To an interpreter if the patient's predominant language is not English or is hard of hearing.

Hospitals are also required to make public the maximum patient census and the number of registered nurses, licensed practical nurses, and licensed nursing assistants providing direct

patient care in each unit during each shift. The information must be posted in a prominent place that is readily accessible to patients and visitors in that unit. <u>18 VSA 1854</u>.

How are these rights communicated to patients?

A summary of the hospital's obligation written in clear language and readable print must be distributed to each patient upon admission and posted conspicuously at each nurse's station throughout the hospital. <u>18 VSA §1852(c)</u>. The notice must inform patients of the hospital grievance procedure and that patients may also contact the licensing agency or the Board of Medical Practice with a complaint.

What if a right is violated?

Failure to comply with any of these rights may constitute a basis for disciplinary action against a physician. A complaint may be filed with the Board of Medical Practice. <u>18 VSA §1852(b)</u>.

PATIENTS' RIGHTS: PALLIATIVE CARE AND PAIN MANAGEMENT

<u>18 VSA §1871</u> establishes a patient's bill of rights for palliative care and pain management. Under the statute:

- A patient has the right to be informed of all evidence-based options for care and treatment, including palliative care, in order to make a fully informed patient choice.
- A patient with a terminal illness has the right to be informed by a clinician of all available options related to terminal care; to be able to request any, all, or none of these options; and to expect and receive supportive care for the specific option or options available.
- A patient with pain has the right to request or reject the use of any or all treatments in order to relieve his or her pain.
- A patient with a chronic condition has the right to competent and compassionate medical assistance in managing his or her physical and emotional symptoms.
- A pediatric patient with a serious or life-limiting illness or condition has the right to receive palliative care while seeking and undergoing potentially curative treatment

ABOUT THE AUTHOR

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PHARMACEUTICAL ISSUES

Topics Covered in this Section:

- Gift Ban and Disclosure Drug Diversion General Prescription Requirements Prescribing Controlled Substances Prescribing for Self and Family Pain Prescribing Generic Substitution Substance Use Disorder Treatment About the Authors
- By: Wajiha Kazmi Associate Attorney at New York State Department of Health John Wallace Healthcare Group at Primmer, Piper, Eggleston & Cramer

GIFT BAN AND DISCLOSURE

What is the difference between the federal law and Vermont's law regarding gift bans and disclosure requirements for manufacturers of prescribed products?

The primary difference between Vermont law and federal law is that the Vermont gift ban law prohibits manufacturers of prescribed products from providing gifts and other remuneration to a broad class of health care providers. The law also mandates that manufacturers report allowable expenditures to the Vermont Attorney General. The narrower federal law merely requires that manufacturers report to the Centers for Medicare and Medicaid Services gifts provided to physicians and certain other health care providers, and teaching hospitals.

The Vermont Gift Ban law was enacted to regulate marketing activities by limiting gifts and require reporting for allowable expenditures to reduce health care costs and protect the public. An act relating to the marketing of prescribed products, Act 59, § 2, (2009) (codified at 18 V.S.A. §4631a-4632) (Gift Ban). The law prohibits manufacturers of prescribed products – pharmaceuticals, biologicals, and medical devices – from giving anything of value such as food, conference prizes, entertainment, lodging, and monetary compensation such as payments related to marketing activities to health care providers. Health care providers is defined broadly to include hospitals and nursing homes, and professionals who prescribe or recommend prescribed products such as physicians, pharmacists, and over twenty other types of licensed health care professionals. The law also identifies manufacturers' allowable expenditures that included fair market value compensation for "significant educational, medical, scientific, or policy making conferences or seminars, or research, promotional and educational speaking, and the provision of educational materials. Manufacturer sponsorships of conferences and seminars must be for bona fide educational purposes and content must be objective, free from industry control and not promotional.

The Vermont Attorney General's Office publishes an annual Guide on the law and manufacturers' reporting requirements : *Guide to Vermont's Prescribed Products Gift Ban and Disclosure Law for Disclosures of 2020 Data* (accessed Nov. 22, 2021), <u>https://ago.vermont.gov/wp-content/uploads/2021/03/RY-2020-Vermont-Prescribed-Products-Gift-Ban-Guide-.pdf</u>

The federal law, the U.S. Provider Payments Sunshine Act ("Sunshine Act"), was enacted to provide transparency for payments made by pharmaceutical and medical device companies specifically to physicians and teaching hospitals. 42 U.S.C. § 132-a-7h. The scope of the law has since been expanded to include a broad list of payments and other remuneration such as debt forgiveness and long-term supply and medical device loans. The law has also been expanded to include additional health care professionals including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetist, and certified nurse midwives. 42 C.F.R. §§ 403.902-904. Like the Vermont law, the Sunshine Act requires manufacturers to report the provision of payments and other things of value. Because of the overlapping federal and state reporting requirements, the federal requirements preempt some of the state reporting requirements. The federal preemption does not affect the prohibition on gifts or the requirement to report the provision of samples.

What type of information must manufacturers disclose to the Vermont Office of the Attorney General?

Manufacturers must report the "value, nature, and purpose, and recipient information" of most permitted gifts or allowable expenditures to health care providers to the Vermont Office of the Attorney General. The reporting information does not include any patient specific information regarding the receipt of free samples or other items

How does the Gift Ban affect free samples?

The Gift Ban law requires that manufacturers report to the Attorney General the provision of free samples. The law defines samples broadly to include a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device. The term includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. The term does not include prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

Does the public have access to reported information?

The data reported by manufacturers is available to the public on the Attorney General's website at <u>https://ago.vermont.gov/vermont-prescribed-products-public-data/</u> The information reported by manufacturers to CMS is available at <u>https://www.cms.gov/OpenPayments/Data</u>

How are is the Gift Ban and Sunshine Act enforced?

The Gift Ban statute authorizes the Attorney General to bring a civil action, including civil monetary penalties, against a manufacturer for failing to disclose gifts and expenditures.

Similarly, the Sunshine Act authorizes CMS to pursue enforcement against manufacturers for failure to report covered payments and transfer of value.

DRUG DIVERSION

What is the definition of "drug diversion"?

Drug diversion is generally defined as diverting controlled substances from their lawful purpose. Vermont criminal law defines drug diversion as where any person unlawfully manufactures, possesses, has under his or her control, sells, prescribes, administers, dispenses, or compounds any regulated drug, except as authorized. 18 V.S.A. § 4205. Federal regulations state that a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 C.F.R § 1306.04(a)

How does Vermont law apply to individuals who seek to obtain regulated drugs through fraud or deceit?

It is a felony to obtain or attempt to obtain a regulated drug, fraud, deceit, misrepresentation, forgery or alteration of a prescription, concealment of a material fact, or by the use of a false name or the giving of a false address. 18 VSA §4223(a). Information communicated to a physician in an effort unlawfully to obtain drugs is not privileged so that it could be used as evidence in a criminal prosecution or other legal proceeding. 18 VSA §4223(b). This includes instances where in the course of treatment, a physician prescribes an individual with a regulated drug, and the individual fails to disclose that they have received the regulated drug by another physician. 18 VSA §4223(h).

Any disclosure to law enforcement regarding unlawful attempts to obtain drugs would need to comply with the HIPAA privacy rule. If a health care provider, in good faith, believes that the use or disclosure of information is necessary to prevent a serious and imminent threat to the health or safety of a person or the public and the disclosure is to a person(s) reasonably able to prevent or lessen the threat, the disclosure may be permitted under the law. 45 CFR §164.512(j)(1)(i). Depending on the circumstances, a practitioner should consult with legal counsel before disclosing patient information to law enforcement.

GENERAL PRESCRIPTION REQUIREMENTS

What are the requirements for prescribing a medication?

It is unprofessional conduct to prescribe or dispense a medication without creating and maintaining and acceptable physician-patient relationship, which includes (1) making a reasonable effort to verify that the individual asking for medication is actually the patient; (2) establishing a documented diagnosis through the use of acceptable medical practices; and (3) maintaining a current medical record. 26 VSA \$1354(33)(A)(i)–(iii). It is not permissible to provide, dispense, or prescribe a medication based solely on electronic communication such as a questionnaire without establishing an appropriate physician-patient relationship. However, it is permissible to rely on electronically transmitted patient information to (1) write initial admission orders for newly hospitalized patients; (2) prescribe for a patient of another physician for whom the prescriber has taken the call; (3) prescribe for a patient examined by a licensed advanced practice registered nurse, physician assistant, or other advanced practitioner authorized by law

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and supported by the physician; (4) continue medication on a short-term basis for a new patient, prior to the patient's first appointment; or (5) respond to an emergency situations where life or health of a patient is in imminent danger. 26 VSA \$1354(33)(C)(i)-(v).

What information do practitioners need to include on a on a prescription drug order?

The Administrative Rules of the Board of Pharmacy require that a prescription drug order include:

- 1. Full name and street address of the patient.
- 2. Name, address, facility or practice name where applicable, and telephone number, and if the drug is a controlled substance, then address and the United States Drug Enforcement Administration (DEA) registration number of the prescribing practitioner.
- 3. Date of issuance.
- 4. Name, strength, dosage form, quantity or stop date, and route of administration of drug prescribed.
- 5. Directions for use by the patient.
- 6. Number of authorized refills and specified time limit. If nothing is stated in terms of refills or time limit, then the prescription is non-refillable.

7. If the script is hand-written, then the prescribing practitioner's handwritten signature.

Vt. Admin. Code 20-4-1400:10.1.

How do practitioners ensure that drug orders are not tampered with?

Handwritten prescriptions must be written on a tamper resistant pad; computer generated printed prescriptions must be printed on a tamper resistant paper or other methods defined by the Centers for Medicaid and Medicare (CMS). These methods include micro-printing and/or printing a "void" pantograph alongside a reverse "Rx," which would cause a word such as "Void," "Illegal," or "Copy" to appear when the prescription is photocopied. Vt. Admin. Code 20-4-1400:10.5.

Is there a rule that applies to the administration of a drug that a patient brings into a health care facility?

If a patient brings in a medication into an institutional facility, the drug must not be administered unless the medication can be identified and the quality of the drug is assured. Ultimately, if it is deemed that the medication cannot be administered, then the pharmacist-manager will have them turned in to the pharmacy. From there, the medication must be packaged and sealed to be returned to an adult member of the patient's immediate family, or stored and returned to the patient upon his or her discharge. Vt. Admin. Code 20-4-1400:11.31.

While most medications are written by physicians and dispensed by pharmacists for patients to take themselves, there may be medications that will most commonly be administered by physicians, physician assistants, or nurses. Drugs that typically are not for self-administration will be injected, intravenous or intramuscular, or sometimes, oral. Ronilee Shye, *Health Care Practitioner-Administered Drugs: What You Need to Know* (Mar. 6, 2015).

What is "white bagging" and "brown bagging"?

White bagging is the distribution of patient-specific medication from a pharmacy to the physician's office, hospital, or clinic for administration. In this practice, the patient does not play a role in transporting his or her medication to the site of administration. On the other hand, Vermont Guide to Health Care Law Page 181

brown bagging is when a medication from the pharmacy is dispensed directly to the patient, who then takes the medication to the physician's office for administration.

However, medications are often patient-specific and require special handling. This can pose safety, operational, and expected financial burdens. For example, if patients are required to handle medications on their own to take to their physicians' offices for administration, they may not know how to appropriately handle and store the medications, which may cause a negative impact on drug efficacy. Under white bagging practices, physicians may face the burden of storing and safeguarding medications until administration. Carmen A. Catizone, *White and Brown Bagging Emerging Practices, Emerging Regulation,* NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (2018), https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf

PRESCRIBING CONTROLLED SUBSTANCES

What practitioners are required to register with the Department of Health for the Vermont Prescription Monitoring System (VPMS)?

The VPMS statute and rule require that all Vermont-licensed prescribers of controlled substances register with VPMS. 18 V.S.A. § 4289(b)(1), and VPMS Rule, § 6.1. Employees of prescribers or health care providers may register with VPMS as a delegate so that they may query VPMS on behalf of a prescriber.

https://www.healthvermont.gov/sites/default/files/documents/pdf/REG_vpms-20170701.pdf

When is a prescriber or their delegate required to query VPMS?

The VPMS Rule includes nine instances when a query is required, and four exceptions to the query requirements. In general, queries are required (1) the first time a provider prescribes an opioid to treat pain for a prescription that exceeds 10 pills; (2) before starting a patient on long-term pain therapy of 90 days or more; (3) before writing a replacement prescription; (4) at least annual for ongoing treatment with an opioid; (5) the first time prescribing a benzodiazepine; (6) prescribing an opioid in an Emergency Department or Urgent Care Center; (7) before prescribing buprenorphine or methadone.

What is a prescriber required to do before prescribing opioids for acute pain?

Before prescribing an opioid for pain for the first time during the course a patient's treatment, a prescriber must follow the seven universal precautions that include:

- 1. Consideration of non-opioid and non-pharmacological treatment for pain management such as nonsteroidal anti-inflammatory drugs, acetaminophen, acupuncture, osteopathic manipulative treatment, or physical therapy;
- 2. Querying VPMS;
- 3. Providing patient education sheet from the Department of Health or equivalent information <u>https://www.healthvermont.gov/response/alcohol-drugs/information-health-professionals-prescribers;</u>
- 4. Engaging in an in-person discussion of risks that includes potential side effects, risk of dependence and overdose, alternative treatments, appropriate tapering and safe storage and disposal, and a co-prescription of naloxone where appropriate;
- 5. Obtaining signed informed consent that includes the specific risks, and potential side

effects;

- 6. Co-prescribing naloxone if the patient's prescription will result in the concurrent use of an opioid and benzodiazepine, or the prescription is equal to or more than a daily dose of 90 morphine milligram equivalents; and
- 7. If the prescriber is not the patient's primary care provider, the prescriber will make a reasonable effort to consult and transfer care to the primary care provider. If the patient is a child, a prescriber in an emergency department or urgent care setting will make a reasonable effort to consult with the primary care provider before prescribing the opioid. For adults, the prescriber will make a reasonable effort to ensure a safe transition of care, which may include a written summary of expectations for ongoing pain treatment.

Vt. Admin. Code 12-5-53:4.1; *also see* VT Rules Governing the Prescribing of Opioids for Pain, Section 4.1, *effective March 2019*.

Can a pharmacist make changes to a Schedule II prescription?

Whether a pharmacist can make changes to a Schedule II prescription varies on a case-by-case situation. One must look at the facts present to determine if changes can be made. The DEA recommends that when information is either missing from or needs to be changed on a Schedule II prescription, pharmacists use their professional judgment and knowledge of relevant state and federal laws and policies to determine if it is appropriate to make changes to the prescription.

Can a pharmacist fill a Schedule II prescription if it does not have a current or future fill date? Prescriptions that fall under Schedule II that do not contain future fill date cannot be filled more than 30 days after the date the prescription was written; additionally, a prescription that has a future fill date cannot be filled more than 90 days after the date the prescription was issues. 18 VSA §4215(b)(3).

Who can pick up Schedule II, III, and IV prescriptions from the pharmacy?

Schedule II, III, and IV prescriptions can only be picked up by the patient for whom the prescription was written for. Before dispensing a prescription for such scheduled medications to a patient not personally known to the pharmacist, then the pharmacist must require the individual receiving the drug to provide a signature and show a valid and current government-issued photo ID as evidence. 18 VSA §4215b.

While travelling, can patients take medications with them without the original container?

While there is a certain limitation in relation to regulated drugs, an individual to whom a regulated drug was prescribed, dispensed, or sold by a physician, dentist, or pharmacist licensed in Vermont or in another state or country may maintain up to a 14-day supply of the regulated drug outside the original container for his or her own personal use if the following conditions are met:

- 1. The drug was prescribed for the individual;
- 2. The individual is in the possession of the original or a copy of the prescription label;
- 3. At all times, the individual intends (or has intended) to use the drug only for legitimate medical use in compliance with instructions from the prescriber and dispenser;
- 4. The individual maintains the limited supply of the drug in a container that reasonably creates a more convenient or portable format to allow the individual's legitimate medical use.

18 VSA §4216(b)(4). Vermont Guide to Health Care Law

Can electronic prescriptions for schedule II-V controlled substances be transferred between registered retail pharmacies for initial filling on a one-time basis?

At the end of November 2021, the DEA proposed a rule regarding the transfer of electronic prescriptions for schedules II–V controlled substances between pharmacies for initial filling.

Presently, DEA regulations do not specify the transfer of such prescriptions between pharmacies for initial filling. Currently, if a paper prescription is presented at a pharmacy that cannot be filled, the paper prescriptions could be returned to the patient, and the patient may then take it to another pharmacy to have it filled. However, electronic prescriptions are sent from the provider directly to the pharmacy in order for it to be filled. 86 Fed. Reg. 64882 (Nov. 19, 2021).

This means that the pharmacy cannot hand over a prescription to the patient for him or her to take to another pharmacy to have it filled. *Id.* Currently, a pharmacy that receives a prescription that it is unable to fill must notify the patient that the prescription cannot be filled; once the patient is notified, he or she could call the prescribing practitioner to request that a new electronic prescription be sent to a different pharmacy. *Id.*

Under the proposed changes, the transfer must be communicated directly between two licensed pharmacists. *Id.* at 64883. Furthermore, the following must be met:

- 1. The pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. He or she must also update the prescription record with the name, address, and DEA registration number of the pharmacy to which the prescription was transferred; the name of the transferring pharmacist, and the date of the transfer. *Id*.
- 2. Similarly, the pharmacist receiving the transfer has obligations regarding documentation. He or she must record the pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. *Id*.
- 3. Lastly, the transfer record must be kept by both the transferring and receiving pharmacy for a period of two years. *Id.*

As mentioned earlier, this is a proposed rule and subject to change. Comments must be submitted, and written comments must be postmarked, on or before January 18, 2022.

PRESCRIBING FOR SELF AND FAMILY

What constitutes as violations of Vermont statutes in relation to prescribing for self and family?

Under the Vermont Medical Practice Act, it is unprofessional conduct to prescribe, sell, administer, distribute, order, or dispense any drug legally classified as a controlled substance for the licensee's own use or to an immediate family member. 26 VSA §1354(37). The Board of Medical Practice Rules, define "immediate family" as "a spouse (or spousal equivalent), parent, grand-parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or any other person who is permanently residing in the same residence as the licensee. The listed familial relationships do not require residing in the same residence." VT Rules of Board of Medical Practice, Section 2.16, *effective March 2020*. The Board Rules state that:

It is unacceptable medical practice and unprofessional conduct for a licensee to prescribe or dispense controlled substances listed in US Drug Enforcement Agency ("D.E.A.") Schedules II, III, or IV for the licensee's own use. It also is unacceptable medical practice and unprofessional conduct for a licensee to prescribe or dispense Schedule II, III, or IV controlled substances to a member of the licensee's immediate family, as defined in subsection 2.16, except in a bona fide emergency, of short-term and unforeseeable character. Prescribing for self or immediate family members, as defined in these Rules, constitutes a violation of 26 VSA § 1354.

VT Rules of Board of Medical Practice, Section 13.2, effective March 2020.

Can physicians prescribe a non-controlled substance for themselves or a family member?

The Board rules discourage a licensee from prescribing or dispensing non-controlled drugs for himself/herself or a family member. The Rules go on to state that, licensees who do prescribe non-controlled substances for their own use or that of a family member are required to meet all standards of appropriate care, including proper establishment of a professional relationship with the patient and maintenance of appropriate patient records. VT Rules of Board of Medical Practice, Section 13.2.2, *effective March 2020*.

<u>AMA Code of Medical Ethics Section E- 8.19</u> states that "physicians generally should not treat themselves of members of immediate families" because their professional objectivity may be compromised in those situations." However, there are exceptions to this – "short term, minor problems" or "in emergency or isolated settings."

Furthermore, the American College of Physicians (ACP) <u>Ethics Manual</u> recommends for physicians to self-prescribe, as well as deter from prescribing for close friends, or family members. One of the reasons given by the ACP not to self-prescribe, unless in emergent situations, is that "a physician cannot adequately interview, examine, or counsel herself or himself, without which ordering diagnostic tests, medications, or other treatments is ill-advised." Additionally, ACP cautions physicians from prescribing or assuming care of those who are closely associated employees.

PAIN PRESCRIBING

What practitioners are required to register with the Department of Health for the Vermont Prescription Monitoring System (VPMS)?

The VPMS statute and rule require that all Vermont-licensed prescribers of controlled substances register with VPMS. 18 V.S.A. § 4289(b)(1), and VPMS Rule, § 6.1. Employees of prescribers or health care providers may register with VPMS as a delegate so that they may query VPMS on behalf of a prescriber.

https://www.healthvermont.gov/sites/default/files/documents/pdf/REG_vpms-20170701.pdf

When is a prescriber or their delegate required to query VPMS?

The VPMS Rule includes nine instances when a query is required, and four exceptions to the query requirements. In general, queries are required (1) the first time a provider prescribes an opioid to treat pain for a prescription that exceeds 10 pills; (2) before starting a patient on long-term pain therapy of 90 days or more; (3) before writing a replacement prescription; (4) at least

annual for ongoing treatment with an opioid; (5) the first time prescribing a benzodiazepine; (6) prescribing an opioid in an Emergency Department or Urgent Care Center; (7) before prescribing buprenorphine or methadone.

What must physicians do if a patient needs opioids because he or she has been in pain for a long time?

First, chronic pain is typically pain that lasts for more than 90 days. If a patient has chronic pain, that the prescriber must do the following:

- 1. Screen, evaluate, and conduct a risk assessment.
- 2. Initiate an opioid prescription for chronic pain.
- 3. Refer and consult.
- 4. Reevaluate treatment no less frequently than once every 365 days.

More information on this regulation can be found at Vt. Admin. Code 12-5-53:6.0; *also see* VT Rules Governing the Prescribing of Opioids for Pain, Section 6.0, *effective March 2019*.

GENERIC SUBSTITUTION

What is "generic"?

Depending on what is being discussed in the context of medicine, there are generic drugs and then there are generic names. One, generic drug means:

A drug listed by generic name and considered to be chemically and therapeutically equivalent to a drug listed by brand name, as both names are identified in the most recent edition of or supplement to the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). 18 VSA §4601(3).

Second, generic name means "the official name of a drug product as established by the U.S. Adopted Names Council (USAN) or its successor, if applicable." 18 VSA §4601(4).

When can a pharmacist substitute a medication for a generic?

There are some instances in which you will dispense a brand name medication. When a pharmacist receives a prescription for a drug that is either listed under the generic name or brand name, he or she will select the lowest priced drug from the list which is equivalent pursuant to the Orange Book. Otherwise, the pharmacist will dispense the brand name medication if instructed to do so by the prescriber, or by the purchaser if he or she agrees to pay any additional costs in excess of the benefits given by the individual's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost of the higher-priced drug. 18 VSA §4605(a)(1).

What does the Vermont statute require regarding information on prescription labels?

Every pharmacy in Vermont must post a sign in a visible place that is clear, unobstructed view that reads, "Vermont law requires pharmacists in some cases to select a less expensive generic equivalent drug or interchangeable biological product for the drug or biological product prescribed unless you or your physician direct otherwise. Ask your pharmacist." 18 VSA §4607(a).

What is "DAW"?

DAW stands for Dispense as Written. Typically, this is found on prescriptions for when a prescriber deems for the patient to take the exact medication (no substitutions) as written on the drug prescription order. Prescribers will indicate that the brand is necessary:

If prescriber has determined that the generic equivalent of a drug or the interchangeable biological product being prescribed has not been effective or with reasonable certainty is not expected to be effective in treating the patient's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient...

18 VSA §4606.

What is Step Therapy?

Step Therapy is when an insurance company may want its members to try less expensive drugs before they try something new and more expensive to treat an illness. It is appropriate for a patient to ask his or her doctor if the lower cost drug is safe and will be effective. If the patient's physician determines that the medication suggested is not safe or effective, then the individual may file an appeal with the insurance company and have the doctor tell the insurance company of the reasons why the medication will not be safe or effective. 8 VSA §4089i(h)(5); *also see* Step Therapy, Office of the Health Advocate, VT Legal Help (updated: Nov. 7, 2018).

SUBSTANCE USE DISORDER TREATMENT

What is Medication Assisted Treatment (MAT)?

Federal regulations define *medication-assisted treatment* as the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder. 42 C.F.R. § 8.2. SAMHSA explains that various medications are used in conjunction with counseling and behavioral therapies to provide a "whole-patient" approach to the treatment of substance use disorder.

What is Vermont's Hub & Spoke System?

The Vermont Department of Health (VDH) and the Department of Vermont Health Access (DVHA) coordinate the state opioid use disorder treatment program the Care Alliance for Opioid Addiction, which is referred to as the hub & spoke system for opioid treatment. The hubs are intensive outpatient treatment facilities that provide daily medication and therapeutic support. There are c nine hub facilities located in Burlington, South Burlington, Newport, St. Johnsbury, Berlin, West Lebanon, NH, Brattleboro, Rutland, and St. Albans.

Spokes are office based opioid disorder treatment settings, which include many primary care practices. In spoke settings, properly credentialed physicians, nurse practitioners, and physician assistants prescribe buprenorphine, naltrexone, and Vivitrol. The spokes are intended to provide treatment for individuals with less complex care needs that can be initiated in a spoke setting or continued following intensive treatment in a hub. Additional information regarding the hub &j spoke system is available from VDH <u>https://www.healthvermont.gov/response/alcohol-drugs/treating-opioid-use-disorder</u>, and DVHA <u>https://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke</u>

What are the requirements for being a MAT provider?

Practitioners who prescribe controlled substances for substance use disorder must comply with a combination of state and federal requirements. The overarching law is the federal Drug Addiction Treatment Act of 2000 (DATA), which allows qualified practitioners with an X-license to dispense or administer narcotic medications for individuals with opioid use disorder. 21 U.S.C. § 803(g). DATA provides the authority for U.S. Department of Health and Humans Services (HHS), Substance Abuse and Mental Health Administration (SAMHSA), and the Drug Enforcement Administration (DEA) to "waive" parts of the Controlled Substances Act that otherwise prohibit the prescription of a narcotic for "maintenance or detoxification treatment" in an office-based setting. DATA allows qualified practitioners. to treat and addiction or acute withdrawal. In an effort to reduce the barriers to prescribing buprenorphine, the SUPPORT Act of 2018, and subsequently promulgated regulations provided flexibility for qualified practitioners and the number of individuals that can receive treatment.

HHS practice guidelines authorize physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives to treat up to 30 patients with buprenorphine without the training and counseling requirements that are applicable to practitioners who treat more than 30 individuals. HHS, Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 Fed. Reg. 22439 (Apr. 28, 2021). Practitioners with credentialing in addiction medication or who provide MAT in a qualified practice setting may treat up to 100 patients. 21 U.S.C. § 823(g)(2)(B). Physicians who have had a waiver to treat 100 patients for at least one year can become eligible for a patient limit of 275.

In 2014, the Vermont Board of Medical Practice developed a policy that outlines the requirements for physicians to provide MAT in the office setting. VBMP, Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office, (June 4, 2014) https://www.healthvermont.gov/sites/default/files/documents/2016/12/BMP_Policies_Data%202 000%20Policy%20with%20Intro%20and%20Refs%2006062014.pdf

Do special substance use disorder treatment confidentiality rules apply to MAT prescribers? Practitioners who provide substance use disorder (SUD) treatment are not subject to SUD confidentiality rules if they work at a *general medical facility* and if their *primary function* is not providing diagnosis, treatment, or referral for SUD treatment. Conversely, practitioners who work in setting that *holds itself out* as providing diagnosis treatment, or referral for SUD treatment, or subject confidentiality rules that are much stricter than HIPAA.

The Confidentiality of Substance Use Disorder Patient Records codified at 42 C.F.R. Part 2, protects the confidentiality of SUD records by imposing restrictions on the disclosure of records without specific patient consent. Providers that are subject to the Part 2 requirements are federally assisted programs in that they receive federal funding in any way, and hold itself out as providing SUD services. SAMHSA, Disclosure of Substance Use Disorder Patient Records, Does Part 2 Apply to Me https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf.

ABOUT THE AUTHORS

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PRACTITIONER HEALTH & RECOVERY PROGRAMS

Topics Covered in this Chapter: Vermont Practitioner Health Program Alternative Program for Nurses Joint Commission Requirements About the Author

By: Jessa Barnard, Esq. Vermont Medical Society

VERMONT PRACTITIONER HEALTH PROGRAM

What is the Vermont Practitioner Health Program?

The Vermont Practitioner Health Program (VPHP) was established by the Vermont Medical Society in 1999. Its purpose is to identify, evaluate and ensure effective treatment for clinicians whose ability to practice medicine is impaired, or is at the risk of becoming impaired. Physicians (including M.D.s and D.O.s), podiatrists, radiology assistants, anesthesia assistants and physician assistants are eligible to participate. VPHP assists practitioners dealing with impairment or risk of impairment due to use of drugs, including alcohol, as well as impairment caused by any factor that interferes with cognition, judgment or behavior. This includes mental health challenges, organic causes of cognitive impairment, and cognitive deficits associated with the aging process. Referrals can come from any source, including colleagues, employers, family members, friends, patients, or as self-referrals. Between 2000 and 2020, VPHP has served 327 participants.

See the program website and brochure here.

Most states have established practitioner health programs, serving a range of health professionals. For a list of state programs, see the Federation of Physician Health Program website at <u>https://www.fsphp.org/state-programs</u>

How is the VPHP program operated?

