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

December 15, 2017

MEMORANDUM

TO: The Honorable Karen S. Rheuban, Chair
Board of Medical Assistance Services

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

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

SUBJECT: Report on the Activities of the Pharmacy Liaison Committee (PLC) and the Drug Utilization Review (DUR) Board

The 2017 Appropriation Act, Item 306 (M), 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 to implement initiatives for the promotion of cost-effective services delivery as may be appropriate. 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.

This report responds to the requirement in Item 306 (M) that the Department annually report on the activities of the Pharmacy Liaison Committee and the Drug Utilization Review (DUR) Board.

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

CBJ/

Enclosure

Annual: Pharmacy Liaison Committee and Drug Utilization Review Board Report – FY2017

A Report to the Virginia General Assembly — *December 15, 2017*

Report Mandate:

2017 Appropriation Act, Item 306 (M) 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 to implement initiatives for the promotion of cost-effective services delivery as may be appropriate. 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 pertinent Medicaid pharmacy issues and the impact on 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); and, (4) the Virginia Pharmacists Association (VPhA).

The PLC met on July 18, 2017 and November 2, 2017 to discuss Virginia Medicaid's proposed new pharmacy reimbursement methodology. The Department of Medical Assistance Services (DMAS) shared with the Committee the recent work the agency has done with particular emphasis on the opioid epidemic, the implementation of the Centers for Disease Control (CDC) Guidelines for prescribing opioids, the new pharmacy reimbursement methodology and the implementation of the pharmacy benefit manager (PBM).

Drug Utilization Review Board

The Drug Utilization Review Board (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-drug interactions, drug-diagnosis interactions, adverse drug reactions, and therapeutic duplication.

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.

A drug-drug interaction is a change in a drug's effect on the body when the drug is taken together with a second drug, which can include a delay, increase or enhanced absorption of either drug. Drug-disease interactions occur when a patient has multiple diseases and a drug that is helpful for one disease are harmful for another. An adverse drug reaction is an injury caused by taking a medication and finally, therapeutic duplication is the practice of prescribing multiple medications for the same aspect of a disease without a clear distinction of when one drug should be administered over another.

The DUR Board 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.

The ProDUR program involves a review of prescription and medication orders and patients' drug therapy history prior to prescription orders being filled. The ProDUR program allows pharmacy claims to be evaluated at the time claims are actually 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-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 needs 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. RetroDUR reviews examine medication utilization (claims data) to identify potentially problematic patterns (e.g., non-compliance, excessive quantities, 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.

Between January 2017 and November 2017, the DUR Board retrospectively reviewed patient profiles and mailed letters on several topics.

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:

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

Seven months after the letters are mailed to providers, the DUR Board conducts re-reviews based on claims data 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. 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 current treatment regimen.

The DUR Board met on February 9, May 11, August 10, and November 9, 2017. 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 new drugs, revised and approved criteria for existing

drugs, and updated existing criteria which were integrated into both the ProDUR and the RetroDUR programs. In addition, the Board reviewed and approved criteria for 19 new drugs, existing drugs, and updated existing criteria. The Board continues to monitor antipsychotic medications in children, Synagis utilization, and place service authorizations on medications.

Key DUR Board Activities in 2017

Pediatric Narcotic Utilization – April 2017 through June 2017

The DUR Board has continued to review pediatric narcotic utilization patterns in the fee for service Medicaid population. There was a significant decrease in pediatric narcotic utilization over the past 19 months. On average, 40 prescription claims per month were written by 28 prescribers for 30 enrollees.

The decrease in opioid utilization for pediatric enrollees is likely a result of compliance with CDC Guidelines for Prescribing Opioids for Chronic Pain and DMAS' implementation of 7-day Short Term Opioid limitations which became effective July 1, 2017.

New FDA Warnings for Tramadol and Codeine

The Board discussed the Federal Drug Administration (FDA) safety announcement restricting the use of codeine and tramadol medications. The FDA's strongest warning, a contraindication, recommends that codeine should not be used to treat children's pain or cough and tramadol should not be used to treat pain in children younger than 12 years old. Also the FDA recommended that tramadol is contraindicated in children under 18 years of age to treat pain after surgery to remove tonsils or adenoids. A new warning was issued regarding a recommendation against their use in adolescents between 12-18 years who are obese or who have obstructive sleep apnea or severe obstructive lung disease. A strengthened warning was also issued against their use in breastfeeding mothers due to serious reactions to their infants. Based on these recommendations, the Drug Utilization Review (DUR) Board approved the addition of system edits (clinical rules programmed into the system) to the point of sale (POS) claims processing system which will deny all claims for codeine and tramadol for members younger than 12 years of age effective on July 1, 2017. Below is a list of these products.

