COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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November 1, 2011

MEMORANDUM

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

The Honorable Lacey E. Putney
Chairman, House Appropriations Committee

The Honorable Benjamin L. Cline
Chairman, Joint Commission on Health Care

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

FROM: Cynthia B. Jones

SUBJECT: Report on Specialty Drug Program

Item 297 (AA) of the 2011 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 2011.

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

Enclosure

Cc: The Honorable William A. Hazel, Jr., M.D., Secretary of Health and Human Resources

Annual Report on the Specialty Drug Program

Virginia Department of Medical Assistance Services

November 1, 2011

Authority for Report

Item 297 (AA) (1) of the 2011 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 297 (AA) (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. All these factors contribute to the high cost of specialty drugs which has a direct impact on DMAS' prescription drug expenditures. National cost trends suggest that specialty drugs and injectibles are the highest growing category of covered drugs. This trend is expected to continue as more injectible and specialty drugs receive FDA approval to address chronic diseases, such as Multiple Sclerosis, Cancer, Arthritis and others.

The DMAS Specialty Drug Program (SMAC) was implemented in July of 2008 to address issues of cost effectiveness and appropriate utilization. The drug classes priced under the DMAS SMAC 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. As of the date of this report, the SMAC reimbursement amount is determined by the SMAC rate of Wholesale Acquisition Cost (WAC) + 4.75%, the Federal Upper Payment Limit, estimated acquisition cost of Average Wholesale Price – 13.1%, or the pharmacy's usual and customary charge, whichever is less. The class of drugs priced under the SMAC program has remained unchanged since the program's inception. Recent changes to the estimated acquisition cost of single source innovator drugs, however, reduced the number of specialty drugs priced using the SMAC rate.

SMAC Program Expenditures

The table below provides specialty drug pricing data for calendar years 2009 and 2010. The table identifies unique recipients, the number of claims and total dollar amount of claims priced using the SMAC pricing logic of WAC + 4.75% for calendar years 2009 and 2010:

Specialty Drug Claims Priced at WAC + 4.75%	**2009**	**2010**	**Change**
Total Recipients	822	702	-120
Total Claims	4965	3230	-1735
Claims Priced at WAC + 4.75%	$6,928,143	$5,317,743	-1,610,400

In calendar year 2010, DMAS reimbursed $5,317,743 in specialty drug claims using WAC, compared to $6,928,143 in claims for calendar year 2009. This decrease was due, in part, to a change in pricing methodology implemented by DMAS for the months of July, August and September of 2010. The estimated acquisition cost for single source, innovator drugs was decreased from Average Wholesale Price (AWP) - 10.25% to AWP - 13.1% for the months of July, August and September of 2010 and, as a result, fewer specialty drugs were priced using the WAC pricing methodology. This rate was changed back to AWP - 10.25% in November of 2010 and remained in effect until July of 2011, when it was decreased again to AWP - 13.1%. All of these pricing changes were implemented by DMAS as a result of actions by the Virginia General Assembly, as well as the impact of stimulus funding by the U.S. Congress in response to the economic downturn.

In addition to a change in pricing methodology, the total number of recipients receiving specialty drugs that fall under the SMAC program declined in calendar year 2010, even though the total number of patients enrolled in FFS Medicaid changed very little from calendar year 2009 to calendar year 2010. The total number of recipients who received specialty drugs reimbursed by DMAS under its FFS program in 2009 was 898, in calendar year 2010 the number of recipients dropped to 784, a reduction of 13%. Although the average dollar amount spent per claim increased in 2010 by an average of $300, the total dollars spent per person and the number of claims per distinct recipient dropped in 2010 as shown in the table below:

	2009	**2010**
Average dollar amount per specialty drug claim	$1,395	$1,715
Average dollar amount of specialty drug claims per person	$9,000	$7,892
Average number of specialty claims per person	5.63	4.60

DMAS expects a significant overall decline in recipients receiving specialty drugs in FFS with the expansion of managed care, although the patients that remain in FFS may have a higher percentage of chronic diseases that require specialty drugs.

Upcoming SMAC Program Initiatives

DMAS is currently exploring ways to modify the current specialty drug program that increases the quality of the services provided to patients, and the health outcomes of patients who receive specialty drugs both through the pharmacy benefit and the medical benefit. DMAS is looking closely at the experience of other state Medicaid programs, as well as commercial health plans in terms of how they price specialty drugs, and how they contract with specialty pharmacies, the appropriate level of clinically appropriate ancillary services required for patients who are dispensed specialty drugs, and their overall approach to specialty drug benefit management.

The current SMAC reimbursement rate of WAC + 4.75% for specialty drugs priced under the SMAC is also under review by DMAS. With the permanent change of the estimated acquisition cost for single source drugs to AWP – 13.1% in July of 2011, many specialty drugs previously reimbursed under the SMAC pricing logic are being reimbursed at AWP – 13.1%, reducing its relevance. Any change in the reimbursement rate used by the SMAC program, however, will be

carefully considered in light of the unique nature of specialty drugs as well as the cost and availability of these drugs to specialty pharmacies serving the Commonwealth of Virginia.

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 297(AA) of the 2011 Appropriations Act

AA.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.