The VPHP program was established by the Vermont Medical Society in 1999 as a peer review committee of the VMS. The Program is managed by a physician medical director and a case management committee, made up of physicians, physician assistants and podiatrists -- a number of whom have personal experience with recovery. Day to day operations are handled by Vermont Medical Society staff.

What services does VPHP offer?

While each individual's experience is unique, the typical process includes:

- 1. Completing intake paperwork.
- 2. Speaking with the VPHP Medical Director for an assessment to establish need for further evaluation or monitoring.
- 3. Referral to an independent in-state or out-of-state expert for comprehensive evaluation and treatment recommendations.
- 4. Working with the Medical Director, VPHP coordinator and a VPHP Peer Advisor to implement and monitor compliance with a treatment plan, which may include primary

care, counseling, group recovery meetings, testing for substances and practice monitoring.

VPHP also offers other services as needed such as referrals to community resources, and conducts regular outreach to educate the medical profession about the program and issues of impairment.

What is the relationship between VPHP and the Vermont Board of Medical Practice?

VPHP is independent of the Vermont Board of Medical Practice. VPHP does not disclose the identity of self-referred participants to the Board except where there has been injury or the risk of injury to a patient, a criminal act, relapse to the use of alcohol or drugs, or repeated failures by the participant to abide by their monitoring contract with VPHP. In instances where the participant is referred by the Board, the participant may be asked to consent to share more information with the Board. Documentation of participation in and compliance with our monitoring program can be essential in helping to restore and/or maintain licensure.

How is the confidentiality of the program's participants protected?

A number of laws protect the confidentiality of the program's participants. VPHP has been established as a peer review program of the VMS. (See <u>26 VSA § 1441</u>). Under Vermont, law peer review activities of the program are confidential and privileged. They are not subject to discovery or introduction into evidence in any civil action. (Information, documents, or records otherwise available from original sources may be discoverable.) <u>26 VSA § 1443</u>

VPHP also complies with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and accompanying regulations (45 CFR Part 164) and the Public Health Services Act/<u>42 CFR Part 2</u> (Confidentiality of Alcohol and Drug Abuse Patient Records).

Under 42 CFR Part 2, records relating to the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with a program relating to substance abuse treatment or rehabilitation may not be disclosed without patient consent, a court order or to medical personnel in a medical emergency. 42 CFR §§ 2.33, 2.51, 2.61. With the exception of the circumstances noted above that trigger reporting to the VBMP, VPHP will not release any information concerning participants to an employer, health plan, hospital or any other party without a signed release from the participant. Participants are typically required to sign authorizations allowing the program to discuss program status and recovery with treating providers, workplace monitors and others involved in the recovery process.

How is the VPHP program funded?

The administrative costs of the VPHP program are funded by a surcharge on licensing fees of those professionals licensed by the Vermont Board of Medical Practice, by a VMS foundation dedicated to the health of physicians and their families, by donations from malpractice carriers and by the VMS general operating fund. Participating health care professionals are responsible for their own evaluation, treatment, and monitoring expenses, although some of these expenses may be covered by the participant's health insurance plan.

Where can I find more information about the VPHP recovery program?

The program is operated by the Vermont Medical Society and can be reached at:

Confidential phone number: 802-223-0400

The program website and brochure can be found on the Vermont Medical Society webpage here.

ALTERNATIVE PROGRAM FOR NURSES

Is there a similar program for nurses?

In 2004 the Vermont State Board of Nursing established by rule a non-disciplinary Alternative Program for eligible nurses and nursing assistants who are physically or psychologically dependent on alcohol or other drugs. <u>See Vermont Board of Nursing Rules, Part 11</u>. See the information and forms <u>here</u>.

In order to participate, nurses must voluntarily request admission to the program, if requested agree to undergo a comprehensive assessment at their own expense, and agree to comply with a contract prepared by the alternative committee of the nursing board. Part 11.3. The contract sets forth the terms, conditions, costs, and restrictions which the committee deems appropriate for the individual participant. The contract is an Order of the Board with which the individual must comply. Part 11.7(a).

Contract conditions may include: substance abuse counseling and treating professional reports; participation in recovery group meetings; random drug and alcohol testing; abstinence from drug and alcohol use; professional practice only with Program approval, work restrictions and supervision; six-month prohibition on administering controlled substances; and self-assessment reports. See Board of Nursing Alternative Program <u>Purpose and Objectives</u>.

Records pertaining to a nurse's participation are confidential, except as necessary to ensure compliance with the program requirements, such as to the nurse's employer to ensure work site monitoring. See Part 11.1(e).

Nurses are not eligible to participate in the program if they: have a pending felony charge or felony conviction related to chemical dependency; have a restricted license for reasons of unprofessional conduct; have diverted controlled substances; have taken or disregarded a substantial risk of harm; present an imminent danger to the public; or have a recent history of chemical dependency with failed treatment. See Part 11.4.

Where can I find more information about the Board of Nursing program?

Information is available from the Vermont Board of Nursing Alternative Program <u>website</u> and confidential phone number: 802-828-1635.

JOINT COMMISSION REQUIREMENTS

Does The Joint Commission require hospitals to establish practitioner health programs?

The Joint Commission (formerly JCAHO) requires each hospital medical staff to implement a process to identify and manage matters of individual health for licensed independent practitioners that is separate from the medical staff disciplinary function. See Standard MS 11.01.01.

According to Standard MS 11.01.01, the purpose of the process is to facilitate rehabilitation, rather than discipline, and to aid a practitioner in retaining or regaining optimal professional functioning, consistent with protection of patients. However, if the practitioner is unable to safely perform the privileges he or she has been granted, the medical staff leadership must take appropriate corrective action.

The process should include the following elements:

- Education of staff about illness and impairment recognition issues;
- Accepting self-referral or referral by other staff;
- Providing referral of the practitioner to internal or external resources for evaluation, diagnosis and treatment of the condition or concern;
- Maintenance of the confidentiality of the practitioner, except as limited by applicable law, ethical obligation, or when the safety of a patient is threatened;
- Evaluation of the credibility of a complaint, allegation or concern;
- Monitoring of the affected practitioner and the safety of patients until the rehabilitation process is complete;
- Reporting to medical staff leadership when a licensed independent practitioner is providing unsafe treatment;
- Initiating appropriate actions when a practitioner fails to complete a required rehabilitation program.

How are hospitals in Vermont meeting this standard?

Hospitals may develop their own education and monitoring programs to address licensed practitioner health, or they may utilize statewide programs, such as the Vermont Practitioner Health Program, to meet this requirement. For example, the University of Vermont Medical Center has its own long-standing <u>Practitioner Health and Advocacy Program</u>. More information about forming a medical staff health committee that complies with MS 11.01.01 can be found from the Massachusetts Medical Society <u>Physician Health Services program</u>.

ABOUT THE AUTHOR

Jessa Barnard is the Vermont Medical Society's Executive Director. She is a native of Bennington and holds a Bachelor's degree from Dartmouth College and a law degree from Stanford University School of Law. She served as VMS' policy specialist from 2002 to 2005. Following her graduation from law school, she founded a program in San Jose, California to address the legal barriers to health stability facing low income individuals living with diabetes. She then spent four years with the Maine Medical Association, most recently as their Associate General Counsel, representing physicians in Augusta and addressing their legal and regulatory concerns. From 2016 to 2017 she served as the VMS' General Counsel and Vice President for Policy before being named Executive Director in 2017.

PROFESSIONAL LIABILITY

Topics Covered in This Chapter: <u>Medical Malpractice</u> <u>Statutes of Limitation</u> <u>Liability with Respect to Informed Consent</u> <u>Liability with Respect to Advance Directives for Health Care, DNR Orders, and COLST Orders</u> <u>Liability with Respect to the Duty to Protect the Endangered Act</u> <u>Alternative Dispute Resolution</u> <u>National Practitioner Data Bank</u> <u>Safe Apology Law</u> <u>Patient Safety Surveillance and Improvement System</u> <u>About the Author</u>

By Angela R. Clark, Esq. Dinse, P.C.

MEDICAL MALPRACTICE

The vast majority of legal claims filed against health care professionals are those filed by patients based on allegations of medical malpractice, that is, a claim that a health care professional was negligent in his or her provision of care. Patients may, however, also other types of claims based on the practice of medicine. These claims are infrequent but can include: battery (unauthorized touching of another person resulting in harm); libel or slander (for untruthful reporting of a physical or mental condition); duress or false imprisonment (for detaining a patient in a hospital or medical facility without just cause); invasion of privacy (such as unlawful use of bodily tissue, etc.); and unauthorized disclosure of information obtained during treatment (with HIPAA and its implementing regulations informing the standard of care and establishing the framework for exceptions to the duty of confidentiality).

What do I do if am being sued?

Step 1: Take a deep breath and try to relax. Not to minimize a medical malpractice suit and the stress inherent in being named in one, but life will go on and worse things happen in life.

Step 2: Immediately upon receiving notice of a lawsuit or the potential for a suit, call your medical malpractice carrier to advise it of the claim and make arrangements to send a copy of whatever papers you received to the insurance adjuster. If you are employed by a health care organization or hospital, the risk manager of that organization should be immediately notified and he or she will assist you. There are deadlines for responding to lawsuits, so, it is important to report any claim to your carrier and/or risk manager promptly.

What is the relationship between my insurance carrier and me?

Fortunately, in Vermont there is almost always an excellent working relationship between insurance carriers, defense counsel, and the physician. The cornerstone of that relationship is trust; the physician must be comfortable with and confident in his or her defense team. In that regard, most medical malpractice insurance carriers will consider a physician's request for a specific attorney, provided that attorney has expertise in medical malpractice litigation. An Vermont Guide to Health Care Law Page 194 important factor in this relationship is an early meeting between the physician and defense counsel not only to discuss the substance of the case, but also to address all questions and concerns the physician may have.

Must the carrier have my best interest in mind? What happens if our interests diverge?

The carrier has fiduciary and contractual obligations to act in the best interest of its insured. In the rare instances where a divergence of interests develops, e.g., a dispute as to coverage, it is important for the physician to consider retaining personal counsel to guarantee that his or her interests are protected.

Should a physician ever talk to the plaintiff-patient after a lawsuit has begun?

Unfortunately, the physician and patient/former patient are in an adversarial posture once a lawsuit has been filed. As a result, there should be no communication between the physician and patient, particularly with respect to any subject implicated by the lawsuit. The safest course of action before taking any significant steps after a lawsuit has been filed is for the physician to speak to his or her attorney to obtain guidance and direction.

On a related note, the physician should keep all communications to and from his or her insurance carrier and legal counsel separate from the patient's chart and clearly mark all such communications as "attorney/client communications not for release." These steps will help preserve the confidentiality of those communications based on the attorney client privilege.

What is a Certificate of Merit?

In 2012, the Vermont Legislature enacted a certificate of merit statute, 12 V.S.A. § 1042, as part of a "broader legislative reform effort aimed at medical-malpractice litigation in Vermont." *McClellan v. Haddock*, 2017 VT 13, ¶ 17 (2017). The statute requires plaintiffs in medical malpractice actions to file a "certificate of merit" simultaneously with the filing of the complaint. In that certificate, the plaintiff or his/her attorney must certify that they have conferred with a qualified health care provider and that, based on the information reasonably available, the health care provider has:

- described the applicable standard of care;
- indicated that based on reasonably available evidence there is a reasonable likelihood that the plaintiff will be able to show that the defendant failed to meet that standard of care; and
- indicated that there is a reasonable likelihood that the plaintiff will be able to show that the defendant's failure to meet the standard of care caused the plaintiff's injury.

12 V.S.A. § 1042(a). The only exceptions to the certificate requirement are cases in which the plaintiff does not need expert testimony to meet their burden of proof or where the only claim asserted against the provider is failure to obtain informed consent. *Id.* § 1042(e), (f).

The statute gives plaintiffs the ability to petition the clerk of the court for an automatic 90-day extension of the statute of limitations so they have the time to confer with an expert as required by the statute. *Id.* § 1042(d).

The consequence for failing to file a certificate of merit simultaneously with the complaint is dismissal of the action without prejudice. *Id.* § 1042(e). A dismissal without prejudice means the plaintiff can refile the lawsuit to correct their error. As a practical matter, however, if the first Vermont Guide to Health Care Law Page 195

suit was filed on the eve of the statute of limitations expiring—as is often the case—a dismissal without prejudice effectively becomes a dismissal with prejudice because the plaintiff will be barred from re-filing their suit by the statute of limitations.

What must a plaintiff-patient prove to recover on a claim of medical malpractice?

In a medical malpractice action brought against a health care professional in Vermont, the plaintiff-patient has the burden of proving:

- The degree of knowledge or skill possessed or the degree of care ordinarily exercised by a reasonably skillful, careful, and prudent health care professional engaged in a similar practice under the same or similar circumstances whether or not within the state of Vermont;
- That the defendant/health care professional either lacked this degree of knowledge or skill or failed to exercise this degree of care; and
- That as a proximate result of this lack of knowledge or skill or the failure to exercise this degree of care the plaintiff suffered injuries that would not otherwise have been incurred.

12 V.S.A. § 1908.

Section 1908 creates an objective, national standard of care in which the defendant's conduct is to be measured against what a reasonable health care professional in a similar practice would have done in the same or similar circumstances. Stated differently, health care professionals are expected to deliver health care with the same degree of care and skill that is ordinarily possessed and exercised in like cases by professionals in the same general line of practice. The failure to do so is medical malpractice.

This does not mean that a physician is required to be infallible. *Utzler v. Medical Center Hosp.*, 149 Vt. 126, 127 (1987). A physician will not be held liable for malpractice as a result of a "mere error in judgment," meaning that a physician may choose from several appropriate treatment alternatives and the mere fact that harm results from the physician's choice of one alternative over the other is not necessarily malpractice. *Rooney v. Medical Center Hosp. of Vermont, Inc.*, 162 Vt. 513, 521 (1994). The standard of care does not require a health care professional to guarantee a good result. If the provider meets the standard of care for his or her profession, then he or she will not be found liable for malpractice regardless of the result of the treatment. *Lockwood v. Lord*, 163 Vt. 210, 217 (1994).

What type of evidence must a plaintiff-patient produce to meet her burden of proof on a medical malpractice claim?

Generally, to meet his or her burden of proof in a medical malpractice action, the plaintiff-patient must present expert medical testimony setting forth:

- The proper standard of medical skill and care;
- That the defendant/health care professional's conduct departed from that standard; and
- That this conduct was the proximate cause of the harm complained of.

Senesac v. Associates in Obstetrics and Gynecology, 141 Vt. 310, 313 (1982); Utzler v. Medical Center Hosp., 149 Vt. 126 (1987). This expert should be another health care professional who is familiar with the specialty and/or type of practice in which the defendant/health care professional is engaged and will offer testimony on the three previously enumerated issues.

Expert testimony is generally required because "the human body and its treatment are extraordinarily complex subjects requiring a level of education, training and skill not generally within our common understanding." *Taylor v. Fletcher Allen Health Care*, 2012 VT 86, ¶ 9 (2012). An exception to this general rule exists only in those cases where the violation of the standard of medical care is so apparent to be comprehensible to any ordinary lay person. *Largess v. Tatem*, 130 Vt. 271, 278-79 (1972); *Larson v. Candlish*, 144 Vt. 499, 502 (1984). For example, when a health care professional treats the wrong patient or body part, the plaintiff is not required to present expert testimony to support his or her claim since the violation of the standard of care is obvious to anyone.

What types of damages can a plaintiff-patient recover in a medical malpractice action?

Both compensatory and punitive damages may be awarded in a medical malpractice case. Compensatory damages are actual damages incurred by the plaintiff-patient such as lost wages, medical expenses (regardless of whether they are paid for by insurance), impairment of earning capacity, pain and suffering, emotional distress, and other related provable damages. Pain and suffering includes compensation for any pain, discomfort, fears, anxiety, and other mental and emotional distress suffered by the patient as a result of the health care professional's conduct. The purpose of compensatory damages is not to punish a defendant or to reward a plaintiff, but rather to compensate the plaintiff for the injuries he or she has suffered.

Punitive damages, on the other hand, are awarded to punish a party for morally culpable conduct and to deter that party and others from acting in the same way in the future. To recover punitive damages, two elements must be proven: (1) wrongful conduct that is outrageously reprehensible; and (2) malice. With respect to the first element, Vermont law limits the recovery of punitive damages to only those cases where the evidence shows that defendant's wrongdoing has the character of outrage frequently associated with crime. The second element requires evidence of malice which has been defined as bad motive, ill will, personal spite or hatred, and reckless disregard. It is not enough for the plaintiff to show that the defendant's acts were wrongful or unlawful; there must be proof of the defendant's bad spirit and wrong intention. *Fly Fish Vermont, Inc. v. Chapin Hill Estates, Inc.*, 2010 VT 33, ¶ 18.

Negligence resulting from mere inadvertence, incompetence, unskillfulness, or a failure to take precautions is not enough to establish liability for punitive damages because it lacks the element of malice. *Id.* at \P 24. Thus, medical malpractice alone is insufficient to establish liability for punitive damages since malpractice is nothing more than professional negligence in the provision of health care.

What is joint and several liability?

Joint and several liability refers to the situation in which two or more individuals may be liable for the same harm. For example, if a patient sues three (3) doctors and the jury finds that each doctor was negligent and awards damages, the patient can choose to collect the entire verdict from any one of the three doctors. In Vermont, if the patient collects the entire award from Doctor A, Doctor A cannot seek reimbursement or contribution from Doctors B and C.

What is vicarious liability?

Generally, vicarious liability or respondeat superior refers to the imposition to liability on one person for the legally actionable conduct of another person based on the relationship between the

two persons. A common relationship to which vicarious liability applies is that of employer and employee; employers are legally responsible for the acts of their employees. *In re Desautels Real Estate, Inc.*, 142 Vt. 326, 337 (1982). Thus, if a physician employs a nurse and that nurse commits malpractice, the physician can be found liable for that malpractice based on his or her status as the nurse's employer.

Are there "caps" on damages in Vermont?

There are no "caps" on compensatory or punitive damages in Vermont in medical malpractice cases.

STATUTES OF LIMITATION

What is a statute of limitation?

A statute of limitation sets forth the maximum time period in which a lawsuit may be brought. Once that time expires, no suit may be filed, regardless of the validity of the claims asserted.

What is the statute of limitation on claims of medical malpractice in Vermont?

Generally, actions for medical malpractice must be brought either within three years of the date of the incident (the alleged negligent treatment) or two years from the date of discovery of (a) the injury, and (b) the fact that it may have been caused by the negligence of a health care provider. 12 V.S.A. § 521; *Lillicrap v. Martin*, 156 Vt. 165, 175-76 (1990). In any case, however, a medical malpractice action may not be filed more than seven years from the date of the incident unless:

- fraudulent concealment has prevented the patient's discovery of the medical malpractice; or
- the action is based upon the discovery of a foreign object in the patient's body, in which case, the action may be commenced within two years of the date of the discovery of the foreign object.

12 V.S.A. § 521.

Vermont law sets forth a separate statute of limitations for ionizing radiation injuries and injuries from other noxious agents (i.e., a substance originating outside of the body that acts upon the body when exposed to the substance) which are medically recognized as having a prolonged latent development. 12 V.S.A. § 518; *Campbell v. Stafford*, 2011 VT 11, ¶¶ 14-15. An action to recover for these types of injuries must be commenced within three years after the person suffering the injury knew or ought reasonably to have known that an injury has been suffered, but in no event can the action be commenced more than twenty years after the date of the last occurrence to which the injury is attributed.

What is the statute of limitations on a wrongful death claim?

Actions for wrongful death must be commenced within two years from the discovery of the death of the person. 14 V.S.A. § 1492(a).

What is the statute of limitations on a survival action?

A survival action is a cause of action that a person had while alive that may be litigated after he/she had died. The cause of action is said to "survive" and may be prosecuted by or against the executors or administrators of the estate of the deceased party. 14 V.S.A. § 1452.

The types of actions that will survive are set forth by statute and include an action for the recovery of damages for bodily hurt or injury, such as medical malpractice. 14 V.S.A. § 1452. For example, if a patient dies sometime after suffering an injury believed to be caused by malpractice, but before filing a lawsuit, his or her executor or administrator may file a lawsuit within the time period outlined below. Similarly, if a physician dies, a legal action against the physician or his estate may be filed or continued after his or her death.

To pursue a survival action, the party must have died before the expiration of the applicable statute of limitation (such as the medical malpractice statute of limitation) or within 30 days of the expiration of that statute of limitation. 12 V.S.A. § 557(a). The cause of action must then be commenced by or against the executor or administrator of the decedent within two years of the issuance of the "letters testamentary" or "letter of administration" by the Probate Court. 12 V.S.A. § 557(a).

What is the statute of limitation on other types of claims?

In Vermont, except as otherwise provided, most civil actions, including contract actions, must be commenced within six years after the cause of action "accrues"; that is, after the injured party discovers or reasonably should discover the injury and its cause. 12 V.S.A. § 511.

There is a specific statute of limitation for claims of assault and battery, false imprisonment, slander and libel, personal injuries, and damage to personal property. These actions must be brought within three years from the date of accrual of the cause of action. 12 V.S.A. § 512. As with the general statute of limitations, a cause of action for these claims accrues when the injured party discovers or reasonably should discover the injury and its cause.

What does it mean when a statute of limitations is tolled?

When a statute of limitations is "tolled," that means the time in which a person has to file a suit is temporarily paused or delayed. In Vermont, statutes of limitation are tolled for a variety of reasons, the most common of which are when the person entitled to bring an action is a minor, lacks capacity to protect his or her interests due to a mental condition or psychiatric disability, or is imprisoned at the time the cause of action accrues. The statute of limitation will begin to run only after the "disability is removed"; that is, when the minor turns 18, the person lacking capacity regains capacity, or the imprisoned person is released from prison. 12 V.S.A. § 551(a).

If a person entitled to bring an action becomes unable to protect his or her interests due to a mental condition or psychiatric disability after the cause of action accrues but before the statute has run, the time during which the person cannot protect his or her interests due to a mental condition or psychiatric disability shall not be included as a part of the time allowed for commencement of the action. 12 V.S.A. § 551(b).

LIABILITY WITH RESPECT TO INFORMED CONSENT

For specific information regarding consent to treatment, see the "<u>Informed Consent for</u> <u>Treatment</u>" section in the "Consent, Privacy and Medical Records. This section addresses civil liability for failure to obtain informed consent for treatment.

When may a physician be held liable for failure to obtain informed consent?

In Vermont, a health care practitioner may be held liable for malpractice when he or she fails to obtain informed consent for treatment. Lack of informed consent is defined as:

- The failure to disclose to the patient treatment alternatives and the reasonably foreseeable risks and benefits involved as a reasonable medical practitioner would have disclosed under similar circumstances, in a manner permitting the patient to make a knowledgeable evaluation; or
- The failure to provide a patient with a reasonable answer to any specific question about foreseeable risks and benefits, or the withholding of requested information.

12 V.S.A. § 1909(a).

With respect to the first category, the patient asserting a claim of failure to obtain informed consent must produce expert medical testimony to establish that he or she was not properly informed of the treatment alternatives and the reasonably foreseeable risks and benefits involved therewith, as a reasonable medical professional under similar circumstances would have disclosed. Without that expert testimony, the plaintiff cannot meet his or her burden of proof.

In assessing whether a physician has obtained informed consent, the focus is on whether the physician advised the patient of the treatment alternatives and reasonably foreseeable risks and benefits which were commonly known to the profession at the time the informed consent discussion did or could have occurred, as well as at the time the treatment was given. In other words, the scope of the information that should be provided in obtaining informed consent is based on the information commonly known to the profession at that time.

Although there is no specific requirement that informed consent be acknowledged in writing, obtaining such written acknowledgement is common and prudent. In any case, the practitioner should document the content of the discussion and the patient's consent in the medical record.

Under what circumstances, if any, does a physician not have to obtain informed consent?

Health care professionals do not need to obtain a patient's informed consent when the provision of medical care and treatment occurs during an emergency. 12 V.S.A. § 1909(b). What constitutes an emergency is not defined in Vermont's informed consent statute and has not been specifically addressed by the Vermont Supreme Court. In *Small v. Gifford Memorial Hospital*, 133 Vt. 552, 349 A.2d 703 (1975), which was decided before the informed consent statute was enacted, the Vermont Supreme Court cited with approval to a case in which the emergency exception was described as encompassing a situation where the "patient is unconscious or otherwise incapable of consenting and the harm from non-treatment outweighs the harm threatened by the treatment."

Whether a particular situation constitutes a medical emergency such that the requirement of informed consent does not apply is measured by an objective medical standard. In all circumstances, the physician should document in the patient's chart the factors which created the emergency, and which informed his or her decision to render the treatment provided. Although

not required by the informed consent statute, the better practice in an emergency situation where a patient is unable to provide consent is to seek the consent of the patient's spouse, significant other, or other close family member if time permits.

What defenses can be asserted in a malpractice action alleging the failure to obtain informed consent?

The informed consent statute in Vermont sets forth four defenses that may be asserted in a suit alleging failure to obtain informed consent. 12 V.S.A. 1909(c)(1)-(4). They are:

- The risk not disclosed is too commonly known to require disclosure and is not substantial;
- The patient assured the medical practitioner he or she would undergo the treatment, procedure or diagnosis regardless of the risk involved, or the patient indicated to the medical practitioner that he or she did not want to be informed of the matters to which he or she would be entitled to be informed;
- Consent by or on behalf of the patient was not reasonably possible; or
- A reasonably prudent person in the patient's position would have undergone the treatment or diagnosis if he or she had been fully informed.

A plaintiff cannot establish liability by simply alleging that he or she would not have undergone the treatment received if he or she had been fully informed. Rather, the statute creates an objective standard focused on whether a reasonably prudent person would give his or her consent to treatment if he or she had been fully informed. If so, then there is no liability for failure to obtain informed consent.

LIABILITY WITH RESPECT TO ADVANCE DIRECTIVES FOR HEALTH CARE, DNR ORDERS, AND COLST ORDERS

"The State of Vermont recognizes the fundamental right of an adult to determine the extent of health care the individual will receive, including treatment provided during periods of incapacity and at the end of life." 18 V.S.A. § 9700. To that end, Vermont allows adults to retain control over their own health care through the use of advance directives.

What is an advance directive?

An advance directive is a written document that may include an appointment of an agent (an adult with capacity to whom authority to make health care decisions for a principal/patient is delegated under an advanced directive), identification of a preferred primary care clinician, instructions on health care desires or treatment goals, an anatomical gift, disposition of remains, and funeral goods and services. It includes documents designated under prior law as a durable power of attorney for health care or a terminal care document. 18 V.S.A. § 9701(1).

In Vermont, health care providers, health care facilities, and residential care facilities shall not provide health care to a patient without capacity, except on an emergency basis, without first attempting to determine whether the patient has an advance directive in effect. 18 V.S.A. § 9707(a).

For specific information regarding advance directives, see the chapter on End of Life Issues.

What is a DNR Order?

A DNR (do-not-resuscitate) order is a written order of the patient's clinician directing health care providers not to attempt resuscitation. 18 V.S.A. § 9701(8). DNR identification is a necklace, bracelet, or anklet identifying the patient as an individual who has a DNR order. 18 V.S.A. § 9701(9).

For specific information regarding DNR orders, see the chapter on End of Life Issues.

What is a COLST Order?

A COLST (clinician order for life-sustaining treatment) order is a clinician's order for treatment such as intubation, mechanical ventilation, transfer to a hospital, antibiotics, artificially administered nutrition, or another medical intervention. COLST orders are designed for use in outpatient settings and health care facilities and may include a DNR order. 18 V.S.A. § 9701(6).

For specific information regarding COLST orders, see the chapter on End of Life Issues.

Is a health care professional who complies with the terms of an advance directive, DNR Order, or COLST Order exposed to civil or criminal liability for doing so?

No. If health care professionals, health care facilities, residential care facilities, and their agents comply with the provisions of Chapter 231 of Title 18 governing advance directives for health care, then they are immune from civil and criminal liability when they:

- provide or withhold treatment or services in good faith pursuant to the direction of a principal/patient, the provisions of an advance directive, a DNR order, a COLST order, a DNR identification, the consent of a principal/patient with capacity or the principal/patient's agent or guardian, or a decision or objection of a principal/patient; or
- rely in good faith on a suspended or revoked advance directive, a DNR order, or a COLST order, unless the provider or facility should have known of the suspension or revocation.

18 V.S.A. § 9713(b)(1). Health care professionals and facilities are not, however, immune from liability for the failure to follow the standards of professional conduct and to exercise due care in the provision of services. 18 V.S.A. § 9713(b)(3).

Additionally, no employee of the previously listed professionals and facilities can be subjected to an adverse employment decision or evaluation for:

- complying with an advance directive, a DNR order, a DNR identification, or a COLST order;
- relying on an amended, suspended or revoked advance directive unless the employee knew or should have known of the amendment, suspension or revocation; or
- for providing notice to his or her employer that he or she is unwilling to comply with an instruction in an advance directive due to a moral or other conflict, so long as the employee has provided ongoing healthcare until a new employee has been found to provide the services.

18 V.S.A. § 9713(c).

When may a health care provider be exposed to civil or criminal liability?

Health care providers, health care facilities, residential care facilities, and their agents having actual knowledge of an advance directive or an instruction of the principal, agent or guardian, are subject to review and disciplinary action by the appropriate licensing entity, and/or civil or criminal liability for failing to comply with the terms of a known advance directive or failing to follow the instructions of a duly appointed agent or guardian. 18 V.S.A. § 9714.

