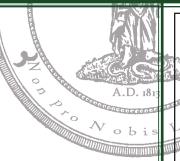
PHE LEGISLATIVE BULLETIN

A PUBLICATION OF THE VERMONT MEDICAL SOCIETY

2013 Legislative Wrap-Up



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On the evening of Tuesday May 14, the Vermont General Assembly adjourned for the year after reaching agreement with Governor Peter Shumlin on the budget for state fiscal year 2014. With the state's response to the federal Affordable Care Act being phased-in through 2019, there will be an ever-increasing need for the VMS to work to ensure the implementation of health care reform is done in a manner that supports physicians 'ability to make clinical decisions in the best interest of their patients.

This legislative bulletin provides a summary of the major bills the VMS worked on during the legislative session. On numerous occasions, VMS requested that physicians come to the state house and provide testimony on proposed legislation that would have added administrative burdens and harmed the physician/patient relationship. We are very grateful for their assistance.

In order to read the full text of the various bills, please go to: http://www.leg.state.vt.us/database/status/status.cfm

H. 522 – Requires Prescribers to Register and Query the Vermont Prescription Monitoring System (VPMS)

H. 522, a bill designed to respond to opioid addiction and methamphetamine abuse passed the House and Senate. As the bill moved through the legislature, VMS worked closely with VAHHS and the Department of Health to amend and narrow the requirements to check the VPMS database. The final version of the bill requires prescribers to check the VPMS database in four circumstances:

- (1) at least annually for patients who are receiving ongoing treatment with an opioid Schedule II, III, or IV controlled substance;
- (2) when starting a patient on a Schedule II, III, or IV controlled substance for non-palliative long-term pain therapy of 90 days or more;
- (3) the first time the provider prescribes an opioid Schedule II, III, or IV controlled substance written to treat chronic pain; and
- (4) prior to writing a replacement prescription for a Schedule II, III, or IV controlled substance pursuant to section 4290 of this title.

Log-in information is available at http://healthvermont.gov/adap/VPMS_prescribers.aspx#register. Prescribers may assign the responsibility to check the VPMS to delegates, who are registered with the VPMS.

The bill requires all prescribers to register with the VPMS on or before Nov.15, 2013. The bill does not require the VPMS registration process to be linked to the physician licensing process, as VMS had recommended, but VMS believes that the Vermont Board of Medical Practice (VBMP) and the Department of Health intend to integrate the two databases in an effort to streamline the registration process. The current registration process requires prescribers to download a paper form and mail the form, a signed privacy statement, and a copy of their DEA and Vermont licenses back to the Department of Health. The form states that it takes about 10 days to process a registration. Forms for prescribers and delegates are available at: http://healthvermont.gov/adap/VPMS_prescribers.aspx#register.

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H. 530 Three Percent Medicaid Reimbursement Increase

The three percent Medicaid reimbursement increase was included the FY 2014 budget, although the implementation of the increase was delayed one month – from October to November 2013. The Senate added language requiring the administration to develop consistent measures to be accountable for the results of cost shift investments. The language will require the Green Mountain Care Board (GMCB) to maintain and report on its dashboard of key indicators "a comparison of the difference between Medicaid and Medicare provider reimbursement rates and additional measures as determined to create standard transparent measurement of a reduced cost shift."

VMS has requested that DVHA use the three percent increase to eliminate the additional two percent cut that DVHA applies to all professional services except the evaluation and management codes and then to adopt Medicare's Part B RBRVS reimbursement system with a single conversion factor at 100 percent of Medicare. DVHA has indicated willingness to consider applying this methodology to the extent possible.

H.107 PRIOR AUTHORIZATION (TIMEFRAME, STEP THERAPY AND PILOT PROGRAM); STANDARDIZED CLAIM EDITS AND PAYMENT RULES; STUDY ON CHARGES FOR COPIES OF ELECTRONIC RECORDS

Timeframe for non-urgent prior authorization - H. 107 shortened the time for health plans to respond to requests for non-urgent requests for prior authorization from 120 hours to two business days. A law passed last year requires insurers to respond to urgent requests for prior authorization in 48 hours.

