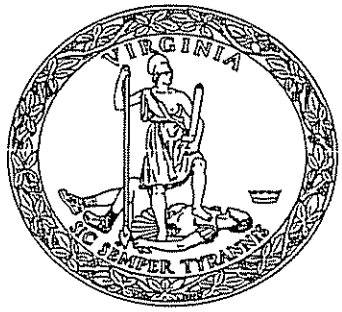
ANNUAL REPORT ON THE SPECIALTY DRUG PROGRAM



VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

NOVEMBER 2006

AUTHORITY FOR REPORT

Item 302 (JJ)(1) of the 2006 Appropriations Act directs the Department of Medical Assistance Services to modify the delivery system of pharmaceutical products to include a specialty drug program. A copy of the Appropriations Act language is provided at Attachment A. This report responds to the requirement in Item 302 (JJ)(1) that the Department report on the cost savings and quality improvements achieved through the program.

OVERVIEW OF SPECIALTY DRUGS

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, injectable and infused medications. They typically require tailored patient education for safe and cost-effective use, patient-specific dosing, close patient monitoring, administration via injection, infusion or orally, and require refrigeration or other special handling.

Specialty drugs have a direct impact on any health benefit program's prescription drug expenditures. A 2004 analysis shows that, nationwide, total spending on specialty medications grew 26.6 percent in 2003. Total public and private sector spending is expected to reach $40 billion by the end of 2006 and $100 billion by 2010. Specialty or "biotechnology" drugs are becoming the fastest growing segment of drug costs in America.

In Virginia, it is estimated that within the fee-for-service component of the Medicaid program, more than $11 million annually is expended on specialty drugs related to only five chronic or genetic conditions. In implementing a specialty drug program, DMAS has focused on generating program savings, managing utilization, and implementing an appropriate care management model for those patients who require specialty drug therapy. In achieving these objectives DMAS is working to limit disruption in the specialty drug market, maintain patient access to specialty drugs, and minimize administrative requirements.

ANALYSIS OF SPECIALTY DRUG PROGRAM MODELS AND COSTS

To better understand specialty drug programs, DMAS' Division of Health Care Services conducted an analysis of specialty drug programs to ascertain which model would be best suited for Virginia's Medicaid program. As part of the analysis, DMAS staff met with experts from:

- Specialty Pharmacy Vendors;
- Pharmaceutical Manufacturers;
- Other States; and
- The Centers for Medicare and Medicaid Services (CMS).

In addition to the informational meetings, Dr. Randy Axelrod, the Chairman of the DMAS Pharmacy & Therapeutics (P&T) Committee, presented information on specialty drug programs and the current specialty drug market at a P&T Committee meeting.

Specialty drugs represent a very broad category of medications and they are not well defined even by the commercial sector. A preliminary analysis of Medicaid cost data focused on those specialty drugs that generated the highest cost and utilization for the current Virginia fee-for-service Medicaid population (following implementation of the Medicare Part D prescription drug program). The analysis included a review of the claims volume, paid claims, and utilization of specialty drugs. As a result of this initial review, a more in-depth analysis was conducted on five specialty drugs (or their associated condition) including Hemophilia, Growth Hormones, Respiratory Syncytial Virus (RSV), Hepatitis C, and Immunoglobulins. This analysis found that, when annualized, these five drugs/conditions account for slightly more than 5,000 claims, more than $11 million in expenditures, and affect over 2,000 unique enrollees.

PHASED IMPLEMENTATION OF A SPECIALTY DRUG PROGRAM

Following a review of the various specialty drug programs in place in other states and the commercial sector, it was determined that the most appropriate course of action was to implement Virginia's specialty drug program in phases. A key piece of information that led to this decision was that only two states (Pennsylvania and Maine) have adopted specialty drug programs for their Medicaid populations; and these are relatively recent developments. Moreover, there is little information available from private sector models focusing on care management strategies for enrollees with chronic or genetic conditions that are treated with specialty drugs. Accordingly, DMAS determined that a phased-in implementation would be the best approach, and that the initial phase would include specialty drug rebate collections. The subsequent phase would involve managing drug utilization and care management protocols.

As directed by the Appropriations Act language, DMAS staff met with the Pharmacy Liaison Committee (PLC) to discuss the implementation of the specialty drug program. The PLC includes representatives from long-term care pharmacies; the Pharmaceutical Research and Manufacturers Association (PhRMA); the Virginia Association of Chain Drug Stores (VACDS); and the Virginia Pharmacists Association (VPhA). During the meeting, the Committee requested a data analysis of utilization and costs by drug and drug class for specialty drugs. The data will be used to assess the drug classes that can be best managed through a specialty drug program for Virginia's enrollees. In addition, data were requested by PhRMA to identify care management programs that may currently exist for drugs that are in the defined specialty drug classes. The PLC will meet again on December 19, 2006 to continue discussion regarding future design criteria for a specialty drug program. The PLC concurred with the Department's approach to a phased-in implementation.

Initial Phase: Specialty Drug Rebates

DMAS determined the first phase of implementation would be to update its drug rebating process to include specialty drugs. (These rebates are the federal rebates that manufacturers pay to Medicaid programs and are not associated with the Department's preferred drug list (PDL)

program where manufacturers may offer supplemental rebates.) This approach provides a means of meeting the savings requirement of the Appropriations Act while the utilization management and care coordination components of the program continue to be developed.

Specifically, the Department submitted invoices to manufacturers for rebates on certain physician-administered specialty drugs (J-codes) for the first quarter of FY 2007 and will continue this process on an ongoing basis. In addition, the Centers for Medicare and Medicaid Services (CMS) notified the Department that it could collect rebates on past claims for these physician-administered specialty drugs. Accordingly, DMAS invoiced manufacturers in August 2006 for specialty drug rebates back to 2003, since the data for the previous three years were the most accurate. While DMAS invoiced for over $5 million in rebates, drug manufacturers may dispute some of the invoiced amounts. As such, the Department does not expect to collect the total invoiced rebate amount. Nonetheless, the estimated rebate collection on this one-time invoicing is still expected to be approximately $3 million.

As of October 27, 2006, the amount collected thus far is approximately $2 million. Therefore, the Department has reached and exceeded the SFY 2007 targeted savings of $1.7 million as mandated in the Appropriations Act. Rebate invoices will continue to be billed for these drugs in future quarters. While the amounts will be less than the one-time collection noted above, these ongoing rebates will assist DMAS in reaching the targeted savings for the program.

Next Phase: Utilization Management and Care Coordination

Specialty drugs are a dynamic group of emerging medications, and different strategies will have to be employed to better manage these expenditures, and coordinate patient care. The Department will be working with its Pharmacy Liaison Committee and other parties to develop appropriate utilization management and care coordination models as the next phase of the specialty drug program. Through this process, DMAS and its partners will identify disease conditions that will lend themselves to improved outcomes when under specialty drug management and develop a program design that will most effectively manage these conditions.

Further information on specialty drug programs in other states and in the private sector will be reviewed. In addition, further analysis of Virginia Medicaid expenditures for specialty drugs will be completed. Based on these analyses, various approaches to utilization management and care coordination will be modeled and vetted with the Pharmacy Liaison Committee to determine the best approach. Next year's report will identify the specifics of the next phase of the program.

ACKNOWLEDGEMENTS

DMAS wishes to acknowledge the contributions of its 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 success of a specialty drug program.

ATTACHMENT A

Item 302 (JJ)(1) of the 2006 Appropriations Act

JJ.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.