There are, however, circumstances when health care providers may properly refuse to comply with the terms of an advance directive or the instructions of a duly appointed agent or guardian. See 18 V.S.A. § 9707 and the chapter on End of Life Issues. In those circumstances, the professional must still comply with the procedures set forth in 18 V.S.A. § 9707 to be protected from civil and/or criminal liability or disciplinary action.

LIABILITY WITH RESPECT TO THE DUTY TO PROTECT THE ENDANGERED ACT

What is the Duty to Aid the Endangered Act?

The purpose of the Duty to Aid the Endangered Act, 12 V.S.A. § 519, is to encourage rescuers to assist others in danger by penalizing them for not acting, while at the same time shielding them from civil liability for acts of ordinary negligence committed during the rescue. *Hardingham v. United Counseling Serv.*, 164 Vt. 478, 483 (1995).

The Vermont Legislature enacted this statute largely due to its concern that medical personnel were reluctant to help those in need for fear of malpractice suits. The statute imposes an affirmative duty on everyone, including health care professionals, to provide reasonable assistance to individuals who are known to be exposed to "grave physical harm." Grave physical harm is not limited to a single, traumatic event such as a car accident, but rather encompasses all situations in which a rescuer knows that someone is exposed to serious harm.

A person who provides reasonable assistance to an individual exposed to grave physical harm shall not be held liable for civil damages arising out of his or her conduct unless his or her acts constitute gross negligence, or he or she will receive or expects to receive remuneration for his or her services. 12 V.S.A. § 519(b). Gross negligence is "more than an error of judgment, momentary inattention, or loss of presence of mind, rather, it amounts to a failure to exercise even a slight degree of care and an indifference to the duty owed to another." *Hardingham v. United Counseling Serv.*, 164 Vt. 478, 482 (1995).

With respect to the receipt of remuneration, the mere fact that a rescuer is paid a regular salary during the time period in which he or she comes to the assistance of an individual does not remove the immunity created by the statute. Rather, it is when the rescuer charges the victim for the services rendered that the statutory immunity becomes unavailable. Nothing in this statute alters the liability of a health care provider for acts committed in the ordinary course of his or her practice.

ALTERNATIVE DISPUTE RESOLUTION

Does Vermont law require screening or arbitration of medical malpractice claims prior to the commencement of a lawsuit? No.

Does Vermont law require participation in alternative dispute resolution after a medical malpractice lawsuit is commenced?

Yes. Parties to medical malpractice actions (and most other civil actions) filed in Vermont, whether in state or federal court, are required to participate in alternative dispute resolution prior to going to trial. V.R.C.P. 16.3.

NATIONAL PRACTITIONER DATA BANK

What is the National Practitioner Data Bank?

The National Practitioner Data Bank (NPDB) is a federal data bank which was created to serve as a repository of information on medical malpractice payments and other adverse actions related to health care providers in the United States. Federal law determines the types of actions reported to the NPDB, who submits the reports, and who may query the data bank to obtain information on a health care provider. The mission of the NPDB is to improve health care quality, protect the public, and reduce health care fraud and abuse in the United States.

The NPDB's website, <u>www.npdb.hrsa.gov</u>, has many resources for practitioners regarding the data bank, including this guidebook: <u>https://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf</u>.

What information must be reported to the National Practitioner Data Bank and by whom?

There are several categories of information that need to be reported to the NPDB and a variety of sanctions, including civil money penalties, which may be imposed for failure to report required information. Below are some of the more common categories of information that must be reported to the NPDB:

(1) Medical Malpractice Payments

Any entity, including an insurance company, that makes a payment for the benefit of a health care practitioner in settlement of a written claim or judgment for medical malpractice against that practitioner must report the payment information to the NPDB and the appropriate state licensing board. The report must be made within 30 days of the date the first payment is made.

Payments made as a result of a suit or claim asserted solely against an entity (such as a hospital, clinic, or practice group), and not against an identified individual practitioner, are not reportable. Additionally, payments made by individual practitioners for their own benefit do not need to be reported to the NPDB. A business corporation or other business entity comprised of a sole practitioner that makes a payment for the benefit of a named practitioner, however, must report that payment to the NPDB.

(2) Adverse State Licensure and Certification Actions

State licensing and certification authorities must report all adverse licensure actions (not just those based on professional competence and conduct) taken against all healthcare practitioners and entities. Such licensure actions include, but are not limited to revocation, suspension, censure, reprimand, probation and surrender of a license or certification. The dismissal or closure

of a licensure action because the health care practitioner or entity surrendered the license or certification, or because the subject of the proceeding left the state or jurisdiction must also be reported. Reports must be made to the NPDB within 30 days from the date of the action.

(3) <u>Adverse Clinical Privileging and Medical Staff Membership Actions</u> Hospitals and other eligible health care entities must report to the NPDB and the appropriate state licensing board any professional review actions that adversely affect a physician's or dentist's clinical privileges or medical staff membership for a period of more than 30 days. They must also report the acceptance of a physician's or dentist's surrender of clinical privileges or the restriction of clinical privileges or medical staff membership (a) while under investigation for possible professional incompetence or improper professional conduct, or (b) in return for not conducting an investigation or professional review action. The report must be made within 30 days from the date adverse action was taken.

In addition, hospitals and other health care entities may (and are encouraged to) report adverse actions taken against the clinical privileges or medical staff membership of licensed health care practitioners other than physicians and dentists when those actions are based on the practitioner's professional competence or professional conduct that adversely affects, or could adversely affect, the health or welfare of a patient.

(4) Adverse Professional Society Membership Actions

Professional societies must report to the NPDB and the appropriate state licensing board any professional review action based on professional competence or professional conduct that adversely affects or may adversely affect a physician or dentist's membership. The report must be made within 30 days from the date adverse action was taken.

Professional societies may report similar adverse actions taken against the membership of health care practitioners other than physicians and dentists.

(5) Exclusions from Medicare/Medicaid

Federal agencies, state law enforcement agencies, state Medicaid fraud control units, and state agencies administering or supervising the administration of a state health care program must report health care practitioners who have been excluded from participating in federal or state health care programs. Exclusion from such a program means a temporary or permanent disqualification of an individual or entity from participation in the program, such that the individual or entity will not be reimbursed under any federal or state health-related program for any services that are provided. The report must be made within 30 days from the date adverse action was taken.

Are health care practitioners notified when reports concerning them are made to the NPDB? Yes, the subject of a report made to the NPDB is notified of the report by the NPDB. The

notification will include instructions for obtaining an official copy of the report through the Report Response Service on the NPDB website.

What recourse do health care practitioners have when they dispute some or all of the information contained in a report to the NPDB?

The NPDB is prohibited by law from modifying the information in the reports. If the information in a report is inaccurate, the subject of that report has several options for seeking a correction. First, he or she can add a statement ("Subject Statement") to a report at any time. The statement will be appended to the report and sent with the report when queries are made. There are specific requirements that must be complied with when submitting a Subject Statement which can be found on the NPDB's website.

Second, the subject of the report can contact the reporting entity to request that it voluntarily correct the information by filing a correction to the report.

Third, at any time, the subject of a report may dispute the report and enter the report into "Dispute Status" to disagree with either the factual accuracy of the report or whether the report was properly submitted under the NPDB's reporting requirements. After a report has been entered into Dispute Status, the subject of the report may do any of the following:

- Leave the report in Dispute Status and the NPDB will take no further action;
- Withdraw the report from Dispute Status; or
- Request that the report be elevated to "Dispute Resolution."

The NPDB will not review a report entered into Dispute Status; such a review will only occur after the report has been elevated to "Dispute Resolution". The subject of the report must meet two prerequisites to have a report elevated to Dispute Resolution:

- During the 60 days after a report has been entered into Dispute Status, the subject of the report must contact the reporting entity in an attempt to resolve the issues raised by the report; and
- The subject of the report must submit to the NPDB proof of his/her attempt to resolve the issues with the reporting entity (such as correspondence to the reporting entity outlining the issues with the report and the entity's response to that correspondence).

The scope of a review once a report is elevated to Dispute Resolution is very narrow. Specifically, the subject of the report may only dispute (1) whether the report was submitted in compliance with the NPDB reporting requirements, and (2) the factual accuracy of the information reported. Thus, the subject cannot seek review of issues such as the merits of a medical malpractice claim or whether the reporting entities complied with due process in connection with its internal processes.

The NPDB website and NPDB Guidebook explain the specific procedures which must be followed when a report is elevated to Dispute Resolution and reviewed by the NPDB, and the relief potentially available to the subject following such a review.

Who can access the information maintained by the NPDB?

Information reported to the NPDB is considered confidential and shall not be disclosed except as specifically provided in the NPDB regulations. Under those regulations, certain information in the NPDB may, and in some cases shall, be requested by a number of entities and individuals including, but not limited to, the following:

(1) Hospitals

Hospitals are the only health care entities that are required by law to query the NPDB. Failure to do so will subject the hospital to sanctions. Hospitals must query the NPDB:

- When a physician, dentist, or other licensed health care practitioner applies for a position on its medical staff (courtesy or otherwise) or for clinical privileges (including temporary privileges);
- Every two years on every physician, dentist, or other licensed health care practitioner who is a member of the medical staff or has clinical privileges;
- When a physician, dentist, or other licensed health care practitioner wishes to add to or expand existing privileges;
- Each time a physician, dentist, or other licensed health care practitioner submits an application for temporary privileges; and
- Whenever residents and interns are appointed to the medical staff or granted clinical privileges to practice outside the parameters of a formal education program (such as moonlighting in the ED of a hospital).

Hospitals may query at other times as they deem necessary.

(2) Other Health Care Entities

Other health care entities may query the NPBD when entering into an employment or affiliation relationship with a health care practitioner, when health care practitioners apply for clinical privileges or medical staff appointments, or when they are engaging in professional review activities.

(3) State licensing and certification agencies

These agencies may query the NPDB on physicians, dentists and other licensed health care practitioners when they are:

- determining the fitness of individuals to provide health care services,
- protecting the health and safety of individuals receiving health care through programs that they administer, or
- protecting the fiscal integrity of the programs that they administer.

(4) <u>Plaintiffs' Attorneys</u>

Plaintiffs' attorneys (or plaintiffs acting on their own behalf) may seek permission to query the NPDB concerning a practitioner only if they have:

- filed a medical malpractice claim against a hospital in state or federal court or other adjudicative body,
- the practitioner whose information is requested is named in that action, and
- the requester must be able to demonstrate that the hospital failed to make a required mandatory query with evidence not obtained from the NPDB.

If the request is granted, the plaintiff's attorney will receive the information that would have been available at the time the hospital was required to submit a query to the NPDB but did not and information on any reports that were subsequently voided. That information can only be used in litigation against the hospital. Plaintiffs and their attorneys may not query the NPDB for information to be used in suits against practitioners. Defense attorneys are not allowed to query the NPDB, even though the defendant-practitioner is allowed to self-query.

(5) Professional Societies

Professional societies may submit a query when entering into an employment or affiliation (membership) relationship with a health care practitioner or in conjunction with professional review activities.

(6) <u>Physicians, dentists and other (licensed health care practitioners</u> All health care practitioners can self-query the NPDB regarding himself or herself at any time. This can be done through the NPDB website.

SAFE APOLOGY LAW

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What is the safe apology law?

In 2006, the Vermont Legislature enacted the so-called safe apology law, which provides that an oral expression of regret or apology, including any oral good faith explanation of how a medical error occurred, made by or on behalf of a health care provider or health care facility (1) does not constitute a legal admission of liability for any purpose, and (2) is inadmissible in any civil or administrative proceeding against the provider or facility. 12 V.S.A. § 1912(a).

The person making the apology may not be questioned at deposition or otherwise with respect to the apology. The apology must be made within 30 days of when the provider or facility knew or should have known of the consequences of the error to come within the protections of this law. Failure to comply with the requirements of the statute will result in a waiver of the protections it offers.

PATIENT SAFETY SURVEILLANCE AND IMPROVEMENT SYSTEM

What is the Patient Safety Surveillance and Improvement System (PSSIS)?

The Patient Safety Surveillance and Improvement System (PSSIS) was created in 2006 for the purpose of improving patient safety, eliminating adverse events in Vermont hospitals, and supporting and facilitating quality improvement efforts by hospitals. 18 V.S.A. §§ 1912-1919.

Under the PSSIS, hospitals are required to do, among other things, the following:

- Develop, maintain and implement internal policies and procedures to:
 - Identify, track, and analyze reportable adverse events, adverse events, and near misses;
 - Determine what type of causal analysis, if any, is appropriate;
 - Conduct causal analyses and develop corrective action plans; and
 - Disclose to patients, or; in the case of a patient death, an adult member of the immediate family, at a minimum, adverse events that cause death or serious bodily injury;
- Report reportable adverse events to the Department of Health, including providing the department with copies of the hospital's causal analysis and corrective action plan in connection with each reportable adverse event;
- For reportable adverse events that must also by law be reported to other departments or agencies, notify the Department of Health or provide a copy of any written report and provide any causal analysis information required by the department; and

• Provide the commissioner and his/her designees reasonable access to (1) confidential patient health information under 12 V.S.A. § 1612(a), and (2) the minutes and records of any peer review committee and any other information subject to peer review protection under 26 V.S.A. § 1443, for the purpose of evaluating compliance with this law.

18 V.S.A. § 1915.

All of the information made available to the Department of Health as part of the PSSIS is confidential and privileged, and exempt from the public access to records law. 18 V.S.A. § 1917(a). In any civil or administrative proceeding against a health care provider arising out of the matters which were evaluated and reviewed by the department:

- The information made available to the Department of Health as part of the PSSIS is immune from subpoena, not subject to discovery and is not admissible into evidence; and
- No person with access to information made available to the commissioner or his/her designees shall be permitted or required to testify as to any findings, recommendations, evaluations, opinions, or other actions of the department in any civil or administrative proceeding against a health care provider arising out of the matters which were evaluated and reviewed by the department

18 V.S.A. § 1917(a), (b).

Hospitals are permitted to replace health care provider identifying information in peer review materials with a surrogate identifier that allows for tracking of adverse events involving the same provider without disclosing the provider's identity. 18 V.S.A. § 1917(e).

Hospitals that fail to comply with any of the requirements of the PSSIS are subject to monetary penalties. 18 V.S.A. § 1918.

ABOUT THE AUTHOR

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REGULATION OF PHYSICIANS

Topics Covered in this Chapter: Overview Licensing Standard of Conduct **Complaint Process** Discipline Appellate Avenues Public Access to Information About the Authors

By: David Pocius, Esq. Ott Lindstrom, Esq. Paul Frank + Collins P.C.

Note: This information is provided to assist interested persons in becoming familiar with the law pertaining to the regulation of physicians in Vermont. It is not an official interpretation or statement of policy by the Department of Health or the Vermont Board of Medical Practice and does not constitute legal advice. This information is accurate as of December 15, 2022, and is subject to change.

OVERVIEW

What state agency is responsible for licensing and disciplining physicians, podiatrists, physician assistants, and anesthesiologist assistants in Vermont?

The Vermont Board of Medical Practice ("Board"), part of the Vermont Department of Health, licenses physicians, podiatrists, and physician assistants, and certifies radiologist assistants and anesthesiologist assistants. The Board also investigates complaints and issues findings and actions regarding unprofessional conduct. The Board's stated mission is to evaluate the fitness of professionals to practice in Vermont, and to take action where needed to protect the public health and safety.

Statutorily, the Board consists of 17 members: nine licensed physicians, one licensed physician assistant, one licensed podiatrist, and six public members. Members are appointed by the governor, with the advice and consent of the Senate. They serve for up to two consecutive fiveyear terms. See here.

The Board operates under administrative rules adopted under the Vermont Administrative Procedure Act. As a result, these rules carry the same force of law as a statute. The Board last revised its rules effective July 1, 2022. See here.

What state agency is responsible for licensing and disciplining doctors of osteopathy, advance practice registered nurses, and other health care professionals in Vermont?

The Board of Osteopathic Physicians and Surgeons regulates osteopathic physicians through the Vermont Office of Professional Regulation, a branch of the Secretary of State's office. The Board consists of five (5) members: three licensed osteopathic physicians and two public Vermont Guide to Health Care Law

members. The Board of Nursing regulates nurses through the Vermont Office of Professional Regulation. The Board consists of eleven (11) members: six registered nurses (including two advanced practice registered nurses), two practical nurses, one nursing assistant, and two public members. Other certified and registered health care professionals are similarly regulated by other boards within the Office of Professional Regulation. These boards function similarly to the Board, but each generally operates under different laws and has adopted its own administrative rules. A list of professions that provide links to each board and its rules can be found <u>here</u>.

Note: the discussion of licensing and discipline below applies to the physicians and other health care professionals licensed by the Board of Medical Practice. The Board Rules are generally framed as applying to "professionals," with "professional" defined as "a member of one of the health care professions licensed by the Board: medical doctor; physician assistant; podiatrist; anesthesiologist assistant, and radiologist assistant." Board Rule 2.2827.

LICENSING

How do I obtain a Vermont Medical License from the Vermont Board of Medical Practice?

In order to obtain a license to practice medicine, an applicant must present evidence satisfactory to the Board that the applicant:

- Is at least 18 years of age;
- Is competent in speaking, writing and reading the English language (This requirement was removed from 26 V.S.A. § 1391 by Act 126 of 2020, but persists in the Board's Rules);
- Completed high school and two years of college or the equivalent;
- Graduated from a Board-approved medical school, or a medical school accredited by the Liaison Committee on Medical Education) (LCME) or the Committee on Accreditation of Canadian Medical Schools (CACMS)(a "Board-approved medical school" means a medical school that (1) appears on the official California Recognized Medical Schools list; (2) a foreign medical school that has been accredited under the system for medical school accreditation established by the Educational Commission for Foreign Medical Graduates (ECFMG) and deemed to meet the minimum requirements substantially equivalent to the requirements of medical schools accredited by the LCME or the CACMS; or (3) a medical school that was approved as provided by the standards established by the United States National Committee on Foreign Medical Education and Accreditation Certification (NCFMEA), but only if the applicant holds American Board of Medical Specialties (ABMS) board certification or meets all eligibility requirements for such certification and is only lacking current licensure. *See* Board Rule 2.6.);
- Meets the criteria for postgraduate training;
- Meets the criteria for license by examination, *see* Rule 17.0 of the Vermont Board of Medical Practice Rules ("Board Rules"); or license by faculty appointment, *see* Board Rule 18.0; and
- Meets requirement for moral character and professional competence. *See also*, 26 V.S.A. §§ 1391, 1395 (statutory licensing requirements).

Board Rule 15.1.

The Board uses the Uniform Application for Physician State Licensure, portions of which must be completed online. All application material can be found <u>here</u>. It is the applicant's personal responsibility to ensure complete and accurate responses to all application questions.

Through a similar application process on the same portal, the Board can issue a limited temporary license for the purpose of completing postgraduate training, which allows the licensee to practice under the supervision and control of a Vermont-licensed physician in an ACGME-accredited training program. *See* 26 V.S.A. § 1392. A limited temporary license may be renewed or reissued upon the completion of a renewal application. Board Rule 21.

NOTE: As of January 1, 2020, Vermont has adopted the Interstate Medical Licensure Compact.. 26 V.S.A. § 1420, et seq. Under this Compact, licensed physicians can qualify to practice medicine across state lines within the Compact if they meet the agreed upon eligibility requirements. The Compact creates another pathway for licensure and does not otherwise change the existing licensing process. See <u>here</u> for more information.

What does the renewal process consist of?

Licenses are renewed on a fixed biennial schedule. It is the responsibility of the licensee to renew their license before it lapses. The date on which a license shall lapse is printed on the license. Ninety days before this date, the Board sends each licensee a notice of renewal application form to the email address last provided to the Board. Board Rule 7.1; 26 V.S.A. § 1400.¹

The licensee must ensure complete and accurate responses to all renewal application questions. If a physician does not return the completed renewal application, all required documentation, and the required fee to the Board by the date on which the license lapses, the physician's license will automatically lapse. Board Rule 7.1.

A licensee whose initial license is issued within 90 days of the next renewal date, will not be required to renew or pay the renewal fee. Instead, the license will be issued with an expiration date at the end of the next full period of licensure. Board Rule 7.2.²

Licensees have a continuing obligation during each two-year renewal period to promptly notify the Board of any change or new information regarding answers on the initial or renewal application, including but not limited to disciplinary or other action limiting or conditioning their license, certification, or ability to practice in any jurisdiction. Failure to do so may subject the licensee to disciplinary action by the Board. Board Rule 7.3; 26 V.S.A. § 1400(d).

What are the continuing medical education requirements?

Board Rule 23 provides rules regarding continuing medical education (CME). A physician seeking to renew their license must certify they have completed at least thirty (30) hours of *qualifying* CME during the most recent two-year licensing period. Board Rule 23.1.1. A CME

¹ The Legislature reduced the minimum timeline to "at least one month" via 26 V.S.A. § 1400(a) by Act 126 of 2020, but it remains 90 days under the Board Rules.

² The Legislature reduced the minimum timeline to "[w]ithin one month" via 26 V.S.A. § 1400(a) by Act 126 of 2020, but it remains 90 days under the Board Rules.

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activity qualifies only if it has been approved by the American Medical Association Physician's Recognition Category 1 Credit. Board Rule 23.2.1.

All licensees must have at least one qualifying hour of CME on the topics of hospice, palliative care, or pain management services. Board Rule 23.1.5. If a licensee prescribes controlled substances, two hours of qualifying CME must also cover controlled-substances prescribing, including a number of specific related topics. *See* Board Rule 23.1.6. Any licensee who is registered with the D.E.A. and holds a D.E.A. number to prescribe controlled substances, or who has submitted a pending application for a D.E.A. number, is presumed to prescribe controlled substances and must meet this requirement. Board Rule 23.1.6.

CME Rules also require that CME hours be designed to assure that the licensee has updated their knowledge and skills in their own specialties and has kept abreast of advances in other fields for which patient referrals may be appropriate. Board Rule 23.1.4. The Board broadly interprets a licensee's "own area of practice," and acknowledges that training in many other fields may be reasonably related to a licensee's own specialties. *Id*.

For physicians licensed in Vermont for the first time during the most recent two-year licensing period, if licensed in Vermont for less than one year, there is no requirement for CME at the time of the first renewal. If licensed for one year or more during that initial period of Vermont licensure, the licensee shall complete at least 15 hours of approved CME activity and those 15 hours shall include any subject-specific CME required by Board rules. Board Rule 23.1.2.

Licensees who are members of the armed forces and subject to mobilization and/or deployment for all or part of a licensing period will be treated the same as licensees licensed for the first time during the licensing period, e.g., a licensee whose military mobilization/deployment covers a year or more is not required to complete CME for that period. A licensee whose military duties during the two-year period total less than one year shall be required to meet the CME requirement of at least 15 hours, including any required subjects. Board Rule 23.1.8.

A licensee is not required to file documentation of CME to verify completion when reported, but the licensee must retain such documentation for four (4) years from the time the information is submitted to the Board. Board Rule 23.1.1.1. The Board may audit such records for up to four years after submission. Board Rule 23.1.1.2.

If a licensee fails to complete the CME requirements by the time of their license renewal, the renewal application must be accompanied by an acceptable make-up plan signed by the licensee or the Board will reject the application. Board Rule 23.3. An acceptable plan must be signed and include a timeline for completing the requirements within 120 days after their license expiration date, an indication of their good faith intent to complete the requirements as indicated, and identify the activities the licensee will attend, although the licensee may later substitute activities. Board Rule 23.3.2. Any licensee not in good standing with respect to CME requirements is subject to investigation by the Board for unprofessional conduct. Board Rule 23.4.4.

How do I reinstate my lapsed license?

To seek reinstatement after failing to renew within a year of the lapse of the license, a physician must complete the renewal application in full and tender it to the Board with any required documentation and late fee, in addition to the fee required for renewal. Board Rule 9.1.1 The Board may deny the renewal of a license on grounds of unprofessional conduct as set forth under Vermont law, or for other good cause shown, after notice and opportunity to be heard has been provided to the physician. Board Rules 9.1.1 & 9.2.3.

If a license is lapsed for one year or more, the physician must complete a reinstatement application in full and pay the associated application fee. The reinstatement application requires additional information beyond that required in the standard renewal application. For example, this must include a chronological accounting of the physician's professional activities in other jurisdictions during the period the license was lapsed in Vermont. Board Rule 9.2.1. The physician must also include:

- If the physician has held hospital privileges, a form completed by the chief of staff of the hospital where privileges were most recently held during the period when the Vermont license was lapsed;
- If the physician is required to practice under supervision, a form completed by each supervisor who provided supervision during the period when the Vermont license was lapsed; and
- A license verification from each state in which the physician held an active license during the period when the Vermont license was lapsed.

A licensee who allows a license to lapse by not timely applying for renewal must also certify completion of all CME requirements that would have been required to remain licensed. Board Rule 23.1.9.

The reinstatement application can be found <u>here</u>.

How are physician assistants regulated?

Physician assistants receive a license that authorizes them to practice only within the employment contract and scope of practice submitted and approved by the Board. Section III of the Board Rules provides rules governing physician assistants, including their licensure.

Physician assistants are licensed by the Board. 26 V.S.A. § 1733. To become licensed, physician assistants must file the necessary documents and obtain Board approval in advance of practicing. Board Rule 26. Under 26 V.S.A. § 1735a, a physician assistant shall engage in practice as a physician assistant in Vermont only if the physician assistant has entered into a written practice agreement with a participating physician. The participating physician's area of specialty must be similar or related to the physician assistant's area of specialty. 26 V.S.A. § 1735(a)(1)–(2). The practice agreement must also comply with the requirements of 26 V.S.A. § 1735a(b).

An application for licensure may be processed without a practice agreement upon written request to the Board; however, any subsequently issued license will be inoperable and ineffective, and the physician assistant unable to practice, until a practice agreement has been received by the Board. Board Rule 26.2.

The ability to practice as a physician assistant terminates upon the dissolution of an employment contract or practice agreement. This includes both leaving one employment and beginning at another and adding a new employer while continuing to work for current employer. There must be a practice agreement that applies to each practice setting.

If a physician assistant's practice agreement includes restrictions that limit its application to a new practice setting with the same employer, such as by geographic location, by department, or by scope of practice allowed, a new practice agreement must be submitted for a new practice setting beyond those restrictions. Following the dissolution of an employment contract or practice agreement, the ability to practice as a physician assistant does not resume unless and until a new practice agreement is submitted to the Board. Board Rule 28.4.

A number of Rules also apply to practice agreements in specific circumstances: (1) the unavailability of a participating physician who is a sole practitioner (Board Rule 28.5), (2) the unavailability of participating physician (Board Rule 28.6), and (3) practice agreements when a physician assistant has multiple practice sites (Board Rule 28.7).

Pursuant to Board Rule 29, physician assistants are subject to specific professional standards, including the requirements not to prescribe DEA controlled substances for the physician assistant's participating physician; not to prescribe for or treat the physician assistant's participating physician (though this is discouraged, and not outright proscribed); not to practice without a practice agreement in place; and to keep up with physician assistant continuing education requirements set forth in Board Rule 29.4. Though not covered in detail in this summary, physician assistants are also bound by their own set of unprofessional conduct rules, provided under 26 V.S.A. § 1736.

Previously, Board Rules provided for a number of unprofessional conduct ramifications for the improper use of physician assistants by physicians. With the passing of Act 123 of 2020, which removed language from 26 V.S.A. § 1354 regarding the improper "use of the services of a physician assistant by a physician," the majority of the rules have been removed. The remaining explicit unprofessional conduct rule regarding the use of physician assistants is that a physician must not request or receive the dispensing of or a prescription for controlled substances listed in D.E.A. Schedules II, III, or IV for the physician's own use from a physician assistant supervised by the physician. Board Rule 21.4.

STANDARD OF CONDUCT

What actions constitute unprofessional conduct?

