COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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November 9, 2020

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

Daniel Timberlake
Director, Department of Planning and Budget

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

SUBJECT: Annual Pharmacy Liaison Committee and Drug Utilization Review Board Report- FY- 2020

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

The 2020 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.

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- 2020

A Report to the Virginia General Assembly

December 15, 2020

Report Mandate:

The 2020 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 16 and is scheduled to meet on December 3, 2020 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 initiatives with particular emphasis on the Agency's response to COVID-19. In addition, DMAS staff shared General Assembly Updates / Legislative Proposals, results of Virginia's Pharmacy Cost of Dispensing Survey, the Pharmacy Benefit Manager (PBM) Transparency Report, COVID–19 Testing and Vaccination by Pharmacists, COVID-19 Flexibilities included in the 1115 Waiver, and pharmacist reimbursement for the administration of Screening Brief Intervention and Referral to Treatment (SBIRT).

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 1.6 million Virginians. Members have access to primary and specialty health services, inpatient care, 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 400,000 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. In this capacity, 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 by addressing situations in which potential medication problems may arise, 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 review of patients' drug therapy history prior to prescription orders being filled. The ProDUR program allows pharmacy claims to be evaluated at the time claims are submitted. Specifically, the ProDUR program is an interactive on-line, real-time process in which pharmacy claims are evaluated for potential problems related to established criteria for appropriate use (e.g., drug to drug interactions). 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 on the most serious potential concerns based on a hierarchy of risks that is continually reviewed by the DUR Board. A pharmacist, based on clinical judgment, can override ProDUR alerts. In these cases, the pharmacist is required to provide justification for the override or the claim will be denied.

Unlike the ProDUR program, which is prospective in nature, the RetroDUR program is a retrospective program. The RetroDUR program examines a history of medication used to identify certain patterns of use RetroDUR reviews examine drug utilization (claims data) to identify potentially problematic patterns (e.g., non-compliance, over-utilization, etc.). The DUR Board decides which drug classes to evaluate, and then the appropriate claims data are extracted. An expert panel of reviewers evaluates a sample of the extracted claims data to identify potentially problematic prescribing practices. When problematic practices (e.g., risk to patient health or safety) are noted, the expert panel requests that the program contractor mail educational intervention letters to providers. The educational letters ("patient profile letters") are customized to each identified case.

Providers are asked to respond to the educational letters to formally acknowledge that they received and reviewed the patient profile letter. Potential responses providers can provide include:

- Aware of situation and no adjustment to current therapy is necessary at this time;
- Plan to discontinue medication(s);
- Information clinically useful and plan to alter treatment regimen for specified patient;
- Information clinically useful and plan to monitor or counsel specific patient;
- Plan to change dose;
- Information regarding patient or provider appears to be incorrect; or,
- Other (additional comments may be added by prescribers).

Seven months after the letters are sent to providers; the DUR Board may conduct re-reviews to assess whether providers accepted recommended changes resulting in increased compliance to accepted treatment guidelines.

Often the goal of the RetroDUR program is not to change the prescriber's treatment pattern, but rather to alert them to recent warnings or research findings pertaining to certain medications. This is an informative program and it is up to the prescriber to determine the potential impact to his/her patients. A change in therapy may not be warranted. The re-review change in therapy rate does not accurately depict the impact of this program. Most of the prescribers responded that they found the information useful and even though a change may not be necessary, they planned to closely monitor the patient's treatment regimen.

The March 12, 2020 DUR Board meeting was cancelled in response to the COVID-19 pandemic. The DUR Board met on June 11, September 10, and December 10, 2020. At each meeting, the DUR Board approved criteria associated with overutilization, therapeutic duplication, drug to disease interactions, drug to drug interactions, appropriate dose and duration for twenty-three (23) new drugs, revised and approved criteria for existing drugs, and updated existing criteria which were integrated into

both the ProDUR and the RetroDUR programs. The Board reviewed impact reports on two specialty drugs in June. These impact reports are based on members' diagnoses and drug indications and can assist the Board in their evaluation process by providing insight into the possible utilization of the new drug and its impact on the Medicaid population. The Board continued to monitor the use of antipsychotic medications in children, Synagis utilization, pediatric and adult narcotic utilization, compounded drug claims and naloxone utilization. In addition, the DUR Board approved service authorization criteria for select drugs not included on the DMAS Preferred Drug List (PDL).

