COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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April 13, 2023

MEMORANDUM

TO: The Honorable Janet D. Howell
Chair, Senate Finance Committee

The Honorable Barry D. Knight
Chair, House Appropriations Committee

Michael Maul
Director, Virginia Department of Planning and Budget

Members, Virginia Board of Medical Assistance Services

FROM: Cheryl Roberts
Director, Virginia Department of Medical Assistance Services

SUBJECT: Annual Pharmacy Liaison Committee and Drug Utilization Review Board Report FY2022

This report is submitted in compliance with Item 304.L. of the 2022 Appropriations Act which states:

304.L. The Department of Medical Assistance Services shall implement continued enhancements to the drug utilization review (DUR) program. The department shall continue the Pharmacy Liaison Committee and the DUR Board. The department shall continue to work with the Pharmacy Liaison Committee, meeting at least semi-annually, to implement initiatives for the promotion of cost-effective services delivery as may be appropriate. The department shall solicit input from the Pharmacy Liaison Committee regarding pharmacy provisions in the development and enforcement of all managed care contracts. The Pharmacy Liaison Committee shall include a representative from the Virginia Community Healthcare Association to represent pharmacy operations and issues at federally qualified health centers in Virginia. The department shall report on the Pharmacy Liaison Committee's and the DUR Board's activities to the Board of Medical Assistance Services and to the Chairmen of the House Appropriations and Senate Finance and Appropriations Committees and the Department of Planning and Budget no later than December 15 each year of the biennium.

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

CR
Enclosure

Pc: The Honorable John Littel, Secretary of Health and Human Resources

Annual Pharmacy Liaison Committee and Drug Utilization Review Board Report FY2022

A Report to the Virginia General Assembly — *April 13, 2023*

Report Mandate:

Item 304.L of the 2022 Appropriation Act states "The Department of Medical Assistance Services shall implement continued enhancements to the drug utilization review (DUR) program. The department shall continue the Pharmacy Liaison Committee and the DUR Board. The department shall continue to work with the Pharmacy Liaison Committee, meeting at least semi-annually, to implement initiatives for the promotion of cost-effective services delivery as may be appropriate. The department shall solicit input from the Pharmacy Liaison Committee regarding pharmacy provisions in the development and enforcement of all managed care contracts. The Pharmacy Liaison Committee shall include a representative from the Virginia Community Healthcare Association to represent pharmacy operations and issues at federally qualified health centers in Virginia. The department shall report on the Pharmacy Liaison Committee's and the DUR Board's activities to the Board of Medical Assistance Services and to the Chairmen of the House Appropriations and Senate Finance and Appropriations Committees and the Department of Planning and Budget no later than December 15 each year of the biennium."

Summary of Activities

The Pharmacy Liaison Committee (PLC) met on December 2, 2021, and July 14, 2022, to discuss initiatives for the promotion of cost-effective services. DMAS shared with the Committee the pharmacy-related activities the Agency has recently completed and planned. This included information on access to Suboxone film and buprenorphine/naloxone sublingual (SL) tablets at pharmacies, Covid-19 updates, Hepatitis C drug class update, the Cardinal Care program, and pharmacist provider status.

The Drug Utilization Review (DUR) Board met on December 1, 2021, March 10, June 2, and September 8, 2022. At each meeting held, the DUR Board reviewed seven characteristics (overutilization, therapeutic duplication, drug-to-disease interactions, drug-to-drug interactions, appropriate dose and duration) and established criteria for a total of seventeen (17) new drugs and revised and discussed criteria for a number of existing drugs. Additionally, the Board continued to monitor anticipated "pipeline" specialty drugs, antipsychotic medication utilization in Pediatrics, concurrent use of opioids and benzodiazepines, concurrent use of opioids and antipsychotics, antidepressant medications in children, mood stabilizer medications in children, synagis utilization for respiratory syncytial virus, pediatric and adult narcotic utilization, and naloxone utilization.

About DMAS and Medicaid

The mission of the Virginia Medicaid agency is to improve the health and well-being of Virginians through access to high-quality health care coverage.

The Department of Medical Assistance Services (DMAS) administers Virginia's Medicaid and CHIP programs for over 2 million Virginians. Members have access to primary and specialty health services, inpatient care, dental, behavioral health as well as addiction and recovery treatment services. In addition, Medicaid long-term services and supports enable thousands of Virginians to remain in their homes or to access residential and nursing home care.