Per statute, 26 V.S.A. § 1354, the following actions constitute unprofessional conduct:

- Fraud or misrepresentation in applying for or procuring a medical license or in connection with applying for or procuring periodic renewal of a medical license;
- All advertising of medical business that is intended or has a tendency to deceive the public or impose upon credulous or ignorant persons and so be harmful or injurious to public morals or safety;
- Abandonment of a patient;
- Habitual or excessive use or abuse of drugs, alcohol, or other substances that impair the licensee's ability to practice medicine;

- Promotion by a physician of the sale of drugs, devices, appliances, or goods provided for a patient in such a manner as to exploit the patient for financial gain of the physician or selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes;
- Conduct that evidences unfitness to practice medicine;
- Willfully making and filing false reports or records in their practice as a physician;
- Willful omission to file or record, or willfully impeding or obstructing a filing or recording, or inducing another person to omit to file or record medical reports required by law;
- Failure to make available promptly to a person using professional health care services, that person's representative, succeeding health care professionals or institutions, when given proper written request and direction of the person using professional health care services, copies of that person's records in the possession or under the control of the licensed practitioner;
- Solicitation of professional patronage by agents or persons or profiting from the acts of those representing themselves to be agents of the licensed physician;
- Division of fees or agreeing to split or divide the fees received for professional services for any person for bringing to or referring a patient;
- Agreeing with clinical or bio-analytical laboratories to make payments to such laboratories for individual tests or test series for patients, unless the physician discloses on the bills to patients or third party payors the name of such laboratory, the amount or amounts to such laboratory for individual tests or test series and the amount of their processing charge or procurement, if any, for each specimen taken;
- Willful misrepresentation in treatments;
- Practicing medicine with a physician who is not legally practicing within the State, or aiding or abetting such physician in the practice of medicine; except that it shall be legal to practice in an accredited preceptorship or residency training program or pursuant to limited exceptions listed in 26 V.S.A. § 1313;
- Gross overcharging for professional services on repeated occasions, including filing of false statements for collection of fees for which services are not rendered;
- Offering, undertaking, or agreeing to cure or treat disease by a secret method, procedure, treatment, or medicine;
- Consistent improper utilization of services;
- Consistent use of nonaccepted procedures that have a consistent detrimental effect upon patients;
- Professional incompetency resulting from physical or mental impairment;
- Permitting one's name or license to be used by a person, group, or corporation when not actually in charge of, or responsible for, the treatment given;
- In the course of practice, gross failure to use and exercise on a particular occasion or the failure to use and exercise on repeated occasions, that degree of care, skill, and proficiency that is commonly exercised by the ordinary skillful, careful, and prudent physician engaged in similar practice under the same or similar conditions, whether or not actual injury to a patient has occurred;
- Revocation of a license to practice medicine or surgery in another jurisdiction on grounds which constitute unprofessional conduct in Vermont;
- Failure to comply with the provisions of 18 V.S.A. § 1852, the "Bill of Rights for Hospital Patients" (*see here*);
- Failure to comply with an order of the Board or violation of any term or condition of a license that is restricted or conditioned by the Board;
- Any physician who, in the course of a collaborative agreement with a nurse practitioner allows the nurse practitioner to perform a medical act that is outside the usual scope of the physician's own practice or that the nurse practitioner is not qualified to perform by training or experience, or that the ordinary reasonable and prudent physician engaged in a similar practice would not agree should be written into the scope of the nurse practitioner's practice;
- Failure to comply with provisions of federal or state statutes or rules governing the practice of medicine or surgery;
- Practice of profession when medically or psychologically unfit to do so;
- Delegation of professional responsibilities to a person whom the licensed professional knows, or has reason to know, is not qualified by training, experience, education, or licensing credentials to perform them;
- Conviction of a crime related to the practice of the profession or conviction of a felony, whether or not related to the practice of the profession, or failure to report to the Board a conviction of any crime related to the practice of the profession or any felony in any court within 30 days of the conviction;
- Use of the services of an anesthesiologist assistant by an anesthesiologist in a manner that is inconsistent with the assistant's certification;
- Use of the services of a radiologist assistant by a radiologist in a manner that is inconsistent with the assistant's certification;
- Providing, prescribing, dispensing, or furnishing medical services or prescription medication or prescription-only devices to a person in response to any communication transmitted or received by computer or other electronic means, when the licensee fails to take the following actions to establish and maintain a proper physician-patient relationship:
 - a reasonable effort to verify that the person requesting medication is in fact the patient, and is in fact who the person claims to be;
 - establishment of documented diagnosis through the use of accepted medical practices; and
 - maintenance of a current medical record;
 - With respect to this conduct, an electronic, on-line, or telephonic evaluation by questionnaire is inadequate for the initial evaluation of the patient.
 - With respect to this conduct, the following would not be a violation if transmitted or received by computer or other electronic means:
 - initial admission orders for newly hospitalized patients;
 - prescribing for a patient of another physician for whom the prescriber has taken the call;
 - prescribing for a patient examined by a licensed advanced practice registered nurse, physician assistant, or other advanced practitioner authorized by law and supported by the physician;
 - continuing medication on a short-term basis for a new patient, prior to the patient's first appointment; or
 - emergency situations where life or health of the patient is in imminent danger;

- Failure to provide to the Board such information it may reasonably request in furtherance of its statutory duties, including but not necessarily limited to, information protected by the patient privilege (*see* <u>https://legislature.vermont.gov/statutes/section/12/061/01612</u>)</u> or a confidentiality agreement entered into in concluding a settlement of a malpractice claim;
- Disruptive behavior that involves interaction with physicians, hospital personnel, office staff, patients, or support persons of the patient or others that interferes with patient care or could reasonably be expected to adversely affect the quality of care rendered to a patient;
- Commission of any sexual misconduct that exploits the physician-patient relationship, including sexual contact with a patient, surrogates, or key third parties;
- Prescribing, selling, administering, distributing, ordering, or dispensing any drug legally classified as a controlled substance for the licensee's own use or to an immediate family member (Board Rule 2.15 defines "Immediate family" as "a spouse (or spousal equivalent), parent, grand-parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or any other person who is permanently residing in the same residence as the licensee. The listed familial relationships do not require residing in the same residence"). Although it may not be considered unprofessional conduct, the Board formally discourages a licensee to prescribe or dispense non-controlled substances for the licensee's own use or to a member of their immediate family, as defined above. If a physician nonetheless does so, the physician must meet all standards of appropriate care, including proper establishment of a professional relationship with the patient and maintenance of appropriate patient records. Board Rule 13.2.2.
- Signing a blank or undated prescription form;
- Use of conversion therapy on a client or patient younger than 18 years of age (18 V.S.A. § 8351 defines "conversion therapy" as "any practice by a mental health care provider that seeks to change an individual's sexual orientation or gender identity, including efforts to change behaviors or gender expressions or to change sexual or romantic attractions or feelings toward individuals of the same sex or gender. 'Conversion therapy' does not include psychotherapies that: (A) provide support to an individual undergoing gender transition; or (B) provide acceptance, support, and understanding of clients or the facilitation of clients' coping, social support, and identity exploration and development, including sexual-orientation-neutral or gender-identity-neutral interventions to prevent or address unlawful conduct or unsafe sexual practices without seeking to change an individual's sexual orientation or gender identity");
- Failure to comply with one or more of the notice, disclosure, or advertising requirements in 18 V.S.A. § 4502 for administering stem cell or stem cell-related products not approved by the FDA;
- Failure to practice competently by reason of any cause on a single occasion or on multiple occasions, where failure to practice competently includes, as determined by the Board:
 - Performance of unsafe or unacceptable patient care; or
 - Failure to conform to the essential standards of acceptable and prevailing practice.

Additionally, the Board may refuse to issue a license to any physician "who, by false or fraudulent representations, has obtained or sought to obtain practice in the profession, or by false or fraudulent representations in practice, has obtained or sought to obtain money or any other thing of value, or who assume names other than the applicant's own for the purpose of misleading others, or for any other immoral, unprofessional, or dishonorable conduct." 26 V.S.A. § 1398. Nonetheless, "a license or certificate shall not be suspended, . . . revoked, or refused until the holder or applicant" is given a hearing before the Board. *Id.* "In the event of revocation, the holder of any license or certificate so revoked shall promptly relinquish the license or certificate to the Secretary of the Board." *Id.*

When does a physician have to report an impaired, incompetent, or unethical colleague?

Any hospital, clinic, community mental health center, or other health care institution in which a licensee performs professional services (collectively, "reporters") shall report to the Board, along with supporting information and evidence, any reportable disciplinary action taken by it or its staff. *See* 26 V.S.A. § 1317(a).

A "reportable disciplinary action" is an action based on one more of the following:

- Acts or omissions of a licensee that relate to the licensee's fitness or competence to practice medicine under the license held;
- Acts or omissions of the licensee that constitute a violation of a law or rule that relates in any way to the practice of medicine;
- Acts or omissions of the licensee that occur in the course of practice and result in one or more of the following:
 - Resignation, leave of absence, termination, or nonrenewal of an employment relationship or contract. This includes a licensee's own initiation of such action following notification to the licensee by the reporter that the reporter or an affiliated entity is conducted an investigation or inquiry regarding an even that, assuming the accuracy of the information or allegation, is likely to result in reportable disciplinary action. The reporter or affiliated entity shall complete the investigation even if the licensee initiates a resignation, leave of absence, termination, or nonrenewal, and shall make a report to the Board if the investigation results in a finding of reportable disciplinary action. Resignations and leaves of absence that are entirely voluntary by the licensee, and terminations and nonrenewals of employment or contract by a required reporter that are not related to acts or omissions of the licensee, are not reportable disciplinary actions.
 - Revocation, suspension, restriction, relinquishment, or nonrenewal or a right or privilege. This includes a licensee's own initiation of such action following notification to the licensee by the reporter that the reporter or an affiliated entity is conducted an investigation or inquiry regarding an event that, assuming the accuracy of the information or allegation, is likely to result in reportable disciplinary action. The reporter or affiliated entity shall complete the investigation or inquiry even if the licensee initiates a resignation, leave of absence, termination, or nonrenewal, and shall make a report to the Board if the investigation results in a finding of a reportable disciplinary action. Relinquishments of privileges that are entirely voluntary by the licensee, and revocations, nonrenewals, or other limitations on privileges by a required reporter

that are not related to acts or omissions of the licensee, are not reportable disciplinary actions.

- Written discipline that constitutes a censure, reprimand, or admonition, if it is the second or subsequent censure, reprimand, or admonition within a 12-month period for the same or related acts or omissions that previously resulted in written censure, reprimand, or admonition. The same or related acts or omissions includes similar behavior or behavior involving the same parties, or both. Oral censure, oral reprimand, and oral admonition are not considered reportable disciplinary actions and notation of an oral censure, oral reprimand, or oral admonition in a personnel or supervisor's file does not transform the action from oral to written.
- Fine or any other form of monetary penalty imposed as a form of discipline.
- Required education, remedial counseling, or monitoring that is imposed as a result of a completed, contested disciplinary process. This includes recommendation or referral for services from the Vermont Practitioner Recovery Network established pursuant to 26 V.S.A. § 1401a, or from an employer wellness program or similar program, as a result of a completed, contested disciplinary process.

These reports must be made within 30 days following the date of the disciplinary action or investigation triggering the reporting obligation. 26 V.S.A. § 1317(c).

The mandatory reporting provision is framed around institutional obligations, not individual obligations, as only institutions are defined as reporters. *See* 26 V.S.A. § 1317(a), (f). Depending on the circumstances and a licensee's ability to determine the conduct of their institution, a licensee's failure to cause the report of a reportable disciplinary action may itself constitute unprofessional conduct on the part of the licensee. *See* 26 V.S.A. § 1354(a)(27) (defining as unprofessional conduct "failure to comply with provisions of federal statutes or regulations, or the statutes or rules of this or any other state, governing the practice of medicine or surgery").

In the past, the Board has followed the approach of the American Medical Association Code of Medical Ethics Opinions on Professional Self-Regulation 9.4.2 and 9.3.2. These Opinions emphasize that a physician has an ethical obligation to report colleagues who are impaired, incompetent, or unethical. Opinion 9.3.2 also states that physicians have an ethical obligation to "[i]ntervene in a timely manner to ensure that impaired colleagues cease practicing and receive appropriate assistance from a physician health program," and to assist recovered colleagues when they resume patient care. These opinions can be found here.

Can a failure to comply with the Hospital Patients' Bill of Rights result in disciplinary action against physicians?

As noted above, the Bill of Rights for Hospital Patients, 18 V.S.A. § 1852, creates standards of conduct that physicians must follow when treating patients admitted to hospitals on an inpatient basis. The violation of the following patients' rights may be reported to the Board and constitute unprofessional conduct:

- The patient has the right to considerate and respectful care at all times and under all circumstances with recognition of their personal dignity.
- The patient shall have an attending physician who is responsible for coordinating a patient's care.

- The patient has the right to obtain, from the physician coordinating their care, complete and current information concerning diagnosis, treatment, and any known prognosis in terms the patient can reasonably be expected to understand. If the patient consents or if the patient is incompetent or unable to understand, immediate family members or a guardian may also obtain this information. The patient has the right to know by name the attending physician primarily responsible for coordinating their care.
- Except in emergencies, the patient has the right to receive from the patient's physician information necessary to give informed consent prior to the start of any procedure or treatment, or both. Such information for informed consent should include the specific procedure or treatment, or both, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care or treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information. The patient also has the right to know the name of the person responsible for the procedures or treatment, or both.
- The patient has the right to refuse treatment to the extent permitted by law. In the event the patient refuses treatment, the patient shall be informed of the medical consequences of that action and the hospital shall be relieved of any further responsibility for that refusal.
- The patient has the right to every consideration of privacy concerning the patient's own medical care program. Case discussion, consultation, examination, and treatment are confidential and shall be conducted discreetly. Those not directly involved in the patient's care must have the permission of the patient to be present. This right includes the right, upon request, to have a person of one's own sex present during certain parts of a physical examination, treatment, or procedure performed by a health care professional of the opposite sex; and the right not to remain disrobed any longer than is required for accomplishing the medical purpose for which the patient was asked to disrobe. The patient has the right to wear appropriate personal clothing and religious or other symbolic items so long as they do not interfere with diagnostic procedures or treatment.
- The patient has the right to expect that all communications and records pertaining to their care shall be treated as confidential. Only medical personnel, or individuals under the supervision of medical personnel, directly treating the patient, or those persons monitoring the quality of that treatment, or researching the effectiveness of that treatment, shall have access to the patient's medical records. Others may have access to those records only with the patient's written authorization.
- The patient has the right to expect that within its capacity a hospital shall respond reasonably to the request of a patient for services. The right shall include if physically possible a transfer to another room or place if another person in that room or place is disturbing the patient by smoking or other unreasonable actions. When medically permissible a patient may be transferred to another facility only after receiving complete information and explanation concerning the needs for and alternatives to such a transfer. The institution to which the patient is to be transferred must first have accepted the patient for transfer.
- The patient has the right to know the identity and professional status of individuals providing service to them, and to know which physician or other practitioner is primarily responsible for their care. This includes the patient's right to know of the existence of any professional relationship among individuals who are treating them, as well as the relationship to any other health care or educational institutions involved in their care.

- The patient has the right to be advised if the hospital proposes to engage in or perform human experimentation affecting the patient's care or treatment. Participation by patients in clinical training programs or in the gathering of data for research purposes shall be voluntary. The patient has the right to refuse to participate in such research projects.
- The patient has the right to expect reasonable continuity of care. The patient has the right to be informed by the attending physician of any continuing health care requirements following discharge.
- The patient has the right to receive an itemized, detailed, and understandable explanation of charges regardless of the source of payment and to be provided with information about financial assistance and billing and collections practices.
- The patient has the right to know what hospital rules and regulations apply to their conduct as a patient.
- Whenever possible, guardians or parents have the right to stay with their children 24 hours per day. Whenever possible, agents, guardians, reciprocal beneficiaries, or immediate family members have the right to stay with terminally ill patients 24 hours per day.
- A patient who does not speak or understand the predominant language of the community has a right to an interpreter if the language barrier presents a continuing problem to patient understanding of the care and treatment being provided. A patient who is hard of hearing has a right to an interpreter if the impairment presents a continuing problem to patient understanding of the care and treatments being provided.
- The patient has the right to receive professional assessment of pain and professional pain management.
- The patient has the right to be informed in writing of the availability of hospice services and the eligibility criteria for those services.
- The patient has the right to know the maximum patient census and the full-time equivalent numbers of registered nurses, licensed practical nurses, and licensed nursing assistants who provide direct care for each shift on the unit where the patient is receiving care.

In addition, a summary of the hospital's obligations under the Bill of Rights for Hospital Patients, written in clear language and in easily readable print, must be distributed to patients upon admission and posted conspicuously at each nurse's station. Such notice must also indicate that as an alternative or in addition to the hospital's complaint procedures, the patient may directly contact the licensing agency or the Board. The address and phone number of the licensing agency and Board must be included in the notice.

Does the Board have a policy on the termination of the physician-patient relationship?

The Board issued a policy statement in 1999 to provide clarification on the termination of the physician-patient relationship. Abandonment of a patient constitutes unprofessional conduct, and the Board has stated that when presented with a complaint of abandonment, the Board will consider:

- Whether the physician gave the patient timely notice of the termination (at least 30 days);
- Whether the physician provided necessary treatment for an existing problem and/or emergency care during the transition period (at least 30 days); and
- Whether the physician diligently transferred records to another physician chosen by the patient.

The notice of termination should be in writing and delivered to ensure that the patient receives the notice, and all records should be transferred promptly regardless of any outstanding bills. The policy statement can be found <u>here</u>.

Does the Board have a policy on the use of controlled substances for the treatment of pain?

In 2014, the Board adopted a Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, which updated a previous policy regarding the use of controlled substances for the treatment of pain. The policy can be found <u>here</u>.

This policy pertains only to the treatment of chronic pain. It largely follows the revised model policy of the Federation of State Medical Boards. It constitutes the Board's view as to how to best meet the standard of care when engaged in this aspect of medical practice. As noted in the document itself, the policy provides guidelines, but on its own, will not be the basis for an allegation of unprofessional conduct. See Policy at page 4. That being said, the guidelines, in part, reflect Vermont and federal laws and regulations. *Id*.

Therefore, any physician who treats chronic pain with controlled substances should be familiar with and follow these guidelines. These guidelines cover many pages and a complete review is not provided herein. Generally, the guidelines address responsibility for appropriate pain management, preventing opioid diversion and abuse, patient evaluation and risk stratification, development of a treatment plan, initiating an opioid trial, monitoring and adapting the treatment plan, consultation and referral, medical records, and compliance with other regulations. *Id.* In addition, in 2014, the Board has adopted a policy on the Drug Addiction Treatment Act of 2000 ("DATA 2000") and Treatment of Opioid Addiction in the Medical Office. The policy can be found here.

This policy provides guidelines addressing treating opioid addiction. It too largely follows the revised model policy of the Federation of State Medical Boards and constitutes the Board's view as to how to best meet the standard of care when engaged in this aspect of medical practice. It provides guidelines, but on its own, will not be the basis for an allegation of unprofessional conduct. See Policy at Page 4. Again, however, the guidelines, in part, reflect Vermont and federal laws and regulations. *Id.*

Therefore, any physician who treats opioid addiction should be familiar with and follow these guidelines. They cover many pages and a complete review is not provided herein. Generally, the guidelines address federal requirements for prescribing buprenorphine for addiction, prescription requirements, Board requirements, State of Vermont opioid addiction treatment programs and standards, physician qualifications, patient assessment, treatment planning, patient education, preventing and managing relapse, and medical records. *Id*.

When prescribing controlled substance, physicians should also be aware of the Vermont Department of Public Health Rule Governing the Prescribing of Opioids for Chronic Pain and the Vermont Prescription Monitoring System Rule. The rules can be found <u>here</u>.

Does the Board have a policy on the use of telemedicine technologies in the practice of medicine?

In 2015, the Board adopted a policy on the Appropriate Use of Telemedicine Technologies in the Practice of Medicine. The policy can be found <u>here</u>. It largely follows the model policy of the

Federation of State Medical Boards. The policy addresses how to determine when physicianpatient relationship is established, assuring privacy of patient data, guaranteeing proper evaluation and treatment of the patient, and limiting the prescribing and dispensing of certain medications. Generally, a physician using telemedicine technologies in the provision of medical services to a patient (whether existing or new) must take appropriate steps to establish the physician-patient relationship and conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation, and as required by Vermont law. See Policy at page 2. Any physician who uses telemedicine technologies should be familiar with this policy.

Does the Board have a policy on the treatment of Lyme disease and other tick-borne illness?

In 2014, the Board adopted a Lyme Policy Statement on the treatment of Lyme disease and other tick-borne illnesses. The policy can be found <u>here</u>. The policy provides that a health care professional licensed by the Board who diagnoses a patient as having Lyme disease, another tick-borne illness, or a related coinfection:

- Must document the basis for the diagnosis and the treatment for Lyme disease, other tickborne illness, or coinfection in the patient's medical record;
- Must provide information to assist patients' understanding of available Lyme disease tests, the meaning of a diagnostic Lyme disease test result, and any limitations to that test result; and
- Must obtain a patient's informed consent in writing prior to ordering or administering any proposed long-term treatment for Lyme disease, other tick-borne illness, or coinfection. The Board considers long-term treatment to be a planned course of treatment expected to extend for more than 28 days.

If a physician meets these requirements, the Board will not pursue disciplinary action solely for the use of medical care recognized by the guidelines of the Centers for Disease Control and Prevention, Infectious Diseases Society of America, or International Lyme and Associated Diseases Society for the treatment of a patient's symptoms when the patient is clinically diagnosed with Lyme disease or other tick-borne illness; however, this does not preclude discipline for errors, omissions, or other unprofessional conduct when practicing within such guidelines.

Does the Board have a policy on unprofessional conduct and COVID-19?

In 2021, the Board adopted a Position Statement on Unprofessional Conduct and COVID-19. The position statement can be found <u>here</u>. The position statement memorializes the Board's support for the Federation of State Medical Boards' July 29, 2021, position statement regarding COVID-19 vaccine misinformation. According to these position statements, licensees who generate or promote misinformation or disinformation about COVID-19 erode public trust in the medical profession and endanger the health of their patients and the public.

The Board's position statement "is not limited to vaccine misinformation and applies to all forms of unprofessional conduct, as defined by Vermont law." The Board's position statement clearly states that willful misstatements in practice and failure to meet the standard of care constitute unprofessional conduct whether they occur during the prevention or treatment of COVID-19 or any other condition.

COMPLAINT PROCESS

What kind of complaints does the Board investigate?

The Board investigates all complaints and charges of unprofessional conduct against any holder of a license or certificate, or any practitioner excepted from licensing requirements by 26 V.S.A. § 1313, and holds hearings to determine whether such charges are substantiated or unsubstantiated. 26 V.S.A. § 1353(2). Anyone wishing to make a complaint of unprofessional conduct against a professional regulated by the Board may file a written complaint with the Board. 26 V.S.A. § 1370(a); Board Rule 36.1.1. The Board can also open an investigation on its own initiative to evaluate instances of possible unprofessional conduct. 26 V.S.A. § 1370(b)(1); Board Rule 36.1.2.

Use of the Board's printed complaint form is preferred, but not required. If applicable, a complaint must include a release of medical records form. Relevant forms may be found <u>here</u>. A complaint must specify the grounds on which allegations of unprofessional conduct are based. Additionally, any hospital, clinic, community mental health center, or other health care institution in which a licensee performs professional services shall report to the Board as required by 26 V.S.A. § 1317, described above. A reporter who fails to make one of these mandatory reports could be subject to a civil penalty of not more than \$5,000, except that if they employ or grant privileges to five or more Board licensees, then they may be subject to a fine of not more than \$10,000.00. 26 V.S.A. § 1317(f).

In addition, by statute, *see* 26 V.S.A. § 1353, the Board has authority to undertake actions and procedures to carry out its duties, including, but not limited to the following:

- Issue subpoenas and administer oaths;
- Investigate complaints and charges of unprofessional conduct, hold hearings, and employ or contract with one or more hearing officers to schedule, oversee prehearing processes, preside over hearings, and assist with the preparation of reports and decisions;
- Take or cause depositions to be taken;
- Require a licensee or applicant to submit to a mental or physical examination, and an evaluation of medical knowledge and skill by individuals or entities designated by the Board if the Board has a reasonable basis to believe a licensee or applicant may be incompetent or unable to practice medicine with reasonable skill and safety;
- Investigate all complaints of illegal practice of medicine and refer any substantiated illegal practice of medicine to the Office of the Attorney General or the State's Attorney in the county in which the violation occurred;
- Inquire into the criminal history backgrounds of all applicants for licensure and biennial license review by inquiring directly of the Vermont Crime Information Center, the Federal Bureau of Investigation, the National Crime Information Center, or other holders of official criminal record information, including by arranging for these inquiries to be made by a commercial service. Each applicant shall consent to the release of criminal history records to the Board on forms developed by the Vermont Crime Information Center. Applicants or licensees shall bear the cost of obtaining a required criminal history background check.
- Inquire of the Vermont Department for Children and Families or of the Vermont Department of Disabilities, Aging, and Independent Living to determine whether any applicant, licensee, or holder of certification who may provide care or treatment to a child

or a vulnerable adult is listed on the Child Protection Registry or the vulnerable adult abuse, neglect, and exploitation registry.

How does the Board conduct its investigation?

As an initial matter, the Board will send the licensee, in this context referred to as the Respondent, a copy of the complaint, a copy of the release of medical records signed by the patient or other authorized person, a copy of the statutory definition of unprofessional conduct, and a standard letter stating that:

- The complaint has been lodged against them;
- The letter is not a notice of a formal hearing; and
- The Respondent must respond in writing, addressed to the Investigating Committee at the address of the Board and filed with the Board within 20 days of the date of the letter.

Board Rule 37.2.1.

A standing investigative committee or one specially appointed, and an assistant attorney general, will investigate each complaint and recommend disposition to the Board. Board Rule 38.1. Each committee consists of three or more Board members, including at least one public member. 26 V.S.A. §1370(b)(2). If there are an insufficient number of Board members to investigate a complaint by reason of disqualification, resignation, vacancy, or necessary absence, the Commissioner of Health may, at the request of the Board, appoint ad hoc members to serve on the investigative committee for that matter only. *Id.* The investigating committee is assisted by an investigator from the Board. Board Rule 38.1.

Any professional licensed by the Boards must cooperate with the investigation. While a Respondent can contest a subpoena, the failure to respond to a subpoena within a reasonable time, in the absence of a bona fide objection to the subpoena, constitutes a violation of Board Rules. Board Rule 38.2.1. Any professional licensed by the Boards must also not engage in any action that may deter a witness from cooperating with the Board, retaliate against any person based on the filing of a complaint, or destroy any evidence that is or may be pertinent to a Board investigation. Board Rule 38.2.2. Professionals are also prohibited from concealing, altering or destroying any evidence that is or may be pertinent to a Board investigation.

In addition, under certain circumstances, the Board, upon a request from the investigating committee, can suspend a license prior to the completion of an investigation. Grounds include misconduct that poses so grave a threat to the public health, safety, or welfare that emergency action must be taken, criminal convictions, and out-of-state discipline. Board Rule 39.

What happens when the Board finishes its investigation?

Once the investigating committee is satisfied that the investigation is complete, it must pursue one of three possible dispositions:

1. <u>Conclude the investigation</u>: When the investigating committee and assistant attorney general determine that the facts established by the investigation do not present cause for pursuing charges of unprofessional conduct, the committee may recommend the Board conclude its investigation. If approved by the Board, the case is closed with no further

action. A concluded investigation may be reopened if new evidence is received, a new and related complaint is made, or upon request for reconsideration. 40.1.1.

2. <u>Settlement</u>: When the investigating committee and Office of the Attorney General determine that the facts established by the investigation present cause for pursuing charges of unprofessional conduct, the committee must explore the possibility of stipulated settlements and consent orders, as established in a Stipulation. A Stipulation resolves the investigation without formal charges, known as a Specification of Charges. The Stipulation, which becomes public, can include terms and conditions on the licensee's ability to practice. A proposed Stipulation is not finalized until after it is accepted by the full Board, after notice to Respondent and an opportunity to be heard. The investigating committee may pursue Specification of Charges if the Board does not accept a proposed Stipulation within a reasonable time. Board Rule 40.1.2.

Recommended Stipulations generally include a concession of wrongdoing by the licensee, terms and conditions, an understanding that the concession may be relied on by the Board in case the licensee is later found to have engaged in unprofessional conduct, and an understanding that this final disposition of the complaint is public and that the Board shall notify the Federation of State Medical Boards Board Action Data Bank and the National Practitioner Data Bank, and may notify other states of its contents.

3. <u>Specification of Charges</u>: When the investigating committee and assistant attorney general determine that the facts established by the investigation present cause for pursuing charges of unprofessional conduct and the committee believes a settlement cannot be reached or is not warranted on the facts, the committee must recommend the filing of a Specification of Charges by the Office of the Attorney General signed by the Executive Director. Board Rule 40.1.3. The charges, which set out the allegations against the licensee, together with a notice of hearing, shall be served upon the Respondent. 26 V.S.A. § 1370(b)(3).

What happens once the Office of the Attorney General files a Specification of Charges?

The Board formally commences disciplinary proceedings by serving a Specification of Charges and a notice of hearing upon the Respondent. The hearing is scheduled no sooner than 30 days after service. 26 V.S.A. §1372(b)(1); Board Rule 41.2. The notice must specify the time and place of the hearing, and must tell the respondent that they may file a response within 20 days of service and state that the respondent has a right to appear at the hearing with counsel, produce their own witnesses and evidence, cross-examine witnesses testifying against them, and examine such documentary evidence as may be produced against them. 26 V.S.A. § 1372(b)(2).

A licensee who is notified that a specification of one or more charges of unprofessional conduct have been made against the individual in accordance with 26 V.S.A. § 1370(b)(3) shall be entitled to inspect and copy all information in possession of the Department of Health pertaining to the licensee, except:

- Investigatory files that have not resulted in charges of unprofessional conduct;
- Materials that constitute attorney work product; and

• Any other document or information that the Board has an obligation to protect from disclosure.

The Executive Director of the Board is required to notify licensees of the right to inspect and copy information. 26 V.S.A. §§ 1371(a)(2), 1372(b)(2).

If the Respondent does not respond to charges or appear at a hearing, after proper notice, the Board may take disciplinary action after hearing the evidence. Upon a written request by the Respondent and a showing of good cause, the Board must issue a written decision making a determination on whether to grant a new hearing. Board Rule 41.2.3; 41.2.4.

After a Specification of Charges has been filed, the Board, or its legal counsel on its behalf, has authority to conduct a prehearing conference or discovery conference and to issue orders regulating discovery and depositions, scheduling, motions by the parties, and such other matters as may be necessary to ensure orderly preparation for hearing. Board Rule 41.3; *see* 26 V.S.A. §§ 1353; 1372(b)(1).

