The Legislative Bulletin

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In This Issue:

Senate Committee Endorses VMS-Supported Bill Limiting Pharmaceutical Company Grants and Gifts to Physicians

Last week the Senate Finance Committee voted out favorably S. 48, an act relating to the marketing of prescribed products. The legislation bans many gifts outright and mandates full disclosure of allowable gifts to physicians, health care organizations, state-funded academic institutions and non-profit groups. The bill also strengthens existing disclosure laws, eliminating an exemption on gifts of less than $25 in value, making the disclosed information easier for the public to access and narrowing trade secret exemptions. The legislation is one further step in Vermont's efforts to control the cost of pharmaceuticals by regulating the marketing activities of drug companies and it is consistent with the VMS's recently adopted resolution on Grants and Gifts to Physicians.

During a statehouse press conference announcing the bill late last month, VMS President John Brumsted, M.D., expressed support for the legislation.

"Patients need to have confidence in the prescribing decisions of their doctors," said Dr. Brumsted. "Greater transparency around relationships with pharmaceutical companies allows for that confidence and protects the doctor/patient relationship."

Under the bill, a new distinction is created between "allowable expenditures" that may or may not be reported to the Office of the Attorney General (OAG), and pharmaceutical "gifts," most of which would be banned. By September 1st of each year, pharmaceutical manufacturers would be required to disclose to OAG the value, nature, purpose, and recipient of any allowable expenditures (with the exception of royalties and licensing fees). The disclosures would be publicly available and searchable on OAG's Web site. By April 1st of each year, OAG would report on the allowable expenditures and gifts disclosed during the past year to the Governor and the General Assembly.

The bill does exempt from the ban and reporting requirements the following gifts: samples of a prescription drug provided to a health care professional for free distribution to patients; peer-reviewed academic, scientific or other clinical articles or journals; scholarships for medical students, residents or fellows to attend an educational seminar of a national professional organization; and rebates and discounts for prescription drugs.

"Allowable expenditures" is defined under the bill as: payment to the sponsor of a seminar, provided that all program content is free from industry influence and does not promote specific products. The definition also includes the following: honoraria and payment of the expenses of a health care professional who serves on the faculty at a seminar; compensation for a bona fide clinical trial; compensation for a research project; royalties and licensing fees paid to health care professionals in return for contractual rights to use a patented or otherwise legally recognized discovery; and other reasonable fees, payments, subsidies, or additional benefits provided by a pharmaceutical manufacturer at fair-market value.

The finance committee rejected an amendment supported by VMS that would have permitted items provided to a physician or the physician's staff that constituted benefit to patients and are not of a substantial value, including textbooks, educational items and modest meals that serve a genuine educational function. Once the legislation passes the Senate, it will be considered by the House Health Care Committee.

VMS meets with Key Legislators and Boards of Nursing and Medical Practice to Discuss APRN Rules

The Vermont Board of Nursing (BON) is currently in the process of redrafting regulations regarding advanced practice nurses (APRNs), potentially ending the requirement that they have a written collaborative agreement with physicians.

While VMS provided extensive comments on a draft of the regulation last summer, earlier this month BON released a second draft of the regulation that in VMS's estimation would provide an even lower standard of accountability for advanced practice nurses. The fact that the Board of Nursing is doing this through rulemaking, as opposed to legislative process, has made it extremely difficult to find a neutral forum to present the concerns of VMS and its members.

As part of an effort to ensure meaningful legislative oversight, VMS staff had an initial conversation with the chairs of the House Health Care and Government Operations committees and raised concerns that this significant expansion of the responsibilities of nurse practitioners was taking place without appropriate legislative input or oversight. This conversation resulted in a follow-up meeting attended by: VMS staff; Vermont Board of Medical Practice (VBMP) Director Bill Wargo and VBMP chairman, Dr. David Clauss; BON Director Mary Botter, RN, PhD; representatives from the Secretary of State's office; members of the House Government Operations Committee; chair of the House Health Care Committee; and, the director of the Health Care Reform Commission.

The meeting began with VMS raising its concerns regarding the process the Secretary of State's office was following in order to allow nurse practitioners to practice independent of any collaborative agreement. As expected, representatives of the Secretary of State's office defended the rulemaking process as allowing for full public input and potential legislative oversight. VBMP Chair Dr. Clauss raised concerns about the need for comparable regulation and accountability if advanced nurse practitioners were to be granted the authority to practice independently.