Medicaid members historically have included children, pregnant women, parents and caretakers, older adults, and individuals with disabilities. In 2019, Virginia expanded the Medicaid eligibility rules to make health care coverage available to more than 600,000 newly eligible, low-income adults.

Medicaid and CHIP (known in Virginia as Family Access to Medical Insurance Security, or FAMIS) are jointly funded by Virginia and the federal government under Title XIX and Title XXI of the Social Security Act. Virginia generally receives an approximate dollar-for-dollar federal spending match in the Medicaid program. Medicaid expansion qualifies the Commonwealth for a federal funding match of no less than 90% for newly eligible adults, generating cost savings that benefit the overall state budget.

Key DUR Board Activities in 2022

High-Impact Reports

In FY2022, the DUR Board generated and reviewed reports on the following high-interest populations and drug classes.

Patients on Diabetic Medications for over six months with a Hemoglobin A1c (*HbA1c*) over nine

At the DMAS DUR Board meetings on December 1, 2021, and March 10, 2022, the Board reviewed the results of a RetroDUR analysis that identified Medicaid members on diabetic medications for over six months with hemoglobin A1c values greater than nine (suggestive of poor diabetic control) and on continuous diabetic medications for at least six months. In December, the report was created with both Fee for Service (FFS) and Managed Care Organization (MCO) data during a six-month period from April 1, 2021, to September 30, 2021. In March, the report was created with one year's worth of data from October 1, 2020, to September 30, 2021. The number of unique FFS members with HbA1c lab values over nine and on continuous diabetic medications for six months was minimal. Among the MCO members with HbA1c labs performed, around 25% of the results ended up with HbA1c lab values over nine. Report findings indicated elevated HbA1c lab values over nine despite relatively high patient adherence to diabetic medication, suggesting that prescribed diabetic medications may be insufficient and that clinicians should update and enhance diabetic medication regimens to achieve improved disease control.

Utilization Management (UM)

At the DUR Board meeting on December 1, 2021, the Board added Utilization Management (UM) to its agenda. Utilization management is a process that works to improve healthcare quality, reduce costs, and improve the overall health of the population. The Board discussed and reviewed clinical criteria and quantity limits for the Movement Disorder Drugs class and made recommendations for the Pharmacy and Therapeutics (P&T) Committee to revisit and change certain criteria. In addition, the Board reviewed and discussed clinical criteria for the Human Immunodeficiency Virus (HIV) drugs class. The Board suggested that the P&T Committee look at a cost comparison and cost-effective alternatives of these drugs.

Class Criteria

Recognizing the low utilization and redundant content of some DMAS service authorization (SA) forms, and the fact that the Virginia FFS Medicaid system has more SA criteria forms than other Magellan Medicaid state client, the DUR Board began reviewing and consolidating individual agent SA criteria and forms into "class" criteria in FY2021. The goal of utilizing class criteria is to streamline providers' receipt of SA approval and member access to necessary drugs. Class criteria under development by the DUR Board include Hepatitis C, oral hypoglycemic, and oral oncology (lung cancer and renal cell carcinoma) agents, based on the circumstances and discussions summarized below.

Hepatitis C

Recent years have seen a rise in rates of Hepatitis C virus (HCV), one of the most deadly—albeit eminently treatable and curable—infectious diseases. Between 2013-2017, HCV prevalence doubled in Virginia, evidence of a growing "syndemic" of HCV and opioid use disorder, with more than two-thirds of new cases related to injection drug use. Nationally, 45% of individuals diagnosed are unaware of their hepatitis C diagnosis, with approximately 50% of those with HCV Medicaid-eligible. Furthermore, Medicaid pharmacy policy plays a critical role in ensuring access to proven therapies and addressing patient suffering, morbidity and mortality as well as "bending the curve" associated with transmission through treatment. Despite Virginia Medicaid's successful efforts to eliminate barriers to initiating treatment for HCV in recent years—in line with clinical guidelines and best practices—a significant percentage of eligible Medicaid members with Hepatitis C remain untreated.