Hearings before a hearing panel are conducted pursuant to statutory guidelines, including 26 V.S.A. § 1372, and the contested case provisions of the Administrative Procedure Act, 3 V.S.A. §§ 809-815. The Board may authorize its legal counsel to act as presiding officer at hearings and pre- and post-hearing conferences for the purpose of making procedural and evidentiary rulings. A presiding officer may administer oaths and affirmations, rule on offers of proof and receive relevant evidence, regulate the course of the hearing, convene and conduct prehearing conferences, dispose of procedural requests and similar matters, and take any other action authorized by the Administrative Procedure Act. Board Rule 41.4.

A hearing panel consists of three members of the Board, including at least one physician member and at least one public member, excluding Board members who participated in the investigation of the complaint. 26 V.S.A. § 1372(a)(1). A party may move to disqualify a member of a hearing panel due to a conflict of interest. *Id.* If there is an insufficient number of members to serve on a hearing panel by reason of disqualification, vacancy, or necessary absence, the Commissioner of Health may, at the request of the Board, appoint ad hoc members to serve on the hearing panel for that matter only. 26 V.S.A. § 1372(a)(2).

The burden of proof in a disciplinary action is on the State to show by a preponderance of the evidence that the person has engaged in unprofessional conduct. 26 V.S.A. § 1354(c).

Within 60 days after holding an evidentiary hearing, unless the Board grants an extension, the hearing panel shall provide a written report of its findings of fact and its recommendations to the full Board, with a transcript of the evidence. 26 V.S.A. § 1372(c).

If the Board deems it necessary, following receipt of the report of the hearing panel and after further notice to the individual complained against, the Board may take additional evidence at a hearing before the Board, which shall be constituted according to the same process as provided for the hearing panel. 26 V.S.A. § 1373(a). Five members of the Board, including at least one

physician member and at least one public member, shall constitute a quorum for the purposes of a hearing before the full Board. 26 V.S.A. § 1373(b)(1).

The Board shall render its decision on the merits of the charge or charges on the basis of the evidence in the record before it. 26 V.S.A. § 1374(a). This record may be based on the findings of the hearing panel alone, the findings of the hearing panel as supplemented by a hearing before the Board, or on the Board's own findings. *Id*.

If a majority of the members of the Board present and voting find that the individual complained against committed unprofessional conduct as specified in one or more of the charges, the Board shall prepare written findings of fact, conclusions, and an order, copies of which shall be served upon the individual complained against. 26 V.S.A. § 1374(b)(1). The hearing officer will prepare the written decision and order in accordance with the Board's instructions, within a reasonable time of the closing of the record in the case. Board Rule 41.5. If the Board finds the individual complained of not guilty of the charge or charges, or the charges against the individual are dismissed, the Board shall promptly order a dismissal of the charges and issue a statement that the charges were not proved. 26 V.S.A. § 1374(c).

DISCIPLINE

What are potential board actions for unprofessional conduct?

Physicians found guilty of unprofessional conduct either after a hearing or by entering into a Stipulation can face a range of actions that the Board determines proper, including but not limited to:

- Reprimands;
- Conditioning of license;
- Limiting of license;
- Suspension of license;
- Revocation of license; and
- Taking such other action relating to discipline or practice as the Board determines appropriate, including imposing an administrative penalty of not more than \$1,000.00 for each act that constitutes an unprofessional conduct violation.

See 26 V.S.A. § 1374(b)(1)(A).

Upon entry of an order taking disciplinary action, the Board opens a compliance investigation file assigned to the investigating committee responsible for the initial investigation of unprofessional conduct. The committee then makes recommendations to the Board regarding compliance, requests for reinstatement, or modification or removal of conditions established by the order. Board Rule 42.1.

A person licensed or certified by the Board who has been disciplined may petition at a later date for reinstatement or modification or removal of conditions. In addition to complying with any restrictions or conditions on reinstatement imposed by the Board in its disciplinary order, an applicant applying for reinstatement may be asked to complete a reinstatement application. An investigating committee will review such information and make a recommendation to the full Board. The Board may hold a hearing to determine whether reinstatement should be granted. Board Rule 42.2.

APPELLATE AVENUES

How does someone appeal a final order of the Board?

A party aggrieved by a final order of the Board may, within 30 days of the order, appeal that order to the Vermont Supreme Court on the basis of the record created before the Board. 26 V.S.A. § 1367; Board Rule 42.3.

PUBLIC ACCESS TO DISCIPLINARY AND LICENSING INFORMATION

What information about physicians is published by the Vermont Department of Health on the Department website?

Vermont requires the Department of Health to maintain a data repository and to publish profiles of all health care professionals licensed, certified or registered by the department. Physicians must provide and update any such requested information with the Department of Health. 26 V.S.A. § 1368. The Vermont Physician Profile for each licensee can be reached through a search located <u>here</u>. The profile is comprised of the following information provided by physicians:

- A description of any criminal convictions for felonies and serious misdemeanors, as determined by the commissioner of health, within the most recent 10 years. A person shall be deemed to be convicted of a crime if they pleaded guilty or was found or adjudged guilty by a court of competent jurisdiction.
- A description of any charges to which a health care professional pleads nolo contendere or where sufficient facts of guilt were found and the matter was continued without a finding by a court of competent jurisdiction.
- A description of any formal charges served, findings, conclusions, and orders of the licensing authority, and final disposition of matters by the courts within the most recent 10 years, and a summary of the final disposition of such matters indicating any charges that were dismissed and any charges resulting in a finding of unprofessional conduct.
- A description of any formal charges served by licensing authorities, findings, conclusions, and orders of such licensing authorities, and final disposition of matters by the courts in other states within the most recent 10 years.
- A description of revocation or involuntary restriction of hospital privileges for reasons related to competence or character that has been issued by the hospital's governing body or any other official of the hospital after procedural due process has been afforded, or the resignation from, or nonrenewal of, medical staff membership or the restriction of privileges at a hospital taken in lieu of, or in settlement of, a pending disciplinary case related to competence or character in that hospital. Only cases which have occurred within the most recent 10 years shall be disclosed by the Board to the public.
- All medical malpractice court judgments and all medical malpractice arbitration awards in which a payment is awarded to a complaining party during the last 10 years, and all settlements of medical malpractice claims in which a payment is made to a complaining party within the last 10 years. The following statement shall accompany information concerning all settlements: "Settlement of a claim may occur for a variety of reasons

which do not necessarily reflect negatively on the professional competence or conduct of the health care professional. A payment in settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred."

- The names of medical professional schools and dates of graduation.
- Graduate medical education.
- Specialty board certification.
- The number of years in practice.
- The names of the hospitals where the health care professional has privileges.
- Appointments to medical school or professional school faculties, and indication as to whether the health care professional has had a responsibility for teaching graduate medical education within the last 10 years.
- Information regarding publications in peer-reviewed medical literature within the last 10 years.
- Information regarding professional or community service activities and awards.
- The location of the health care professional's primary practice setting.
- The identification of any translating services that may be available at the health care professional's primary practice location.
- An indication of whether the health care professional participates in the Medicaid program and is currently accepting new patients.

The Department of Health must provide individual health care professionals with a copy of their profiles prior to the initial release to the public and each time a physician's profile is modified or amended. A health care professional must be provided a reasonable time to correct factual inaccuracies that appear in such profile, and may elect to have some items related to appointments, publications, and community service activities and awards omitted from disclosure, if this discretionary information was previously provided. 26 V.S.A. §1368(b).

What other information about physicians is available on the Internet?

Physician profiles, similar to those provided by the Vermont Department of Health, can be found on most state Medical Board web sites. These state web sites contain various information ranging from demographic profiles to malpractice settlements. In addition to the state funded profiles, many private organizations provide information about their members. Each individual organization should be contacted to correct any information. See also the section on the National Practitioner Data Bank.

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REPORTING & DISCLOSURE REQUIREMENTS

Topics Covered in this Chapter: <u>Reports of Abuse, Possible Criminal Activity or Potential Harm to Third Persons</u> <u>Reports of Specific Health Conditions or Treatments</u> <u>Reporting to the Department of Motor Vehicles</u> <u>Reports Relating to Licensed Health Care Providers and Facilities</u> <u>Disclosures Related to Identification of Patients and Deceased Patients</u> <u>Confidentiality of Health Care Records After Disclosure</u> <u>Enforcement Authority</u> <u>About the Authors</u>

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Vermont law requires or permits health care providers and other professionals to report or disclose particular health information to certain state or local government entities. This section of the Health Law Guide highlights these reporting or disclosure requirements.

REPORTS OF ABUSE, POSSIBLE CRIMINAL ACTIVITY OR POTENTIAL HARM TO THIRD PERSONS

How must information about the abuse of a vulnerable adult be reported and by whom?

A mandatory reporter who suspects, knows of, or has information relating to the abuse, neglect or exploitation of a vulnerable adult is required to report that information within forty-eight (48) hours to the Commissioner of the Department of Aging and Independent Living ("DAIL"). <u>33 V.S.A. §§ 6903, 6904</u>. A report may also be made to a law enforcement officer, if desired by the reporter.

Under the law, "mandatory reporters" include physicians, osteopaths, chiropractors, physician assistants, nurses, licensed nurse assistants, emergency medical services personnel, dentists, psychologists, hospitals, nursing homes, residential care homes, home health agencies, school administrators, teachers, other school employees, social workers, mental health professionals, and others. 33 V.S.A. § 6903.

A vulnerable adult is defined as a person who is eighteen (18) or older, and:

- Is a resident of a nursing home, psychiatric care hospital or psychiatric care unit within a hospital;
- Is receiving personal care services at home in excess of a month from a home health agency; or
- Regardless of residence or services received, has a disability or impairment and requires the assistance of others to meet their daily needs or to protect them from abuse, neglect or exploitation.

<u>33 V.S.A. § 6902(14).</u>

The report to the Commissioner of DAIL may be in writing or be made orally so long as it is followed within one week by a report in writing. The report must contain the following information:

- The name and address of the reporter, the vulnerable adult and persons responsible for their care;
- A description of the adult's age and disability; and
- The nature and extent of abuse, neglect, or exploitation together with any evidence of previous abuse, neglect, or exploitation of the vulnerable adult.

<u>33 V.S.A. § 6904</u>.

A penalty up to \$500 per violation may be imposed on any mandatory reporter who willfully fails to report as required by law. For purposes of the penalty provision, each 24-hour period that passes beyond the initial 48-hour period, during which the report was due, will constitute a separate violation and additional penalties may be imposed up to a maximum of \$5,000 for each reportable incident. <u>33 V.S.A. § 6913(b)</u>.

Anyone who makes a report in good faith under this statute will be immune from any civil or criminal liability for making the report. <u>33 V.S.A. § 6908</u>.

How must information about the abuse of a child be reported and by whom?

Under Vermont's child abuse reporting law, any mandatory reporter who has reasonable cause to believe that any child has been abused or neglected is required to make a report to the Commissioner of the Department of Children and Families ("DCF") within 24 hours of the time information regarding the suspected abuse or neglect was first received or observed. <u>33 V.S.A.</u> <u>§§ 4913, 4914</u>.

Mandatory reporters include physicians (including residents and interns), surgeons, osteopaths, chiropractors, physician assistants, hospital administrators, nurses, medical examiners, emergency medical personnel, dentists, psychologists, pharmacists, other health care providers, individuals employed by a school district (e.g., school administrators, teachers and other school employees), childcare workers, mental health professionals, social workers, probation officers, police officers, camp counselors and employees, clergy and others. <u>33 V.S.A. § 4913</u>.

The report to the Commissioner of DCF may be made orally or in writing. Oral reports must be followed up with a written report upon a request from DCF. The report must contain the following information:

- The name and address or other contact information of the reporter;
- The names and addresses of the child, the parents and/or others responsible for the child's care;
- The child's age (if known);
- The nature and extent of the injury and any evidence of abuse or neglect, current or previous, of the child or the child's sibling (s); and
- Any other information that might be helpful in establishing the cause of injuries or the reasons for the neglect.

<u>33 V.S.A. § 4914</u>.

A penalty up to \$500 will be imposed on any mandatory reporter who fails to report as required by law. A reporter who fails to report with intent to conceal abuse or neglect could face imprisonment for six (6) months and/or a fine up to \$1000. 33 V.S.A. § 4913.

Anyone, other than someone suspected of child abuse, who makes a report in good faith under this statute will be immune from any civil or criminal liability for making the report. <u>33 V.S.A.</u> <u>§ 4913(f)(1)</u>.

Can substance use disorder treatment information be disclosed in a report of abuse? Restrictions on disclosures of substance use disorder patient information, protected by <u>42 C.F.R.</u> <u>Part 2</u> (see Consent, Privacy and Medical Records: Subchapter Substance Use Disorder Diagnosis and Treatment Records do not apply to the *reporting* of incidents of suspected child abuse and neglect to the appropriate authorities. <u>42 C.F.R. § 2.12(c)(6)</u>. The Part 2 rules do not provide a similar exception for reporting the suspected abuse, neglect or exploitation of a vulnerable adult. Further, the Part 2 restrictions continue to apply to the original substance use disorder patient record, which may not be disclosed in other circumstances, including for disclosure and use in a civil or criminal proceeding arising out of the reported suspected child abuse or neglect, absent consent from the patient, an order of a court, or another applicable law authorizing the disclosure. <u>42 C.F.R. Part 2</u>.

How must information about gunshot wounds, or wounds from other firearms be reported? Every physician, hospital, or other institution attending or treating a case of a bullet wound, gunshot wound, powder burn, or other injury caused by the discharge of a gun, pistol or other firearm must report such case to local law enforcement officials or the state police, unless the injured person is a member of the armed forces and was on duty when the injury occurred. A penalty of up to \$100 will be imposed on anyone who fails to report as required by law. <u>13</u> <u>V.S.A. § 4012</u>.

Are health care providers required to report blood alcohol levels to law enforcement?

When a health care provider is treating a patient in the emergency room for injuries related to a motor vehicle accident, if the provider learns that the patient's blood alcohol level meets or exceeds the level prohibited by law, the provider must report that fact to law enforcement, as soon as reasonably possible. They must report to the law enforcement agency that has jurisdiction over the location where the accident occurred. A penalty up to \$500 will be imposed on anyone who fails to report as required by this law. Anyone who makes a report in good faith under this statute will be immune from any civil or criminal liability *for making the report*. 23 V.S.A. § 1203b.

When are pharmacists and providers required to report prescription records regarding dispensing of Schedule II, III and IV controlled substances?

The Vermont Prescription Monitoring System ("VPMS") is the Vermont Department of Health electronic database and reporting system for monitoring dispensed prescriptions of controlled substances. Reports to the VPMS must include information related to the patient, prescription, dispenser and prescriber. See <u>Vermont Prescription Monitoring System Rule</u>.

Pharmacies and prescribers (i.e., health care professionals licensed to prescribe controlled substances) that dispense Schedules II, III or IV controlled substances ("Controlled Substances") to their patients are required to report to the Vermont Prescription Monitoring System ("VPMS") each dispensed prescription for a Controlled Substance within twenty-four (24) hours or one (1) business day of dispensing the prescription. See <u>Vermont Prescription Monitoring System Rule</u>. Pharmacies and prescribers that dispense Controlled Substances must submit a "zero controlled substances report" on any day that no controlled substances are dispensed. See <u>Vermont Prescription Monitoring System Rule</u>.

Each pharmacy shall provide to every customer to whom a controlled substance is dispensed an advisory notice informing the customer that all prescriptions for Controlled Substances are entered into a statewide VPMS database in order to protect patients and the public. The notice, available on the Department of Health's website, must either be posted by the pharmacy in a prominent manner readily accessible to customers or duplicated in its entirety on a written insert for delivery to the patient. See <u>Vermont Prescription Monitoring System Rule</u> and see Vermont Department of Health VPMS Website.

Reporting to VPMS is not required when a drug is administered directly to a patient or dispensed by a health care provider at a facility licensed by the Department of Health, provided that the quantity dispensed at the facility is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours. A pharmacy that does not stock or dispense Controlled Substances may request an exemption from reporting from the VPMS program office. The exemption shall terminate when the pharmacy dispenses any controlled substance. See <u>Vermont Prescription Monitoring System Rule</u>.

See also the Vermont Guide to Health Care Law chapter entitled, "Consent, Privacy and Medical Records".

Are health care providers required to report information about crimes against minors?

Yes, physicians, dentists, chiropractors, and nurses are required to disclose information indicating that a patient who is under sixteen (16) has been the victim of a crime. Although the statute provides no further provisions, presumably this disclosure would be made to law enforcement or other entities authorized to request such information. <u>12 V.S.A. § 1612(b)</u>.

How must information about unusual or suspicious deaths be reported?

When a person dies in any of the following manners, any doctor notified of the death or the superintendent of a psychiatric hospital must immediately notify the medical examiner who resides nearest the town where the death occurred:

- By violence
- Suddenly when in apparent good health
- When unattended by a physician or a recognized practitioner of a well-established church
- By casualty
- By suicide
- As a result of injury
- When in jail or prison
- When in any psychiatric hospital

- In any unusual, unnatural, or suspicious manner, or
- In circumstances involving a hazard to public health, welfare, or safety.
- <u>18 V.S.A. § 5205(a).</u>

What information must be disclosed to a medical examiner?

A physician, dentist, chiropractor, mental health professional or nurse is required to produce information as to the mental or physical condition of a deceased individual if requested to do so by the chief medical examiner. <u>12 V.S.A. § 1612(c)(2)</u>. Any suspicious or unusual deaths should also be reported to the medical examiner, see list above. <u>18 V.S.A. § 5205(a)</u>.

Who must report possible cases of bioterrorism and what are the requirements for reporting?

Health care providers are required to report in writing within twenty-four (24) hours to the Commissioner of Health all cases of persons who exhibit any illness, disease, injury or death identified by the Department of Health as likely to be caused by a weapon of mass destruction, which may include illnesses, diseases, injuries or deaths which can result from bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins or which may be caused by specific biological agents. <u>13 V.S.A. § 3504</u>(a).

For purposes of this bioterrorism reporting, **out-of-state medical laboratories** that have agreed to the reporting requirements of Vermont are required to comply with the reporting requirements of health care providers. Results must be reported by the laboratory that performs the test, but an in-state laboratory that sends specimens to an out-of-state laboratory is also responsible for reporting results. <u>13 V.S.A. § 3504(e)</u>.

Similarly, **pharmacists** are required to report in writing within twenty-four (24) hours to the Commissioner of Health any unusual or increased prescription requests, unusual types of prescriptions, or unusual trends in pharmacy visits that may result from bioterrorist acts, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins, and might pose a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability. Prescription-related events that require a report include an unusual increase in the number of prescriptions to treat fever, respiratory or gastrointestinal complaints, an unusual increase in the number of prescription on over-the-counter pharmaceuticals to treat fever, respiratory or gastrointestinal complaints, and any prescription that treats a disease that is relatively uncommon and may be the result of bioterrorism. <u>13 V.S.A. § 3504(b)</u>.

In addition, veterinarians, livestock owners, veterinary diagnostic laboratory directors or other persons having the care of animals, are required to report within twenty-four (24) hours to the Commissioner of Health any animals having or suspected of having any disease that can result from bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins, and might pose a risk of a significant number of human and animal fatalities or incidents of permanent or long-term disability. <u>13 V.S.A. § 3504(d)</u>.

The reports required by this law must be made to the Commissioner of Health and, for reports of health care providers and pharmacists, must include all available information such as the patient's name, date of birth, sex, race and current address (including city and county), the name and address of the health care provider and of the reporting individual, if different. Reports from veterinarians

and others relating to animals must include all available information such as the location or suspected location of the animal, the name and address of any known owner, and the name and address of the reporting individual. <u>13 V.S.A. § 3504</u>. Health care providers who make good faith reports to the Department of Health under this law will be immune from prosecution, suit, administrative or regulatory sanctions for defamation, breach of confidentiality or privacy, or any other cause of action based on such reports or errors contained in such reports.

Do health care providers have a duty to report, or "warn," when patients threaten harm to identifiable individuals?

When a **mental health professional** knows or, based on the standards of the mental health profession, should know that a patient poses a serious risk of danger to an identifiable individual, the professional has a duty to exercise reasonable care to protect the identifiable victim from that danger even if it requires the disclosure of confidential patient information. <u>18 V.S.A. § 1882</u>. A "mental health professional" is defined under state law as physicians, psychologists, social workers, mental health counselors, nurses, and other qualified persons so designated by the Commissioner of Mental Health "with professional training, experience, and demonstrated competence in the treatment of mental illness...." <u>18 V.S.A. § 7101(13)</u>. In almost all instances, consultation with a colleague is advised to determine the most appropriate course of action given the conflicting duties imposed on the mental health professional.

The mental health professional's "duty to warn," as incorporated into statute in Vermont, evolved from case law in Vermont and other states and is an exception to the patient privilege of confidentiality. The duty to warn exception originated in California with the case of *Tarasoff v. Regents of the University of California*, 551 P.2d 334 (1976). In *Tarasoff*, a university hospital psychologist was told by his patient that the patient intended to kill a woman, Tatiana Tarasoff. Two months later, he did so. The Supreme Court of California ruled that the "public policy favoring protection of patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert danger to others." 551 P.2d at 347.

In *Peck v. Counseling Service of Addison County*, the Vermont Supreme Court adopted the *Tarasoff* ruling in a situation where a patient receiving mental health services threatened to burn his father's barn down. 146 Vt. 61 (1985). The Court held that if a mental health professional knows or should know that their patient poses a serious risk of danger to an identified person, the professional has a duty to take whatever steps are reasonably necessary to protect the identifiable victim from that danger, which could include reporting confidential patient information. The mental health professional has a duty to exercise due care in determining what steps may be necessary to protect the identifiable victim of a patient's threat of harm and what confidential information must be disclosed. The mental health professional must report confidential information discretely, and in a fashion that would preserve the privacy of the patient to the fullest extent compatible with the prevention of the threatened danger, ensuring that only that information which is necessary to protect the potential victim is revealed. *Peck*, 146 Vt. at 67-68, *citing Tarasoff*, 7 Cal.3d at 441. As noted above, the Vermont legislature has adopted the mental health professional's duty to warn as described in *Peck*. <u>18 V.S.A. § 1882</u>.

The duty to warn has been extended to situations beyond mental health including when a patient is incapacitated as a result of medical treatment or disease and the person poses an obvious risk of serious harm to others (e.g., the patient is taking medication that makes them drowsy and,

consequently, poses a danger to other drivers). In these situations, a health care provider may have a duty to warn reasonably identifiable potential victims or a duty to take action to avoid the harm.

In the 2019 case, *Lawson v. Halpern-Reiss and Central Vermont Medical Center*, the Vermont Supreme Court held that a nurse, who disclosed to a law enforcement officer that a patient who was intoxicated was recently discharged and likely to operate a motor vehicle, did not violate that patient's right to privacy, as disclosure was necessary and permissible to prevent imminent and serious harm to public health and safety. *Lawson v. Halpern-Reiss*, 210 Vt. 224 (2019).

How does the mental health professional's duty to warn relate to HIPAA Privacy and Security Rules requirements?

The HIPAA Privacy and Security Rules do not create a duty to warn or mandate disclosure. Rather, under the HIPAA Privacy and Security Rules, a covered entity is permitted to use and disclose protected health information – including psychotherapy notes – if the covered entity believes, in good faith, that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and the disclosure is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat. <u>45 C.F.R.</u> <u>§ 164.512(j)</u>.

A covered entity may also disclose protected health information if the covered entity believes, in good faith, that the use or disclosure is necessary for law enforcement to identify or apprehend an individual because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim, or where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody.

In the above situations, medical records and psychotherapy notes may be disclosed without authorization or consent of the patient. The disclosure must be made to a person or persons reasonably able to prevent or lessen the threat or to the target of the threat. The disclosure must be limited to the minimum amount of information necessary to prevent the harm from occurring.

REPORTS OF SPECIFIC HEALTH CONDITIONS OR TREATMENTS

What are the requirements for reporting communicable diseases?

A physician, health care provider, infection preventionist, administrator of a long-term care or assisted living facility, laboratory director, nurse practitioner, nurse, physician assistant, or school health official (collectively, "Reporters") who has reason to believe that a person is sick or has died of a diagnosed or suspected disease that has been identified by the Department of Health as a reportable disease and as dangerous to the public health shall report the diagnosis or suspicion within twenty-four (24) hours to the Department of Health.

The following diseases must be reported to the Department of Health immediately:

- Anthrax;
- Botulism;
- SARS-CoV-2 or COVID-19*;
- Diphtheria;
- Individuals cases of influenza due to a novel strain of Influenza A;

- Measles;
- Meningococcal Disease;
- Plague;
- Poliovirus infection, including poliomyelitis;
- Rabies Human (post-exposure is reportable irrespective of evidence of disease);
- SARS;
- Smallpox;
- Tularemia; or
- Viral Hemorrhagic Fever.

Reporters also are required to have policies and procedures in place, which meet a number of criteria set by rule, to ensure confidentiality of the reports. <u>18 V.S.A. §§ 1001</u> et seq.; also see <u>VDH Reportable and Communicable Diseases Rule</u> for a comprehensive list of reportable diseases.

* For more information on evolving COVID-19 reporting requirements, visit the VDH website: <u>https://www.healthvermont.gov/covid-19/health-care-professionals/health-care-professionals-guidance</u> (last accessed September 8, 2021)).

The reports are required to include the following information regarding the affected person:

- Name;
- Date of birth;
- Age;
- Sex;
- Address;
- Telephone number;
- Name of health care provider/physician;
- Address of health care provider/physician;
- Disease name;
- Date of onset of disease; and
- Any other pertinent information.

VDH Reportable and Communicable Diseases Rule, 5.2.

How must information about communicable diseases or laboratory findings be reported to the Vermont Department of Health ("VDH")?

Health care providers shall report a suspected or confirmed case of a reportable communicable disease by contacting the VDH Infectious Disease Epidemiology Program at 802-863-7240 or 800-640-4374 (within Vermont only) from 7:45 a.m. through 4:30 p.m. on business days. An epidemiologist is available 24/7 for diseases that require prompt public health follow-up. In addition, providers can fax paper reports to the Epidemiology Program's confidential fax machine at 802-951-4061.

Laboratories shall report reportable laboratory results electronically. The VDH accepts HL7 2.5.1 messages from facilities reporting laboratory findings (to connect to VDH, email <u>AHS.VDHELRSupport@vermont.gov</u>). Laboratories that are not ready to report electronically can

report using a lab report form that is faxed to the Infectious Disease Epidemiology Program at 802-951-4061.

An epidemiologist is available 24/7 at 802-863-7240 or 800-640-4374 (within Vermont only) for diseases that require immediate public health reporting.

Specimens or isolates of certain organisms must be sent to the Health Department Laboratory. Contact the Health Department Laboratory at 802-338-4724 or 800-660-9997 (within Vermont only) for information about how to submit cultures and specimens. <u>VDH Reportable and Communicable Diseases Rule</u>, 6.0.

What are the requirements for reporting diagnosis of HIV and AIDS?

HIV and AIDS are both reportable communicable diseases under Vermont law. Prior to performing an HIV test, health care providers must inform the individual to be tested that the provider is required to report a positive result and the individual's name to VDH. <u>18 V.S.A.</u> § 1001(g). The provider must also tell the patient that there are testing sites that provide anonymous testing that are not required to report positive results. AIDS and HIV reports should be made on VDH's confidential report form. VDH has established procedures to ensure the confidentiality of the reports it receives related to HIV and AIDS diagnoses. Except for the limited purpose of de-duplication of case records, VDH does not release information relating to HIV and AIDS without prior notice to and written authorization from the individual.

VDH has additional information about HIV/AIDS surveillance on its website at: <u>https://www.healthvermont.gov/immunizations-infectious-disease/hiv/surveillance</u> (last visited August 17, 2021).

What are the requirements for reporting emerging infectious diseases such as COVID-19 during and after a public health emergency?

During the COVID-19 pandemic, providers are required to report suspected cases immediately to VDH's Infectious Disease Epidemiology by calling 802-863-7240 (a 24-hour, 7 days per week hotline set up to address the pandemic specifically). More information is available here: https://www.healthvermont.gov/covid-19/health-care-professionals/health-care-professionals-guidance (last visited August 17, 2021).

Providers are urged to follow developments in COVID-19 reporting requirements and other future reporting requirements associated with infectious disease and public health emergencies.

How must information about a case of an animal bite or potential rabies be reported?

A physician is required to report to a local health officer the name, age and address of any person who has been bitten by an animal of a species subject to rabies within twenty-four (24) hours of notice of the bite. <u>VDH Reportable and Communicable Diseases Rule</u> 7.0 - 7.1.2.

How must information about immunizations be reported?

A health care provider must report to VDH all data regarding immunizations of children under the age of eighteen (18) within seven (7) days of the immunization. A health insurer must report to the VDH all data regarding immunizations of adults and of children under the age of eighteen (18) at least quarterly. In addition, reports of adult immunizations are required commencing within one

(1) month after the health care provider has established an electronic health records system. <u>18</u> V.S.A. § <u>1129</u>.

A health care provider with an electronic health record system must record vaccinations in the jurisdiction's immunization information system or vaccine registry as required by state and federal law. In Vermont, the provider must report vaccinations to the <u>Vermont Immunization Registry</u> ("IMR"). <u>18 V.S.A. § 1129</u>.

How must information about adverse reactions to vaccines be reported?

