The Legislative Bulletin

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Senate makes significant changes to physician assisted suicide legislation

On February 14th, the Vermont Senate passed amended legislation that would provide legal immunity to physicians and families if a terminally ill patient chooses to hasten his or her own death by taking medication intended to relieve pain. The amendment replaced language in the original version of S.77.

As introduced, S.77 creates a process that patients may use to request medication from their physicians to be self-administered for the purpose of ending life. The attending physician must make a determination that the patient is suffering from a terminal condition, is a Vermont resident, has capacity and has made a voluntary request for the medication. Patients are required to make both an oral and a written request to their physician and to reaffirm the oral request no sooner than 15 days after the initial request. The written request must be signed and witnessed. The physician must also refer the patient to a consulting physician for medical confirmation of capacity, diagnosis, prognosis, and voluntariness. Finally, there is a requirement that the physician submit a report to the department of health noting compliance with all requirements of the law.

Lt. Gov. Phil Scott, an opponent of the original bill cast tie-breaking votes Wednesday and Thursday to support the alternative version. He and others who opposed the original bill supported the alternative version offered Wednesday by Sen. Peter Galbraith and altered by Sen. Ann Cummings. Sen. Galbraith argued after the vote that his version has significant support and would help change the debate to keeping the process simpler than the original bill would have. "I don't want government to be involved," he said. "I think there are plenty of people who agree this ought to be between a patient and her doctor."

House Speaker Shap Smith, D-Morristown, has indicated the House of Representatives will take the bill up and that representatives are more inclined to support the Senate's original version of S.77 creating a program similar to the physician assisted suicide laws in Oregon and in Washington State. Since the legislature will be in recess the week of March 4th for Town Meeting Day, the earliest the bill could be considered by the House would be the week of March 11th.

VMS testified against the original version of S.77 before both the Senate Health and Welfare Committee and the Senate Judiciary Committee based on its current policy[1] on physician assisted suicide, adopted in 2003, stating there should be no laws for or against physician assisted suicide due to a concern that such laws could hinder the provision of high quality end-of-life care. The policy was reaffirmed by the VMS Council in February of 2011. The VMS will continue offering testimony in opposition to laws related to physician assisted suicide in the House of Representatives.

VMS strongly encourages physicians to share their views on the legislation with members of the House of Representatives. For a list of members of the House of Representatives and their contact information, please go to: *http://www.leg.state.vt.us/legdir/LegDirMain.cfm*

To read the full text of S.77 as introduced and as passed by the Senate, please go to: *http://www.leg.state.vt.us/database/status/summary.cfm?Bill=S.0077&Session=2014*

[1] *http://www.vtmd.org/sites/all/themes/vms/documents/policies/2003/PASpolicy.pdf*

Contact Us

P.O. Box 1457
Montpelier, Vermont 05601

Toll-Free: 800-640-8767
Fax: 802-223-1201

Online at: www.vtmd.org

Working for Vermont Physicians at the State House

Paul Harrington
Executive Vice President
pharrington@vtmd.org

Madeleine Mongan
Deputy Exec. Vice Pres.
mmongan@vtmd.org

Stephanie Winters
Operations Director
swinters@vtmd.org

Vermont Medical Society Education and Research Foundation (VMSERF) whitepaper highlighted in joint hearing on Effective Prescribing for Chronic Pain

On Thursday, February 14, Dr. Cyrus Jordan, Director of the Vermont Medical Society Education and Research Foundation (VMSERF) testified to a joint hearing of the House Judiciary Committee and the House Human Services Committee about the whitepaper he submitted to the VMS foundation in November of 2012 – *Safe and Effective Treatment of Chronic Pain in Vermont*[1]. Dr. Jordan was joined by several physicians, most of whom had contributed to the report, including: Dr. Trey Dobson, an emergency physician and the Chief Medical Officer at Southwestern Vermont Medical Center; Dr. Carlos Pino, Director of the FAHC Pain Medicine Center; Dr. Gilbert Fanciullo, Director of the Pain Management Center at DHMC; and Dr. Zail Berry, a pain specialist in private practice. The five physicians' testimony in front of the two committees began in the morning and continued through most of the afternoon, and provided an excellent opportunity for physicians to present their perspectives on this timely and difficult issue.

Dr. Jordan began the hearing by reviewing the findings of the report. Developing standard recommendations for treatment of chronic pain was identified in the VMSERF report as necessary by almost all contributors. Standard treatment recommendations would allow measurement of improvement and serve as the basis for regulations and benefit coverage. The report also identified a number of improvements to the Vermont Prescription Monitoring System (VPMS) that would make it easier to use and more reliable, such as the inclusion of real-time data. Other recommendations in the report addressed public education, professional oversight, differentiating law enforcement from care giving, payment reforms and innovations. Finally, the report expressed concern that payment policies may unintentionally encourage pill prescribing by not covering other types of treatment such as procedures or therapies.

