

Vermont
Medical
Society

2020-2021

THIRD THURSDAY
WEBINAR SERIES

12:00 pm to 1:00 pm

Vermont
Medical
Society

THIRD THURSDAY WEBINAR SERIES

Date: May 20, 2021

Title: What You Have Missed in Compliance!

134 MAIN STREET, MONTPELIER, VERMONT, 05602

TEL.: 802-223-7898

WWW.VTMD.ORG

In support of improving patient care, this activity has been planned and implemented by the Robert Larner College of Medicine at the University of Vermont and the Vermont Medical Society. The University of Vermont is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

The University of Vermont designates this internet live activity for a maximum of *1 AMA PRA Category 1 Credit(s)*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Please watch your email from the Vermont Medical Society
providing directions for claiming CME credit.**

CME credit must be claimed within 30 days of participating in the event.

What You Have Missed in

Compliance!

Speakers: Anne Cramer & Shireen Hart

Planning Committee Members:

Jessa Barnard, ESQ, Catherine Schneider, MD, Stephanie Winters & Elizabeth Alessi

Purpose Statement/Goal of This Activity: After a year of enormous disruption and change, this program will educate you on areas of critical federal and state regulatory compliance for physician practices in 2021.

Learning Objectives: To provide updates on the following:

- New informed consent requirements for audio-only telehealth
- New information blocking rules
- Vaccine mandates
- Employment law changes

Disclosures:

Is there anything to Disclose? Yes No

Did this activity receive any commercial support? Yes No

(The CMIE staff do not have any possible conflicts)

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ATTORNEYS
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CRAMER PC

WHAT YOU HAVE MISSED IN COMPLIANCE: 2021

PRESENTERS



Anne E. Cramer, Esq.



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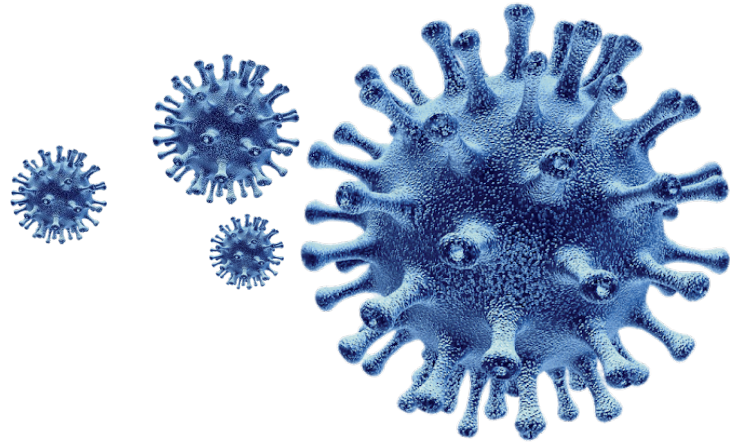


AGENDA



- COVID-19 Regulatory Changes
- Audio-Only Telehealth
- Medical Practice Board Reporting Update
- Health Equity
- Opioids/MAT Update
- Patient Access and Information Blocking
- Cybersecurity
- Employment Law and Vaccines

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COVID-19

VDH COVID-19 Infection Control After
Vaccination Guidance for Health Care
Organizations



Post-Vaccine Infection Control

- **Pre-entry screening:** all staff, patients and visitors for vaccination status & COVID-related symptoms
- **Masks required:** All health care personnel (HCP), patients and visitors
 - Exception: Fully vaccinated HCPs not providing patient care may dine, socialize and meet in person w/o masks, unless unvaccinated HCPs present
- **Physical distancing required:** All patients and visitors on premises (outside of exam rooms), and for unvaccinated HCP
- **Post-Travel Testing & Quarantine:**
 - Vaccinated HCP: No requirement
 - Unvaccinated HCP: Testing required 3 -5 days after return & quarantine for 7 days



Regulatory Flexibilities Act VT Act 6

March 2021

VT extended health care regulatory flexibility during and after the COVID -19 pandemic.