A health care provider is required to report certain adverse events related to administering vaccines to the <u>Vaccine Adverse Event Reporting System</u> ("VAERS"). VAERS is national database that is co-managed by the CDC and FDA track and analyze reports of adverse events and potential vaccine side-effects. Anyone can report an adverse vaccine event to VAERS, but health care providers are required to report certain adverse reactions (see the <u>VAERS Table of Reportable Events Following Vaccination</u> for a list of adverse events or reactions that must be reported by health care providers).

How must information regarding fetal deaths be reported?

Physicians, hospitals and funeral directors are required to report certain fetal deaths to the Commissioner of Health within seven (7) days for statistical purposes. <u>18 V.S.A. § 5222</u>.

Reportable fetal deaths are:

- All fetal deaths of twenty (20) or more weeks of gestation, or if gestational age is unknown, of 400 or more grams, fifteen (15) or more ounces, fetal weight shall be reported; or
- Fetal deaths which involve therapeutic or induced abortion regardless of length of gestation or size.

If the physician treating a woman for a miscarriage or abortion does not know whether the fetal death has been previously reported, the physician is required to report the death. If there is evidence of violence or other unusual or suspicious circumstances, the medical examiner shall be immediately notified and they shall complete the medical items on the report. The reports are not public records and shall be destroyed after five (5) years. <u>18 V.S.A. § 5222</u>.

What are the requirements for reporting cancer cases?

Health care facilities and health care providers diagnosing or providing treatment to patients with cancer are required to report each cancer case to the Commissioner of Health within 180 days of admission or diagnosis. Health care *providers* are not required to report if the patient has been previously diagnosed or admitted for treatment of cancer at a Vermont facility. <u>18 V.S.A. § 153</u>. If a health care facility fails to report a cancer diagnosis or admission, the Commissioner has the authority to enter the premises, obtain the information and report it, at the expense of the facility. Willful failure to grant access to records is punishable by a fine of up to \$500 for each day access is refused. 18 V.S.A. § 153.

Anyone who makes a good faith report in compliance with this law will not be subject to any action for damages. <u>18 V.S.A. § 156</u>.

Does Vermont allow mammogram results to be reported?

Vermont law permits the good faith submission of mammography and pathology data relating to breast cancer to the Vermont Mammography Registry. All information reported to the VMR is confidential and privileged. <u>18 V.S.A. § 157</u>.

Anyone who makes a good faith report in compliance with this law will not be subject to any action for damages. <u>18 V.S.A. § 156</u>.

Are providers required to notify patients of mammography reports regarding breast density?

As of January 15, 2017, women in Vermont must receive notification of their breast density classification in the summary of a mammography report. <u>18 V.S.A. § 158</u>. The law states that all health care facilities that perform mammography examinations must inform all women of their breast tissue classification based on the <u>Breast Imaging Reporting and Data System</u> ("ACR BI-RADS®") established by the American College of Radiology. If a woman has heterogeneously dense or extremely dense breasts, the report must also contain a notice explaining that dense breast tissue may make it more difficult to detect cancer on a mammogram and may be associated with a slightly increased risk of cancer. The notice must further state that the information is provided to raise awareness and encourage patients to discuss this issue with their health care providers. See <u>18 V.S.A. § 158</u> for the full requirement and notice language.

How must information regarding lead poisoning diagnoses be reported?

Any laboratory that analyzes blood samples of Vermont residents (including adults and children) for lead levels must report to VDH. All health care providers who analyze blood samples for lead levels or who use laboratories outside Vermont to analyze blood samples for lead levels must report to the Department immediately by telephone if the result of any analysis is forty-five (45) micrograms or more of lead per deciliter of blood, or by electronic means within fourteen (14) days of analysis if the result of the analysis is less than forty-five (45) micrograms of lead per deciliter of blood. All blood lead data reports to the Department must include: the name, date of birth, date of blood test, and address of the individual whose blood is analyzed and, if known, the owner of the residence of the individual. <u>18 V.S.A. § 1755(d)</u>.

How must information regarding involuntary hospitalizations be reported?

The head of the hospital must immediately provide notice to the parents, legal guardian, nearest known relative or interested party (if known), or spouse of an individual who has been involuntarily hospitalized due to a mental health related condition. If the hospital admission was not pursuant to court order, the head of the hospital must also notify the district court judge for the district where the hospital is located. If the hospital admission was pursuant to court order, the head of the hospital admission was pursuant to court order, the head of the hospital must immediately notify the court and the Commissioner of Mental Health of the admission and also of discharge. <u>18 V.S.A. § 7106</u>.

When an application for involuntary hospitalization is filed with a court, the court will transmit a copy of the application, the physician's certificate (if any) and a notice of hearing to the proposed patient, their attorney, guardian, or any person having custody and control of the proposed patient, the state's attorney, or the attorney general, and any other person the court believes has a concern for the proposed patient's welfare. <u>18 V.S.A. § 7613</u>. A copy of the notice of hearing shall also be transmitted to the applicant and certifying physician. If the court has reason to believe that notice to the proposed patient will be likely to cause injury to the proposed patient or others, it shall direct Vermont Guide to Health Care Law Page 243

the proposed patient's counsel to give the proposed patient oral notice prior to written notice under circumstances most likely to reduce likelihood of injury. <u>18 V.S.A. § 7613</u>.

REPORTING TO THE DEPARTMENT OF MOTOR VEHICLES

Are physicians obligated to report a patient to the Department of Motor Vehicles if the patient seems unfit to drive?

There is nothing in Vermont law that either authorizes or requires physicians to report drivers to the Department of Motor Vehicles ("DMV").

Federal HIPAA Privacy and Security Rules permit, but do not require, disclosure of a serious and imminent threat to the health or safety of a person or the public without authorization from the patient. <u>45 C.F.R. § 164.512(j</u>). The disclosure may only be made to someone who is able to prevent or lessen the threat and disclosure and must be based on a good faith belief that disclosure is necessary to prevent the threatened harm from occurring. Consistent with this, if a health care provider reasonably believes that a patient poses a serious and imminent threat to the health and safety of a person or the public by driving, the provider is permitted to disclose the threat to the DMV to prevent or lessen such a threat.

The American Medical Association ("AMA") provides physicians with ethical guidance about reporting patients who may be impaired drivers. The AMA explains that in deciding whether and how to intervene when a patient's medical condition may impair driving, physicians must balance the duty of confidentiality to their patient with the protection of public safety. The AMA advises physicians, within their areas of expertise to:

- Assess at-risk patients individually for medical conditions that might affect driving, using best professional judgment and keeping in mind that not all physical or mental impairments create an obligation to intervene.
- Before reporting, take initial steps, including a candid discussion with the patient and family and suggesting voluntary steps to improve or limit driving.
- Prior to reporting, physicians should disclose and explain to patients that they may have a responsibility to report a medically at-risk driver.
- Report only the minimal amount of information necessary.

AMA Code of Medical Ethical Opinion 8.2: Impaired Drivers and Their Physicians.

If any person has concerns about an individual's driving, including a doctor, family member, or neighbor, the Vermont DMV advises them to request, in writing, that a patient be reexamined by the DMV. See more information on the DMV Mature Driver website. A reexamination involves the evaluation of an individual by a DMV examiner and consists of a vision test and a driving test. A written test may be required depending on specific circumstances. Following the re examination, the examiner will decide whether any action should be taken regarding the individual's driving privilege, such as restrictions, suspension or revocation of a license or permit.

Reexamination requests can be sent to:

Vermont Department of Motor Vehicles 120 State Street

Montpelier, VT 05603-0001 Attention: DMV Commissioner's Office

The request must include the driver's name, date of birth, address, your name and contact information (address and phone number), your relationship to the driver, and specific reasons for requesting a re-examination (this must be specific and should include details of any personal observations).

See the Vermont DMV Mature Drivers Website: <u>https://dmv.vermont.gov/licenses/mature-drivers</u> (last visited August 17, 2021); Vermont DMV <u>Universal Medical Evaluation/Progress Report</u> and Driver Eyesight Evaluation.

REPORTS RELATING TO LICENSED HEALTH CARE PROVIDERS AND FACILITIES

How must information regarding a physician's unprofessional conduct be reported?

Any hospital, clinic, community mental health center or other health care institution in which a licensee performs professional services shall report to the Vermont Board of Medical Practice any reportable disciplinary action was taken by or its staff along with supporting information and evidence. A required report must be made within thirty (30) days following the date on which disciplinary action was taken or upon completion of an investigation or inquiry.

Reportable disciplinary action is based on one or more of the following:

- Acts or omissions of a licensee that relate to the licensee's fitness or competence to practice medicine under the license held.
- Acts or omissions of the licensee that constitute a violation of a law or rule that relates in any way to the practice of medicine.
- Acts or omissions of the licensee that occur in the course of practice and result in one or more of the following:
 - Resignation, leave of absence, termination, or nonrenewal of an employment relationship or contract.
 - This includes a licensee's own initiation of such action following notification to the licensee by the reporter that the reporter or an affiliated entity is conducting an investigation or inquiry regarding an event that, assuming the accuracy of the information or allegation, is likely to result in reportable disciplinary action.
 - The reporter or affiliated entity shall complete the investigation or inquiry even if the licensee initiates a resignation, leave of absence, termination, or nonrenewal, and shall make a report to the Board if the investigation results in a finding of a reportable disciplinary action.
 - Revocation, suspension, restriction, relinquishment, or nonrenewal of a right or privilege.
 - This includes a licensee's own initiation of such action following notification to the licensee by the reporter that the reporter or an affiliated entity is conducting an investigation or inquiry regarding an event that, assuming the accuracy of the information or allegation, is likely to result in reportable disciplinary action.

- The reporter or affiliated entity shall complete the investigation or inquiry even if the licensee initiates a resignation, leave of absence, termination, or nonrenewal, and shall make a report to the Board if the investigation results in a finding of a reportable disciplinary action.
- Written discipline that constitutes a censure, reprimand, or admonition, if it is the second or subsequent censure, reprimand, or admonition within a twelve (12) month period for the same or related acts or omissions that previously resulted in written censure, reprimand, or admonition.
 - The same or related acts or omissions includes similar behavior or behavior involving the same parties, or both.
 - Oral censure, oral reprimand, and oral admonition are not considered reportable disciplinary actions, and notation of an oral censure, oral reprimand, or oral admonition in a personnel or supervisor's file does not transform the action from oral to written.
- Fine or any other form of monetary penalty imposed as a form of discipline.
- Required education, remedial counseling, or monitoring that is imposed as a result of a completed, contested disciplinary process. This includes recommendation or referral for services from the Vermont Practitioner Recovery Network or from an employer wellness program or similar program, as a result of a completed, contested disciplinary process.

If reportable disciplinary action is reported to the Board based on the licensee's provision of mental health services, the Commissioner of Health shall forward the report to the Commissioners of Mental Health and Disabilities, Aging, and Independent Living. The report must include any supporting information and evidence. <u>26 V.S.A. § 1317</u>.

The reporting requirements of this law do not apply to cases of resignation or separation from service for reasons unrelated to disciplinary action. Resignations and leaves of absence that are entirely voluntary by the licensee, and terminations and nonrenewals of employment or contract by a required reporter that are not related to acts or omissions of the licensee, are not reportable disciplinary actions. Relinquishments of privileges that are entirely voluntary by the licensee, and revocations, nonrenewals, or other limitations on privileges by a required reporter that are not related to acts or omissions of the licensee, and revocations, nonrenewals, or other limitations on privileges by a required reporter that are not related to acts or omissions of the licensee, and revocations. <u>26 V.S.A.</u> <u>§ 1317</u>.

A reporter who violates this reporting requirement shall be subject to a civil penalty up to \$5,000; a provider who employs or grants privileges to five or more Medical Board licensees and violates this requirement could face a civil penalty up to \$10,000.

No one who makes a good faith report in compliance with this law will be liable for damages in any civil action. 26 V.S.A. § 1317.

How must unprofessional conduct information regarding a licensed health care provider other than a physician be reported?

Any hospital, clinic, community mental health center or other health care institution in which a licensed professional performs services shall report to the Vermont Office of Professional Regulation any disciplinary action that limits or conditions the licensee's privilege to practice or leads to suspension or expulsion from the institution. $3 V.S.A. \S 128(a)(1)$.

Reports are kept confidential and must be made within ten (10) days of the date of disciplinary action taken, regardless of whether the action is pending appeal. For licensees employed by or under contract with a community mental health center, a copy of the report must also be sent to the Commissioners of Mental Health and of Disabilities, Aging, and Independent Living. <u>3 V.S.A.</u> <u>§ 128(a)(2)</u>.

Reportable disciplinary action includes:

- Disciplinary or adverse action;
- Adverse action report to the National Practitioner Data Bank;
- An unexpected adverse outcome in care or treatment of a patient;
- Misconduct or allegations of misconduct ;
- The initiation or process of an action to limit, condition, or suspend a licensee's privilege to practice at an institution;
- An action to expel the licensee from an institution; or
- Any other action that could lead to one of the above-listed outcomes.

Disciplinary action does not include resignation, separation, or changes in privilege that are *not* related the above-listed outcomes. <u>3 V.S.A. § 128(a)(3)</u>.

Reports of any judgment or settlement involving professional negligence must be reported within thirty (30) days. <u>3 V.S.A. § 128(d)</u>.

A person who makes a good faith report shall not be held liable for civil action; however, violation of this statute may carry a civil penalty up to \$1,000. <u>3 V.S.A. § 128(e)</u>.

For more information, see the Office of Professional Regulations site: <u>https://sos.vermont.gov/opr/</u>.

Is reporting of medical errors or unsafe acts required?

Hospitals are required to report to VDH for the purposes of the Patient Safety Surveillance and Improvement System ("PSSIS") certain information relating to adverse events and intentional unsafe acts. Each hospital must establish an internal reporting system and develop and implement policies and procedures to identify, track, and analyze reportable adverse events, non-reportable adverse events, and near misses and use that data to improve patient safety. The reports must be submitted using the secure transmission system established by the Department for this purpose. The reportable adverse events are the serious reportable events and specifications as published by the National Quality Forum. The adverse event report must be filed within seven (7) calendar days of the discovery of the event, and a causal analysis and corrective action plan must be filed no later than sixty (60) calendar days after the initial report. Hospitals are required to disclose to patients, or in the case of death, to an immediate family member, adverse events that cause death or serious bodily injury. <u>18 V.S.A. §§ 1915, 1916, 1918</u>; Vermont Patient Safety Surveillance and Improvement System Regulation.

Reports of intentional unsafe acts must be filed no later than seven (7) calendar days after the information available to the hospital supports a reasonable, good faith belief that an intentional unsafe act has occurred. Intentional unsafe acts are defined as adverse events or near misses that result from criminal acts, purposefully unsafe acts, alcohol or substance abuse, or patient neglect, exploitation or abuse. The complete names of the involved in the intentional unsafe act must be

provided in the report to the PSSIS. <u>18 V.S.A. §§ 1915, 1916, 1918</u>; Patient Safety Surveillance and Improvement System Regulation.

All reports made to the Department under the PSSIS have strict confidentiality protections. They are confidential and privileged, exempt from disclosure as a public record and are not subject to discovery or introduction into evidence in civil or administrative proceedings.

DISCLOSURES RELATED TO IDENTIFICATION OF PATIENTS AND DECEASED PATIENTS

Are providers required to disclose information to identify patients?

Dentists are obligated to disclose information necessary for the identification of patients. It is presumed that the disclosure would be made to law enforcement or to a medical examiner or other entity authorized to request or receive the information. <u>12 V.S.A. § 1612(b)</u>.

Do health care providers have to disclose information on deceased patients?

Physicians, nurses, and chiropractors are required to disclose information as to the mental or physical condition of deceased patients in certain circumstances (e.g., a will contest) unless the information would be considered "to disgrace the memory of the decedent." In such circumstances, the privilege must be waived by either the decedent's personal representative, the surviving spouse of the decedent, or the next of kin of the decedent. In addition, physicians, dentists, chiropractors, mental health professionals, and nurses are required to produce information as to the mental or physical condition of a deceased patient if requested to do so by the chief medical examiner. 12 V.S.A. § 1612(c).

When can the government have access to health care records?

While there are a number of circumstances when government agencies are authorized to review health care records, including patient information or payment information, the following situations are of particular importance to health care providers and facilities:

- Under the federal Medicare program, access to patient information must be granted by a health care provider to the Secretary of the U.S. Department of Health and Human Services and/or representatives of the Centers of Medicare and Medicaid Services and others involved in enforcement of the requirements of federally funded health programs;
- When seeking to collect reimbursement for the care of a Medicaid beneficiary from a third party, the Department of Vermont Health Access is entitled to obtain any records of the treatment of any individual that are in any way relevant to the treatment paid for through Medicaid (<u>33 V.S.A. § 6705(b)</u>); and,
- As a condition of participation as a Medicaid provider in Vermont, health care providers must allow the State to review medical records at any time and without advanced notice. <u>Vermont Medicaid Provider Manual</u>, Section 7.2.1.

CONFIDENTIALITY OF HEALTH CARE RECORDS AFTER DISCLOSURE

What laws and rules govern how health care records are protected after disclosure?

After health care records have been received by the state agency as permitted or required by state law, the records are generally subject to statutory and regulatory provisions governing their use and further disclosure. These confidentiality provisions vary depending on the reporting requirement. For example, reports received by VDH under the patient safety statute ("PSSIS") are confidential and privileged, exempt from disclosure as a public record and are not subject to discovery or introduction into evidence in civil or administrative proceedings. Other statutes and regulations may have different requirements permitting or prohibiting further disclosure of the information by the state agency and many of the reports will be subject to the provisions of the HIPAA Privacy and Security Rules. Health care providers are encouraged to review the applicable statutes or regulations or the Consent, Privacy and Medical Records chapter of this Guide to Health Care Law in Vermont for further information about the variety of confidentiality provisions applicable to reports received by state agencies.

ENFORCEMENT AUTHORITY

What enforcement authority of the required reporting laws does the Department of Health have?

VDH works collaboratively with health care providers and facilities in public/private partnerships to educate providers and to make them aware of reporting requirements, and to resolve obstacles to implementation of public health requirements. However, the Department also has significant enforcement authority.

There are a number of specific enforcement provisions related to reporting requirements. For example, a fine of up to \$500 may be imposed on anyone failing to comply with the fetal death reporting requirements. <u>18 V.S.A. § 5225</u>.

Similarly, there are also enforcement provisions and authorizations to seek civil penalties related to willful, malicious and negligent disclosure of confidential communicable disease information. Negligent disclosures not authorized by law may be subject to a civil penalty of up to \$2,500. Penalties range from \$10,000 to \$25,000 and potential jail time for willful and malicious disclosure.

For further information about these enforcement provisions, health care providers can refer to the specific public health laws. *See e.g.*, 18 V.S.A. §§ <u>130</u>, <u>131</u> (general), § <u>1001</u> (communicable disease disclosure), § <u>1918</u> (patient safety reports), § <u>5225</u> (fetal death); and <u>26 V.S.A. § 1317</u>(e) (unprofessional conduct reports).

ABOUT THE AUTHORS

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REPRODUCTIVE HEALTH/RIGHTS

Topics Covered in this Chapter: <u>Statewide Health and Sexuality Education</u> <u>Access to Contraception</u> <u>Access to Abortion</u> <u>Non-Traditional Labor and Delivery Care</u> <u>Coverage for LGBTQ Patients</u> <u>Assisted Reproductive Technology (ART)</u> <u>About the Authors</u>

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STATEWIDE HEALTH AND SEXUALITY EDUCATION

Does Vermont require comprehensive sexuality education?

Not exactly, but schools are required to provide Comprehensive Health Education.

What is Comprehensive Health Education?

Comprehensive Health Education is defined as "systematic and extensive elementary and secondary educational programs designed to provide a variety of learning experiences based upon knowledge of the human organism as it functions within its environment." 16 V.S.A.§131. In general, the curriculum should include information about body structure and functioning, sexuality, reproduction, HIV and other sexually transmitted infections (STI), HIV and STI prevention, how to recognize sexual abuse and sexual violence, and promotion of healthy relationships. Curriculum must include "information regarding the possible outcomes of premature sexual activity, contraceptives, adolescent pregnancy, childbirth, adoption, and abortion."16 V.S.A.§131 (8).

Is the Health Education Curriculum Standardized?

No, not every student will have the same health education experience. In addition to a religious exemption, school boards are entitled to create an advisory council for interested community members; the advisory council is intended to represent various viewpoints while assisting the school board in curriculum development and implementation. 16 V.S.A §§131, 134, 135. For more information see: <u>http://education.vermont.gov/student-learning/content-areas/health-education</u>

ACCESS TO CONTRACEPTION

Are secondary schools required to provide free access to condoms?

Yes, school districts in Vermont are required to make condoms available to all students in their secondary schools, free of charge. 16 VSA §132.

If my patient has health insurance, what contraceptives are insurance required to cover?

Vermont law requires health insurance plans, including Medicaid and other public assistance programs to cover outpatient contraceptive services, including voluntary sterilization. Coverage includes the purchase of all FDA approved prescription contraceptives and contraceptive devices. 8 V.S.A §4099c.

How much of the cost are insurance companies required to cover?

Annually, an insurance company must provide complete coverage for a contraceptive device, voluntary sterilization, or one year's worth of prescription contraceptives. 8 V.S.A §4099c.

Are there exceptions to coverage?

Yes, there are two exceptions to insurance coverage of contraceptives:

- 1. If a patient is enrolled in an insurance program without prescription drug coverage, the insurance company is not required to cover the cost of prescription contraceptives or prescription contraceptive devices. 8 V.S.A §4099c(b)
- 2. If a patient with a high deductible insurance plan elects sterilization and insurance coverage of the procedure disqualifies the patient from eligibility for a health savings account under 26 U.S.C §223. 8 V.S.A §4099c(d).

Does contraceptive coverage apply only to the policyholder?

No. Contraceptive coverage applies to a policyholder, an insured partner (through marriage or civil union), and other insured dependents. 8 V.S.A §4099c(g).

Does contraceptive coverage apply to services beyond the tangible prescription, procedure, or device?

Yes. In addition to contraceptive prescriptions, devices, voluntary sterilization, and outpatient contraceptive services, insurance companies must cover parallel services including counseling and clinical services associated with access to and use of contraceptive devices, 8 V.S.A §4099c(c)(1), as well as related follow-up services, including management of side effects, counseling for continued adherence, and device insertion and removal. 8 V.S.A §4099c(e).

With regard to contraceptive coverage, is there anything Vermont law covers that the Affordable Care Act does not?

Yes, the Affordable Care Act only covers female prescription contraception and sterilization procedures, Vermont law is gender inclusive and requires insurance companies to provide coverage for voluntary male sterilization procedures (vasectomy). 8 V.S.A §4099c(d), 45 C.F.R §147.130(a)(I)(iv), https://www.healthcare.gov/coverage/birth-control-benefits/.

ACCESS TO ABORTION

Are there restrictions to abortion in Vermont?

No. In 1972, in *Beecham v. Leahy,* the Vermont Supreme Court clarified a woman's right to obtain a legal abortion in Vermont. Prior to *Beecham*, it was legal for a woman to get an abortion, but it was illegal for a doctor to provide an abortion. In *Beecham,* the Court struck down the criminal statute and held "that the legislature, having affirmed the right of a woman to abort, cannot simultaneously,... prohibit its safe exercise." 130 Vt.164, 170 (1972).
Abortion is recognized in Vermont law as a "fundamental right" and is legal without restriction, including without waiting periods, or mandated parental involvement. 18 V.S.A §9493(b). (For more information on minors and abortion can be found in the Minor Consent section of this guide.) Vermont law prohibits any "public entity" from denying or interfering with an individual's right to "choose or refuse contraception or sterilization or to choose to carry a pregnancy to term, to give birth to a child, or to obtain an abortion." 18 V.S.A §9494(a). The law also prohibits any prosecution of an individual that induces, performs or attempts to induce their own abortion. 18 V.S.A §9494(b). In addition, the law prohibits any "public entity" from depriving an individual the choice to terminate their pregnancy; interfering or restricting an individual's choice to terminate their pregnancy; and, or interfering with or prohibiting a qualified health care provider from terminating or assisting in the termination of a consenting patient's pregnancy. 18 V.S.A §9497. "Public entity" is defined to include all state and local government agencies, departments and elected officials. 18 V.S.A §9496 (2).

In 2019, the Vermont legislature began the long process of amending the Vermont Constitution to ensure that all Vermonters are afforded personal reproductive liberty. The proposed amendment was on the ballot of the general election in November 2022 and approved by a majority of Vermont voters. A new Article will now be added to the Vermont Constitution as follows:

Article 22. [Personal reproductive liberty]

That an individual's right to personal reproductive autonomy is central to the liberty and dignity to determine one's own life course and shall not be denied or infringed unless justified by a compelling State interest achieved by the least restrictive means.

With this amendment, Vermonters will continue to have the right to access abortion, unrestricted by the Vermont government, as they have since 1972.

What if my patient wants an abortion procedure or pill and I believe their choice is morally wrong?

Vermont law does not protect physicians or other medical providers' right to refuse to provide reproductive health care services because of moral or other beliefs. However, federal law, known as the Church Amendments, prohibits recipients of federal health care funds like Medicare, from discriminating against health care personnel who decline to perform or assist in the performance of abortions contrary to their religious or moral convictions. 42 U.S.C. § 300a-7(c)(1). Most hospitals and health care providers in Vermont receive federal health care funds and are therefore bound by the Church Amendments.

If I provide a patient with an abortion, do I need to notify anyone?

Yes. Hospitals, physicians, and funeral directors must report fetal death to the Commissioner of the department of public health within 7 days for all therapeutic or induced abortions legally preformed. Fetal death reports are used only for statistical purposes, are not public record, and information is destroyed after 5 years. 18 V.S.A §5222.

Do private insurance companies cover the cost of abortion services?

If a patient has private insurance, coverage of abortion services is dependent on their individual insurance plan. Unlike coverage of contraception, there is no state mandate for insurance companies to cover abortion services.

Does Medicaid cover the cost of abortion?

Federal Medicaid dollars are prohibited from funding an elective abortion through the Hyde Amendment. However, Vermont has no such prohibition on elective abortion coverage, therefore, a patient covered by Medicaid does qualify for Medicaid funded abortion services.

NON-TRADITIONAL LABOR AND DELIVERY CARE

Do my patients have options with regard to assistance for labor and delivery?

Yes. Health insurance plans that provide maternity benefits are required to provide coverage for a licensed midwife at no more cost to a consumer than similar labor and delivery benefits. 8 V.S.A §4099d.

Under this provision, if my patient wishes to give birth at home, can she?

Yes. Midwifery services can be provided at a hospital, health care facility, or in the home. 8 V.S.A §4099d.

COVERAGE FOR LGBTQ PATIENTS

If I have a patient seeking gender affirming medical services, are there barriers to treatment? Possibly. Insurance companies cannot unfairly discriminate against individuals because of their gender identity. Vermont law prohibits insurance companies from excluding coverage for medically necessary treatment, including gender affirmation surgery for gender dysphoria or related health conditions. 8 V.S.A §4724 See also Vermont Department of Financial Regulation, Insurance Bulletin 174, Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity Including Medically Necessary Gender Dysphoria Surgery and Related Health Care, at https://dfr.vermont.gov/reg-bul-ord/guidance-regarding-prohibited-discrimination-basis-genderidentity-including-medically. In addition, insurers may not deny coverage of gender affirmation surgery as not medically necessary on the basis of age without other clinical factors or circumstances supporting the decision.

However, under federal law, denial of Medicaid benefits for gender affirmation surgery and transgender health care has been found to not violate the equal protection clause of the 14th Amendment. *Casillas v. Daines*, 580 F.Supp 2d 235 (2008). See also the Guide Section, <u>Non-Discrimination in Health Care</u>. Therefore, patients covered under health care plans that are not regulated by Vermont law (ERISA, military, federal employees...) may not cover these services.

ASSISTED REPRODUCTIVE TECHNOLOGY (ART) LAW

Assisted reproductive technology (ART) law is both an emerging and evolving area of law, nationally and internationally. Unless otherwise stated, Vermont law applies to the scenarios described below. There are currently no internationally recognized ART laws and, in the United States, the approach to ART law is state-specific. *See* The United States Surrogacy Law Map: Vermont Guide to Health Care Law Page 254 State-by-State Gestational Surrogacy Law & Statutes,

<u>https://www.creativefamilyconnections.com/us-surrogacy-law-map/</u>. However, there are organizations whose members are dedicated to the highest ethical and quality standards of reproductive medicine and ART law including the American Society for Reproductive Medicine (ASRM), Academy of Adoption and Assisted Reproductive Technology Attorneys (AAAA), Society for Ethics in Egg Donation and Surrogacy (SEEDS).

The law regarding ART is still in a relatively early stage of development. In some states there is some, although little, case law. Some state legislatures have passed laws covering some aspects of ART; many states have virtually no law on the subject. Vermont has little if any law on any aspect of ART. Therefore, the information contained in this section is a general overview of the law throughout the United States. This information is not to be construed as legal advice and is provided for purposes of information only.

Does Vermont have laws regarding assisted reproduction?

Yes! On July 1, 2018, Vermont enacted the Vermont Parentage Act, 15C V.S.A. § 101 *et seq.*, which finally established laws for parentage by assisted reproduction and surrogacy in Vermont: <u>https://legislature.vermont.gov/statutes/title/15C</u>.

The Vermont Parentage Act provides legal security to individuals growing their families through surrogacy and other assisted reproductive technologies such as gamete donation or embryo donation. Intended parents can petition the probate court for a pre- and/or post-birth parentage order, declaring them as the parents of the child conceived and directing the Department of Health designate them as the parents of the child on the child's birth certificate.