All of the physicians who testified at the hearing praised the Vermont Prescription Monitoring System (VPMS) and spoke about how helpful it was in their practices. At the same time they noted that it was somewhat difficult and time consuming to use, although improving. At this point the VPMS cannot be easily coordinated with electronic medical records, and records must be printed and scanned in order to include them in a patient's electronic health record. Patient confidentiality can be a concern for physicians when using delegates in a larger setting. The physicians uniformly stated that they did not believe that the VPMS should be checked every time a controlled substance is prescribed, but they supported developing guidelines for when to check the database. Treating pain is complex and difficult. Policies that create unnecessary hassles for physicians and that do not improve care could result in unintended consequences and should be avoided. Dr. Berry recommended that the Department of Health notify prescribers when their patients are obtaining controlled substances from multiple prescribers or pharmacies. Dr. Fanciullo described a program he is developing that would create satellite clinics where opiates would be prescribed under strict protocols. Care provided through the satellite clinics would be coordinated with the pain center and would include patient education, treatment contracts and urine monitoring. The program is close to completion, but funding to develop the educational materials for patients is needed. Dr. Pino described the pain care center at FAHC and identified the deficits in the availability of mental health care and substance abuse care as contributing to the problem. Many patients with substance abuse have co-occurring mental health problems and access to mental health treatment is a key solution. One way to improve the integration of mental health and substance abuse care with primary care could be through increasing access through telemedicine.

[1] *http://www.vtmd.org/sites/default/files/files/Safe_and_Effective_Treatment_of_Chronic_Pain_in_VT.pdf*

H. 212 – Registry for Ephedrine and Pseudoephedrine

H. 212 would establish an electronic registry system for monitoring the purchase of products containing ephedrine, pseudoephedrine, or phenylpropanolamine, over the counter drugs that can be used to manufacture amphetamines. Retail pharmacies will be required to record all sales of these products in an electronic registry system. The system would be free, operate in real time and enable communication among in-state users and users of similar systems in neighboring states.

The House Human Services Committee and the House Judiciary will be meeting jointly this week to begin consideration of this bill.

H. 331 – Prescription drug abuse and the Vermont Prescription Monitoring System

H. 331, like S. 67 the Senate bill reviewed in the last Legislative Bulletin, is designed to create a systemic response to the problem of prescription drug abuse and to maximize the effectiveness of the Vermont Prescription Monitoring System (VPMS). All eleven members of the House Human Services Committee co-sponsored H. 331. The bill is almost identical to S. 67 and to the bill passed last year by the House and Senate that died in the conference committee. There are two notable differences in the House and Senate bills this year. First, like last year, the Senate in S. 67, but not the House in H. 331, would permit law enforcement drug diversion investigators to obtain reports of data from the VPMS and use the information from the reports in the normal course of business. Second, H. 331 would require a study of whether practitioners should be able to prescribe naloxone or opioid antagonists to someone who is at risk of experiencing an opiate-related overdose or to a family member, friend or another person who is in a position to provide to someone at risk of overdose.

VMS does not have a position on the issue of providing access to law enforcement.

An outline of the topics addressed in H. 331 follows:

- Prescriptions for regulated drugs will be required to include the quantity of the drug in both numeric and word form;
- Individuals who pick up prescriptions for Schedule II, III, or IV controlled substances will be required to show a photo ID;
- The Department of Public Safety is required to adopt operating guidelines for accessing patients' pharmacy records from pharmacies and the initial guidelines and any amended guidelines must submitted to legislative committees;
- The Medical Director of the Department of Vermont Health Access (DVHA) and the Office of the Chief Medical Examiner are authorized to access the VPMS database;
- Health care professionals or medical examiners licensed in other states are authorized to access the VPMS database as necessary to provide care to Vermonters or investigate deaths of Vermonters;
- In specified circumstances, the Department of Health may also provide reports of data from the VPMS to the Commissioner or Deputy Commissioner of Public Safety or a prescription monitoring system in another state under a reciprocal agreement;
- The Department of Health is authorized to use information from the VPMS for trend analysis, to post the analyses for use by health professionals and the public, and send alerts about trends by email to prescribers and dispensers;
- Professional boards are required to develop evidence-based standards for prescribing Schedule II, III, and IV controlled substances for treatment of chronic pain;
- All providers who prescribe controlled substances on Schedule II, III, or IV are required to register with the VPMS;
- All dispensers who dispense controlled substances on Schedule II, III, or IV are required to register with the VPMS. Licensing authorities for dispensers must create standards for reporting prescription data to the VPMS, which must be no less frequent than once a week;
- Licensing authorities for prescribers and dispensers will develop standards addressing the recommended frequency for VPMS queries. Standards for querying and reporting to VPMS will be considered in disciplinary proceedings by licensing boards;
- "Replacement" prescriptions will be identified on the prescription and in the VPMS.
- A Unified Pain Management System Advisory Council comprised of clinicians will be created to advise the Commissioner of Health on the appropriate use of controlled substances in treating chronic pain and addiction and preventing drug abuse;
- The Commissioners of Health and Public Safety are required to design, implement and publicize a statewide drug disposal program for unused prescription and over the counter drugs;
- The Departments of Health and Vermont Health Access (DVHA) are required to work with manufacturers of buprenorphine, prescribing practices and pharmacies to create a "track and trace" pilot project to use to identify irregularities related to buprenorphine dosing and quality; and,
- The Department of Health would study prescribing naloxone for use in cases of overdose by patients, their family, friends or caregivers. There are naloxone programs in several states that will be reviewed as part of this process.