Potential pharmacy strategies to increase HCV diagnosis and treatment include standardizing and streamlining treatment regimens, in addition to engaging providers in education and trainings. To that end, it was agreed to review and revisit criteria for HCV treatments at the December 2021 DUR meeting, to identify ways to facilitate increased patient access to HCV treatments. The Board reviewed and voted in agreement with the P&T Committee's decision to remove the service

authorization criteria from the preferred Hepatitis C agents and their limit of three one-month prescription fills without a service authorization.

Oral Hypoglycemic

The DMAS Preferred Drug List (PDL) currently imposes a metformin step edit on all oral hypoglycemics, which prevents prescriptions of any other oral hypoglycemic agent without completing a 90-day trial of metformin, except in select narrowly defined and proven scenarios (i.e., A1c > 7.5, history of intolerance, severe renal impairment, known metformin intolerance, metabolic/acidosis/DKA). Historically, there have been questions regarding the net impact of the edit on patients and providers due to the burden imposed on providers/pharmacists, the delay in patients' ability to start therapy, the fact that many of these medications are efficacious and well-tolerated, and that providers tend to be well-educated around these medications. These factors make an edit unlikely to meaningfully redirect providers to alternatives that are more effective or have lower side effects. New professional clinical guidelines have raised additional concerns that this edit inappropriately delays initiation of evidence-based therapy. The 2018 ACC guidelines and 2020 ADA guidelines recommend access to SGLT-2 agents as first-line therapy in select patient populations, such as patients with atherosclerotic cardiovascular disease (ASCVD), heart failure, or chronic kidney disease.

In 2021, the DUR Board began discussions around removing the metformin step-edit form oral hypoglycemic medications (i.e. including sulfonylurea, meglitinide, alpha-glucoside inhibitors, thiazolidinediones, DPP-4 and SGLT-2). During the December 2021 DUR meeting, the Board voted to remove the metformin step edit that was required before use of all oral hypoglycemics.

Oral Oncology – Lung Cancer

The DUR Board reviewed the overall low utilization of lung cancer oral oncology drugs and discussed a newly proposed and consolidated Oral Oncology Lung Cancer Service Authorization class criteria prepared by Magellan Health Services. This change consolidates the criteria for lung cancer oral oncology drugs into a single form with standardized criteria. During the December 2021 DUR meeting, the new SA form was reviewed, which would eliminate the multitude of single SA forms for individual lung cancer oral oncology drugs. The Board voted to rename and further modify the Lung Cancer Drugs SA form.

Oral Oncology – Renal Cell Carcinoma

The DUR Board reviewed newly proposed Oral Oncology Renal Cell Carcinoma SA class criteria. The new criteria combine all the renal cell carcinoma oral oncology drugs to create one SA criteria for the entire class. This new SA form would eliminate the single SA criteria forms for individual renal cell carcinoma oral oncology drugs. The DUR Board also reviewed the utilization of these renal cell carcinoma oral oncology drugs for FFS. At the December 2021 DUR meeting, the Board voted to rename and further modify the Renal Cell Carcinoma Drugs SA form.

Clinical Lab Data

As the first Medicaid program to initiate the incorporation of lab data in 2018, Virginia Medicaid's DUR program was at the forefront of state Medicaid DUR programs, and has continued to leverage these data in 2021 and 2022.

RetroDUR Topics and Educational Letters

Below is a list of the topics addressed via RetroDUR Educational Letters in FY2022:

- Central Nervous System (CNS) polypharmacy
- High risk medications in the elderly
- Opioid utilization and no naloxone claims
- Antipsychotics in children
- Aripiprazole without an FDA approved indication in history in the last 180 days
- Non-adherence with atypical antipsychotics
- Prescriber letter to enroll in VA Medicaid

Managed Care Organizations (MCOs) DUR Programs

Pursuant to 42 CFR§ 438.3, each Medicaid Managed Care Organization (MCO) is required to develop and maintain a DUR program that complies with the DUR program standards as described in Section 1927(g) of the Social Security Act and 42 CFR 456, subpart K, including prospective DUR, retrospective DUR and the DUR Board. DMAS contractually requires the MCOs to establish a DUR program that, at a minimum, includes all the DUR activities conducted by DMAS. In 2022, some of the DMAS DUR Board RetroDUR topics were reviewed and addressed by individual MCO DUR boards. These include opioid utilization and no naloxone claims; and hemoglobin A1c lab value over nine and on diabetic medications for six months. In addition, the MCO DUR Boards reviewed their antipsychotic monitoring in pediatrics programs, naloxone utilization, concurrent use of opioids and benzodiazepines, concurrent use of opioids and antipsychotics, and other similar analyses conducted by DMAS. The Department's clinical DUR pharmacist participates, provides oversight, and serves on each MCO's DUR Board as a voting representative. At each quarterly DMAS DUR meeting in 2022, the Board was able to review and compare the same utilization reports for the FFS members as well as those members in each of the contracted MCOs.