Before the Vermont Parentage Act of 2018, Vermont was generally considered a "surrogacy friendly" state. However, no statute was in place to provide intended parents with the legal security of a pre-birth parentage order. Similarly, same-sex couples had to pursue second parent adoptions to secure their parentage.

The Act also provides legal security to the gestational carriers, gamete donors, and embryo donors who support family formation via ART. Parentage orders can declare that the gestational carrier, gamete donor, or embryo donor is <u>not</u> a parent of the child, thereby offering legal security from future claims of parentage, child support, or inheritance.

What qualifies as assisted reproduction under Vermont law?

Vermont law defines assisted reproduction as "a method of causing pregnancy other than sexual intercourse," including:

- intrauterine, intracervical, or vaginal insemination;
- gamete donation;
- embryo donation;
- in vitro fertilization and embryo transfer; and
- intracytoplasmic sperm injection.

15C V.S.A. §102(4). Parentage by assisted reproduction is governed by Chapter 7 of the Vermont Parentage Act, 15C V.S.A. §§ 701–709, and parentage by surrogacy is governed by Chapter 8, 15C V.S.A. §§ 801–809.

What is gamete donation and what is the legal status of the parties in a gamete donation?

Gamete donation is when a person (the gamete donor) contributes a gamete or gametes to another person (the intended parent) for assisted reproduction or gestation. 15C V.S.A. § 102(8). A gamete can be a sperm, an egg, or any part of a sperm or egg. § 102(9). The gamete donor is not a parent of the resulting child <u>unless</u> the gamete donor provided gametes to conceive a child with their spouse via ART, or the gamete donor has a written agreement with the person giving birth that the donor is intended to be a parent. § 702.

Gamete donors donate their genetic material voluntarily and without any intention of parenting, supporting, or claiming parentage to any resulting child or children. In other words, gamete donors do not intend to establish a legal relationship with any child or children conceived and born from embryos created with their donated gametes.

Gametes can be fresh or frozen, and gamete donors can be personally known or unknown to the intended parent(s). A known donor may be a friend or family member, or a person matched with the intended parents via a matching agency. Unknown donors generally come from cryobanks or egg donor banks, which are facilities that preserve and store gametes for future use and share non-identifying information about the donor (unknown donors may also choose to make identifying information available to intended parents and/or the child). As a result of the accessibility of DNA testing companies, the term "anonymous" is used less frequently for unknown donors who do not share any identifying information.

What is reciprocal IVF and what is the legal status of each party?

Reciprocal IVF is when one female partner ("Intended Parent 1") undergoes the egg retrieval and embryos are created with donor sperm, and the other female partner ("Intended Parent A") undergoes the embryo transfer to gestate their child. Intended Parent 1 is both a gamete donor and an intended parent of the child. § 702(b). If Intended Parent 1 is married to Intended Parent A at the time of the child's birth, Intended Parent 1 is also a presumed parent. § 401(a)(1). Intended Parent A is the birth parent and an intended parent of the child. § 902(a).

What is embryo donation and what is the legal status of the parties in an embryo donation?

Embryo donation is when a person (the embryo donor) contributes an embryo or embryos to another person (the intended parent) for assisted reproduction or gestation. 15C V.S.A. § 102(8). An embryo is defined as "a cell or group of cells containing a diploid complement of chromosomes or a group of such cells, not including a gamete, that has the potential to develop into a live born human being if transferred into the body of a person under conditions in which gestation may reasonably expected to occur." § 102(9). Embryo donation is not a form of adoption. The embryo donor is <u>not</u> a parent of the child <u>unless</u> the embryo donor provided embryo(s) to conceive a child via ART with their spouse, or the embryo donor has a written agreement with the person giving birth that the donor is intended to be a parent. § 702.

Like gamete donors, embryo donors donate their embryos voluntarily and without any intention of parenting, supporting, or claiming parentage to any resulting child or children. Embryo donors may also be known or unknown to the intended parent(s).

Can gamete and/or embryo donors receive compensation?

Consideration <u>does not in any way</u> constitute payment for or purchase of either genetic material or a child, or relinquishment of a child. Oocyte donors may (and usually do) receive compensation as a result of the risk and complexity of the medical procedures associated with egg donation. Compensation should not vary based on the number or the quality of the oocytes, and should not unduly entice a donor to an extent that the compensation negatively impacts her ability to weigh the risk involved. See American Society for Reproductive Medicine, *Financial Compensation of Oocyte Donors: An Ethic's Committee Opinion*, Fertility and Sterility, Vol. 116, No. 2, 319–324 (Aug. 2021). Sperm donors may receive a nominal amount but are more likely are simply reimbursed for their out-of-pocket expenses associated with their donation (e.g., gas, parking, and tolls to drive to clinic). Embryo donors do not receive any compensation. Rather, intended parents become responsible for the storage costs for the embryos.

Why is it important for the parties to have written gamete or embryo donor agreement?

In addition to the medical and psychological components and potential issues involved in gamete and embryo donation, it is important for the parties to understand the legal issues and have a written agreement prepared and negotiated with independent legal counsel. The parties' agreement sets forth their intentions including an intended parent's status as the child's legal parents and a donor's status as a donor and not a parent of the child.

Gamete and embryo donation agreements also require a unique balance of interests, rights, and duties of each party as well as the interests and rights of the resulting child. In April 2019, ASRM issued an Ethics Committee opinion discussing some of these issues, including:

- levels of information sharing (basic to comprehensive)
- donor's duty to provide medical updates when appropriate
- donor identity disclosure and future contact
- notice regarding outcome of the donation
- repeated donations

American Society for Reproductive Medicine, *Interests, Obligations, and Rights in Gamete and Embryo Donation: An Ethics Committee Opinion*, Fertility and Sterility, Vol. 111, No. 4, 664–670 (April 2019).

In Vermont, do couples using assisted reproduction need to go through the process of a second parent adoption?

No. Under the Vermont Parentage Act, couples can petition the probate court for a pre- and/or post-birth order and judgment of parentage, declaring them as the legal and intended parents of their child conceived via assisted reproduction. The process is simpler and less intrusive than a second parent adoption. For example, a parentage petition generally involves filing a verified petition, a copy of the parents' donor contract, copies of their birth certificates (and marriage certificate, if applicable), and a filing fee. If the parents pursued a second parent adoption instead, the second parent would need to go through an unnecessarily longer and more rigorous

procedure including a criminal background check, a home study (unless waived upon request), and requesting an interim custody order while the adoption is pending.

What is the difference between gestational surrogacy and traditional surrogacy?

In a gestational surrogacy, the surrogate gestates an embryo created using gametes that are not the surrogate's own. In a traditional surrogacy, the surrogate gestates an embryo created using her eggs and sperm from the intended parent or sperm donor.

Can gestational carriers receive compensation?

Yes, under a valid gestational carrier agreement in Vermont, a gestational carrier may receive payment of consideration and reasonable expenses. § 802(d). However, not all gestational carriers elect to receive compensation. Currently, compensation rates generally range from \$30,000-\$40,000 for first-time carriers and \$35,000-\$45,000 for experienced carriers.

What makes a gestational carrier agreement enforceable in Vermont?

It is important that the parties retain independent legal counsel experienced in ART law, especially as ART law continues to evolve nationally and internationally.

In Vermont, the parties must first meet the eligibility requirements set forth in § 801. Then, their gestational carrier agreement must meet the requirements set forth in § 802(b).

The eligibility requirements include:

- all parties must be at least 21-years old
- all parties must complete a medical evaluation and mental health consultation
- the gestational carrier cannot contribute gametes that will result in an embryo that she will attempt to carrier to term (unless the gestational carrier is a family member)
- all parties must have independent legal representation of their own choosing
- the intended parents must pay for the gestational carrier's attorney's fees

The gestational carrier agreement requirements include:

- in writing and signed by all parties, each before at least one witness
- executed before the start of any medical procedures (except the medical evaluations required to be eligible to enter into a gestational carrier agreement)
- cannot require more than one-year to achieve pregnancy
- at least one party is a resident of Vermont
- if any party is married, that party's spouse is a party to the agreement
- includes a written acknowledgment having received a copy of the agreement
- includes written declaration by legal counsel that the agreement is in compliance with the Vermont Parentage Act
- other express provisions regarding each party's rights, responsibilities, and duties under the Vermont Parentage Act

§§ 801, 802(b).

Can family members qualify as gamete donors and/or gestational carriers?

Familial gamete donors and gestational carriers are considered generally ethically acceptable, except that additional screening and care is recommended to ensure each party is fully informed and counseled and entering into the arrangement voluntarily and without coercion. It is also recommended that intergenerational arrangements be given special attention and that additional research be done on the long-term impacts of intrafamilial reproduction on those involved and the resulting child(ren). American Society for Reproductive Medicine, <u>Using family members as gamete donors or gestational carriers</u>, Fertility and Sterility, Vol. 107, No. 5, 1136 (May 2017).

What happens if there is a laboratory error regarding the child conceived and born via surrogacy or other assisted reproductive technologies?

If there is a laboratory error, the intended parents are the parents of the child unless otherwise determined by a court of competent jurisdiction. §§ 102(14), 709.

What happens to cryopreserved gametes and/or embryos in a divorce?

Under Vermont law, all property owned by either or both parties is subject to jurisdiction of and equitable distribution by the family court. Title to the property is immaterial (i.e. whether the property is in both spouses' names or just one spouse), except where the court can make an equitable distribution without disturbing separate property. 15 V.S.A. § 751(a). Therefore, cryopreserved gametes and/or embryos will be subject to jurisdiction of the Vermont family court but, absent an agreement between the spouses, the outcome is otherwise unknown.

While there is no Vermont statute or Vermont Supreme Court case law specifically on the issue of frozen gametes/embryos as marital property, it is becoming an increasingly litigated issue throughout the country. However, the Vermont Parentage Act does address the effect of divorce on the legal parentage of a child conceived by assisted reproduction.

Generally, courts have held that frozen embryos are property or "special property" in a divorce and taken approaches to embryo disputes in divorce often categorized as follows: (1) a contractual approach (enforcing fertility clinic contracts), (2) a balancing approach (weighing parties' competing interests, such as a sterile spouse who has survived cancer and wants to build a family versus a divorcing spouse who does not want to become a parent or to have their genetic material used without their consent), and (3) a mutual consent approach (requiring parties' contemporaneous mutual consent for use or disposition).

In Vermont, if a marriage is dissolved before the transfer or implantation of gametes or embryos, the former spouse is not a parent unless otherwise consented in a signed record. The former spouse's consent may be withdrawn in a signed record and with notice to the person giving birth and any other intended parent. § 706.

What legal and ethical issues are raised in posthumous reproduction?

Posthumous reproduction occurs when a person's genetic material is used to procreate after their death. This can happen in a variety of ways, and the resulting children are generally referred to as posthumously conceived children.

While still alive and capable of consent, the person can choose to have their gametes frozen and stored for later use. They can also choose to have their gametes, and gametes of a spouse or a known or unknown donor, used to create embryos for their family formation plan. This may also be done by persons about to undergo chemotherapy or other medical treatment that could cause sterility and, to a lesser extent, by some armed services members prior to deployment. Should the individual then die while on active duty, the gametes are available, usually to a spouse or partner, for use in ART procedures.

In Vermont, a person's death does not preclude the establishment of their parentage of their child conceived by assisted reproduction if the intended parent died between the gamete or embryo transfer and the child's birth, and that person intended to be the parent under Vermont law. 15C V.S.A. § 707(a). However, if that person dies before the transfer or implantation of gametes or embryos, the deceased person is not a parent unless the deceased person consented to parentage in a record, or the deceased person's intent to be an intended parent of the child is established by a preponderance of the evidence; provided, however, that the embryo is in utero within 36 months' after the person's death or the child was born no later than 45 months after the person's death. § 707(b).

Another form of posthumous reproduction is more controversial and involves the harvesting of sperm from an already deceased man, usually at the request of a partner or spouse, for the purpose of using the sperm to procreate. Some hospitals will perform this procedure, which must be done within a short time after death; medical literature suggests 72 hours. Many hospitals refuse to do this, citing the inability of the deceased to consent to the procedure and to the subsequent reproduction. There have been some cases in which someone other than a spouse, e.g., parents of the deceased, have made the request. Posthumous reproduction involving the removal of eggs from a deceased woman is uncommonly rare since harvesting immature eggs would be medically useless. However, advances in medical capabilities may allow the harvesting of ovarian tissue, which under certain medical circumstances, could produce mature eggs for use in reproductive procedures.

Posthumous reproduction can raise complex legal and ethical issues. Unlike a divorcing spouse involved in a gamete or embryo disposition dispute in family court, a genetic contributing decedent is not available to participate in such a dispute. Even if a decedent left a clear expression of their intent regarding the use of their genetic material upon death, their expressed intent may not be enough. For example, the decedent may have executed consent documents with his spouse and the fertility clinic in State A, later executed estate planning documents in State B with provisions that contradict the clinic's forms from State A, and then died in State C where there is no statutory or case law addressing posthumous reproduction.

Additionally, children who are born as a result of these forms of posthumous reproduction must sometimes fight to be recognized as the legitimate offspring of the deceased for purposes of government benefits such as Social Security, life insurance, and estate purposes.

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RISK MANAGEMENT

- Topics Covered in this Chapter: What is risk management? Risk Management Guidance Medical Records: Documentation of Patient Care Biopsy Specimen Send Outs Closing Your Practice Diagnostic Test Tracking Systems Appointment Management Informed Consent When Patients Hit Record Social Media Risks in Healthcare Mobile Devices in Healthcare Termination of the Physician-Patient Relationship About the Authors
- By: Lou Anne McLeod Medical Mutual Insurance Company of Maine Risk Management

WHAT IS RISK MANAGEMENT?

Risk management is the process of identifying and mitigating risk. Clinical risk management improves quality of care by identifying circumstances that put patients at risk and implementing solutions. Each healthcare team member has a role to play in the risk management process. Whether it is a physician writing a medication order, a pharmacist dispensing the medication, or the nurse administering the medication, each team member plays a part in that medication getting safely to the patient.

The risk management process has matured over time. While the traditional risk management model consisted of risk identification and analysis, risk control and financing, and claims management, the process is evolving to an Enterprise Risk Management (ERM) model. Enterprise risk management (ERM) is a broad-based interdisciplinary process through which an organization identifies, analyzes, prioritizes, and addresses risks and opportunities that affect its strategic objectives. Enterprise Risk Management was first implemented in the financial sector and has spread to other industries, including healthcare.

ERM encompasses clinical risk management and expands the program to include all aspects of the organization. Categories of risk are often referred to as domains. The American Society for Healthcare Risk Management (ASHRM) identifies eight domains: Operational, Financial, Human Capital, Strategic, Legal/Regulatory, Technology, Hazard, and Clinical/Patient Safety. In evaluating potential or actual risk, the impact on all domains is assessed.

RISK MANAGEMENT GUIDANCE

Healthcare providers occasionally need guidance in determining the best approach to a risk concern. When patients refuse to follow a suggested treatment plan, are disruptive, or lodge a significant complaint, obtaining outside assistance can be helpful.

Providers who are part of a healthcare system should contact their system risk manager for direction. Independent providers can contact their medical professional liability carrier. Most carriers offer risk management consultative services to assist their clients in risk reduction.

Medical Mutual Insurance Company of Maine (MMIC) provides direct risk management support to its insureds. The following are frequent topics addressed by MMIC risk management consultants. Access Medical Mutual Insurance Company of Maine's complete online library of Practice Tips at <u>Medical Mutual Insurance Company of Maine</u>

Complete Medical Records: Your Best Defense

In medical malpractice litigation, the defense of claims frequently rests on the quality of the patient care documentation. By the time a claim goes to trial, it can be many years after the patient was treated. Because memories fade, objective, timely, and complete documentation is your best defense. To a jury, the documentation quality equates to the quality of the patient care provided.

The legal record is generally the information used by the patient care team to make decisions about the treatment of a patient. The elements that constitute an organization's legal health record vary depending on how the organization defines its legal record but must explicitly identify the sources and location of the individually identifiable data that it includes. The legal record is typically used when responding to formal requests for information for evidentiary purposes.

Excellent documentation supports medical decision-making and serves as a communication tool for all care team members. It will justify reimbursement from third-party payers, protect against allegations of medical malpractice, and meet statutory, regulatory, and professional requirements for clinical and business purposes.

The guiding principles for documentation of patient care can be found at <u>Complete Medical</u> <u>Records: Your Best Defense (medicalmutual.com)</u>

Biopsy Specimen

Delay in cancer diagnosis is one of the leading causes of professional liability claims associated with mismanaging biopsy specimens in the office practice setting. Factors contributing to these claims are:

- Mislabeling of the specimen(s).
- Failure to track receipt of the results.
- Failure to notify the patient in a timely manner of the biopsy results.
- Failure to provide treatment planning options, including appropriate specialty referral.
- Failure to document the biopsy results management and treatment plan in the patient's medical record.

Recommendations for improving biopsy specimen management in the office practice setting can be found at <u>Biopsy Specimen (medicalmutual.com)</u>

Closing Your Practice: Retirement - Relocation - Selling your practice

Circumstances may lead a physician to end their current practice arrangement. Providing notice in a timely manner promotes continuity of patient care, avoids allegations of abandonment, and fulfills contractual and regulatory obligations. When feasible, begin planning your departure years in advance.

Key areas to be addressed can be found at <u>Closing Your Practice – Retirement - Relocation -</u> <u>Selling your practice (medicalmutual.com)</u>

Results Management

Failure to diagnose is one of the most frequent allegations in malpractice claims. A direct relationship exists between this allegation and the lack of a comprehensive, reliable test/consult tracking system. Juries believe that if a test or consultation is important enough for a physician to order, it is important enough to ensure the results are received.

A reliable test/consult tracking system should include:

- Tracking of results of ordered labs, diagnostic tests, and consultations.
- Follow-up with the patient if results are not received.
- Physician review of results and development of the treatment plan.
- Notifying the patient of the results and communicating the treatment plan.
- Determining the patient's understanding of results and the treatment plan.
- Tracking patient completion of the treatment plan.

A comprehensive, reliable test/consult tracking system must be established, adhered to, and monitored routinely for system failures. Find the steps in the process at <u>Results Management</u> (medicalmutual.com)

Appointment Management

Managing patient appointments and referrals is an essential function of any office practice. A poorly managed appointment process risks patient safety, continuity of care, and the practice's financial well-being.

Practices should determine their appointment management and referral system. Once the process has been defined, a policy should be written. All staff members involved in the process should receive education on the steps and the importance of these steps to assure patient safety and the practice's financial stability.

Appointment and referral management is key to providing safe patient care. Find out more about the process at <u>Appointment Management (medicalmutual.com)</u>

Informed Consent Guidelines

Informed consent should be obtained for all major therapeutic, diagnostic, and invasive procedures/treatments to be completed in the hospital, surgery center, or physician's

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office. Informed consent is a process whereby the patient is informed of the risks and benefits of a potential procedure/treatment and gives consent to proceed. It is the physician's responsibility to obtain informed consent from their patient. Hospital or office staff may assist in obtaining consent documentation according to the organization's policies and procedures. A signature on a form is not sufficient to demonstrate a patient's informed consent.

To improve your understanding of the informed consent process, access this tip at <u>Informed</u> <u>Consent Guidelines (medicalmutual.com)</u>

When Patients Hit Record in Healthcare

As technology advances, you may have more patients record their visits with or without your knowledge. Your first reaction may be to prohibit patients from recording any visit, but there is supporting evidence that it can be beneficial for recall and compliance. Since this is a growing issue, consider having a video/audio recording policy in the healthcare setting. This tip will help you identify your state laws regarding consent requirements and things to consider when developing a plan.

To review the complete tip on patients recording in healthcare, go to <u>When Patients Hit Record</u> in the <u>Healthcare Setting (medicalmutual.com)</u>

Social Media Risks in Healthcare

Social media has become a part of daily life for most people and many businesses. While healthcare organizations can benefit from a well-designed social media presence, they must also be aware of healthcare providers' unique risks when engaging in the online world. Being aware of these risks and planning to address them can help reduce patient privacy violations and reputational harm.

To learn more about the risks of social media and how to protect yourself, go to <u>Social Media</u> <u>Risks in Healthcare (medicalmutual.com)</u>

Mobile Devices

Mobile devices are widespread, and accessing patient health information through one is fast and convenient. However, without proper safety measures, mobile devices present a risk to the security of protected health information. If personal devices transmit or receive protected health information, a secure HIPAA compliant messaging platform must be installed on the staff member's device.

Learn more about the steps you should take to access and address your mobile device risks at Mobile Devices (medicalmutual.com)

Termination of the Physician/Patient Relationship

A physician's improper termination of the physician-patient relationship may put the physician at risk for a claim of abandonment. Consideration should be given to the following:

• Evaluate whether all options have been exercised to salvage the relationship. Don't act hastily in making a decision.

- For "patient noncompliance," facilitate a face-to-face conversation with the patient to communicate expectations. Allow the patient to voice their understanding and expectations. Clarify any misunderstandings or misperceptions. Facilitate a mutual agreement to a plan and provide the patient with a copy of the written agreement.
- Review the documentation in the patient record to determine if the documentation supports the decision to terminate the relationship.
- Review managed care contracts to determine if the relationship with the patient can be terminated.
- If the patient is in a protected class or disabled, consult an attorney to determine if the termination is prohibited.

To review the complete tip on termination of the physician/patient relationship, go to <u>Termination of Physician-Patient Relationship (medicalmutual.com)</u>

ABOUT THE AUTHORS

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WORKERS' COMPENSATION

Topics Covered in this Chapter: <u>Navigating Workers' Compensation in Vermont</u> <u>The Workers' Compensation Act: General Considerations for Medical Providers</u> <u>Workers' Compensation Issues When Treating a Patient Injured at Work</u> <u>Special Rules Relating to Opioid Medication</u> <u>Prescribing of Opioids for Chronic Pain</u> <u>Medical Marijuana</u> <u>Resources</u> About the Authors

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NAVIGATING WORKERS' COMPENSATION IN VERMONT

Vermont first adopted a no-fault workers' compensation insurance program in 1915, with the passage of Act No. 164, "An act relating to compensation to employees for personal injury." At that time, quarries, factories, and other physical labor comprised the majority of the state's workforce and the legislation was viewed as a "grand compromise between labor and management." The new law provided injured workers with access to prompt medical attention and wage replacement benefits for work-related injuries and, in exchange, granted employers immunity from personal injury civil lawsuits stemming from those workplace injuries. More than 100 years later, the core principles of the Workers' Compensation Act remain the same.

Once an employee is injured or claims they were injured at work, whether by a discrete incident or a gradual onset type injury, and the employer receives notice of the injury, the employer or insurance carrier must notify the Department of Labor's Workers' Compensation Division of the injury within 72 hours. This sets in motion a series of deadlines for the employer and the employer's insurance carrier, and a set of rules, which must be met in the adjusting of the claim. Many of these deadlines and rules may intersect with the function of medical providers who find themselves treating an injured worker.

For the casual practitioner in the realm of workers' compensation, it can be a complicated system to navigate. This article seeks to give medical providers treating patients with work injuries a basic understanding of the Act and important rules, caselaw, and deadlines that apply to treating providers.

THE WORKERS' COMPENSATION ACT: GENERAL CONSIDERATIONS FOR MEDICAL PROVIDERS

The first step in any Vermont workers' compensation matter is the filing of a First Report of Injury (Form 1) by the employer or the insurance carrier/third-party administrator (collectively hereinafter "carrier"). This form, which provides basic information about the injury, employee, and employer, is filed even if the employer or carrier disputes the facts of the injury or the relationship to the injured worker's work.

The employer and carrier can then either accept the claim of injury or exercise their right to a 21day investigatory period to determine whether they will accept or deny the claim. This determination is typically made on the basis of the injured worker's statement, employer's and/or carrier's investigation of the alleged injury and the workplace in which it occurred, and medical evidence. Notably, when an injury occurs, the employer/carrier is entitled to all medical records relating not just to the injury, but also all prior medical records relating to the same body part or condition and will contact medical providers to obtain these records. If the claim is denied, the carrier will not pay either indemnity benefits or medical expenses for the injury, but the injured employee can appeal this decision with the Workers' Compensation Division, which will adjudicate the dispute. If the Department finds the injury compensable following such an appeal, it will order the carrier to retroactively begin paying benefits to the injured worker.

The Vermont Department of Labor also allows payment of a workers' compensation claim on a "without prejudice" basis. However, the employer or carrier must notify the Department of Labor and the injured worker of its election to pay any portion of the claim, including specific medical treatment, on a without prejudice basis. If an employer or carrier elects to pay a claim, or any portion thereof, on a without prejudice basis, the employer or carrier must deny the claim within 90 days of making a without prejudice payment. If the claim is not denied within 90 days of making a without prejudice payment, the claim will be deemed accepted by the employer or carrier/administrator.

When presented with a new claim of injury, the employer or carrier has the right to designate a health care facility and/or provider to initially treat an injured worker for a claimed work-related injury. 21 V.S.A. §640(b). At any time after the initial treatment, the injured worker can transfer their care to another health care provider by filing a Notice of Intent to Change Health Care Provider (Form 8).

Medical providers make some of the most important determinations in workers' compensation claims, including whether an injured worker has a work capacity. Injured workers tend to recover faster from work injuries if they remain engaged in the workplace and feel that the employer is invested in having them return to the workplace. If an injured worker has a partial work capacity, they may return to work on a light or reduced duty basis. Most employers are willing to work to find or create a job that meets an injured worker's physical and temporal limitations during the period of recovery in order to keep the employee engaged. Medical providers should keep this in mind and, rather than thinking strictly about the injured worker's typical job assignment, should complete work capability forms that indicate whether there are other physical activities the injured worker could still perform during the period of recovery.

Independent medical examinations figure heavily into workers' compensation claims. While an injured worker is receiving benefits under the Workers' Compensation Act, the employer/carrier has the right to schedule the injured worker for independent medical examinations at reasonable intervals and with due regard for the injured worker's schedule and ability to travel. Independent medical examinations must be scheduled with a medical provider within a two-hour driving radius of the injured worker's home. However the Commissioner of the Department of Labor has the discretion to order an independent medical examination outside the two-hour driving radius if the injured worker consent and/or if the injured worker's condition warrants the specialized expertise of a more remotely located provider. In practice, the Commissioner rarely grants permission to send an injured worker to a provider more than two hours away unless the injured worker consents.

An employer/carrier must give the injured employee and their attorney at least seven days' notice prior to the date of the scheduled examination and must provide a copy of the examiner's COVID-19 protocols. If an injured worker does not plan to attend the independent medical examination, they must notify the employer or carrier of their plan not to attend at least three days prior to the scheduled examination. The injured worker also has a right to make a video or audio recording of an independent medical examination, as long as they provide notice to the carrier at least three days prior to the examination. The carrier will in turn notify the examiner that the injured worker is exercising this right. The examiner can of course refuse to conduct the examination due to video recording. The examiner cannot create their own video recording of the examination but can create an audio recording as long as the examiner notifies the injured worker before the examination that they will be doing so.

WORKERS' COMPENSATION ISSUES WHEN TREATING A PATIENT INJURED AT WORK

Types of Injuries

There is a basic definition in the Vermont Workers' Compensation and Occupational Disease Rules (hereinafter "the Rules") of what is considered by the Department to be an injury. Under Rule 2.2600, "injury" means any harmful work-related change in the body, whether occurring instantaneously or gradually, and includes a claimed or apparent injury or disease. The term also includes damage to and the cost of replacement of prosthetic devices, hearing aids and eyeglasses when the damage or need for replacement arises out of and in the course of employment. 21 V.S.A. §601(7). Depending on the circumstances, the term "injury" also includes "aggravation," "flare-up" or "recurrence" as those terms are defined in Rules 2.1200, 2.2300 and 2.3900.

The Rules discuss four basic types of injuries in detail, although not every injury will fall into one of these special groupings. The four groupings are: 1) first aid only injuries, 2) recurrences, 3) aggravations, and 4) flare ups. Whether an injury is an aggravation, recurrence, or flare-up is a commonly litigated issue. The outcome of an aggravation/recurrence/ flare-up analysis, in a case involving multiple employers, will determine who will be held responsible for benefit payments. In cases of causation not involving multiple employers it will determine whether there is a responsible employer or whether there is a non-work related cause.

The first type of injury is the "first aid only" injury, defined in Rule 2.2200 as "an injury for which the injured worker loses no time from work (except for the time, not exceeding one day of

work, related to medical treatment and recovery), and which requires only one treatment that generates a bill for less than \$750.00." *See also* 21 V.S.A. §640(e). Even though these injuries require limited medical treatment at the time, they can evolve into much greater injuries over time and therefore employers are required to report these injuries fully by completion of a Form 1 First Report of Injury.

The determination of whether an injury is an aggravation vs. recurrence vs. flare-up is one of the more complex and heavily litigated analyses in workers' compensation claims due to the fact that it is often determinative of which amongst several employers or carriers is liable for paying the claim. A recurrence is defined in Rule 2.3900 as "the return of symptoms following a temporary remission." An aggravation is defined in Rule 2.1200 as "an acceleration of exacerbation of a pre-existing condition caused by some intervening event or events." A flare-up is defined by Rule 2.2300 as "a temporary worsening of a pre-existing condition caused by a new injury for which a new employer or insurance carrier is responsible, but only until the condition returns to baseline and not thereafter."

