COMMONWEALTH of VIRGINIA
Department of Medical Assistance Services

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November 1, 2017

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 2017 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

Annual: Specialty Drug Program Report- FY 2017

A Report to the Virginia General Assembly — *November 1, 2017*

Report Mandate:

The 2017 Appropriation Act Item 306 (S)(5), 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 of Health Care, and the Department of Planning and Budget by November 1 of each year.

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 the Department of Medical Assistance Services' (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 Food and Drug Administration (FDA) approval to address chronic diseases, such as multiple sclerosis, cancer, Hepatitis C and others.

The DMAS Specialty Drug Program 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 identified for the Specialty Drug Program include: (1) hematopoietic agents (drugs prescribed for Anemia); (2) anti-tumor necrosis factor agents (drugs prescribed for 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 drug classes included in the Specialty Drug Program have remained unchanged since the program's inception. To control expenditures, DMAS adopted a specialty drug reimbursement methodology known as the Specialty Maximum Allowable Cost (SMAC) for all drugs included in the Specialty Drug Program. SMAC was defined as the drug's Wholesale Acquisition Cost (WAC) + 4.75 percent. The WAC is the

About DMAS and Medicaid

DMAS' mission is to ensure Virginia's Medicaid enrollees receive high quality and cost effective health care.

Medicaid plays a critical role in the lives of over a million Virginians, providing health care for those most in need. Medicaid enrollees include children, pregnant women, parents and care takers, older adults and individuals with disabilities. Virginians must meet income thresholds and other eligibility criteria before qualifying to receive Medicaid benefits.

Medicaid covers primary and specialty health care, inpatient care, and behavioral health and addiction and recovery treatment services. Medicaid also covers long term services and supports, making it possible for thousands of Virginians to remain in their homes or to access residential and nursing home care.

Quick Medicaid facts:

- Covers 1 in 8 Virginians
- Covers 1 in 3 births and 33% of children
- Supports 2 in 3 nursing facility residents

Virginia Medicaid and Children's Health Insurance Program (CHIP) are administered by the Department of Medical Assistance Services (DMAS) and are jointly funded by Virginia and the federal government under the Title XIX and Title XXI of the Social Security Act. Virginia generally receives $1 of federal matching funds for every $1 Virginia spends on Medicaid.

list price from a manufacturer to a wholesaler or a direct purchaser without discounts.

DMAS' Pharmacy reimbursement amount as established in 12 VAC 30-80-40 (Fee-For-Service Providers: Pharmacy) is the lesser of: (1) SMAC; (2) the Federal Upper Limit (FUL); (3) the estimated acquisition cost (EAC) of Average Wholesale Price (AWP) – 13.1 percent; or (4) the pharmacy's usual and customary (U&C) charge. As defined in federal regulations at § 42 CFR 447.514, FULs are equal to 175 percent of the weighted average of the most recently reported monthly average manufacturer prices (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. As defined in federal regulations at § 42 CFR 447.502, estimated acquisition cost is the state's best estimate of the prices currently paid by providers for a drug marketed or sold by manufacturers or labelers in the package size of the drug most frequently purchased by providers. A provider's U & C charge to the public is identified by the drug claim charge.

Specialty Drug Program Expenditures

Table 1 provides FFS specialty drug pricing data for state fiscal years 2016 and 2017. The table identifies unique Medicaid enrollees, the number of claims and the total reimbursement of claims for specialty drugs that fall under the specialty drug program. In FY 2017, DMAS spent approximately $199.00 per enrollee more on specialty drugs than in FY 2016. The increase in FFS costs correlates with the increase in spending for drugs used to treat Hepatitis C. In October 2016, DMAS' Pharmacy and Therapeutics Committee revised the service authorization criteria for Hepatitis C to allow Medicaid enrollees diagnosed with Hepatitis C, regardless of the severity of the disease, access to drug therapy. In accordance with the national practice guidelines and CMS guidance, DMAS eliminated the fibrosis scoring (Metavir) requirement as part of the approval process for Hepatitis C drugs effective January 1, 2017. As a result of these changes, many Virginians covered under the Medicaid program have received Hepatitis C treatment earlier in the course of the disease, preventing the often fatal complications of liver failure, cirrhosis and liver transplants. DMAS and the health plans still maintain the requirements for approval for these drugs through the service authorization process.

Table 1: DMAS Specialty Drug Utilization and Spend (FFS) SFY 2016 - 2017

Specialty Drug Claims	FY 2016	FY 2017	% Change
Total Unique Medicaid enrollees	298	296	-0.67%
Total Claims	1,437	1,367	-4.87%
Total Dollar Amount	$3,855,459	$3,888,629	0.86%
Average spend per Medicaid enrollees	$12,938	$13,137	1.54%

Table 2 provides DMAS FFS pricing data for drugs used to treat Hepatitis C. Since January 2014, the FDA has approved eleven 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 2017 as compared to FY 2016, and this trend is expected to continue to increase as clinical treatment guidelines have expanded to provide coverage for more members. In State FY 2017, 63.4 percent of Hepatitis C drug claims were for Medicaid enrollees covered under the Governor's Access Plan (GAP) as compared to 24.51 percent in SFY 2016.

Table 2: DMAS Hepatitis C Utilization and Spend (FFS) SFY 2016 - 2017

Hepatitis C Claims	**FY 2016**	**FY 2017**	**% Change**
Total Unique Medicaid enrollees	43	94	118.60%
Total Claims	102	205	100.98%
Total Dollar Amount	$2,188,297	$5,039,142	130.28%
Average Spend per Medicaid enrollees	$50,890	$53,608	5.34%

Upcoming Specialty Drug Program Initiatives

The growing number 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 number 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 ensuring access to as many qualifying Medicaid members as possible to what may prove to be highly beneficial and effective drug therapies.

DMAS implemented a new pharmacy reimbursement methodology based on CMS' National Average Drug Acquisition Cost (NADAC) on January 9, 2017. The NADAC rate, defined by drug grouping, drug category, and pharmacy type is calculated as the average of the per unit cost observations. The NADAC is a simple average of the drug acquisition costs submitted by retail community pharmacies. Specialty drugs usually do not have the pricing history to calculate a NADAC price. Also these drugs usually have a limited distribution network, which hinders calculation of the NADAC price. Due to these factors, it has been determined that most specialty drugs will not have a published NADAC. As a result, DMAS will use a WAC + 0 percent reimbursement rate for all drugs without a NADAC. This will decrease the reimbursement rate for Specialty drugs to a more meaningful price since both the NADAC price and WAC are more reflective of an actual drug price than the previously based EAC of AWP.

Summary

DMAS continues to explore ways to modify the current Specialty Drug Program in order to improve the quality of the services provided and the health outcomes to Medicaid enrollees who receive specialty drugs through the pharmacy and medical benefit. This spring, DMAS publicly procured a Pharmacy Benefits Manager (PBM) to manage the Commonwealth's Medicaid FFS pharmacy program. The RFP included a requirement that the new vendor create a robust Specialty Drug Program. DMAS is currently working with the selected vendor, Magellan Medicaid Administration, to develop an enhanced Specialty Drug Program that will provide appropriate care management for Medicaid enrollees and control drug expenditures. DMAS is specifically interested in the PBM's proposals for specialty drugs reimbursement methodologies, development of specialty pharmacy networks and integration of clinically appropriate support services for Medicaid enrollees who are prescribed specialty drugs.