List of Prescription Codeine and Tramadol Products
Pain and Cough Medicines

Medicines Containing Codeine	Medicines Containing Tramadol
Codeine Sulfate	Conzip
Butalbital, Acetaminopen, Caffeine, and Codeine	Ultracet
Fiorinal with codeine	Ultram
Soma Compound with codeine	Ultram ER
Tylenol with codeine	Generics containing tramadol
Promethazine with codeine	
Prometh VC with codeine	
Triacin-C (cough)	
Tuxarin ER (cough)	
Tuzistra-XR (cough)	
Generic products	
Medicines Containing Dihydrocodeine	
Synalgos-DC	

Proton Pump Inhibitors (PPIs) Review

The Board reviewed the updated practice standards of the American Gastroenterologist Association's recommendations for the use of Proton Pump Inhibitors (PPIs) with focus on long-term use for gastroesophageal reflux disease (GERD), Barrett's esophagus (BE) and non- steroidal anti-inflammatory drug (NSAID) bleeding prophylaxis. Below are 2017 best practice recommendations.

Advice 1: Patients with GERD and acid-related complications should take a PPI for short-term healing, maintenance of healing, and long-term symptom control.

Advice 2: Patients with uncomplicated GERD who respond to short-term PPIs should subsequently attempt to stop or reduce them. Patients who cannot reduce PPIs should consider ambulatory esophageal pH/impedance monitoring before committing to lifelong PPIs to help distinguish GERD from a functional syndrome.

Advice 3: Patients with BE and symptomatic GERD should take a long-term PPI.

Advice 4: Asymptomatic patients with BE should consider long-term PPIs.

Advice 5: Patients at high risk for ulcer-related bleeding from NSAIDs should take a PPI if they continue to take NSAIDs.

Advice 6: The dose of long-term PPIs should be periodically reevaluated so that the lowest effective dose can be prescribed to manage the condition.

Advice 7: Long-term PPI users should not routinely use probiotics to prevent infection.

Advice 8: Long-term PPI uses should not routinely raise their intake of calcium, beyond the Recommended Dietary Allowance (RDA).

Advice 9: Long-term PPI users should not routinely screen or monitor bone mineral density, serum creatinine, magnesium or vitamin B12.

Advice 10: Specific PPI formulations should not be selected based on potential risk.

This class of drugs is routinely one of the highest utilized in the Medicaid program. Based on these new recommendations, the DUR Board is reviewing current program parameters in regard to term limitations on acute dosing of PPIs without service authorization. A 3 month (March through May 2017) retrospective claims review of all paid claims identified 608 enrollees who have received acute dosing of proton pump inhibitors (one or more agents) for 90 consecutive days. Diagnosis information is not currently part of pharmacy claims processing.

Based on the American Gastroenterologist Association's advice regarding best practices DMAS added a 90-day limit in its reissuance of acute dosing limit of PPIs. The new point of sale claims system, which became operational on October 1, 2017, has an accumulation edit which is able to calculate days' supply and identify patients who have reached the 90-day threshold for acute dosing of PPIs. A claims denial message is sent to the dispensing pharmacy requiring either a service authorization for continuation of therapy or a decrease in the dosage of the PPI to maintenance therapy.

Compounded Drug Claims Analysis

Over the past 18 months the DUR Board has focused on a review of compounded prescriptions specifically the safety and efficacy of these medications. From January through March 2017, these orders accounted for 1.7 percent of all paid claims with an average cost of $149.16 per prescription with cost increases noted each quarter. A targeted intervention was recommended by the Board to require service authorizations for those compounded prescriptions over $500. Criteria for approval was based on three components:

1. Is there a commercially available product for treatment? If so, is there a documented treatment failure?
2. Is there medical justification for each ingredient in the compound?
3. Are there peer reviewed studies that the compound order is safe and effective?

A targeted retrospective DUR letter was sent to prescribers in May identifying current enrollees whose prescriptions would be affected by the program change, along with a service authorization form to ensure no disruption in medically needed treatments.

Summary

In conclusion, DMAS will continue to work with the PLC to implement initiatives for the promotion of cost-effective services and continue to implement enhancements to the DUR program. The DUR board will continue to provide direction to the department regarding appropriate medication utilization for Virginia's Medicaid enrollees.

ACKNOWLEDGEMENTS

DMAS wishes to give a special thanks to the healthcare professionals on the Drug Utilization Review Board who willingly volunteer their time and expertise for the benefit of Virginia's Medicaid patients. DMAS also wishes to acknowledge the many health care professionals and industry groups who have participated in the development and implementation of pharmacy program initiatives over the past year. In addition, DMAS acknowledges Conduent, fiscal agent for Virginia Medicaid, for its collection, analysis, and reporting of the claims data for the DUR Program.

Appendix A

PHARMACY LIAISON COMMITTEE MEMBERS

NAME	AFFILIATION
Bill Hancock	Long Term Care Pharmacy Coalition
Rusty Maney	Virginia Association of Chain Drug Stores
Alexander M. Macaulay	Community Pharmacy (EPIC)
Anne Leigh Kerr	Pharmaceutical Research & Manufacturers of America
Johnny Moore	Virginia Pharmacists Association

DUR BOARD MEMBERS

Name	Profession
Randy Ferrance, Chairman	Physician
Denese Gomes	Nurse
Kathryn B. Reid	Nurse
Sandra Dawson	Pharmacist
Jonathan Evans	Physician
Avtar Dhillon	Physician
Bill Rock, Vice Chairman	Pharmacist
Denise Lowe	Pharmacist
Michele Thomas	Pharmacist
Kathy Sardegna	Physician
Wendy Nash	Pharmacist
Seth Brant	Physician
Rachel Cain	Pharmacist