ANNUAL REPORT ON THE SPECIALTY DRUG PROGRAM

VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

NOVEMBER 2007

AUTHORITY FOR REPORT

Item 302 (JJ) of the 2007 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, pharmacies, pharmaceutical manufacturers, patient advocates, the Pharmacy Liaison Committee, and others as appropriate. A copy of the Appropriations Act language is provided at Attachment A. This report responds to the requirement in Item 302 (JJ) 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. Specialty or "biotechnology" drugs are becoming the fastest growing segment of drug costs in America, estimated at $40 billion at the end of 2006.

In Virginia, it is estimated that within the fee-for-service component of the Medicaid program, about $12 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 (1) implementing an appropriate care management model for those patients who require specialty drug therapy, and (2) establishing a discounted pricing model. 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 (1) specialty pharmacy vendors, (2) pharmaceutical manufacturers, (3) other states, and (4) the Centers for Medicare and Medicaid Services (CMS).

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). This is a growing class of drugs that may not be able to be analyzed conclusively. The Department's preliminary analysis included a review of the claims volume, paid claims, and utilization of five 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. Based on point-of-sale data for fiscal year 2007, these five drugs/conditions accounted for about $12 million in expenditures, slightly more than 5,000 claims, and affected about 1,600 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 discounted pricing and care management.

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 in October 2006 and December 2006. 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 October meeting, a presentation on the background of the specialty drug program development and options for implementation was shared. An update on the retrospective rebate invoicing for certain physician-administered (J-Codes) specialty drugs (*described below*) was also provided. The Committee was asked to consider which drug classes would be best managed through a specialty drug program for Virginia Medicaid's enrollees. In addition, PhRMA was asked to identify care management programs that may currently exist for drugs in certain specialty drug classes. The PLC concurred with the Department's approach to a phased-in implementation.

Phase I

Rebates on Physician-Administered J-Code Drugs

Many specialty drugs are physician-administered and billed on medical claim forms using J-codes. Consequently, DMAS determined the first phase of implementation would include collecting rebates on physician-administered J-code 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 drug pricing 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) beginning the first quarter of FY 2007. In addition, CMS notified the Department that it could collect rebates on past claims for these physician-administered specialty drugs. Consequently, 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. In August 2006, DMAS invoiced over $5 million in rebates and collected $3.5 million (drug manufacturers disputed some of the invoiced amounts and therefore, collections were less than invoiced amounts). Therefore, the Department reached the SFY 2007 targeted savings of $1.7 million as mandated in the Appropriations Act.

The Department continues to bill manufacturers on an on-going basis for J-code rebates. It is estimated that the Department will collect approximately $290,000 per quarter. Although the amount will be less than the one-time collection noted above, these ongoing rebates will enable DMAS to achieve the targeted savings for the program of $1 million for SFY 2008. Also, beginning July 1, 2007, the Department started collecting rebates on multi-source, physician-administered drugs. All pharmacy claims on medical claim forms now require both the J-codes and National Drug Codes; if both are not provided, the claim is denied. This is a provision of the Deficit Reduction Act; however, the Department implemented this requirement prior to the federally required implementation date of January 1, 2008.

Phase II

Care Management

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 work with its PLC and other parties to develop appropriate care coordination models as part of the second phase of the specialty drug program. Through this process, DMAS and its partners will identify disease conditions that lend themselves to improved outcomes when under specialty drug management and develop a program design that will most effectively manage these conditions.

DMAS may contract with a vendor to create a care management program for recipients with selected conditions requiring specialty drugs. Care management will provide monitoring of patients' utilization of services and relevant clinical data specific to each condition. The patient would be contacted directly and care coordination would be provided, when necessary. This program would be similar to the current disease management model being used by DMAS to manage selected health conditions (e.g., asthma, chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and diabetes). DMAS staff completed a review of the current care management of recipients diagnosed with hemophilia. Based on preliminary results, the majority of these recipients receive care management services from their specialty pharmacy provider. Some of these services include confidential counseling, compliance monitoring, educational information and health care coordination. DMAS will continue to research opportunities to improve care management for recipients with hemophilia and implement services directly and/or through coordination with specialty pharmacies.

Conditions managed as part of the second phase of the specialty drug program may also be phased-in. The selected conditions will be based on current costs and utilization, the number of unique recipients, and most importantly, the ability to manage the health care condition.

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 care coordination will be modeled and vetted with the PLC to determine the best approach. Next year's report will identify the specifics related to Phase II of the specialty program.

Discounted Pricing Model

The Department expects to work with a vendor to establish, maintain and publish a discounted pricing model for designated specialty drug classes. The discount rate will be a fair, "market bearing" price with consideration for pharmacies' acquisition costs and a reasonable margin. This model would be similar to the maximum allowable cost (MAC) program for multi-source drug pricing.

SUMMARY

In the next year, the Department will explore several care management options. The discounted pricing model is expected to be implemented in 2008. Drug classes may also be phased-in to introduce these pricing changes to the pharmacy community. All pharmacy providers willing to accept these prices may render services; an exclusive specialty drug vendor would not be contracted. A list of specialty drugs with their discount prices would be published as mandated in the Appropriations language. In addition, the classes may be reviewed as part of normal practices by the Drug Utilization Review Board and Pharmacy & Therapeutics Committee as the need arises. However, it is our goal to work with the pharmacy community and develop a comprehensive program addressing both the care management and pricing in the next year.

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) of the 2007 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.