# COMMONWEALTH of VIRGINIA

## *Department of Medical Assistance Services*

GREGG A. PANE, MD, MPA
DIRECTOR

SUITE 1300
600 EAST BROAD STREET
RICHMOND, VA 23219
804/786-7933
800/343-0634 (TDD)
www.dmas.virginia.gov

November 1, 2010

**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: Gregg A. Pane, MD, MPA

SUBJECT: Report on Specialty Drug Program

Item 297 (AA) of the 2010 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 2010.

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, 2010**

## Authority for Report

Item 297 (AA) (1) of the 2010 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.

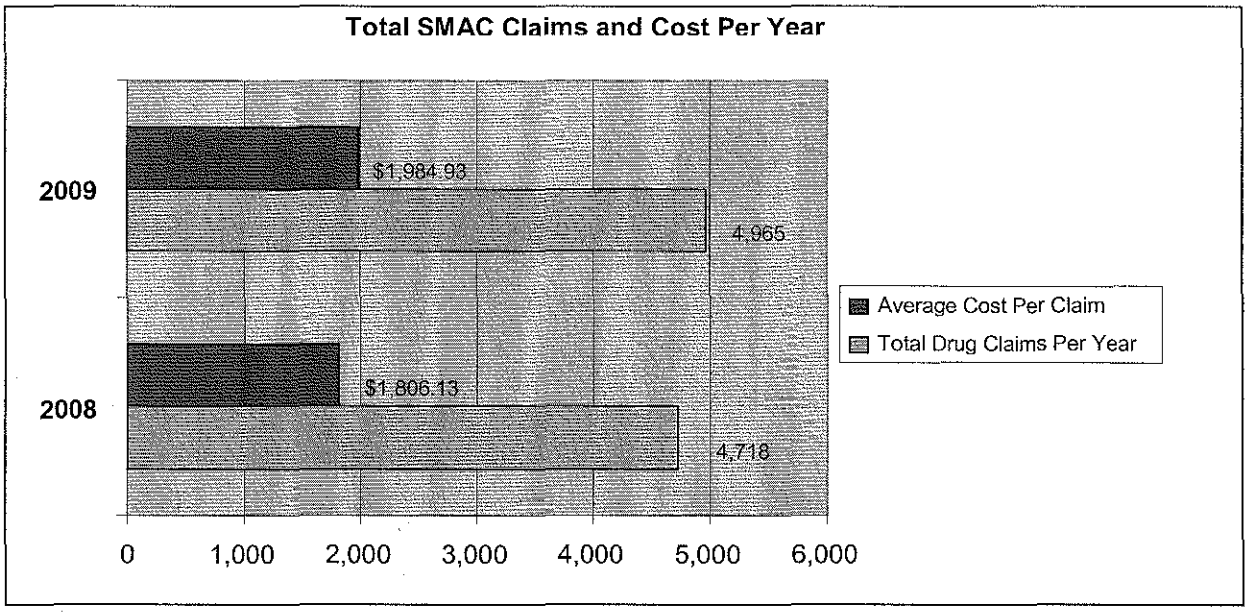
## Overview

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.

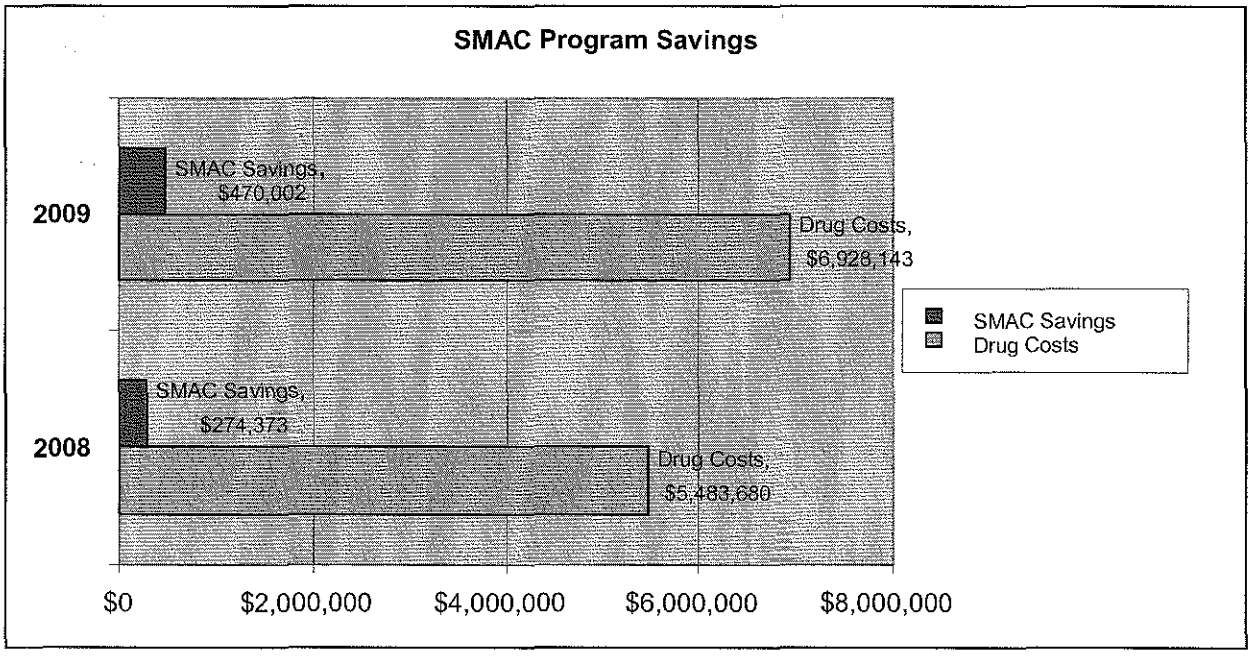
The DMAS Specialty Drug Program (SMAC) was implemented in July of 2008 to address issues of cost effectiveness and appropriate utilization. The drug classes priced under the DMAS Specialty MAC program include: (1) hematopoietic agents (Anemia); (2) anti-tumor necrosis factor agents (Rheumatoid Arthritis); (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 SMAC reimbursement amount is determined by the Wholesale Acquisition Cost (WAC) + 4.75%. The class of drugs priced under the SMAC program and the reimbursement amount has remained unchanged since the program's inception.