- Extends COVID-19-related regulatory flexibilities to March 31, 2022
- Relaxed provider enrollment credentialing with Medicaid and insurance plans
- Early prescription refill for chronic maintenance medications
- Ability for out -of-state licensee & recently retired/inactive VT licensees to provide telehealth or services as a Medical Reserve Corp volunteer and on staff of licensed facility or FQHC
- Extends **waiver** of telehealth requirements, including HIPAA-compliant -connection to extent permitted by federal law and obtaining and documenting patient's informed consent (sunsets 60 days after SOE)

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Audio -Only Telehealth



Audio -only Telehealth Insurance Coverage

- Requires health plans & Medicaid (as allowed by CMS) to cover audio -only telehealth services to extent in person visit is covered
- Patient's free choice to agree to audio -only telehealth; cannot be required
- No unnecessary delay in service if patient chooses in person or telemedicine
- Document or include patient informed consent in medical record
- Document reasons for audio -only telehealth visit and why clinically appropriate
- Neither patient nor HCP may record audio -only telehealth visit
- Provide information on whether audio -only will be billed to insurance and patient's out -of-pocket responsibilities

Audio -only Telehealth Consent Requirements

- Patient informed consent (oral or written) at or before first audio -only telehealth visit
- Informed consent must be in language easily understood
- Can use one form for all telehealth visits, but must include all consent requirements:
 - patient is entitled to choose services by audio -only telephone, in person or by telemedicine
 - receiving services by audio -only telephone does not preclude in person or telemedicine follow up
 - explanation of pros and cons of audio -only telephone
 - patient will be informed and may approve of others who can listen/participate in audio -only visit
 - patient will be provided info on billing to insurance plan and their out of pocket responsibility
 - not all health plans will provide coverage for all audio -only health care services
- VMS collaborated with BiState and VAHHS on a patient -friendly notice:
[https://vtmd.org/telehealth -guidance -2020](https://vtmd.org/telehealth-guidance-2020)

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Reporting Update

Updates to Medical Practice Board
Reporting Requirements

CHECKLIST

-
-
-
-





Reporting Requirements

In 2017, Vermont updated requirements for reporting disciplinary action to the Board of Medicine (MDs, PAs, etc.)

26 V.S.A. § 1317

Who: Required reporters: Hospitals, clinics, community mental health centers, other health care institutions in which licensees perform professional services

- *What:* Any reportable disciplinary action:
 - Related to fitness/ competence to practice medicine;
 - Violation of law or rule related to practice of medicine;
 - After acts/ omissions that result in (at least one of the following):
 - Resignation, leave of absence, termination, nonrenewal of contract (includes voluntary acts in response to disciplinary action);
 - Revocation, suspension, restriction, relinquishment, nonrenewal of privilege
 - **Second—in 12 month period—written discipline that constitutes censure, reprimand, or admonition**
 - Fine or monetary penalty
 - Required education, remedial counseling, monitoring after completed, contested disciplinary process

- *When:* within 30 days of disciplinary action



What are noteworthy changes?

Written discipline that constitutes a censure, reprimand, or admonition **second time** , within a 12-month period, for same or related acts or omissions (involving similar behavior or behavior involving the same parties, or both). **Examples:** – if

- Refusal to adhere to hospital's PPE requirements.
- Mistreatment of staff members.

When act or omission leads provider to go out on “leave of absence” or results in “suspension.”

- This does not require a minimum duration (such as 10 days or 30 days) to trigger a reporting obligation.

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Health Equity



Health Equity for BIPOC Communities

COVID-19

Disproportionately impacted BIPOC communities —

- exposing systemic failures in health care and multiple opportunities for growth.



Health Equity for LGBTQ+ Communities

5/10/21: HHS announces prohibition on sex discrimination including discrimination on the basis of sexual orientation and gender identity

Examples

- Assignment of patient rooms
- Use of transgender patient's name and pronoun
- Identifying and assessing victims of domestic abuse

Take away

Review your practices and policies to ensure that they do not discriminate on the basis of sexual orientation and gender identity.

Look at your registration procedures and your EHR.

Discuss with your staff what to do when a patient presents whose gender identity does not match the gender in their medical record.



Vermont Resources

VT Medical Society: <https://vtmd.org/health-equity>

VT DOH: <https://www.healthvermont.gov/about-us/our-vision-mission/health-equity>

VT Diversity Health Project (focus on LGBTQ people):

<https://www.pridecentervt.org/programs/health/vdhp/>

“Our goal is to help patients identify safe, affirming, supportive, and effective healthcare providers, and offer trainings and other support to enhance providers’ skill in working with LGBTQ people.”