Step Therapy - The bill prohibits health insurers that use step therapy from requiring patients to fail on the same medication more than once. Health insurers may continue to use tiered co-payments when drugs are not subject to a step-therapy protocol. The provision also requires health insurers to limit step-therapy to drugs that are indicated by the FDA for the diagnosed condition, and does not permit insurers to require use of off-label drugs as part of step therapy.

Prior Authorization Pilot Program - After hearing testimony from VMS and Green Mountain Care Board member Dr. Allan Ramsay, the House Health Care Committee added a prior authorization pilot program to the bill. The pilot program will measure changes in system costs within primary care associated with eliminating prior authorization requirements. It will also examine the effect of eliminating prior authorization on provider satisfaction and on the number of requests for and expenditures on imaging, medical procedures, prescription drugs, and home care.

Standardized Claim Edits and Payment Rules - The bill requires the Green Mountain Care Board (GMCB), in consultation with the Department of Vermont Health Access (DVHA) to develop a complete set of standardized edits and payment rules. Insurers will be required to begin using the standardized edits and payment rules on Jan. 1, 2015. Medicaid will be required to begin using the

standardized edits and payment rules on Jan. 1, 2017. DVHA and the GMCB will report to the legislature on progress made toward developing a complete set of standardized edits and payment rules. Private insurers (by 2015) and DVHA (by 2017) will be required to ensure that their contracts for benefit management and claims management include full transparency of edit standards, payment rules, prior authorization guidelines and other utilization review provisions, including the basis in evidence for the standards and guidelines. Currently many insurers use benefit managers and claims management systems that are proprietary, and consequently it is difficult for practices to understand the standards and guidelines that apply to payment of claims or prior authorization, which leads to inefficiency. Often claims must go back and forth from a practice to insurers several times. It would be more efficient for payers and practices if practices could load payment rules into their practice management systems and claims could be billed correctly the first time.

Study on Charges for Medical Records - The Vermont Association for Justice (VAJ) formerly known as the Vermont Trial Lawyers Association (VTLA), requested that H. 107 include a study of the fees charged for copies of electronic medical records. Currently, Vermont law allows practitioners to charge \$.50 per page and the trial lawyers believe that this amount is exorbitant when they receive a compact disc (CD) in response to a request for records. The Green Mountain Care Board will conduct the study and will consult with stakeholders, such as VAHHS and VMS. The study will include a review of related laws and policies in other states and will be submitted to the legislature on or before Jan. 15, 2014.

NATUROPATHS' AUTHORITY TO PRESCRIBE DRUGS

Last year, the Office of Professional Regulation (OPR), in consultation with the Commissioner of Health was authorized to adopt rules that would permit naturopaths to prescribe legend drugs. OPR has recently filed the proposed rules and there will be a public hearing on the rules on June 18, 2013 at 10:30 am at 32 College Street, Shulmaier Hall, in Montpelier. Written comments may be submitted to OPR until June 26, 2013. Comments may be emailed or mailed. Link to proposed rules: http://vtprofessionals.org/opr1/naturopaths/rules/

Administrative_Rules.pdf. VMS will testify at the public hearing and will submit written comments.

Summary of Provisions in Naturopaths' Prescribing Endorsement Rules

<u>Examination</u> - To obtain the license endorsement, the proposed rules require naturopaths to take and pass the examination(s) given in the Medical Pharmacology course taught within the Department of Pharmacology through Continuing Medical Education at the University of Vermont's College or Medicine, or a substantially equivalent course approved by the Director of OPR.

<u>Prescription review</u> - The proposed rules require that the first 100 prescriptions written by a naturopath after receiving the license endorsement must be reviewed by a supervising physician. The supervision and prescription review process must be performed by a medical or osteopathic doctor. The naturopath must have a formal agreement with an allopathic or osteopathic physician who agrees to participate in the supervision and prescription review process and agrees to advise, mentor and consult with the naturopath concerning the naturopaths' ability to safely prescribe and administer drugs within his or her scope of practice and in compliance with federal and state statutes and the rules of the Vermont Board of Pharmacy.

<u>Off-label Prescribing</u> - The rules authorize naturopaths to prescribe medications off-label in conformance with generally accepted standards of practice, including safety and efficacy, for both allopathic and naturopathic physicians.

<u>All classes of drugs permitted</u> - For naturopaths who go through the steps in the rules to obtain an endorsement to prescribe drugs, the rules do not limit the drugs or classes of drugs that they may prescribe, on or off label, or on the routes of administration.