Key DUR Board Activities in 2020

Implementation of Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

Section 1927(g) of the Social Security Act (the Act) requires each state to develop a DUR program targeted, in part, at reducing clinical abuse and misuse of prescription drugs covered under the State's Medicaid Program. The recently-enacted SUPPORT Act includes measures to combat the opioid crisis in part by reducing opioid abuse and misuse by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs. There are several Medicaid-related DUR provisions contained within Section 1004 of the SUPPORT Act with respect to FFS and MCO pharmacy programs. These provisions establish drug review and utilization standards to supplement existing requirements under Section 1927(g) of the Act, in an effort to reduce opioid-related fraud, abuse and misuse. State implementation of these strategies were required by October 1, 2019.

The SUPPORT Act requires State Medicaid Programs to have in place the following:

I. Claims Review Requirements

1.Safety Edits Including Early, Duplicate, and Quantity Limits: States are required to have in place prospective safety edits for subsequent fills for opioids and a claims review automated process that indicates when an individual enrolled under the State plan is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state. State-identified limitations should include restrictions on duplicate fills, early fills, and drug quantity limitations.

2. Maximum Daily Morphine Milligram Equivalents (MME) Safety Edits: States are required to have prospective safety edits on maximum MMEs that can be prescribed to an individual enrolled under the State plan for treatment of chronic pain and a claims review automated process that indicates when an individual enrolled under the plan is prescribed the morphine equivalent for such treatment in excess of the maximum MME dose limitation identified by the state.

3. Concurrent Utilization Alerts: States are required to have an automated process for claims review that monitors when an individual enrolled under the State plan is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics.

II. Program to Monitor Antipsychotic Medications to Children - The state must have in place a program to monitor and manage the appropriate use of antipsychotic medications in children enrolled under the State plan.

III. Fraud and Abuse Identification Requirements - The state must have a process that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

DMAS' DUR Program is currently compliant with the SUPPORT Act requirements. In addition, the DUR Board reviews and discusses, Concurrent Use of Opioids and Benzodiazepines, Concurrent Use of Opioids and Antipsychotics utilization reports for Fee For Service (FFS) and Managed Care Organizations (MCOs) Medicaid populations.

Also CMS encouraged the states to implement a Medicaid pre-payment edit for opioid "naïve" prescribing in an effort to encourage the co-dispensing of naloxone with opioids.

- Opioid naïve member will be defined as no claims for any opioid drugs in the member's drug profile in the previous 60 days

- The dispensing pharmacist will receive a message, “Opioid naïve member. Potential Risk. Offer Naloxone.”, when an opioid naïve member is trying to fill an opioid prescription

Naloxone Utilization

In response to the opioid epidemic and increased incidence of opioid overdoses, the Board wanted to explore options to increase the dispensing of naloxone to Medicaid members prescribed opioids. The DUR Board reviewed multiple naloxone reports in an effort to monitor naloxone utilization. These reports included reviewed Opioid Use with Risk Factors and No Naloxone or Getting Naloxone reports for FFS and MCOs. The DUR Board requested a report identifying the number of claims with the new ProDUR edits (opioids with antipsychotics and opioid naïve with the messaging to offer naloxone). As mentioned above in the SUPPORT ACT section, DMAS enhanced the ProDUR edit to include a message to the pharmacist at POS to recommend naloxone.

*Patients on Diabetic Medications for over 6 months with a Hemoglobin A1c (*HgbA1c*) over 9*

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 9. A hemoglobin A1C value of 9 or greater in diabetic patients, may indicate that the patient’s diabetes is not under control. Since the majority of members who meet this criterion are enrolled in managed care, the Board recommended that DMAS share the criteria, lab values, etc. with each of the MCOs so that they could replicate the analysis for the members.