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Opioids/MAT

New prescribing exemptions for medication assisted treatment (MAT)



Prescribing Exemptions

In April 2021

DHHS issued new exemptions aimed at expanding access to take-at-home treatment for opioid use disorder (OUD).

Highlights:

- Removes 8-hour training requirement for DEA registered doctors prescribing buprenorphine
- Expands prescribing eligibility to mid-level providers (PA, NP, CNS, CRNA, CNM (midwives))
- Still requires a “Notice of intent” to prescribe buprenorphine for OUD
- Cap of 30 patients under exemption
- For more detail: <https://public-inspection.federalregister.gov/2021-08961.pdf>

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Patient Access/ Information Blocking

Consumer -centric regulations that
promote patient access to records



Information Blocking

21st Century CURES Act (2016)

42 U.S.C. 300jj52 *et seq.*

Purpose

- Increase information flow
- Prevent barriers to patient care
- Discourage anti-competitive practices

HIPAA paradigm shift

- *Requires* and *facilitates* patient access to electronic health information (EHI)

Information blocking

- Practices by actors (below) that
- Prevent or materially discourage
- Access, exchange, or use of
- Electronic health information (EHI)

Actors

- Health care providers
- HIN/ HIE
- Health IT developers

Enforcement

- Appropriate agency/ appropriate disincentives



EHI Requests

Presumption of EHI disclosure unless otherwise required by law or an exception to the information blocking rules

Practice

Focus on practices that *may* implicate the IB Rule

Examples

Interference with:

- Patients' access to their own EHI
- Treatment and care coordination between providers
- Payers seeking to assess clinical value
- Quality Improvement/ Population Health management by providers
- Patient safety and public health



Information Blocking Exceptions

Denial of request to access, exchange, or use EHI based on:

- **Preventing harm:** reasonable belief practice will reduce risk of harm
- **Privacy:** denial of access pursuant to State and Federal privacy law
- **Security:** directly related to safeguarding EHI
- **Infeasibility:** due to technical limitations, uncontrollable events, or inability to segment EHI
- **Health IT performance:** unavailability due to maintenance/ performance needs

Procedures for fulfilling request to access, exchange, or use EHI:

- **Content and Manner:** fulfill request for EHI as requested unless technically unable to do so or with agreement
- **Fees:** reasonably related to cost
- **Licensing:** related to protecting investment in HIT innovation



Information Blocking Exceptions

Privacy

Denial of access pursuant to HIPAA/other law

- Required preconditions
- Authorization/ Consent Efforts

How to prepare

Review and update:

- Authorization/ Consent process
- Right of access and Personal Representatives
- Minors Rights
- Request for confidential communications
- Process for denying requests

Infeasibility

Resulting from:

- Technological limitations
- Uncontrollable events
- Inability to segment EHI
- Infeasibility under the circumstances

How to prepare

- Create and use infeasibility decision tree/ process
- “Notice of Infeasibility” If unable to fulfill a request, must provide written notice ***within ten (10) business days*** of request

Preventing Harm

- Reasonable belief
- Practice will ***substantially reduce risk of harm (physical harm, threat to life)***

How to prepare

- Develop organizational policy to address
- Create and use harm decision tree/ process for individualized determination by HCP

Re: “Bad News”

Test results: under the preventing harm exception, emotional distress is not a basis to withhold EHI from patient



What to know

- Studies show that health transparency does promote patient involvement
- Have a conversation with patients about access to records in the patient portal (e.g. instant access to labs)
- Develop or review your organization's plan to address patient requests for electronic health records in a timely manner
- Understand the exceptions to the Information Blocking Rules and how they apply to patient requests for EHI
- Resources:
 - AMA: <https://www.ama-assn.org/topics/electronic-health-information-blocking>
 - Information Blocking Resource Center : <https://infoblockingcenter.org/>



