REPORT OF THE GOVERNOR AND
THE SECRETARY OF HEALTH AND HEALTH RESOURCES

Progress Report on Implementation of a Policy Barring Physicians or Health Care Practitioners from Prescribing an Alternative Brand of Medications because of Financial Incentives

TO THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2009

Progress Report
Implementation of a policy barring physicians or health care practitioners from prescribing an alternative brand of medications because of financial incentives

Executive Summary

On behalf of the Governor and Secretary of Health and Human Resources, the Director of the Department of Health Professions and staff met with the interested parties, obtained background information, sought additional input, researched the issues, and provided suggestions.

Background:

House Joint Resolution 79 (2008) requests the Governor and the Secretary of Health and Human Resources to implement a policy barring physicians or other health care practitioners from prescribing an alternative brand of medication because of financial incentives offered to the physician or other health care practitioner without first disclosing the incentives offered to the patient or the patient's parent, legal guardian, or other authorized representative.

The resolution was supported by:

- NAMI, National Alliance on Mental Illness in Virginia
- Lupus Foundation of Virginia, Inc.
- National Kidney Foundation of the Virginias
- Virginia Interfaith Center for Public Policy
- Men's Health Network
- Patient Centered Quality Alliance
- American Lung Association of the Atlantic Coast
- Alzheimer's Association in Virginia
- Allergy & Asthma Network Mothers of Asthmatics

Progress:

During meetings with the requestor and Pfizer representative concerning the resolution, there appeared to be no immediate concern about conduct or practices in Virginia. However, concerns were expressed that Pharmacy Benefits Managers (PBMs) and health plans incentivized prescribers to write prescriptions for generic drugs or certain brands over other name brands, as well as action taken in other states.

According to the information submitted by the advocates, HJR 79 was designed to create transparency for patients in prescription drug care. Concerns were expressed that across the country, healthcare practitioners are switching medicines based increasingly on cost considerations and perhaps without appropriate regard for what the best treatment option is for individual patients.

Further, according to the supporter representatives, inappropriately cost-driven switching can hurt patients by:

- Undermining a physician-patient relationship;
- Prioritizing profits over patient health;
- Ignoring important differences between medicines;
- Reducing adherence to treatment;
- Creating dose confusion;

Concerns were raised by hospitals and nursing homes about implications for facility formularies. Requests were made to ensure that any policy be carefully drafted so it does not unintentionally impact legitimate practices such as prescribing under formularies or clinical trials.

Additional background information including articles and relevant states' laws and regulations regarding these issues were requested. *See attachment for articles received.*

Information provided from other states reviewed included:

- North Carolina's Medical Board position statement regarding referral fees and fee splitting was reviewed: http://www.ncmedboard.org/Clients/NCBOM/Public/NewsandForum/fee.htm
- Information was also provided regarding North Carolina's statute concerning *Referral Fees and Payment for Certain Solicitations Prohibited.*

http://www.ncga.state.nc.us/EnactedLegislation/Statutes/HTML/ByChapter/Chapter_90.html

- New York State Assembly bills introduced in 2008 but not enacted: SO7516; A11237; prohibiting incentive arrangements for inducing a health care provider to change prescriptions.

Statement from the American Medical Association on physicians receiving payments from health insurers for switching a patient to a generic drug:

"A physician accepting payment from an insurer in exchange for moving a patient from a brand name to a generic drug could potentially face both criminal and civil liability exposure under the federal antikickback statute (Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)). The antikickback statute prohibits individuals or entities that knowingly and willfully offer or receive anything of value (1) in order to induce or reward the referral of business, or (2) in return for ordering any good, if payment for the good or referred business is at least

partially made by a federal health care program (e.g., Medicare Advantage). Accepting payment for moving patient from a brand name to a generic could be viewed as an antikickback statute violation (e.g., the physician receiving something of value, such as a cash payment, to prescribe the generic instead of the brand name drug). Violations of this law are punishable by up to five years in prison, criminal fines of up to $25,000, civil monetary penalties up to $50,000, and exclusion from participation in federal health care programs like Medicare."

Current Standards of Conduct and/or Practice Act which would prohibit a practitioner from receiving "Kickbacks" in Virginia

Virginia Department of Health Professions' staff reviewed existing scope of practice and unprofessional conduct laws or regulations for all professions regulated by the Department including doctors, nurse practitioners, physician assistants, dentists, pharmacists, optometrists, and veterinarians to see if the conduct was already barred. None of the 14 boards reported receiving complaints concerning the issues raised.

- The Board of Medicine has the following laws and regulations that could apply:

  § 54.1-2915. Unprofessional conduct; grounds for refusal or disciplinary action.