The Board’s requested report includes members with HgbA1c Lab Values over 9 and the member is on continuous diabetic medications for at least six months for FFS and MCO. The MCO will need to be separated by the individual MCO plans. The time frame to review this is October 1, 2019 through March 31, 2020. The HgbA1c test and the continuous diabetic meds are all to be included in that specific six-month period.

The idea is to be aware of cases in which the patient is compliant on their diabetic medications, but their HgbA1c lab value is still high (over nine). This would alert DMAS to the possibility that the member’s diabetic medication may not be working, and that the physician may need to either change the diabetic medication or add additional diabetic mediations to the member’s treatment plan. No more than an eight-day gap of therapy between refills would be considered compliant.

At the December 2019 DUR meeting the DUR Board Members requested that DMAS add a denominator and percentage for these members. They would like for the denominator to be the number of members getting HgbA1c lab test done (just getting the lab test done and not concerned about the actual lab value results) in that specific six month time frame and note whether the member is on continuous diabetic medications for at least six months. Then the percentage would be the number of members with HgbA1c lab value over 9 and on continuous diabetic medications / number of members getting HgbA1c lab test done and on continuous diabetic medications (all in that specific six month time frame).

Clinical Lab Data

In 2018, Magellan Health Services presented a Lab Data demonstration to the DUR Board. Through contractual agreements established with major lab companies, lab/clinical information for DMAS members is received and loaded into the RetroDUR clinical rules engine (FirstIQ) based on the unique VA Medicaid Identification Number for Fee-for-Service and Medicaid Managed Care members. DMAS can utilize member laboratory values in the RetroDUR process. During RetroDUR interventions, the lab information can be included in the prescriber letter and referenced in the targeted communication. As the first Medicaid program to initiate the incorporation of lab data in 2018, Virginia Medicaid’s DUR program is at the forefront of other state Medicaid DUR programs. In 2019, Magellan was able to capture the MCO information for review and comparison.

RetroDUR Topics and Educational Letters

Below is a list of the topics addressed within the RetroDUR Educational Letters this year:

- Non-compliance to Antidepressants
- Non-compliance to Anticonvulsants
- Atypical Antipsychotics in Children Less than 18 Years of Age Without Metabolic Testing

- Aripiprazole without an FDA approved indication in history in the last 365 days
- Quetiapine without an FDA approved indication in history in the last 365 days
- CNS Stimulants may retard growth in pediatric patients ages 4-10
- Bipolar Disorder with Antidepressants and No Mood Stabilizer
- ADHD Amphetamines Linked to Higher Risk of Psychosis
- FDA Alert: Possible association between use of Montelukast and behavior/mood changes, suicidality, and suicide.
- Use of Antibiotics for URI - Antibiotic Overutilization and Resistance Non-compliance with Atypical Antipsychotics
- Non-compliance with Atypical Antipsychotics

Managed Care Organizations (MCOs) DUR Programs

Pursuant to 42 CFR § 438.3, the Managed Care Organizations (MCOs) are 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 having a DUR Board in place. DMAS contractually requires the MCOs to establish a DUR program that at a minimum includes all the DUR activities conducted by DMAS.

In 2020, several of the DMAS DUR Board RetroDUR topics were reviewed, and discussed by the individual MCO DUR boards. A few of these topics were the issue that Amphetamine type ADHD meds have a higher risk of psychosis in children and young adults; Diabetics ages 40-75 with no statins; FDA Alert: Possible association between use of Montelukast and behavior/mood changes, suicidality, and suicide; and lastly, Hemoglobin A1c lab value over 9 and on diabetic medications for 6 months. In addition, DUR Board addressed the topic of MCO DUR Boards reviewing and discussing their Antipsychotic monitoring in Pediatrics Programs, Naloxone utilization, 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 2020, 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

In conclusion, DMAS will continue to work with the Pharmacy Liaison Committee to promote cost-effective pharmacy services and continue to implement enhancements to the DUR program. The DUR board medical experts will continue to provide counsel to the department regarding appropriate medication utilization for Virginia's Medicaid members.

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	Physician
Wendy Nash	Pharmacist
Seth Brant	Physician
Rachel Cain	Pharmacist