COMMONWEALTH of VIRGINIA
Department of Medical Assistance Services

CYNTHIA B. JONES
DIRECTOR

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

November 30, 2016

MEMORANDUM

TO: The Honorable Thomas K. Norment, Jr.
Co-Chairman, Senate Finance Committee

The Honorable Emmett W. Hanger, Jr.
Co-Chairman, Senate Finance Committee

The Honorable S. Chris Jones
Chairman, House Appropriations Committee

Daniel Timberlake
Director, Department of Planning and Budget

The Honorable Charles W. Carrico
Chair, Joint Commission on Health Care

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

SUBJECT: Annual Report on the Specialty Drug Program

The 2016 Appropriation Act, Item 306 (S) (5), 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 306 (S) (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

ADMINISTERING MEDICAID AND THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM IN VIRGINIA

DMAS' mission is to provide a system of high quality and cost effective health care services to qualifying Virginians and their families.

The Medicaid program, signed into law by President Lyndon B. Johnson on July 30, 1965, celebrated its 50th year in 2015.

Medicaid is a joint federal and state program authorized under Title XIX of the Social Security Act that provides health and long-term care coverage for specific groups of Virginians with low incomes. In Virginia, Medicaid is administered by the Department of Medical Assistance Services (DMAS) and is jointly funded by Virginia and the federal government. Virginia's federal matching rate, known as the Federal Medical Assistance Percentage (FMAP) is generally 50%, so Virginia receives $1 of federal matching funds for every $1 Virginia spends on Medicaid.

Medicaid is primarily available to children in families with low-income, pregnant women, elderly, individuals with disabilities, and parents below strict income limits.

DMAS also administers Virginia's Children's Health Insurance Program (CHIP) known as FAMIS. FAMIS covers children and pregnant women in families earning too much to qualify for Medicaid but too little to afford private insurance.

All states must follow federal Medicaid/CHIP guidelines regarding who is covered, but set their own income and asset eligibility criteria. Virginia's eligibility criteria are among the strictest in the nation.

VIRGINIA'S MEDICAID PROGRAM

DMAS

Report to the Governor and General Assembly
From the Department of Medical Assistance Services (DMAS)
Report on the Specialty Drug Program

November 2016

Report Mandate: The 2016 Appropriation Act, Item 306 (S5), requires:
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 306 (S) (5) that the Department annually report on the cost savings and quality improvements achieved through the program.

Background: 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, hepatitis C 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 in the DMAS fee-for-service (FFS) program. 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 Multiple 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 FFS specialty drug pricing data for state fiscal years 2015 and 2016. The table identifies unique members, the number of claims and the total reimbursement of claims for specialty drugs that fall under the specialty drug program. In FY 2016, DMAS spent approximately $37,533 less on specialty drugs than in FY 2015. This decrease in FFS costs correlates with continued expansion of managed Medicaid with Commonwealth Coordinated Care (CCC), Health and Acute Care Program (HAP), foster-care and adoption assistance members moving from fee-for-service Medicaid into managed Medicaid.

Table 1: DMAS Specialty FFS Drug Pricing SFY 2015 - 2016

Specialty Drug Claims	FY 2015	FY 2016	% Change
Total Unique Recipients	344	298	-13.37%
Total Claims	1,618	1,437	-11.19%
Total Dollar Amount	$3,892,992	$3,855,459	-0.96%
Average spend per Recipient	$11,316	$12,938	14.33%

Table 2 provides DMAS FFS pricing data for drugs used to treat hepatitis C. Since January 2014, the Food and Drug Administration (FDA) has approved eight new oral hepatitis C virus (HCV) drugs. These drugs had an immediate impact on the budgets for all insurers including Medicaid. In an effort to appropriately manage the new class of drugs used to treat hepatitis C, the DMAS Pharmacy and Therapeutic (P&T) Committee adopted clinical criteria which must be met in order for the drugs to be authorized for coverage. Table 2 reflects an increase in overall expenditures for the treatment of hepatitis C in FY 2016 as compared to FY 2015, as this trend is expected to continue to increase as clinical treatment guidelines have expanded to provide coverage for more patients.

Table 2: DMAS Hepatitis C FFS Drug Pricing SFY 2015 - 2016

Hepatitis C Claims	FY 2015	FY 2016	% Change
Total Unique Member	20	43	115.00%
Total Claims	58	102	75.86%
Total Dollar Amount	$986,222	$2,188,297	121.89%
Average Spend per Member	$49,311	$50,890	3.20%

Upcoming SMAC Program Initiatives: The growing pipeline of high cost Specialty Drugs (including drugs used to treat hepatitis C) requires concerted action by State Medicaid Programs, Medicaid Managed Care Plans, and the Federal Government to manage the high costs and provide appropriate access to Specialty Drugs. The escalating costs and growing pipeline of very expensive Specialty Drugs will indeed put state Medicaid budgets at substantial risk without the combined efforts of all public and private parties involved in providing access to what may prove to be highly beneficial and effective drug therapies.

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 of:

- 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 Average Wholesale Price (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 members have access to needed specialty drugs. Changes 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.

With DMAS anticipating the implementation of a pharmacy reimbursement methodology based on CMS' National Average Drug Acquisition Cost (NADAC) in the fall of 2016, it has been determined that most specialty drugs will not have a published NADAC. As a result, DMAS will use a WAC + 0% reimbursement rate for all drugs without a NADAC. This will decrease the reimbursement rate for the Specialty drugs to a more meaningful level.

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 306(S) of the 2016 Appropriation Act

S.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.