COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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October 23, 2009

MEMORANDUM

TO: The Honorable Charles J. Colgan
Chairman, Senate Finance Committee

The Honorable Lacey E. Putney
Chairman, House Appropriations Committee

The Honorable R. Edward Houck
Chairman, Joint Commission on Health Care

Daniel S. Timberlake
Director, Virginia Department of Planning and Budget

FROM: Patrick W. Finnerty

SUBJECT: Report on Specialty Drug Program

Item 306 (CC)(5) of the 2009 Appropriations Act requires the Department of Medical Assistance Services to report on the implementation of a specialty drug program to Chairmen of the Senate Finance and House Appropriations Committees, the Joint Commission on Health Care, and the Department of Planning and Budget by November 1 of each year. I have enclosed for your review the report for 2009.

Should you have any questions or need additional information, please feel free to contact me at (804) 786-8099.

Enclosure

Cc: The Honorable Marilyn B. Tavenner, Secretary of Health and Human Resources

Annual Report on the Specialty Drug Program

Virginia Department of Medical Assistance Services

November 1, 2009

Authority for Report

Item 306 (CC) (1) of the 2009 Appropriations Act directs the Department of Medical Assistance Services (DMAS) to modify the delivery system of pharmaceutical products to include a specialty drug program, in consultation with physicians, pharmacists, pharmaceutical manufacturers, patient advocates, the Pharmacy Liaison Committee, and others as appropriate. A copy of the Appropriations Act language is provided in Attachment A. This report responds to the requirement in Item 306 (CC) (5) that the Department annually report on the cost savings and quality improvements achieved through the program.

Overview

Specialty drugs are a category of prescription medications that have grown out of advances in drug development research, technology, and design. These drugs are used to treat specific chronic or genetic conditions. Specialty drugs include biological drugs, blood-derived products, complex molecules, and select oral and injectable medications. They typically require tailored patient education for safe and cost-effective use, patient-specific dosing, close patient monitoring, administration (via injection or orally), and refrigeration or other special handling.

Specialty drugs have a direct impact on any health benefit program's prescription drug expenditures. They represent a very broad category of medications and are not well defined even by the commercial sector. However, specialty or "biotechnology" drugs are becoming the fastest growing segment of drug costs in America. Industry sources estimate that spending on specialty drugs increased to $54 billion in 2007, or nearly a quarter of U.S. drug spending. It is estimated that drug spend for specialty drugs will increase to $99 billion by 2010. In state fiscal year (SFY) 2008, DMAS spent approximately $18 million on specialty drugs related to eight chronic or genetic conditions in the Medicaid fee-for-service program.

Recent Activities

This is DMAS' third year submitting an annual report to the General Assembly on the specialty drug program. Previous reports have provided detailed descriptions of DMAS' efforts to implement a specialty drug program (to access copies of previous reports, please visit the DMAS website at http://www.dmas.virginia.gov/). This year's report differs from previous reports because it just includes a brief update on recent activities related to the program. Specifically, this report summarizes:

- Pharmacy & Therapeutics (P&T) Committee action related to specialty drugs;
- A cost savings analysis of the Specialty Maximum Allowable Cost (SMAC) Program in SFY 2009, the first year the SMAC program was operational; and,
- DMAS' efforts to gather information on Contractors' capabilities and expertise delivering specialty drug care management services.

A description of each follows.

Pharmacy & Therapeutics Committee Action: The P&T Committee is comprised of eight physicians and four pharmacists and meets 2-3 times a year. At the April 2009 P&T meeting, the Committee reviewed self-administered drugs for rheumatoid arthritis (RA) and multiple sclerosis (MS) agents. Both of these drug classes were deemed to be PDL eligible. Criteria were also established for recipients' health and safety. These two drug classes were added to the PDL effective July 1, 2009. To date, there have been no issues with the addition of specialty drug classes on the PDL.

SMAC Program-Cost Savings Analysis: On July 1, 2008, DMAS implemented the SMAC program. This program works in conjunction with the current Virginia Maximum Allowable Cost (MAC) program and the Preferred Drug List (PDL). The SMAC program does not affect the Managed Care Organizations (MCOs) because they have their own pharmacy benefits and programs.