VMS will continue to provide comments and raise concerns with the Office of Professional Regulation and the Department of Health through the rulemaking process. Please send VMS your thoughts and comments about the proposed rules. In particular, please let us know about classes of drugs that should be excluded from the naturopaths' authority to prescribe. Also, if you have shared patients with a naturopath, or patients have come to you after seeing a naturopath, please let VMS know about your experience.

H. 178 ORGAN DONATION WORKING GROUP REAUTHORIZED; DISPOSITION OF REMAINS

H. 178 reauthorizes the work of the organ and tissue donation working group. VMS participates on the working group to increase awareness and support for anatomical gifts, and in particular to encourage living organ donation, consistent with the resolution adopted at the 2010 annual meeting: $\frac{1}{2} \frac{1}{2} \frac{1}{2}$

H. 178 also clarifies state agency responsibility for the costs of disposition of the remains of individuals who die without representatives. The bill repeals a law that allowed physicians to use as cadavers, bodies that were not claimed by family members. UVM supported the repeal and testified that this means of obtaining cadavers had not been used for over forty years.

S.77 -- ALLOWS PHYSICIANS TO PRESCRIBE LETHAL DOSES OF MEDICATION TO TERMINALLY ILL PATIENTS

On the day before adjournment, the Vermont legislature approved S.77 – a bill that would allow physicians to prescribe lethal doses of medication to terminally ill patients in order for the patient to end their lives. By a 75-65 vote, the House concurred with a Senate version of the bill that passed 17-13. The legislation largely mirrors a similar law in Oregon law for first three years and then shifts to a system with less government monitoring. However, there's widespread expectation that lawmakers may push to eliminate the changes set to take effect in 2016, leaving an Oregon-style law in place.

The legislation creates a new chapter 113 in Title 18 of Vermont Statutes Annotated entitled "Patient Choice at End of Life." The two key provisions of the bill are found in section 5283 that establishes the fifteen requirements for legal immunity if a physician prescribes lethal doses of medication for a patient to self-administer, and in section 5285 that states a physician shall not be under any duty, by law or contract, to participate in the provision of a lethal dose of medication to a patient. These provisions go into effect once the bill has been signed into law by the Governor.

Under section 5283, a physician would not be subject 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 the physician affirms by documenting in the patient's medical record that all of the following fifteen requirements occurred:

- (1) The patient made an oral request to the physician in the physician's physical presence for medication to be self-administered for the purpose of hastening the patient's death.
- (2) No fewer than 15 days after the first oral request, the patient made a second oral request to the physician in the physician's physical presence for medication to be self-administered for the purpose of hastening the patient's death.
- (3) At the time of the second oral request, the physician offered the patient an opportunity to rescind the request.
- (4) The patient made a written request for medication to be self-administered for the purpose of hastening the patient's death that was signed by the patient in the presence of two or more witnesses who were not interested persons, who were at least 18 years of age, who affirmed 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.
- (5) The physician determined that the patient: was suffering a terminal condition, based on the physician's physical examination of the patient and review of the patient's relevant medical records; was capable of making an informed decision; had made a voluntary request for medication to hasten his or her death; and was a Vermont resident.

- (6) The physician informed the patient in person, both verbally and in writing, of all the following: the patient's medical diagnosis; the patient's prognosis, including an acknowledgement that the physician's prediction of the patient's life expectancy was an estimate based on the physician's best medical judgment and was 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 and the patient's diagnosis; if the patient was 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 medication to be prescribed; and the probable result of taking the medication to be prescribed.
- (7) The physician referred the patient to a second physician for medical confirmation of the diagnosis, prognosis, and a determination that the patient was capable, was acting voluntarily, and had made an informed decision.
- (8) The physician either verified that the patient did not have impaired judgment or referred the patient for an evaluation by a psychiatrist, psychologist, or clinical social worker licensed in Vermont for confirmation that the patient was capable and did not have impaired judgment.
- (9) If applicable, the physician consulted with the patient's primary care physician with the patient's consent.
- (10) The physician informed the patient that the patient may rescind the request at any time and in any manner and offered the patient an opportunity to rescind after the patient's second oral request.
- (11) The physician ensured that all required steps were carried out in accordance with this section and confirmed, immediately prior to writing the prescription for medication, that the patient was making an informed decision.
- (12) The physician wrote the prescription no fewer than 48 hours after the last to occur of the following events: the patient's written request for medication to hasten his or her death; the patient's second oral request; or the physician's offering the patient an opportunity to rescind the request.
- (13) The physician either: dispensed the medication directly, or, with the patient's written consent: contacted a pharmacist and informed the pharmacist of the prescription; and delivered the written prescription personally or by mail or facsimile to the pharmacist, who dispensed the medication to the patient, the physician, or an expressly identified agent of the patient.
- (14) The physician recorded and filed the following in the patient's medical record: the date, time, and wording of all oral requests of the patient for medication to hasten his or her death; all written requests by the patient for medication to