The Department will consider five factors in order to determine which category an injury falls under: Whether a subsequent incident or work condition has destabilized a previously stable condition; whether the injured worker had stopped treating medically for the earlier condition; whether the injured worker had successfully returned to work for the earlier condition; whether the injured worker had reached medical end result for the earlier condition; and whether the subsequent work contributed independently to the final disability. If all of these factors are met, then the Department will most likely consider the injury to be an aggravation. If only some of these factors are met, the Department will consider each matter on a case-by-case basis

Reasonable Medical Care

Another aspect of workers' compensation claims that is frequently litigated is whether a particular treatment is appropriate or compensable. Treatment that an injured worker receives for a work injury will only be a compensable part of the workers' compensation claim if it is "reasonable medical treatment." Reasonable medical treatment is defined under Rule 2.3800 as "treatment that is both medically necessary and offered for a condition that is causally related to a compensable work injury." A determination of whether a treatment is reasonable will be based primarily on evidence establishing "the likelihood that it will improve the patient's condition, either by relieving symptoms and/or by maintaining or increasing functional abilities." *See also* 21 V.S.A. §601(27), defining "medically necessary care."

Preauthorization Request Guidelines

Oftentimes when there is doubt about whether a carrier will cover a particular treatment, a medical provider or the injured worker's attorney, if represented, will complete a preauthorization request prior to moving forward with treatment. This is optional and not a requirement under the Workers' Compensation Act, as the statute states that a provider or injured worker "may submit a request to an employer or insurance carrier that a proposed medical treatment or diagnostic procedure to be preauthorized." 21 V.S.A. §640b The request must be in writing and must be accompanied by documentation supporting both the medical necessity of the proposed treatment or procedure and its causal relationship to the injured worker's compensable injury or condition. This documentation should include relevant medical records. The request also must clearly delineate the extent of any treatment or diagnostic procedure proposed, in terms

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of amount, duration, and frequency. While no specific form is required for a preauthorization request, the Department of Labor provides one <u>here</u>.

When a preauthorization request is received, the employer or carrier has 14 days from the receipt of both the request for preauthorization and the supporting medical documentation within which to respond. 21 V.S.A. §640b(a). The employer/carrier can respond in one of three ways: 1) By authorizing the proposed treatment or diagnostic procedure. 21 V.S.A. §640b(a)(1). Once authorized, the employer or insurance carrier shall be obligated to pay all appropriately billed charges related to the proposed treatment or diagnostic procedure in accordance with Rule 40.000. 2) By denying the proposed treatment or diagnostic procedure on one or more of the following grounds: That the preauthorization request was not accompanied by the required supporting documentation; That compensability of the injury or condition for which the treatment or diagnostic procedure (a) is not medically necessary and/or (b) is not causally related to the injured worker's compensable injury or condition; or 4) By ordering a medical record review and/or scheduling an independent medical examination for the purpose of determining whether the proposed treatment or diagnostic procedure is medically necessary and causally related to the injured worker's compensable injury or condition.

When an employer/carrier responds to a preauthorization request by ordering a medical records review and/or scheduling an independent medical examination, it has 45 days following the receipt of the preauthorization and supporting medical documentation in which to either approve or deny the preauthorization request. This means that the employer/carrier must receive the records review or IME report within that 45 day window in order to make their determination. In limited instances the employer/carrier may be able to receive an extension of up to 10 days from the Commissioner, but only upon a showing of extremely unusual and/or emergency circumstances. 21 V.S.A. § 640b (a)(3). Alternatively, if both parties agree in writing an extension of ten or more days may be granted for any reason, provided the time period within which to respond is clearly and specifically stated.

Should the employer/carrier fail to respond to the preauthorization request either within the initial 14-day window or complete the records review or IME within the 45-day period of records reviews or IMEs, either the injured worker or the treating medical provider may request that the Commissioner issue an interim order authorizing the treatment or diagnostic procedure by operation of law. 21 V.S.A. § 640b(b).

There are two matters that do not qualify for preauthorization requests, and they are as follows: 1) A demand that the charges for a treatment or diagnostic procedure already undertaken, including prescription medications already purchased, be paid; 2) A request that the charges for medical supplies, including special clothing, footwear or equipment, but excluding prescription medications proposed as a course of treatment, be paid or reimbursement.

³ This defense shall not be available to an employer or carrier against whom an interim order to pay benefits has been issued. 21 V.S.A. 640b(a)(2)(A).

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Medical End Result

Much in workers' compensation claims turns upon the injured worker reaching "medical end result," "end medical result," or "maximum medical improvement"—terms which are often used interchangeably. End medical result is defined as "the point at which a person has reached a substantial plateau in the medical recovery process, such that significant further improvement is not expected, regardless of treatment. A finding of medical end result triggers other activity in a workers' compensation claim, including a permanent impairment rating, a discontinuance of temporary indemnity benefits, and sometimes a return to work or vocational rehabilitation, if a work capacity/work release was not already provided during the recovery period. Medical end result will also often lead to a discontinuance of medical treatment (or at least the carrier's liability for medical treatment) other than ongoing palliative care. Under Rule 2.3400, palliative care is defined as "medical services rendered to reduce or moderate temporarily the intensity of an otherwise stable medical condition" but not "medical services rendered to diagnose, heal or permanently alleviate or eliminate a medical condition."

Medical Case Management

Carriers are allowed to assign medical case managers to files under Rule 2.2900. Medical case management is defined as "the planning and coordination of health care services appropriate to achieve the goal of medical rehabilitation. Medical case management may include medical case assessment, including personal interview with the injured worker, assistance in developing, implementing and coordinating a medical care plan with health care providers in consultation with the injured worker and his or her family, and evaluation of treatment results."

Permanent Partial Impairment – How It Is Calculated

Following a finding of medical end result, the treating provider may be asked to rate the injured worker's permanent impairment. If the treating provider does not perform ratings, the injured worker and carrier will discuss finding an alternative medical provider to examine the injured worker and perform a rating. For non-psychological injuries, the Workers' Compensation Act require the physician to use the AMA 5th Guides to rate any permanent partial impairment. Rule 10.1300. For psychological injuries, the physician is required to use the AMA 6th Guides. Rule 10.1310.

The impairment rating is then used by the carrier to calculate the amount of permanent impairment benefits due to the injured worker. Any non-spine rating is multiplied by 405 to determine the number of weeks of benefits to which an injured worker is entitled for that injury; this figure is then multiplied by the injured worker's weekly compensation rate. The same formula is used for spine ratings, the only difference being that the multiplier used for spine ratings is 550 rather than 405.

SPECIAL RULES RELATING TO OPIOID MEDICATION

It is well recognized in the medical, legal, and insurance professions that the over-prescribing of opioids has created a crisis in American society. This crisis is visible in Vermont workers' compensation claims as well, where opioid medications are often prescribed long-term for chronic pain, particularly back pain. Many states, including Vermont, have responded by putting forth rules that seek to begin addressing this crisis. At the same time, medical marijuana has become a hot topic around the country. Vermont has legalized medical marijuana, but until

recently also explicitly stated that workers' compensation carriers are not obligated to pay for medical marijuana, even if it found to be reasonable medical treatment. The current status of medical marijuana as medical treatment in Vermont is uncertain, as detailed later in the article.

Vermont's new rules addressing the prescription of opioids went into effect on November 1, 2016. These track the Vermont Department of Health's *Rule Governing the Prescribing of Opioids for Chronic Pain* that was promulgated by the Department of Health as best practices. Failure of a medical provider treating an injured worker to comply with the best practices creates a rebuttable presumption on behalf of the carrier, allowing the carrier to deny or discontinue payment for opioid medications prescribed to treat an injured worker's chronic pain. These new workers' compensation rules can be found at Rule 11.1400 and 12.1720, which follow in their entirety:

11.1400 - Denying payment for opioid medications. A medical provider who prescribes opioid medications to an injured worker for chronic pain resulting from a compensable workrelated injury must comply in all respects with the Rule Governing the Prescribing of Opioids for Chronic Pain, as currently promulgated at 4A Code of Vermont Rules 13 140 076 (2015) and as amended from time to time by the Vermont Department of Health. If credible evidence establishes that he or she has failed to do so, a rebuttable presumption shall arise that the medications, as prescribed, do not constitute reasonable medical treatment. If the employer or insurance carrier seeks to deny payment on those grounds, it shall file a Denial of Workers' Compensation Benefits (Form 2) with the Commissioner and the injured worker, and shall comply in all respects with the requirements of this Rule 11.0000. In addition, it shall notify the prescribing provider of the specific basis for its determination that he or she has failed to comply with the above-referenced Vermont Department of Health rule. Thereafter, the injured worker shall have the burden of proving that the treatment is reasonable, notwithstanding the prescribing provider's failure to comply. In any event, the Commissioner shall not approve a proposed discontinuance under this Rule unless credible medical evidence establishes that the effective date thereof comports with a safe taper plan. 21 V.S.A. §640c.

12.1720 - If the proposed discontinuance pertains to narcotic or other medications for which a safe taper plan is medically necessary, the employer or insurance carrier shall provide credible medical evidence establishing that the date of its proposed discontinuance comports with such a plan. 12.1730 A medical provider who prescribes opioid medications to an injured worker for chronic pain resulting from a compensable work-related injury must comply in all respects with the Rule Governing the Prescribing of Opioids for Chronic Pain, as currently promulgated at 4A Code of Vermont Rules 13 140 076 (2015) and as amended from time to time by the Vermont Department of Health. If credible evidence establishes that he or she has failed to do so, a rebuttable presumption shall arise that the medications, as prescribed, do not constitute reasonable medical treatment. If the employer or insurance carrier proposes to discontinue payment on those grounds, it shall file an Employer's Notice of Intention to Discontinue Payments (Form 27) with the Commissioner and the injured worker, and shall comply in all respects with the requirements of this Rule 12.0000. In addition, it shall notify the prescribing provider of the specific basis for its determination that he or she has failed to comply with the above-referenced Department of Health rule. Thereafter, the injured worker shall have the burden of proving that the treatment is

reasonable, notwithstanding the prescribing provider's failure to comply. In any event, the Commissioner shall not approve a proposed discontinuance under this Rule unless credible medical evidence establishes that the effective date thereof comports with a safe taper plan as required by Rule 12.1720. 21 V.S.A. §640c

The Department of Health's *Rule Governing the Prescribing of Opioids for Chronic Pain* can be difficult to locate online and is copied here for ease of reference.

13 140 076. Prescribing of Opioids for Chronic Pain

Section 1.0 - Authority

This rule is adopted pursuant to Act No. 75 of the Acts of the 2013 Sess. (2013) (An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse), Sections 14(e) and 11(e).

Section 2.0 - Purpose

This rule provides legal requirements for the appropriate use of opioids in treating chronic pain in order to minimize opportunities for misuse, abuse, and diversion, and optimize prevention of addiction and overdose.

Section 3.0 - Definitions

3.1 - "Abuse" means a maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed. (Federation of State Medical Boards)

3.2 - "Abuse-deterrent opioid" means an opioid analgesic medicine determined by the U.S. Food and Drug Administration (FDA) to be expected to result in a meaningful reduction in abuse. These properties may be obtained by : (i) Physical/Chemical barriers that prevent chewing, crushing, cutting, grating, or grinding or chemical barriers that resist extraction using common solvents like water; (ii) Antagonist/Agonist drugs that interfere with, reduce, or defeat the euphoria associated with abuse; (iii) Aversion where substances can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used; (iv) Delivery Systems where drug release designs or the method of drug delivery can offer resistance to abuse; (v) Prodrugs where a formulation lacks opioid activity until transformed in the gastrointestinal system; or (vi) a combination of any of the above methods.

3.3 - "Addiction" means a primary, chronic, neurobiological disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm or risk of harm. (Federation of State Medical Boards)

3.2 - "Chronic Pain" means pain caused by various diseases or abnormal conditions and that continues longer than 90 days. For the purposes of this rule, chronic pain does not include pain from cancer or pain experienced during hospice or end-of-life care.

3.3 - "Controlled Substance" means a drug, other substance, or immediate precursor, included in Schedules II, III, or IV of the federal Controlled Substances Act (CSA).

3.4 - "Controlled Substance Treatment Agreement" means a document that is signed and agreed upon by both the prescriber and the patient, acknowledging the rights and responsibilities of being on and prescribing controlled substances, and the treatment expectations.

3.5 - "Diversion" means the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution including, but not limited to, the sharing or purchasing of drugs between family and friends or individual theft from family and friends. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances.

3.6 - "Functional Status Examination" means an examination used to describe an individual's ability to perform key daily activities and to evaluate changes in the activities of everyday life. It encompasses physical, social, and psychological domains, and covers outcomes from baseline functions through death.

3.7 - "High Risk" means a patient at increased risk for misuse, abuse, diversion, addiction, overdose, or other aberrant behaviors as determined by the patient's history and/or the risk assessment tool chosen by the provider.

3.8 - "MED" means Morphine Equivalent Daily Dose.

3.9 - "Prescriber" means a licensed health care professional with the authority to prescribe controlled substances.

3.10 - "Misuse" means the use of a medication (with therapeutic intent) other than as directed or as indicated whether willful or unintentional, and whether harm results or not.

3.11 - "OTP" means an Opioid Treatment Program as defined and regulated by federal regulation 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing of OTP's (1301.72). OTP's are specialty addiction treatment programs for dispensing opioid-replacement medication including methadone and buprenorphine under carefully controlled and observed conditions. In Vermont, OTP's are sometimes referred to as "Hubs".

3.12 - "Risk Assessment" means a process for predicting a patient's likelihood of misusing or abusing opioids in order to develop and document a level of monitoring for that patient. An example of a screening tool is the Screener and Opioid Assessment for Patients with Pain (SOAPP), but prescribers can use any evidence-based screening tool.

Section 4.0 - Screening, Evaluation, and Risk Assessment

4.1 - The prescriber shall conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record when prescribing opioids for chronic pain.

4.2 - The prescriber shall document in the patient's medical record any diagnoses which support the use of opioids for relief of chronic pain.

4.3 - The prescriber shall evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of opioids prior to writing an opioid prescription for chronic pain. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.11 of this rule.

Examples of risk assessment screening tools are available on the Department of Health website.

Section 5.0 - Prescribing Opioids for Chronic Pain

5.1 - Prior to prescribing an opioid for the treatment of chronic pain, the prescriber shall consider and document in the patient's medical record:

5.1.1 - Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments, have been considered;

5.1.2 - Trial use of the opioid;

5.1.3 - Any applicable requirements to query the Vermont Prescription Monitoring System;

5.1.4 - That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone from an OTP or prescribed and taken any other controlled substance. The prescriber shall explain that this information is important for the patient's safety and that the patient is required by law to disclose this information. (18 V.S.A. §4223).

5.2 - The prescribing of opioids for chronic pain for permanent residents of skilled and intermediate care nursing facilities is excluded from the provisions of this rule.

5.3 - For patients prescribed opioids for 90 days or more for chronic pain, the prescriber shall:

5.3.1 - Receive, and include in the patient's medical record, a signed Informed Consent from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for misuse, abuse, diversion, and addiction; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates

5.3.2 - Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, and safe storage and disposal of medication. It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;

5.3.3 - Schedule and undertake periodic follow-up visits and evaluations at a frequency determined by the patient's risk factors, the medication dose and other clinical indictors. Patients who are stable in terms of the medication dose and its effectiveness in managing chronic pain must be reevaluated no less than once every year.

5.3.4 - Write the maximum daily dose or a "not to exceed" equivalent on the prescription for the dispensing pharmacy.

5.4 - Examples of Informed consent documents and controlled substance Treatment agreements are available on the Department of Health's website.

Section 6.0 - Referrals and Consultations

The prescriber shall consider referring a patient for a consultation with an appropriate specialist (such as a pain specialist or substance abuse specialist) when:

6.1. - The patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain;

6.2. - The patient is at high risk for substance misuse, abuse, diversion, addiction, or overdose as determined by the patient's history or a screening undertaken pursuant to Section 4.0 of this rule.

6.3 - The prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances;

6.4 - The patient is seeing multiple prescribers and/or utilizing multiple pharmacies;

6.5 - The patient has been prescribed multiple controlled substances.

Section 7.0 - Reevaluation of Treatment

7.1 - Controlled Substance Treatment Agreements for people receiving treatment for chronic pain shall be reviewed by the prescriber and patient no less frequently than once every 365 days to reevaluate the patient. These reviews shall be documented in the patient's medical record.

7.2 - Prior to prescribing a dose of opioids, or a combination of opioids, that exceeds 120 MED/day the prescriber of opioids to treat chronic pain shall document in the patient's medical record: [1]

7.2.1 - A reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of the patient's adherence to the treatment regimen;

7.2.2 - The potential for the use of non-opioid and non-pharmacological alternatives for treating pain;

7.2.3 - A functional status examination of the patient;

7.2.4 - A review of the patient's Controlled Substance Treatment Agreement and Informed Consent, making any necessary revisions, including pill counts and directly observed urine testing to monitor adherence and possible use of other substances;

7.2.5 - An assessment of any co-morbid conditions affected by treatment with opioids. This may be best conducted by a mental health or addictions professional;

7.2.6 - Any other related actions by the patient that may reasonably lead a prescriber to modify the pain management regimen, including but not limited to aberrant behaviors, early refills of controlled substances, or other known risks associated with misuse, abuse, diversion, addiction, or overdose.

7.3 - Based on the reevaluation required by 7.1, the prescriber shall determine and document:

7.3.1 - Whether to continue the treatment of pain with opioids or if there are available alternatives;

7.3.2 - The possible need for a pain management, substance abuse or pharmacological consultation to achieve effective pain management, avoidance of dependence or addiction or taper from the prescribed analgesics;

7.3.3 - Acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addictions specialist.

Section 8.0 - Prescription of Extended Release Hydrocodones and Oxycodones without Abuse Deterrent Opioid Formulations

Whereas, extended release hydrocodones and oxycodones that are not manufactured as Abuse-deterrent Opioids are easily misused, abused, diverted, and pose an increased threat to those who unintentionally ingest them, this rule enacts specific conditions for their prescription that are in addition to provisions of Sections 4.0 through 7.0 of this rule.

8.1 - Prior to prescribing an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid, the prescriber shall:

8.1.1 - Conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record;

8.1.2 - Document in the patient's medical record any diagnoses which support the use of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid for pain relief;

8.1.3 - Evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid prior to writing a prescription for such a substance. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.0 of this rule;

8.1.4 - Document in the patient's medical record that the prescription of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid is required for the management of pain severe enough to require daily, around-the-clock, long-term, opioid treatment for which alternative treatment options, including non-pharmacological treatments, are ineffective, not tolerated, or are otherwise inadequate to provide sufficient management of pain;

8.1.5 - Receive, and include in the patient's medical record a signed Informed Consent from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for misuse, abuse, diversion, and addiction; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol;

8.1.6 - Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or if the patient lacks the capacity to provide consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, safe storage and disposal of medication, and urine testing (no less frequently than annually with the actual frequency to be determined by the clinician on the basis of the patient's risk assessment and ongoing behavior). It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;

8.1.7 - Query the Vermont Prescription Monitoring System (VPMS) and document it in the patient's medical record:

8.1.7.1 - A review of other controlled substances prescribed to the patient prior to the first prescription of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioids;

8.1.7.2 - A query no less frequently than once every 120 days for any patient prescribed 40 mg or greater of hydrocodone or 30 mg or greater of oxycodone per day of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioids as long as the patient possesses a valid prescription for that amount;

8.1.7.3 - A query no less frequently than as described in Section 6.2 of Vermont Prescription Monitoring System rule.

8.1.8 - A determination of a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted;

8.1.9 - The writing of a prescription that must be filled within seven (7) days of the date issued and does not exceed a 30-day supply;

8.2 - Prescribers subject to this section shall schedule and undertake periodic follow-up visits and evaluations (no less frequently than every 180 days), during which the following must be documented in the patient's medical record:

8.2.1 - Whether to continue the treatment of pain with an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioids or if there are available alternatives;

8.2.2 - The possible need for a pain management or substance abuse consultation;

8.2.3 - A provider explanation and a patient acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addictions specialist.

MEDICAL MARIJUANA

Until March 1, 2022, according to 18 V.S.A. § 447(c), a workers compensation carrier was not obligated to pay for medical marijuana even if it is considered to be reasonable medical treatment. The provision read in relevant part:

(b) This chapter <u>shall not</u> be construed to <u>require that coverage or reimbursement for</u> the use of marijuana for symptom relief be provided by:

(1) a health insurer as defined by section 9402 of this title, <u>or any insurance</u> <u>company regulated under Title 8</u>;

(2) Medicaid or any other public health care assistance program;

(3) an employer; or

(4) for purposes of workers' compensation, an employer as defined in 21 V.S.A. § 601(3).

However, this section was repealed effective March 1, 2022. Vermont has now legalized marijuana with restrictions on its sale, the number of plants or amount of marijuana one person can possess at any one time, and classes of license for those wish to grow, vend, or otherwise dispense it. Given the recency of the repeal, and with the complication that marijuana remains illegal under Federal law, there are no decisions from the Department of Labor to guide this

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question, and the use of medical marijuana in Workers' Compensation cases remains an open question.

SPECIAL CONSIDERATIONS FOR COVID-19:

Like so many other areas of law and life, COVID-19 led to significant changes in Vermont Workers' Compensation law. Most importantly, the Vermont Legislature passed a series of laws collectively known as Act 150, which established presumptions for COVID-19 cases allegedly caused by exposure at work. These presumptions apply from the beginning of the pandemic until July 15th, 2021 (a month after the Governor's emergency order in Vermont was revoked. The first question, therefore, is whether the alleged exposure occurred during that period. If the COVID diagnosis was from a later date, then the usual rules of Vermont Workers' Compensation apply.

If the alleged exposure is within the Act 150 period, then the usual burden of proof is reversed. While the injured worker must still demonstrate that they indeed suffered from COVID-19 during the Act 150 period – by producing either a positive COVID test or a diagnosis of COVID from a medical provider – the employer/carrier may now have the burden of demonstrating that the injured worker's COVID was *not* due to work, rather than the injured worker having to demonstrate that it was.

The first question is whether the injured worker was a "frontline worker." Though many professions (health care professions, first responders, funeral homes, etc.) are listed in the statute, the central inquiry is the injured worker's level of interaction with the public. If the injured worker demonstrates that they were a frontline worker who contracted COVID-19 during the Act 150 period, it is presumed that the injured worker contracted COVID at work. In order to overcome this presumption, burden is then on the employer/carrier to demonstrate that the injured worker contracted COVID due to non-work exposure. The employer/carrier may therefore be entitled to medical records to which they would not normally be entitled – for example, the medical records of other people co-habiting with the injured worker's medical records is usually given via a Form 7, additional permissions may be necessary in a COVID-19 case.

If the injured worker was not a frontline worker, then the injured worker is also entitled to the presumption above. However, this presumption may be rebutted in two ways: 1) as above, by demonstrating non-work exposure led to the Claimant's COVID OR 2) by demonstrating that at the time of the Claimant's potential exposure, the Employer complied with all relevant COVID-related guidance. This is an extremely fact-intensive inquiry; a posted policy or email is not enough. Depending on the measures required by the Vermont Department of Health, CDC, etc. at the time of exposure, various information may be required.

Naturally, there is limited guidance regarding the potential Workers' Compensation implications of emerging issues such as so-called "long COVID." However, there are two additional issues that medical providers should be aware of: 1) liability regarding reactions to COVID-19 vaccinations, and 2) COVID-19 protocols for independent medical evaluations.

According to guidance in a memo from the Department of Labor, the central question regarding any reaction to a COVID-19 vaccine by a worker is whether the injured worker's employer

either required or strongly encouraged vaccination. Factors can include whether the injured worker was given paid time off for the vaccination, whether the vaccination was conducted on the premises of the employer, and whether certain privileges at work were reserved for people who were vaccinated. A general encouragement by the employer for all employees to be vaccinated is not enough to trigger employer liability.

Finally, medical providers should provide a copy of their COVID-19 protocols with confirmation of the date and time of any independent medical examination. These protocols should include any additional cleaning measures being taken, any masking or vaccination requirements, and should specify whether additional persons (such as spouses, translators, or videographers) will be permitted in the examination room with the injured worker. The protocols do not impact the injured worker's rights to a translator or to record the examination, but early notice of these protocols will allow the parties to determine the best method of safeguarding these rights while abiding by the medical provider's practices.

RESOURCES

Workers' Compensation <u>Rules</u> Workers' Compensation <u>Statute</u> Workers' Compensation <u>Medical Fee Schedule</u> (Rule 40) Workers' Compensation <u>Forms</u>

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Kurt M. Hughes, Esq. (Assisted Reproductive Technology Section) For over 30 years, Kurt has been assisting families with the legal aspects of adoption and assisted fertility, including gestational surrogacy and gamete and embryo donation. In 2014, Kurt launched Vermont's first and only local surrogacy matching program, the Vermont Surrogacy Network, LLC. Through this program, he has developed strong connections with fertility clinics throughout New England, including Northeastern Reproductive Medicine in Colchester, Vermont. In 2018, Kurt helped to write a sweeping overhaul of Vermont's Parentage Act, finally providing legal security for Vermonters growing their families through surrogacy and other assisted Reproductive technologies. Kurt is a Fellow of the Academy of Adoption and Assisted Reproduction Attorneys (AAAA), an invitation-only national academy of attorneys who have distinguished themselves in the fields of adoption and ART law. Kurt received his undergraduate degree from Colgate University and his law degree from Vermont Law School.

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Elijah T. LaChance (Workers' Compensation) is an attorney with Ryan Smith & Carbine, Ltd. The majority of his practice consists of representing institutions and employers in defense of workers' compensation matters. Mr. LaChance graduated summa cum laude with a J.D. from Vermont Law School and with distinction with a B.A. from Hamilton College.

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Glenn S. Morgan (Workers' Compensation), a leading expert in the field of workers' compensation law, is Chairperson of the five attorney Workers' Compensation Practice Group at Ryan Smith & Carbine, Ltd in Rutland, Vt. Mr. Morgan has practiced in the area of workers' compensation for over 40 years, representing national, regional and local employers and insurance carriers before the Vermont Department of Labor, the Vermont Superior Court and the Vermont Supreme Court. Mr. Morgan is a Fellow of the College of Workers' Compensation Lawyers. Mr. Morgan has been recognized as a Vermont Top Lawyer by VT Business Magazine, Best Lawyers® in America, and "Super Lawyer" in the Workers' Compensation category and Top Attorneys in New England. He has received Martindale-Hubbell, Inc.'s highest "AV" rating. Mr. Morgan graduated with a J.D. degree from Suffolk University School of Law and a B.A. from the University of Vermont.

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Stephanie P. Romeo (Workers' Compensation) is a shareholder of Ryan Smith & Carbine, Ltd. The majority of her practice consists of representing institutions and employers in defense of workers' compensation matters. Ms. Romeo frequently provides training and guidance for insurance adjusters in handling workers' compensation claims in the State of Vermont. Ms. Romeo graduated cum laude with a J.D. from Vermont Law School and magna cum laude with a B.A. from Northeastern University.

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Michelle A. Tarnelli, Esq. (Assisted Reproductive Technology Section) is an attorney and partner at Tarnelli & Hughes Family Law, PLLC, focusing her practice in the areas of assisted reproductive technology, adoption, and family law. Michelle is a Fellow of the Academy of Adoption and Assisted Reproductive Technology Attorneys (AAAA), a highly selective international and credentialed organization of experienced family formation attorneys, dedicated to the competent and ethical practice of assisted reproductive Technologies and member of the American Bar Association (ABA) Assisted Reproductive Technologies and Family Law Groups, American Society for Reproductive Medicine (ASRM), Society for Ethics in Egg Donation and Surrogacy (SEEDS), and RESOLVE New England. Michelle graduated *cum laude* from Fordham University and *magna cum laude* from Vermont Law School.

John Wallace (Pharmaceutical Issues Section) is an attorney in the Healthcare Group at Primmer, Piper, Eggleston & Cramer. John has worked as a health care attorney for more than twenty years including work as in-house counsel, general counsel, and as a chief compliance officer. His regulatory expertise and familiarity with healthcare operations allow him to be a uniquely efficient, insightful, and effective advisor and advocate for healthcare providers.

Lindsey Wells, B.S., (Marijuana for Therapeutic Use) received her Bachelor of Science Degree in Business Administration in 2005 from Norwich University. She has an extensive work history with state and federal regulations. She was employed by the Department of Public Safety as the Marijuana Program Administrator for the Vermont Marijuana Registry since 2012 and is now the Marijuana Program Administrator for the Medical Marijuana Program within the Cannabis Control Board.

Elizabeth Wohl (Mental Health and Substance Abuse Treatment Issues Section) practices health law at the prominent New England law firm Downs Rachlin Marin PLLC. She served as inhouse General Counsel and Chief Compliance Officer at the Brattleboro Retreat for four years and continues in that role as outside counsel. Before joining the Retreat, she practiced health law for nine years at firm Downs Rachlin Martin PLLC completing an accelerated track from associate to director. She chaired DRM's health law practice group and provided advice to hospitals, health systems, nursing homes, assisted living facilities, designated agencies, and individual providers. Her experiences in both in-house and private practice settings have given Elizabeth rare and valuable insights into the many pressures and tensions affecting the varied parts of the health care system in the region. She particularly enjoys teasing out the complex legal issues that arise in the course of providing high-quality mental and physical health care for Vermonters.