



COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND



January 11, 2017

COMMITTEE ASSIGNMENTS:
COMMERCE AND LABOR (VICE CHAIRMAN)
FINANCE
SCIENCE AND TECHNOLOGY

KATHY J. BYRON
POST OFFICE BOX 900
FOREST, VIRGINIA 24551
TWENTY-SECOND DISTRICT

The Honorable Bill R. DeSteph, Jr.
General Assembly Building, Room 306
Capitol Square
Richmond, Virginia 23219

The Honorable Frank W. Wagner
General Assembly Building, Room 304
Capitol Square
Richmond, Virginia 23219

Re: Senate Bill 331 - Step therapy, psychiatric medicines; and
Senate Bill 332 - Step therapy protocols.

Dear Senator DeSteph and Senator Wagner:

By letter dated April 27, 2016, Susan Schaar advised me that the Senate Committee on Commerce and Labor referred the subject matter contained in Senate Bill 331 and Senate Bill 332 to the Health Insurance Reform Commission (the Commission). I was asked to provide each of you, as patron of Senate Bill 331 and Senate Bill 332 and as chairman of the Senate Committee on Commerce and Labor, respectively, with a written report.

As you will recall, Senate Bill 331 would prohibit a health insurer or other carrier from using step therapy in a manner that results in a denial or delay in coverage for any psychiatric medication under a health insurance policy or plan. Senate Bill 332 would require health benefit plans that use a step therapy protocol to have a process for requesting an override of such protocol.

During the September 27, 2016, meeting, the Commission received testimony on the practice of step therapy. A summary of the testimony received at the meeting is enclosed. The proponents of the legislation testified that step therapy protocols interfere with a physician's ability to adequately treat his patients and are particularly problematic when treating patients with mental health needs. The opponents of the proposed legislation testified that the steps are based on sound clinical evidence, there are already systems in place to circumvent step therapy protocols, and step therapy protocols are required to avoid unnecessary costs associated with the over-prescription of name-brand pharmaceuticals.

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The Honorable Frank W. Wagner
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The Department of Human Resource Management (DHRM) conducted a fiscal impact analysis for the bills related to step therapy and concluded that the fiscal impact of House Bill 362 would be \$1.25 million. The analysis is enclosed.

The Commission studied the issue without making a recommendation and does not plan to take any further action on SB 331 and SB 332.

With kind regards, I am

Sincerely,

A handwritten signature in black ink that reads "Kathy Byron". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Kathy J. Byron, Chair
Health Insurance Reform Commission

Enclosures

cc: Susan Schaar, Clerk of the Senate
Emma Buck, Division of Legislative Services
Franklin D. Munyan, Division of Legislative Services
Scott Maddrea, House Committee Operations

Step Therapy Protocols

Report on Senate Bill 331 and Senate Bill 332

Senate Bill 331, introduced by Senator Bill De Steph, Senate Bill 332, introduced by Senator De Steph and House Bill 362, introduced by Delegate Glenn Davis, all propose requiring a process for the granting of an override to the step therapy protocol when the treating physician believes it to be necessary. HB 362 and SB 332 apply to all prescription drugs and require no protocol for patients who either satisfied the protocol or were granted an override. HB 362 was passed by indefinitely with a letter in the Senate Commerce and Labor Committee on a vote of 15-0. SB 332 was passed by indefinitely with a letter in the House Commerce and Labor Committee on a vote of 15-0. SB 331 applies to psychiatric medications only. This bill was passed by indefinitely with a letter in the House Commerce and Labor Committee on a vote of 15-0.

During the September 27, 2016, meeting, the Health Insurance Reform Commission (the Commission) received testimony on the practice of step therapy. Delegate Davis, patron of HB 362, introduced the topic of step therapy as a process whereby an insurer establishes a specific sequence in which prescription drugs for a certain medical condition are medically appropriate and covered by a health plan. Under step therapy, coverage of a prescription medication is often conditioned on a patient's first trying an alternative, often generic, medication without success. Delegate Davis gave a personal testimonial about his wife's struggle to obtain needed medicine that her doctor prescribed because of step therapy protocols in place under her health insurance coverage.

Delegate Davis introduced Denise Marksburg and Marcus Jones, who each provided personal testimony about the difficulty of obtaining required medication due to step therapy protocols. Ms. Marksburg testified that she has rheumatoid arthritis and goes through an appeals process each time her medication is changed and that she has been following step therapy protocols for four years. Mr. Jones, Chair of Government Relations for the Multiple Sclerosis Society for West Virginia and Virginia, testified that the generic drug that his wife was required to try before gaining access to the drug originally prescribed by her doctor was ineffective and left her very weak. When she eventually obtained the prescribed drug, Mr. Jones testified, her quality of life improved significantly.

Senator DeSteph, patron of SB 331 and SB 332, testified to the importance of this issue and of the doctor-patient relationship. He explained that step therapy protocols can interfere with the choices made by the patient and the prescribing doctor. The prescribing doctor, rather than the insurance company, knows the patient the best.