VPMS

(Cont'd from pg. 1) VMS does not support mandating the use of diagnostic risk assessment tools such as the VPMS by law. The final version of the bill is, however, more narrowly tailored than the bill initially introduced in the House, which had mandated checking the VPMS whenever a Schedule II, III, or IV controlled substance was prescribed for any condition, for any patient.

Requirements to register with the VPMS database and the statutory requirements to check the VPMS data become effective Nov. 15, 2013.

A requirement to check the VPMS "when a patient requests renewal of a prescription for an opioid Schedule II, III, or IV controlled substance written to treat acute pain," was not included in the final version of the bill, but the Commissioner of Health is required to determine whether to address this by rule.

Prior to adopting rules, the Commissioner of Health will consult with the Unified Pain Management System Advisory Council (Council), an interdisciplinary group of clinicians that includes clinicians with expertise in pain management and addiction. The Council has 25 members and includes clinicians representing the VMS, BiState Primary Care Association, the American College of Emergency physicians – Vermont Chapter, the American Academy of Family Physicians - Vermont Chapter, the UVM College of Medicine - academic detailing, the UVM College of Medicine - addiction or pain management, the Board of Medical Practice, and the Board of Osteopathic Physicians. The Feb. 25, 2013 report of the Unified Pain Management System Advisory Council is available at: http://healthvermont.gov/adap/documents/UPM_Advisory_Co uncil_Final_Report_022513.pdf. VMS believes that the Council is an appropriate group to make recommendations to licensing boards about prescription of controlled substances, including use of diagnostic tools such as the VPMS.

VMS supported a provision in the bill that requires licensing authorities, such as the VBMP, to develop "evidence-based standards to guide health care providers in the appropriate prescription of Schedules II, III, and IV controlled substances for treatment of chronic pain and for other medical conditions." The VBMP includes nine physicians, a podiatrist, a physician assistant and six public members.

VMS recommended that the legislature include provisions designed to improve the completeness and timeliness of the VPMS data and the functionality of the VPMS system. The final version of the bill includes only minor proposals to improve the VPMS. The bill requires a report on the

integration of electronic medical records with the VPMS that will assess the feasibility of integration and identify barriers to integration and potential costs associated with integration. An advisory committee is required to recommend ways to maximize the effectiveness of the VPMS database and report on the feasibility of increasing the frequency of dispenser reporting to the VPMS from weekly to daily and on the feasibility of obtaining real-time data from the VPMS.

VMS also recommended that the Department of Health "push" information about patients from the VPMS database to physicians, to inform them when their patients are obtaining controlled substances from multiple prescribers or pharmacies. The bill authorizes the Department of Health to use the VPMS data for research and trend analysis and requires the Department to post the results of trend analyses on its website, and requires the Department to send alerts relating to identified trends to prescribers and dispensers by email.

ADDING "APRN" TO LAWS THAT REFER TO "PHYSICIANS" OR "DOCTORS"

The bill adding "APRN" to all statutory references to "physician" or "doctor" will not be taken up this year. VMS will work with the licensing boards, professional associations and other interested stakeholders to review this proposal before the next legislative session. This proposal touches a very broad range of issues, for example: disability certification, mental health (involuntary treatment), guardianship, education (ability to attend school), public health, regulated drugs, sterilization reports, motor vehicles (handicap tags, school bus drivers), municipalities, corrections, and child abuse. Please let VMS know if you would be willing to help with this proposal.

