COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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December 1, 2021

MEMORANDUM

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

The Honorable Luke E. Torian
Chair, House Appropriations Committee

The Honorable Mark D. Sickles
Vice Chair, House Appropriations Committee

FROM: Karen Kimsey
Director, Virginia Department of Medical Assistance Services

SUBJECT: Annual Pharmacy Liaison Committee and Drug Utilization Review Board Report- FY- 2021

This report is submitted in compliance with the Virginia Acts of the Assembly – Item 313.M.1., which 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 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 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.

KK/REC
Enclosure
Pc: The Honorable Daniel Carey, M.D., Secretary of Health and Human Resources

Annual Pharmacy Liaison Committee and Drug Utilization Review Board Report FY-2021

A Report to the Virginia General Assembly

December 15, 2021

Report Mandate:

The 2021 Appropriation Act, Item 313.M.1. 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 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 Committees and the Department of Planning and Budget no later than December 15 each year of the biennium.

Background

Pharmacy Liaison Committee

The Pharmacy Liaison Committee (PLC) is comprised of appointed members who meet periodically to discuss Medicaid pharmacy issues impacting the pharmacy community. The PLC includes representatives from:
(1) long-term care pharmacies; (2) the Pharmaceutical Research and Manufacturers Association (PhRMA); (3) the Virginia Association of Chain Drug Stores (VACDS); (4) the Virginia Pharmacists Association (VPhA); (5) Community Pharmacy (EPIC); and (6) the Virginia Community Healthcare Association (VCHA).

The PLC met on July 15 and is scheduled to meet on December 2, 2021 to discuss initiatives for the promotion of cost-effective services. The Department of Medical Assistance Services (DMAS) shared with the Committee the pharmacy-related activities the Agency has completed and planned, with particular emphasis on the Agency's pharmacy program updates and response to COVID-19. This included information related to the General Assembly, the Pharmacy Benefit Manager (PBM) Transparency Report, COVID–19 testing and vaccination by pharmacists, COVID-19 flexibilities, immunization administration fees, and the Vaccines For Children Program.

About DMAS and Medicaid

DMAS's mission is to improve the health and well-being of Virginians through access to high-quality health care coverage.

DMAS administers Virginia's Medicaid and CHIP programs for more than 1.8 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 500,000 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 a 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 percent for newly eligible adults, generating cost savings that benefit the overall state budget.

Drug Utilization Review Board

The Drug Utilization Review Board (hereafter "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 an interactive on-line, real-time process 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 assess whether additional interventions may be helpful at increased adherence to accepted treatment guidelines.

The March 11, 2021 DUR Board meeting was cancelled in response to the COVID-19 pandemic. The DUR Board met on June 10, September 9, and is scheduled to meet on December 9, 2021. At each meeting held to date, the DUR Board reviewed seven characteristics (overutilization, underutilization, therapeutic duplication, drug-to-disease interactions, drug-to-drug interactions, appropriate dose and duration) and established criteria for twenty-eight (28) new drugs and revised and discussed criteria for a number of existing drugs. Additionally, the Board continued to monitor anticipated "pipeline" specialty drugs, as well as the use of antipsychotic medications in children, Synagis utilization for Respiratory Syncytial Virus, pediatric and adult narcotic utilization, and naloxone utilization.

Key DUR Board Activities in 2021

Naloxone Utilization Promotion

In response to the opioid epidemic and increased incidence of opioid overdoses, the Board continues to monitor and explore options to increase the dispensing of naloxone to Medicaid members prescribed opioids at high-risk for opioid-related overdose. Naloxone is an opioid antagonist that can be utilized to reverse an opioid-related overdose. It is an important tool in combatting the opioid epidemic. In FY2021, these efforts resulted in the FFS pharmacy program instituted a ProDUR real-time alert encouraging pharmacists to recommend naloxone to high-risk opioid-using patients at the time they receive their opioid prescriptions.

High-Impact Reports

In FY2021, the DUR Board generated and reviewed reports on the following high-interest populations and drug classes:

Patients on Diabetic Medications for over 6 months with a Hemoglobin A1c (*HgbA1c*) over nine

At the June 11, 2020 DMAS DUR Board meeting, 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 between October 1, 2019 to March 31, 2020. Report findings indicated elevated HbA1c lab values over nine despite patient relatively high patient adherence to diabetic medication, suggesting that prescribed diabetic medications may be insufficient and that clinicians should update and enhance diabetic medication regiments to achieve improved disease control.

Respiratory Drugs in Members Less than 4 Years of Age (excluding Inhaled Corticosteroids [ICS] and Short-Acting Beta 2 –Agonist [SABAs])

At the September, 2021 meeting, the Board reviewed the extent of the generally unadvised use respiratory drugs in members less than four years of age. Data were reviewed from the period of October 1, 2020 through March 31, 2021. In the FFS population, there was only one member with documented use (age 1). In the MCO population, there were 53 members with documented use under the age of four.