Delegate Davis introduced Dr. Kent McDaniel, a psychiatrist with Henrico Area Mental Health and Development Services. Dr. McDaniel testified about his concerns regarding step therapy and the algorithms used by the insurance companies to create the step therapy protocols. The algorithms are based on population studies rather than on the unique characteristics of the patient. For patients with mental health needs, he maintained, it is very important to provide the right drug the first time instead of trying something else first to see if it fails; the failure of medication could mean that such patients end up in the hospital or in jail. Additionally, such patients often miss follow-up appointments or grow distrustful of medication, so it is detrimental to their health to waste time on potentially ineffective medication. Obtaining prior authorizations

is time consuming, and Dr. McDaniel reported that he sometimes pays for patients' medication out of pocket rather than wait for the prior authorizations. Dr. McDaniel stated that his group records the time spent on obtaining prior authorizations, which totals 1,500 hours a year. Senator Frank Wagner asked if he receives automatic authorization for patients with Medicaid or Medicare, and Dr. McDaniel responded that he does with Medicaid but not with Medicaid HMO.

Dr. Olabisi Oshikanlu, Medical Director for Aetna, spoke on behalf of the Virginia Association of Health Plans. Dr. Oshikanlu explained that health plans develop their step therapy programs in accordance with Virginia law, which requires that health plans have a Pharmacy and Therapeutics Committee comprising independent practicing physicians and pharmacists to develop the drug formularies. The purpose of the step therapy protocols is to ensure that doctors are using tried and true medications rather than prescribing medications because they are being pushed by pharmaceutical companies or requested by a patient on the basis of advertising. The goal is to use effective, less risky drugs before advancing to potentially more risky and expensive options. Dr. Oshikanlu stated that Aetna uses a holistic approach to managing mental health, where case managers follow the patient and ensure that methods of care beyond just medication are being employed. "Transition Fill" programs, which permit a one-time fill for the medication to allow time for the prior authorization to occur, are available for most maintenance medications. Step therapy programs ensure portability because, by state law, once patients go through step therapy, they will not have to repeat the steps even if they go to a new plan so long as they can prove that they completed the steps. Costs are a motivating factor in step therapy programs because of the high cost of prescription drugs, particularly specialty drugs. These high-cost drugs can increase noncompliance if patients cannot afford the deductible, which leads to a burden on the health system and other negative consequences. Prior authorization policies are on the health plan websites, and health professionals handle the calls.

The Bureau of Insurance (BOI) noted that it receives complaints about step therapy protocols and assists individuals seeking to appeal the application of a protocol to obtain prescribed medication.

The Department of Human Resource Management conducted a fiscal impact analysis for the bills related to step therapy. This analysis concluded that the fiscal impact of HB 362 and SB 332 would be \$1.25 million. The fiscal impact of SB 331 would be less than \$45,000.

Doug Gray, Director of the Virginia Association of Health Plans, concluded the discussion on step therapy. He testified that managed care is necessary for adequate access to care and that managed care is a group effort with protections in place. He stated that health plans can currently be fined if there are excessive wait times and that if the providers are having issues with work hours spent on prior authorizations, they should be reporting those instances to the BOI.

The Commission received testimony on HB 362, SB 331, and SB 332 but did not make any recommendations.



COMMONWEALTH of VIRGINIA

SARA REDDING WILSON
DIRECTOR

Department of Human Resource Management

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RICHMOND, VIRGINIA 23219
(804) 225-2131
(TTY) 711

September 21, 2016

Dear Health Insurance Reform Commission:

This letter includes the Department of Human Resource Management's estimates of the fiscal impact of the following 2016 bills: HB 601, HB 362 / SB 332, and SB 331.

HB 601- Mandated coverage for treatment of inborn errors of metabolism

Analysis: The Commonwealth's health benefits program currently provides coverage for products and services as referenced in HB 601, if they are prescribed by a physician and required to maintain adequate nutritional status. The current pharmacy benefit has a prior authorization requirement to ensure appropriate therapy.

Methodology: In FY 2015, there were fewer than 75 claims for medical foods, nutritional supplements and metabolic infant formulas. For FY 2016, the utilization of these products under the pharmacy benefit decreased and drug spend was minimal.

HB 601 Fiscal Impact: Less than \$10,000 assuming that prior authorization requirements are allowed to continue.

HB 362/SB 332- Step therapy protocols, disclosure of information

Analysis: Step therapy is a process by which patients must try proven, lower cost drugs before moving on to higher cost medications. These steps are designed by a plan's Pharmacy and Therapeutics Committee, a regulated group of physicians and pharmacists who identify common, evidence-based treatment methods. This legislation potentially removes important safety and cost saving measures from the process of administering the prescription drug plan.

Methodology: The Commonwealth plans achieved significant savings as a result of step therapy protocols, approaching \$5 million in FY 2016. Our modeling used the fiscal impact factors and cost avoidance realized during FY 2016 and assumed 25% of step therapy cases would be bypassed if prescribers were given the opportunity.

HB 362/SB 332 Fiscal Impact: Based on current modeling, it is anticipated that the fiscal impact would be \$1.25 Million.

SB 331- Step therapy for psychiatric medications

Analysis: Step therapy is a process by which patients must try proven, lower cost drugs before moving on to higher cost medications. These steps are designed by a plan's Pharmacy and Therapeutics Committee, a regulated group of physicians and pharmacists who identify common, evidence-based treatment methods. This legislation potentially removes important safety and cost saving measures from the process of administering the prescription drug plan.

Methodology: The fiscal impact is based on FY 2016 utilization and current step therapy protocols. A 1% increase in Rx claims is anticipated.

SB 331 Fiscal Impact: Less than \$45,000

I hope this information is helpful. I look forward to the Health Insurance Reform Commission meeting on September 27, 2016. If you have additional questions, please let me know.

Sincerely,



Gene Raney
Director, Office of Health Benefits