COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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January 10, 2014

MEMORANDUM

TO: The Honorable Walter A. Stosch
Chairman, Senate Finance Committee

The Honorable Lacey E. Putney
Chairman, House Appropriations Committee

The Honorable Linda T. Puller
Chair, Joint Commission on Health Care

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

FROM: Cynthia B. Jones Cynthia Jones
Director, Virginia Department of Medical Assistance Services

SUBJECT: Report on the Specialty Drug Program

The 2013 Appropriation Act, Item 307 (T), requires:

> *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.*

This report responds to the requirement in Item 307 (T) (5) that the Department annually report on the cost savings and quality improvements achieved through the program.

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

CBJ/

Enclosure

pc: The Honorable William A. Hazel, Jr., MD, Secretary of Health and Human Resources

Department of Medical Assistance Services
Annual Report to the General Assembly

Report on Specialty Drug Program

November 2013

Report Mandate

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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, and refrigeration or other special handling. All of the above factors contribute to the high cost of specialty drugs and therefore have a direct impact on DMAS' prescription drug expenditures. National cost trends suggest that specialty drugs and injectables are the fastest growing category of Medicaid-covered drugs. This trend is expected to continue as more injectable 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 of specialty drugs. 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. The classes of drugs priced under the SMAC program have remained unchanged since the program's inception. As of the date of this report, the SMAC reimbursement amount is the lesser of: (1) the SMAC rate of Wholesale Acquisition Cost (WAC) + 4.75%; (2) the Federal Upper Payment Limit; (3) the estimated acquisition cost of Average Wholesale Price – 13.1%; or (4) the pharmacy's usual and customary charge.

SMAC Program Expenditures

Table 1 provides specialty drug pricing data for state fiscal years 2012 and 2013. The table identifies unique recipients, the number of claims and the total reimbursement of claims for specialty drugs that fall under the specialty drug program. In FY 2013, DMAS's spent approximately $2.8 million less on specialty drugs than in FY 2012. This decrease correlates with the July 1, 2012 expansion of managed Medicaid into southwestern Virginia with over 100,000 members moving from fee-for-service Medicaid into managed Medicaid.

Table 1: DMAS Specialty Drug Pricing SFY 2012 - 2013

Specialty Drug Claims	**FY 2012**	**FY 2013**	**% Change**
Total Unique Recipients	700	485	-30.7%
Total Claims	3,680	2,244	-39%
Total Dollar Amount	$8,360,659	$5,567,647	-33.4%

Upcoming SMAC Program Initiatives

DMAS continues to explore ways to modify the current specialty drug program that improve the quality of the services provided 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 in terms:

- How specialty drugs are priced;
- How states 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 management.

The current SMAC reimbursement rate of WAC + 4.75% for specialty drugs is also under review by DMAS. This pricing methodology was changed in July 2011 from using the estimated acquisition cost for single source, innovator drugs from AWP – 10.25% to AWP – 13.1%. Many specialty drugs previously reimbursed under the SMAC pricing logic are now reimbursed at AWP – 13.1%, reducing the relevance of the WAC + 4.75% pricing. DMAS will continue its efforts to optimize pricing while ensuring that beneficiaries have access to needed specialty drugs. However, any change in the reimbursement rate used by the SMAC program will be carefully considered in light of the unique nature of specialty drugs as well as the cost and availability of these drugs to Virginia's specialty pharmacies.

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

Appropriation Act. The collaborative efforts of the provider community will be essential to the continued success of a specialty drug program.

ATTACHMENT A

Item 307(T) of the 2013 Appropriation Act

T.1. The Department of Medical Assistance Services may 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.