Utilization of Anticoagulant Reversals When Using Novel Oral Anticoagulants

At the September, 2021 meeting, the Board reviewed the use of reversal agents for Novel Oral Anticoagulants (NOACs) among FFS and MCO members from October 1, 2020 through March 31, 2021. The newest agents in this class include Praxbind (HIC3 = M9W) and Andexxa (HIC3 = M9Y). The Board reviewed use of these agents and noted no utilization of either across both FFS and MCOs.

Class Criteria

Recognizing the low utilization and redundant content of some DMAS SA forms—and the fact that the Virginia fee-for-service (FFS) Medicaid system has more service authorization (SA) criteria forms than other Magellan Medicaid state client—beginning in FY2021 the DUR Board began reviewing and consolidating individual agent SA criteria and forms into “class” criteria with the goal of streamlining 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. Recent cost trends show that treating HCV is cost effective, realizing cost savings within a few years. 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 upcoming December 2021 DUR meeting, to identify ways to facilitate increased patient access to HCV treatments.

Oral Hypoglycemics

The DMAS 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 more effective or lower side effect alternatives. 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.

To that end, 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) and agreed to continue these discussions during the December 2021 DUR meeting.

Oral Oncology – Lung Cancer

The DUR Board reviewed the overall low utilization of lung cancer oral oncology drugs, and discussed newly proposed, and consolidated, Oral Oncology Lung Cancer Service Authorization (SA) class criteria, prepared by Magellan Health Services. The new criteria consolidate the criteria for lung cancer oral oncology drugs into a single form with standardized criteria. This new SA form would eliminate the multitude of single SA forms for individual lung cancer oral oncology drugs, and is expected to be reviewed at the December 2021 DUR meeting.

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.

Clinical Lab Data

In 2018, Magellan Health Services presented on the laboratory data available to the DUR Board. Through contractual agreements with major lab companies, lab/clinical information for DMAS FFS and MCO members is able to be used to make decisions around RetroDUR activities via the FirstIQ clinical rule engine. Additionally, this allows lab information to be included in letters to prescribers and referenced in targeted communications. 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 this data in 2020 and 2021.

RetroDUR Topics and Educational Letters

Below is a list of the topics addressed via RetroDUR Educational Letters in FY2021:

- Diabetic Patients on Insulin without Claims for Glucose Monitoring Products
- Nonadherence with Antihypertensive Agents
- Opioid Utilization and No Naloxone Claims
- Diabetic Ages 40-75 with No Statins
- Atypical Antipsychotics without Metabolic Testing
- Anti-anxiety Benzodiazepine without an SSRI or SNRI
- Use NSAIDs Cautiously in Patients with Hypertension
- Nonadherence with Antidepressants
- Benzodiazepines – Increased FDA Warnings for Abuse and Misuse
- ACE Inhibitors & ARBs in Diabetes and Hypertension
- Nonadherence with Anticonvulsants

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 2021, several of the DMAS DUR Board RetroDUR topics were reviewed and addressed by individual MCO DUR boards. These include Opioid Utilization and No Naloxone Claims; Diabetics ages 40-75 with no statins; Nonadherence with Antidepressants; and Hemoglobin A1c lab value over nine and on diabetic medications for six months. In addition, the MCO DUR Boards review and discuss 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 2021, 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.

Summary

DMAS will continue to work with the Pharmacy Liaison Committee to promote cost-effective pharmacy services and continue to advance the health and safety of Virginia's Medicaid patients via the DUR program its Board members' insights into appropriate medication utilization.

Appendix

PHARMACY LIAISON COMMITTEE MEMBERS

NAME	AFFILIATION
Bill Hancock	Long Term Care Pharmacy Coalition
William Droppleman	Virginia Association of Chain Drug Stores ((VACDS)
Alexander M. Macaulay	Community Pharmacy (EPIC)
Anne Leigh Kerr	Pharmaceutical Research & Manufacturers of America (PhRMA)
Christina Barille	Virginia Pharmacists Association (VPhA)
David Christian	Virginia Community Healthcare Association (VCHA)

DUR BOARD MEMBERS

Name	Profession
Randy Ferrance	Physician
Denese Gomes	Nurse
Kathryn B. Reid	Nurse
Vacant	Pharmacist
Melissa Chouinard	Physician
Vacant	Physician
Vacant	Pharmacist
Denise Lowe	Pharmacist
Michele Thomas	Pharmacist
Chethan Bachireddy/John Morgan	Physician
Wendy Nash	Pharmacist
Seth Brant	Physician
Rachel Cain	Pharmacist