A recommendation was made by the chair of the House Health Care Committee that the process going forward should follow two tracks: allow the current BON rulemaking process now underway to continue; and, simultaneously pursue a legislative process that would begin drafting legislation to ensure statutory oversight requirements comparable to those in place for other regulated professionals, such as physicians, physician assistants, osteopathic physicians, podiatrists, and anesthesiologist assistants.

The VMS committed to BON that it would provide both comments to its most recent draft of the proposed rule as well as a suggested legislative framework for its April board meeting.

The meeting represents a milestone in the VMS's involvement in this issue. It has clearly put the APRN issue on the radar screen of key legislators as well as created a heightened awareness among BON staff that their rule will receive extensive scrutiny. Additionally, legislators' interest in creating a statutory requirement for advanced nurse practitioners will give us an opportunity to recommend a parallel level of accountability and oversight.

As the rule moves forward VMS will continue to express concern about the nursing board's proposal to allow advance practice registered nurses to practice independently without a collaborative agreement with a physician. This proposal is not supported by evidence and VMS believes that it is likely to create a double standard of care for patients, as well as a double standard of oversight and regulation for comparable professionals. VMS is particularly concerned about the proposal to permit APRNs of any specialty including nurse anesthetists (CRNAs), nurse midwives (CNMs) and psychiatric nurse practitioners to practice independently as independent practice by these specialties has not been studied.

Likewise, VMS fully supports concerns raised and recommendations made by VBMP, which are directed at minimizing risks to patient safety and maximizing access of Vermonters to high-quality medical care. VBMP's recommendations, which were included in a letter sent to BON last January, address requiring clinical training for APRNs, requiring practice under a collaborative arrangement or mentorship prior to independent practice, charging a multidisciplinary group with creating a formulary for APRNs practicing independently, and regulation by a board made up of professionals with at least the same level of training as the APRNs. VMS also recommends that the level of regulation, training and oversight for APRNs in Vermont be at least comparable to the level established in New Hampshire and Maine.

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VMS meets to Discuss APRN Rules

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Finally, VMS recommends that the basic provisions of regulation for APRNs be included in statute, not be left to the discretion of BON to establish by rule without comprehensive legislative oversight. Comparable professionals such as physician assistants and anesthesiologist assistants each have their own chapter of law governing the requirements for certification, education, examination, renewal of certification, supervision and scope of practice, unprofessional conduct, legal liability, fees, and notice of use of a physician assistant. While the general unprofessional conduct provisions that apply to all professions regulated by the office of professional regulation (from accountants to veterinarians) and the provisions for registered nurses would apply to APRNs, there are a number of provisions that should be added to address independent practice.

FTC Issues Red Flags Rules for Possible Identify Theft

The Federal Trade Commission (FTC) has announced that it has extended the deadline for compliance with the "red flags rules" from Nov. 1, 2008, to May 1, 2009, giving covered entitles additional time to develop and implement written identity theft prevention programs. In extending the deadline, the FTC noted the confusion and uncertainty about coverage under the rule in certain industries and entities, including the health care industry. Depending on their billing practices, physicians could potentially be required to comply with the red flags rules.

In late 2007, the FTC in conjunction with other federal agencies issued the so-called red flags rules requiring financial institutions and other creditors to develop and implement identity theft prevention programs. A red flag is a suspicious circumstance that should prompt the financial institution or creditor to be alert for possible identity theft.

Staff attorneys at the FTC have taken the position that physicians are "creditors" for purposes of the red flags rules unless they require full payment up front at the time that services are provided to a patient. Accordingly, a physician who bills patients after services are provided or allows installment payments could be considered a creditor and, therefore, required to develop and implement a written identity theft prevention program, in accordance with these rules.

According to a letter to the FTC dated Sept. 30, 2008, the American Medical Association (AMA) and other health care organizations strongly disagree with the conclusion that physicians are creditors and the application of the red flags rules to physicians. It is unknown, however, when or if the FTC will respond to the AMA letter or provide further clarification on the application of the rules to physician practices or other healthcare providers.