## SMAC Program Expenditures and Savings

In calendar year 2009, DMAS spent $6,928,143 for specialty drugs administered under the SMAC program, an increase of 21% from the prior calendar year of $5,483,680. This increase was due primarily to the increased cost of specialty drugs and a slight increase in claims volume. The average cost per specialty drug for calendar year 2009 was $1,984.93, which represented a 9.1% increase from the prior year of $1,806.13. Total claims also increased by 5%, with 4,965 total claims in calendar year 2009 and 4,718 claims in calendar year 2008. The bar chart below represents the increase in total claims and the average cost per claim for calendar years 2008 and 2009.




DMAS realized a savings of $470,002 by pricing specialty drugs under the SMAC program in calendar year 2009, an increase in savings of $195,629 from the savings accrued in calendar Year 2008 of $274,373. The chart below provides a graphical comparison for calendar years 2009 and 2008.



## Recent Activities

The following information provides summaries of key activities related to the SMAC program:

- Pharmacy & Therapeutics (P&T) Committee action related to specialty drugs;
- The award of the SMAC, MAC and PDL Programs to a new vendor, Provider Synergies; and,
- Next Steps.

A description of each follows:

***Pharmacy & Therapeutics (P&T) Committee Action:*** The P&T Committee is comprised of eight physicians and four pharmacists and meets 2-3 times a year. In 2009-2010, the DMAS P&T Committee conducted annual reviews of the specialty drug classes on Virginia Medicaid's Preferred Drug List (PDL) which included hematopoietic agents, anti-tumor necrosis factor agents, topical immunomodulators, agents use for the treatment of muscular sclerosis, growth hormones, and interferon agents used to treat hepatitis C. The classes remained unchanged with the exception of agents used to treat multiple sclerosis. A new drug, Ampyra® which is used to treat gait issues associated with multiple sclerosis, was evaluated by the P&T Committee for inclusion on the PDL at the April 2010 meeting. The Committee recommended that Amprya® be a non-preferred agent on the PDL and developed utilization criteria that a patient must meet in order for a service authorization to be granted.

***New Vendor Contract for SMAC, MAC and PDL Services:*** DMAS recently contracted with a new SMAC vendor, Provider Synergies. In addition to the SMAC program, Provider Synergies administers DMAS' Maximum Allowable Cost (MAC) program and the Preferred Drug List (PDL) Program. This contract was awarded in July of 2010. As part of the contract, Provider Synergies is required to review other specialty drug classes to determine their appropriateness for placement on the SMAC program, conduct an analysis of the feasibility of modifying the current SMAC rate to generate additional cost savings, and propose enhancements to the patient and drug management components currently lacking in the program due to financial and regulatory constraints.

***Next Steps:*** DMAS will evaluate the cost savings of the SMAC program with the decrease in reimbursement that resulted from pricing the estimated acquisition cost of single source innovator drugs at Average Wholesale Price (AWP) -13.1% from the previous rate of AWP – 10.25% as required by the Virginia General Assembly. This decrease in reimbursement became effective on July 1, 2010. Although this rate reduction will be reversed on October 1, 2010, and extended through June 30, 2011, as a result of additional Medicaid federal funding approved by Congress in the American Recovery and Reinvestment Act of 2009, it is estimated that this decrease in reimbursement (AWP-13.1%) for single source, innovator drugs, which includes the majority of drugs classified as specialty drugs priced under the SMAC program, will likely be utilized as the reference price for SMAC drugs during the three-month period of July 1 through September 30, 2010.

DMAS will conduct a re-evaluation of the SMAC program prior to next year's report due to this change in the estimated acquisition cost of single source innovator drugs by the Virginia General Assembly and the potential for other changes in how the ingredient costs of both single source innovator and generic drugs are priced. DMAS anticipates significant changes to reference pricing as a result of Federal health care reform, the elimination of the use of AWP by First databank and other market forces. DMAS will work closely with pharmacy stakeholders to develop pricing policies that provide adequate reimbursement, maintain sufficient access and promote quality clinical outcomes and cost effectiveness.

## 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 2010 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.