ACT 25 (H. 136) COST SHARING FOR COLORECTAL SCREENINGS AND MAMMOGRAMS

Act 25 prohibits insurers from imposing cost-sharing requirements on preventive screenings including mammograms and colorectal screenings. The law also requires coverage of mammograms and colorectal cancer screening, including coverage of additional views and interpretations as needed for mammograms and coverage of physician services, lab services, facility use, removal of tissue, and anesthesia for colorectal screenings. It also covers concurrent removal or biopsy of polyps. Act 25 was signed by the governor last week and will apply to health benefit plans on their renewal dates but not later than October 1, 2014.

S.77

(Cont'd from pg. 4) hasten his or her death; the physician's diagnosis, prognosis, and basis for the determination that the patient was capable, was acting voluntarily, and had made an informed decision; the second physician's diagnosis, prognosis, and verification that the patient was capable, 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 patient's oral and written requests for medication to hasten his or her death or that the physician informed the patient of all feasible end-of-life 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 has 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 the request for medication at the time of the patient's second oral request; and a note by the physician indicating that all requirements under this section were satisfied and describing all of the steps taken to carry out the request, including a notation of the medication prescribed.

(15) After writing the prescription, the physician promptly filed a report with the Department of Health documenting completion of all of the requirements under this section.

In order to be fully eligible for legal immunity following the writing of a lethal prescription, physicians also need to be familiar with the bill's definitions found in section 5281. Among the key definitions used in the above fifteen requirements are the following:

"Capable" means that a patient has the ability to make and communicate health care decisions to a physician, including communication through persons familiar with the patient's manner of communicating if those persons are available (term is used in above requirements 5, 7, 8 and 14).

"Impaired judgment" means that a person does not sufficiently understand or appreciate the relevant facts necessary to make an informed decision (term is used in above requirements 8 and 14).

"Interested person" means: the patient's physician; a person who knows that he or she is a relative of the patient; (C) a person who knows that he or she would be entitled upon the patient's death to any portion of the assets of the patient; or an owner or employee of a health care facility where the patient is receiving medical treatment or is a resident (term is used in above requirement 4).

"Patient" means a person who is 18 years of age or older, a resident of Vermont, and under the care of a physician (term is used in above requirements 1 through 14).

"Terminal condition" means an incurable and irreversible disease which would, within reasonable medical judgment,

result in death within six months (term is used in above requirement 5).

Of great importance to VMS, is the language found in section 5288 stating the new law shall not limit or otherwise affect the provision, administration, or receipt of palliative sedation consistent with accepted medical standards.

The bill also contains a "compromise" that would sunset the above fifteen requirements of section 5283 on July 1, 2016, and replace them with a new set of five more limited requirements as found in section 5289 of the bill. However, it is likely that the statute will be further amended prior to July 1, 2016, and the fifteen requirements will be maintained.

VMS adopted its current policy on physician assisted suicide in 2003 and the VMS Council reaffirmed it in February of 2011. As stated in the policy, VMS believes that any discussion of physician-assisted suicide must be pursued within a broad societal dialogue about the care of sick and dying patients. VMS does not support the passage of laws for or against physician assisted suicide due to a concern that such laws could stifle this dialogue and hinder the provision of high quality end-of-life care. Accordingly, during the legislature's deliberations on the bill, VMS testified there should be no laws concerning physician assisted suicide and it was opposed to the passage of S.77.

Physicians supporting the VMS policy expressed the belief that decisions about dying should be made at the bedside by physicians with their patients. They did not support using multiple legal procedures requiring additional paperwork for physicians and their terminally ill patients as the patients approach end of life.

VMS will continue to be actively engaged in promoting initiatives that assure all dying Vermonters receive good, comprehensive palliative care. These include ensuring that all members of the Society become educated in the goals and techniques of palliative care and that all members become adept at dealing with the dying patients' special needs. The Society believes that such care and training will provide a strong alternative for patients who ask for assisted suicide. Notwithstanding its opposition to S.77, VMS intends to provide physicians with information on the bill's requirements as they are made available by the Department of Health. In addition, VMS will develop and post on its website a frequently-asked-questions on the provision of S.77, as well as update the Guide to Vermont Health Law.

Please contact VMS if you have any questions or suggestions.

To read the text of S.77, as passed, please go to: http://www.leg.state.vt.us/database/status/summary.cfm?Bill=S.0 077&Session=2014