ANNUAL REPORT ON THE SPECIALTY DRUG PROGRAM

VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

NOVEMBER 1, 2008

AUTHORITY FOR REPORT

Item 306 (CC) (1) of the 2008 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 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 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 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. Industry sources estimate that spending on specialty drugs increased to $54 billion in 2007, or nearly a quarter of U.S. drug spending. In Virginia, for the fee-for-service component of the Medicaid program, about $18 million is expended annually on specialty drugs related to eight chronic or genetic conditions.

In implementing a specialty drug program, DMAS has focused on (1) consulting with medical, pharmacy, and other interested groups; (2) implementing an appropriate care management model for those patients who require specialty drug therapy; and, (3) establishing a discounted pricing program. 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 & Medicaid Services (CMS).

Specialty drugs represent a very broad category of medications, and they are not well defined even by the commercial sector. Preliminary analyses of Medicaid cost data have focused on those specialty drugs that generate the highest cost and utilization for the current fee-for-service population (post Medicare Part D prescription drug program implementation).

The Department reviewed eight specialty drugs (or their associated condition), including Hematopoietic Agents; Agents for Rheumatoid Arthritis; Immunomodulator Agents; Agents to treat Muscular Sclerosis (MS); Growth Hormones; Agents for Hepatitis C; Respiratory Syncytial Virus (RSV); and, Hemophilia. Based on state fiscal year (SFY) 2008 point-of-sale data, these eight drugs/conditions accounted for about $18 million in expenditures, slightly more than 9,000 claims, and affected about 2,700 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 a few states 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. Phase I consisted of consulting with medical, pharmacy, and other interested groups, and Phase II involved establishing a discounted pricing model and researching various care management options.

Phase I: Consultation with Medical, Pharmacy, and Other Interest Groups

During Phase I, DMAS consulted with various medical, pharmacy, and other interested groups to seek their input on how the specialty drug program should be implemented and for their guidance and review of selected specialty drug classes. Specifically, DMAS consulted with the Drug Utilization Review (DUR) Board, the Pharmacy Liaison Committee (PLC), and the Pharmacy & Therapeutics (P&T) Committee. Each group's input and actions follow.

Drug Utilization Review Board

The DUR Board is an expert panel composed of physicians, pharmacists and nurse practitioners appointed by the DMAS Director. In August 2007, the DUR Board conducted typical drug reviews (e.g., therapeutic duplication, drug to diagnosis alert, adverse drug reactions) for Growth Hormone, Hepatitis C, and Low Molecular Weight Heparin drug classes.

Pharmacy Liaison Committee

As directed by the Appropriations Act language, DMAS staff held a meeting with the PLC to discuss the implementation of the specialty drug program in September 2007. 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 September 2007 meeting, a review of the specialty drug program was presented, including implementation options.

Pharmacy & Therapeutics Committee

The P&T Committee is comprised of eight physicians and four pharmacists and meets 2-3 times a year. At the October 2007 P&T meeting, the Committee reviewed Hepatitis C and Growth Hormones, two specialty drug classes proposed for initial review by the Committee. During the October 2007 P&T meeting, both classes were determined to be PDL eligible. Criteria were also established for recipients' health and safety. These two drug classes were added to the PDL effective January 1, 2008. To date, there have been no issues with the implementation of these new classes on the PDL.

Phase II: Discounted Pricing Model and Care Management Program

Phase II of Virginia's specialty drug program consisted of implementing a Specialty Maximum Allowable Cost (SMAC) Program and researching various options for the care management programs. Specifics are described below.

Discounted Pricing Model – Specialty Maximum Allowable Cost (SMAC) Program

On July 1, 2008, DMAS implemented the specialty drug discounted pricing model, referred to as the Specialty Maximum Allowable Cost (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 that have been initially priced by the Specialty MAC program include:

- Hematopoietic Agents (Anemia)
- Anti Tumor Necrosis Factor Agents (Rheumatoid Arthritis)
- Immunomodulator Agents
- Agents to treat Muscular Sclerosis
- Growth Hormones
- Interferon Agents for Hepatitis C

The new Specialty MAC reimbursement amount is determined by and based on the Wholesale Acquisition Cost (WAC) + 4.75%. Drugs are priced (for reimbursement to the dispensing pharmacy) according to rates based on a fair, "market bearing" price with consideration for pharmacies' acquisition costs and a reasonable margin. The pricing is specific to each National Drug code (NDC) for each drug in the initial six specialty drug classes. All pharmacy providers willing to accept these prices may render services; an exclusive specialty drug vendor was not contracted.

Optima Health, DMAS' current MAC vendor, also administers the SMAC program. For this reason, many elements of the SMAC program are similar to the MAC program. For instance, the dispute resolution process is the same as the MAC program. To date, there have not been any disputes associated with the SMAC program.

As mandated in the Appropriations language, DMAS publishes a list of specialty drugs and their associated discount prices on the DMAS website at

http://www.dmas.virginia.gov/downloads/pdfs/pharm-special_mac_list.pdf. Additional specialty drug classes may be added to the SMAC program as the program matures. In addition, the classes may be reviewed by the Drug Utilization Review Board and P&T Committee, as the need arises.

In SFY 2008, the Department spent approximately $7 million on the initial six drug classes included in the SMAC program. Because the SMAC program was implemented on July 1, 2008, DMAS does not have cost savings to report yet. However, DMAS will report cost savings in next year's report. DMAS plans to analyze cost savings associated with the SMAC program by comparing the new SMAC prices to the next highest pricing methodology the claim would have paid at if the new SMAC program had not been implemented.

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 may 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). In 2007, 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 this aspect 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 improve patient outcomes through enhanced care management.

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.

ACKNOWLEDGEMENTS

DMAS wishes to acknowledge the contributions of its Pharmacy & Therapeutics Committee, the Drug Utilization Review Board, 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 306(CC) of the 2008 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.