Appendix

Pharmacy Liaison Committee

The Pharmacy Liaison Committee (PLC) is comprised of appointed members who meet twice a year to discuss the promotion of cost-effective services to assist Medicaid pharmacy issues impacting the pharmacy community. The PLC includes representatives from

- long-term care pharmacies;
- the Pharmaceutical Research and Manufacturers Association (PhRMA);
- the Virginia Association of Chain Drug Stores (VACDS);
- the Virginia Pharmacists Association (VPhA);
- Community Pharmacies; and
- the Virginia Community Healthcare Association (VCHA).

Pharmacy Liaison Committee Members

NAME	AFFILIATION
John Seymour	Community Pharmacy (Independent)
Bill Hancock	Long Term Care Pharmacy Coalition
Richard Grossman	Pharmaceutical Research & Manufacturers of America (PhRMA)
William Droppleman / Derek Parvizi	Virginia Association of Chain Drug Stores (VACDS)
David Christian	Virginia Community Healthcare Association (VCHA)
Christina Barille	Virginia Pharmacists Association (VPhA)

Drug Utilization Review (DUR) Board

The DUR Board is an expert panel comprised of physicians, pharmacists and nurse practitioners appointed by the DMAS Director. The DUR Board defines the parameters of appropriate medication use within federal and state guidelines; meets periodically to review, revise and approve new criteria for the use of prescription drugs; and develops drug utilization review criteria to address potential threats to the health and safety of patients, such as high doses, drug-to-drug interactions, drug-diagnosis interactions, adverse drug reactions, and therapeutic duplication.

Drug Utilization Review, as defined in section 1927(g) of the Social Security Act, consists of two programs (1) the prospective DUR (ProDUR) and (2) the retrospective DUR (RetroDUR). The intent of both programs is to help ensure the health and safety of patients by reducing clinical abuse and misuse of outpatient prescription drugs.

The ProDUR program involves a process that is interactive, online and real-time in which submitted prescriptions are reviewed for potential problems related to established criteria (e.g., drug-to-drug interactions) at the time claims are submitted, before they are filled or dispensed to patients. Due to the short turn-around time associated with point-of-sale processing (30 seconds or less per transaction), immediate alert messages are sent to pharmacists for the most serious potential concerns based on a hierarchy of risks established and managed by the DUR Board. Of note, given the nuances of clinical situations and risks, a pharmacist is able to override ProDUR alerts using their clinical judgement. In these cases, the pharmacist is required to provide clinical justification for the override. If pharmacists are unable to provide clinical justification, the claim will be denied.

Unlike the ProDUR program, which is prospective in nature, the RetroDUR program uses claims data to retrospectively monitor drug utilization and identify concerning trends around prescription practices (e.g., non-adherence to medication, over-utilization of medications with high side effect profiles and preferred alternatives). When problematic practices (e.g., risk to patient health or safety) are identified by the DUR Board, an expert panel, under the direction of the Board, drafts and mails educational letters to the providers of affected DMAS members, identifying the prescription practice of concern and reinforcing current—often new—best practices. Seven months after letters are sent, the DUR Board may reassess prescription practices to determine whether additional interventions may be helpful at increased adherence to accepted treatment guidelines.

DUR Board Members

Name	Profession
Denese Gomes	Nurse
Kathryn B. Reid	Nurse
Kristi Fowler	Pharmacist
Matthew Estes	Pharmacist
Denise Lowe	Pharmacist
Michele Thomas	Pharmacist
Wendy Nash	Pharmacist
Rachel Cain	Pharmacist
Randy Ferrance	Physician
Melissa Chouinard	Physician
Elizabeth Gaughan	Physician
John Morgan	Physician
Seth Brant	Physician