CMS Interoperability Rule

What Physicians Should Know

- Rule effective May 1, 2021
- Requires providers to obtain and register digital contact information (e.g. direct address) with NPPES (National Plan and Provider Enumeration System)
- Also, register for NPPES account and review and update regularly: [https:// npiregistry.cms.hhs.gov](https://npiregistry.cms.hhs.gov)
- CMS will publically report names of providers who do not list/ update



HIPAA/Part 2 Updates

HIPAA Privacy rule: DHHS OCR announced modification proposal in Dec. 2020 :

- Goal to support & remove barriers to coordinated care and individual engagement
- Proposes to enhance patient right of prompt access & right to direct EHR to another provider
- NPRM published on 1/ 21/ 21; Comment period extended to 5/ 6/ 21

42 C.F.R. Part 2: Amendments required by 2020 CARES Act—rule still pending:

- New rule must allow a general consent to permit Part 2 program record disclosure and re-disclosure for treatment, payment & health care operations consistent w HIPAA Privacy Rule & apply HIPAA breach notification
- In April-2021, SAMHSA announced it's working with OCR on amendments "later this year"

DHHS goal to align rules and coordinate between SAMHSA (Part 2), OCR (HIPAA) and ONC (Information Blocking)

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Cybersecurity

HEALTHCARE CYBERSECURITY STATISTICS



For 2021



More than

90%

of healthcare organizations have experienced a data breach in the past 3 years.

varonis.com

34%

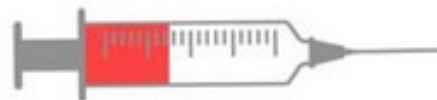
of healthcare data breaches come from unauthorized access or disclosure.

techjury.net



88% *of healthcare workers open phishing emails.*

techjury.net



Hospitals account for

30%

of all large data breaches.

techjury.net



Prevention

- Most cyber -threats (94%) originate via email
 - Train end users to recognize and report phishing emails and other suspicious communication
- Maximize system & firewall alerts for unusual activity (24/7)
 - Especially during off -hours; weekends over night
 - Who has authority to disconnect the system?
- Back up everything
- Cyber insurance coverage
- Have a down -time contingency plan



Takeaways

Great AMA Resource: [https:// www.ama-assn.org/ practice-management/ sustainability/ what-doctors-can-do-thwart-cybercriminals-2020-closes](https://www.ama-assn.org/practice-management/sustainability/what-doctors-can-do-thwart-cybercriminals-2020-closes)

Vigilance

Keep an eye out for system vulnerabilities and report ASAP.

Be wary of emails, texts, calls from unknown sources.

Passwords

Keep private, change often, and use a unique password for access to health records.

123456 ([is still the most common password in 2021!!](#))

Report

Suspicious email (or other activity) to your IT or cybersecurity department/ vendor as soon as possible.



Employment Law & Vaccines



COVID-19 Vaccine Policies

Can employer implement policy requiring COVID Vaccines?

- Yes, if necessary to protect health and safety of workplace
 - Exemptions:
 - Medical conditions
 - Religious reasons
 - Pregnancy



Can we ask if someone has been vaccinated?

- Yes, employer can ask employees whether they have received the COVID -19 vaccine, but cannot ask questions beyond that, such as, “why not?”
- What if patients ask whether we have unvaccinated staff members?
 - Under Americans with Disabilities Act (ADA) you must treat employee medical information as confidential.

Suggested response

- We recommend that you and your staff consistently respond by informing anyone who asks:
 - that you are obligated to keep all employee medical information confidential; and
 - that you are following all applicable guidelines and safety precautions.

Voluntary disclosures

If a patient asks an individual employee about their vaccination status, you cannot stop your staff from volunteering their vaccination status, but you should make it clear to all staff they **are not required to answer a patient or co-worker question about their vaccination status.**

Again, they could respond: *“That’s personal health information that I prefer to keep private, but I will share that I am following all applicable guidelines and safety precautions .”*

Can we require that staff wear stickers/badges confirming vaccination status?

- No. We do not recommend that you do this.
- However, an employee may voluntarily opt to disclose vaccination status.
- We recommend that you inform staff that they are not expected to do so and should not feel pressured to share this information with their co-workers and patients.

We hope this has been informative and helpful. However, it is not intended to constitute legal advice or to create an attorney-client relationship. Please be sure to consult with your own legal counsel.

Any questions?

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