The House Human Services Committee will begin to review this bill this week.

Office of Professional Regulation Report (OPR) on Naturopaths Prescribing

The Office of Professional Regulation (OPR) recently released a report addressing prescriptive authority for naturopaths. The purpose of the report was to determine if naturopaths receive sufficient academic training in pharmacology and clinical training to safely prescribe and administer all prescription drugs including all controlled substances, both on and off label, by all routes of administration. OPR consulted closely with the Department of Health throughout the process of preparing the report and the Commissioner of Health, Harry Chen, M.D., testified that he was very supportive of the report and the recommendations, finding that it struck a conservative balance. He noted that the naturopaths are professionals and know what they are trained to do. He thought legislators could rely on the naturopaths' professionalism, the OPR regulatory system and the tort system to protect the public, if naturopaths were authorized to prescribe all drugs.

Vermont has had a formulary in place for the naturopaths since they were first licensed in 1996. A new formulary was created by a group of physicians, pharmacists and naturopaths working collaboratively with the Department of Health and OPR, around 2007. The formulary included safe drugs that would typically be used by primary care year one residents without intense supervision. The proposal agreed on by the group was that the naturopaths would qualify to use this formulary by passing a test agreed on by the same group. In 2009 the naturopaths and OPR, without consulting with the multi-disciplinary group, approved an open-book test and subsequently authorized the use of the formulary developed by the group.

Last year OPR and the Naturopath Advisors proposed to repeal the formulary and permit naturopaths to obtain a license endorsement that would enable them to prescribe all prescription drugs. Prior to implementing this change, at the request of VMS, the legislature asked OPR, in consultation with others, to review the academic curricula and the clinical training that naturopaths receive in order to determine if they had sufficient academic and clinical training to prescribe without limitation, any drug, any dosage regimen, by any route of administration, including controlled substances, either on-label or off-label.

The report submitted by OPR in early February found that naturopaths "complete a four-year post-graduate education that includes clinical pharmacology training to prepare them for prescribing medications commonly used in general and primary care practice." The report found, however, that the exam that the naturopaths take focuses on drug interactions and side effects and not on dosing or safe, effective prescribing. Due to the variations the report found in the training received by naturopaths, the report proposed three recommendations.

First, the report requires naturopaths to take and pass all the course examinations required for the UVM College of Medicine's Medical Pharmacology CME course or a substantially equivalent course. The course is a full-day, one-month pharmacology course designed for medical students and is rigorous and accredited. VMS believes that this examination proposal is much better than the proposal last year, which was to continue use of the open-book test designed by two Vermont naturopaths that was not validated. While VMS is very much in support of this test, VMS believes that taking one academic course and passing a test is only one part, and a small part, of the education and training that is needed to prescribe drugs safely and effectively. VMS also supports continued use of a formulary.

Second, the report would require a prescription review process for new practitioners of not less than one year. As explained by the Director of OPR, naturopaths' prescriptions would be reviewed by MDs or DOs, at least at first. After five years, new practitioners' prescriptions could be reviewed by naturopaths who have had at least five years of prescribing experience. This prescription review requirement will be spelled out in the rules, but OPR testified that they are "leaning towards" requiring no less than a minimum of 100 prescriptions be reviewed.

The third recommendation is not specific at this point. It states that in the rules OPR will propose that use of certain off-label indications, dose regimens and routes of administration by naturopaths may be limited or prohibited. VMS will continue to advocate for public safety in the rulemaking process.

VMS members are concerned about their patients who receive care from naturopaths. Prescribing drugs is not easy. Allowing full prescribing authority for naturopaths is not consistent with physicians' understanding of the naturopaths' approach to care. Physicians believe that naturopaths' practice is not focused on prescription drugs; and similarly the majority of their training is not in prescribing prescription drugs. Physician training in prescribing is not just a single course in pharmacology. Clinical training in how to prescribe drugs is a major part of clinical rotations in both medical school and residency programs.

The administrative rules process will begin soon and will include a public hearing and an opportunity to submit written comments.