Earlier this month VMS joined AMA and other health care organizations in signing a second letter to the FTC that strongly objected to physicians being subject to the red flags rule and raised objections to the process FTC has undertaken to implement the new rules (*see the letter at www.vtmd.org).*

At least for now, physicians have a reprieve until May 1, 2009 from requirements to have an identity theft prevention program in place. In a recent communication to the VMS, the AMA indicated that it will continue its efforts to convince not only the FTC but the broader Obama administration of its objections to the FTC's interpretation that physicians are creditors and, therefore, subject to the "red flags rule." The VMS will keep physicians informed on this issue as it receives additional information.

For more information, please go to:
http://www.ftc.gov/opa/2008/10/redflags.shtm

Free DocSite Registry Licenses

Ninety five free DocSite registry licenses are available to assist Vermont physicians in small practices successfully report in 2008 and 2009 under Medicare's PQRI program.

In April 2008, the Centers for Medicare and Medicaid Services (CMS) announced simplified PQRI reporting requirements, authorizing sanctioned registries such as DocSite to use clinical data instead of administrative codes for patient tracking and data submission.

Vermont physicians using DocSite, or other approved registries, will have a simple and effective way to earn the Medicare PQRI bonuses in 2008 and 2009. DocSite submits clinical data on behalf of the provider, completely avoiding the G-code / CPT-II codes and claims data modification in the standard PQRI submission process.

For information on obtaining a free DocSite registry license, please contact Colleen Magne at (800) 640 8767.

Governor proposes to cut Medicaid reimbursement to physicians by Eight percent - $6.6 million payment cut will save only $2.0 million in State expenditures

Governor Douglas' state fiscal year 2010 (SFY10) budget proposes to cut physician Medicaid reimbursement in three areas by a total of $6.6 million, effective July 1st. This represents an eight-percent cut, based on $81.7 million in projected physician payments in SFY10.

Since Medicaid is paid for jointly by federal and state governments, any reduction in payments to physicians would be significantly less than the savings to the state. President Obama's economic stimulus package increases federal support for the state's Medicaid program in SFY10 from 60 percent to approximately 70 percent. With this additional federal financial support, Vermont would only save $0.30 in state expenditures for every $1.00 reduction in physician Medicaid reimbursement. Thus the $6.6 million cut in reimbursement to physicians would only save the state $2.0 million in expenditures.

Four-percent cut in physicain reimbursement for all non-evaluation and management procedures. Total reimbursement cut $1.7 million ($0.5 million state savings) - OVHA has recommended that Medicaid reimbursement for all non-evaluation and management procedures be reduced by four percent. This four-percent reduction is on top of the 7.5-percent reduction for the same procedures that took place on July 1, 2005 (there has not been an increase for these procedures since that date). Under the proposal, reimbursement for evaluation and management codes (99201-99499) would not be effected by the reduction and they would continue to be reimbursed at the 2006 Medicare rate.

Cut Primary Care and Case Management fees in half. Total Reimbursement cut $2.6 million ($0.8 million state savings) - OVHA has recommended that the Primary Care and Case Management fees paid to primary care physicians be cut from five dollars per month to $2.50 per month. This reduction will put at risk a primary care case management program in which 60,000 beneficiaries select their Primary Care Provider (PCP) and access health services through a PCP working with them to assure high quality medical care.

20-percent cut in reimbursement for most procedures for 16,000 Medicare/Medicaid eligible patients. Total Reimbursement cut $2.3 million ($0.7 million state savings) - OVHA has recommended paying crossover-claims at the Medicaid rate in instances where the patient is covered under both Medicare and Medicaid. Under this proposal, the state's Medicare 20 percent beneficiary co-insurance payment on behalf of the patient would be limited to the Medicaid amount. For procedures where the Medicaid fee schedule is less than 80 percent of Medicare, physicians would receive no payment for the 20 percent co-insurance amounts paid by patients under Medicare Part B. The policy change could also result in an even greater cut in payment for psychiatric services, since the Medicare beneficiary co-insurance amount for these procedures is 50 percent. Under the proposed policy, primary care physicians would receive a 12-percent cut in their reimbursement for most routine office visits, since Medicaid is paying 88 percent of the current Medicare rate for 99213, the most frequently billed evaluation and management code.

<u>In order to help ensure that Vermonters covered by the Medicaid program have continued access to medical services, VMS urges physicians to contact members of the House and Senate Appropriations Committees</u>
(*go to the VMS website www.vtmd.org for contact info.*)

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