The drug classes initially priced by the Specialty MAC program include: (1) hematopoietic agents (Anemia); (2) anti-tumor necrosis factor agents (Rheumatoid Arthritis); (3) immunomodulator agents (used to regulate or normalize the immune system); (4) agents to treat Muscular Sclerosis; (5) growth hormones; and, (6) interferon agents for hepatitis C.

The SMAC reimbursement amount is determined by the Wholesale Acquisition Cost (WAC) + 4.75%.

In SFY 2009, the Department spent approximately $4.6 million on the initial six drug classes included in the SMAC program. A cost savings analysis revealed that DMAS saved $351,000 in SFY 2009, the first year the SMAC program was operational.

In SFY 2009, DMAS reviewed additional specialty drug classes to assess whether any classes presented opportunities for further cost savings. However, no new drug classes were added to the SMAC program in SFY 2009. DMAS will continue to review potential opportunities on an annual basis.

Specialty Drug Care Management Services: In August 2009, DMAS issued the Pharmacy Services Administrator Request for Proposal (RFP). The RFP requests a Contractor administer multiple pharmacy-related programs, such as the pharmacy call center, the PDL, prior authorization, and the MAC and SMAC programs. Several optional services were also listed in the RFP, including operating a specialty drug care management program. This affords DMAS the opportunity to explore potential Contractors' capabilities and expertise delivering care management services to Medicaid members with chronic, high-cost or rare diseases.

Next Steps

In the next year, the Department will continue to operate the SMAC program and evaluate savings associated with the program. DMAS will also re-evaluate the program and decide if additional specialty drugs classes should be added to the program. DMAS will also continue to work with the pharmacy community to develop a comprehensive program that addresses care management. Lastly, DMAS will evaluate the proposals that are submitted in response to the RFP mentioned above and determine the feasibility of moving forward with the care management program.

Acknowledgements

DMAS wishes to acknowledge the contributions of its Pharmacy & Therapeutics Committee, the Drug Utilization Review Board, the Pharmacy Liaison Committee, representatives of the pharmacy community, and pharmaceutical manufacturers who are assisting the Department in developing an effective specialty drug program that is consistent with the intent of the Appropriations Act. The collaborative efforts of the provider community will be essential to the continued success of a specialty drug program.

ATTACHMENT A

Item 306(CC) of the 2009 Appropriations Act

CC.1. The Department of Medical Assistance Service shall amend the State Plan for Medical Assistance Services to modify the delivery system of pharmaceutical products to include a specialty drug program. In developing the modifications, the department shall consider input from physicians, pharmacists, pharmaceutical manufacturers, patient advocates, the Pharmacy Liaison Committee, and others as appropriate.

2. In developing the specialty drug program to implement appropriate care management and control drug expenditures, the department shall contract with a vendor who will develop a methodology for the reimbursement and utilization through appropriate case management of specialty drugs and distribute the list of specialty drug rates, authorized drugs and utilization guidelines to medical and pharmacy providers in a timely manner prior to the implementation of the specialty drug program and publish the same on the department's website.

3. In the event that the Department of Medical Assistance Services contracts with a vendor, the Department shall establish the fee paid to any such contractor based on the reasonable cost of services provided. The Department may not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a program contractor based on the denial or administrative delay of medically appropriate prescription drug therapy, or on the decreased use of a particular drug or class of drugs, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the Medicaid program. Bonuses cannot be based on the percentage of cost savings generated under the benefit management of services.

4. The department shall: (i) review, update and publish the list of authorized specialty drugs, utilization guidelines, and rates at least quarterly; (ii) implement and maintain a procedure to revise the list or modify specialty drug program utilization guidelines and rates, consistent with changes in the marketplace; and (iii) provide an administrative appeals procedure to allow dispensing or prescribing provider to contest the listed specialty drugs and rates.

5. The department shall report on savings and quality improvements achieved through the implementation measures for the specialty drug program to the Chairmen of the House Appropriations and Senate Finance Committees, the Joint Commission on Health Care, and the Department of Planning and Budget by November 1 of each year.

6. The department shall have authority to enact emergency regulations under § 2.2-4011 of the Administrative Process Act to effect these provisions.