  A. The Board may refuse to admit a candidate to any examination; refuse to issue a certificate or license to any applicant; reprimand any person; place any person on probation for such time as it may designate; suspend any license for a stated period of time or indefinitely; or revoke any license for any of the following acts of unprofessional conduct:

  1. False statements or representations or fraud or deceit in obtaining admission to the practice, or ***fraud or deceit*** *in the practice of any branch of the healing arts;*
  16. Performing any act ***likely to deceive, defraud, or harm the public****;*
  18. Violating or cooperating with others in violating any of the provisions of Chapters 1 (§ 54.1-100 et seq.), 24 (§ 54.1-2400 et seq.) and this chapter or regulations of the Board;

  18VAC85-20-28. Practitioner-patient communication; termination of relationship.

  A. Communication with patients.
  1. Except as provided in §32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately inform a patient or his legally authorized representative of his medical diagnoses, prognosis and prescribed treatment or plan of care. A practitioner ***shall not deliberately make a false or misleading statement*** *regarding the practitioner's skill or the* ***efficacy or value of a medication****, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition.*
  2. A practitioner shall present information relating to the patient's care to a patient or his legally authorized representative in understandable terms and encourage participation in the decisions regarding the patient's care.

- The Board of Pharmacy has the following regulation that applies:

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.

A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders unless fully disclosed in writing to the patient and any third party payor.

B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

Policy Options:

1. No additional action is needed as existing policies noted above within the Department of Health Professions are in effect through current specific regulations by the Board of Pharmacy and related law and regulation governing the Board of Medicine. No known complaints exist by any of the health regulatory boards.

2. Additional action could be considered to further the intent of the resolution requesting the Governor and the Secretary of Health and Human Resources to implement a policy barring physicians or other health care practitioners from prescribing an alternative brand of medication because of financial incentives offered to the physician or other health care practitioner without first disclosing the incentives offered to the patient or the patient's parent, legal guardian, or other authorized representative, by adopting a policy statement which stresses the need for disclosure or transparency of information.

However, it is doubtful that a policy statement adopted by the Governor and the Secretary would have a direct impact on all prescriber practices or disclosures of incentives.

The only program where such a policy would have a direct effect would be Medicaid, which has a formulary (list of drugs) used as a basis for payment. Caution is expressed by hospitals and nursing homes to avoid unintentional consequences that might impact legitimate practices such as prescribing under hospital formularies or clinical trials. Additional stakeholders would need to be involved in any additional actions considered.

Emphasis on prescriber-patient communication and transparency about a relationship with a supplier of drugs, such as a pharmaceutical company or drug warehouse, is an important consideration.

3. Additional regulations regarding the issues **could be introduced** for consideration by relevant entities as provided by the following provisions in the Administrative Process Act:

§ 2.2-4007.01. Notice of intended regulatory action; public hearing.

A. In the case of all regulations, except those regulations exempted by § 2.2-4002, 2.2-4006, 2.2-4011, or 2.2-4012.1, an agency shall provide the Registrar of Regulations with a Notice of Intended Regulatory Action that describes the subject matter and intent of the planned regulation. At least 30 days shall be provided for public comment, to include an on-line public comment forum on the Virginia

Regulatory Town Hall, after publication of the Notice of Intended Regulatory Action. An agency shall not file proposed regulations with the Registrar until the public comment period on the Notice of Intended Regulatory Action has closed.

§ 2.2-4007. Petitions for new or amended regulations; opportunity for public comment.

A. Any person may petition an agency to request the agency to develop a new regulation or amend an existing regulation. The petition shall state (i) the substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections, and (ii) reference to the legal authority of the agency to take the action requested.

4. Other policy options may be considered in the future if the need arises.

HOUSE JOINT RESOLUTION NO. 79

Requesting the Governor and the Secretary of Health and Human Resources to implement a policy barring physicians or other health care practitioners from prescribing an alternative brand of medication because of financial incentives. Report.

Agreed to by the House of Delegates, January 17, 2008
Agreed to by the Senate, March 4, 2008

WHEREAS, across the United States, physicians and patients are often encouraged to switch medicines based on cost considerations; and

WHEREAS, the best treatment option for each individual should be the primary concern for physicians and other health practitioners in determining such treatment options, including prescriptive medications; and

WHEREAS, FDA-approved generics are safe and effective and often represent an opportunity for much-needed health care cost savings; and

WHEREAS, patients assume that physicians and other health practitioners authorized to prescribe medications base treatment decisions, including decisions regarding prescription of medication, on their clinical expertise and ethical guidelines; and

WHEREAS, the patient-health practitioner relationship relies on the confidential, honest, and transparent exchange of information; and

WHEREAS, physicians or health practitioners receiving financial incentives to prescribe certain medications violate that relationship when patients are not informed of said practitioner's financial incentives; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Governor and the Secretary of Health and Human Resources be requested to implement a policy barring physicians or other health care practitioners from prescribing an alternative brand of medication because of financial incentives offered to the physician or other health care practitioner without first disclosing the incentives offered to the patient or the patient's parent, legal guardian, or other authorized representative.

The Governor and the Secretary of Health and Human Resources shall submit to the Division of Legislative Automated Systems an executive summary and report of its progress in meeting the request of this resolution no later than the first day of the 2009 Regular Session of the General Assembly. The executive summary and report shall be submitted for publication as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.