COMMONWEALTH of VIRGINIA
Department of Medical Assistance Services

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December 15, 2016

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 2016 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

pc: The Honorable William A. Hazel, Jr., MD, Secretary of Health and Human Resources

DMAS' mission is to provide a system of high quality and cost effective health care services to qualifying Virginians and their families.

Medicaid is a joint federal and state program authorized under Title XIX of the Social Security Act that provides health and long-term care coverage for specific groups of Virginians with low incomes. In Virginia, Medicaid is administered by the Department of Medical Assistance Services (DMAS) and is jointly funded by Virginia and the federal government. Virginia's federal matching rate, known as the Federal Medical Assistance Percentage (FMAP) is generally 50%, meaning Virginia receives $1 of federal matching funds for every $1 Virginia spends on Medicaid.

Medicaid coverage is primarily available to Virginians who are children in low-income families, pregnant women, elderly, individuals with disabilities and parents meeting specific income thresholds.

All states must follow general federal Medicaid guidelines regarding who is covered, but states set their own income and asset eligibility criteria. Virginia's eligibility criteria are among the strictest in the nation.

VIRGINIA'S MEDICAID PROGRAM
DMAS
INNOVATION · QUALITY · VALUE

Report to the Governor and General Assembly from the Department of Medical Assistance Services Annual Pharmacy Liaison Committee and Drug Utilization Review Board Report

December 15, 2016

Report Mandate

The 2016 Appropriation Act, Item 306 (M), requires:

> 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.

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.

I. ROLE OF THE DRUG UTILIZATION REVIEW (DUR) BOARD IN VIRGINIA MEDICAID'S FEE-FOR-SERVICE PROGRAM

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-drug interactions, drug-diagnosis interactions, adverse drug reactions, and therapeutic duplication.

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. The RetroDUR program examines a history of medication used to identify certain patterns of use. After a computer analysis of claims data, an expert panel of reviewers evaluates a sampling of records, identifies potential problems and requests the generation of educational intervention letters in appropriate circumstances.

II. KEY DUR BOARD ACTIVITIES IN 2016

A. Criteria Reviews and Updates

The DUR Board met on May 12, August 11, and November 10, 2016. 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. Specifics are provided below.

Criteria for new drugs. In 2016, the DUR Board reviewed and approved criteria for 49 new drugs, including:

- Alecensa® (Antineoplastic)
- Cotellic™ (Antineoplastic)
- Lonsurf® (Antineoplastic)
- Ninlaro® (Antineoplastic)
- Tagrisso™ (Antineoplastic)
- Genvoya® (Antiviral)
- Evzio® (Opioid Antagonist)
- Narcan® Nasal Spray (Opioid Antagonist)
- Veltassa™ (Potassium Binder)
- Synjardy® (Hyperglycemic Agent)
- Tresiba®Flextouch® (Hyperglycemic Agent)
- Seebri™Neohaler® (Pulmonary Agent)
- Utibron™Neohaler® (Chronic Obstructive Pulmonary Disease Agent)
- Viberzi™ (Gastrointestinal Agent)
- Belbuca™ (Analgesic)

- Vivlodex™ (Analgesic)
- Empliciti™ (Monoclonal antibody/SLAMF7-directed)
- Kanuma™ (Enzyme)
- Portrazza™(Monoclonal antibody/EGFR blocker)
- Bendeka™(Alkylating Agent)
- Praxbind® (Antidote)
- Onivyde™ (Topoisomerase I inhibitor)
- Strensiq™ (Enzyme)
- Yondelis® (Alkylating agent)
- Imlygic™ (Oncolytic viral therapy)
- Nucala® (Monoclonal antibody/interleukin-5 (IL-5) receptor antagonist)
- Darzalex™ (Monoclonal antibody/CD38 blocker)
- Odefsey® (Antiviral)
- Adezenys XR-ODT® (Stimulant)
- Zembrace Symtouch® (Antimigraine Agent)
- BabyBig® (Immune globulin)
- Taltz® (Monoclonal antibody/IL-17A antagonist)
- Cinqair® (Monoclonal antibody/interleukin-5 (IL-5) receptor antagonist)
- Defitelio® (Thrombolytic agent)
- Descovy® (Antiviral)
- Epclusa® (Antiviral)
- Ocaliva® (farnesoid X receptor (FXR) agonist.)
- Cabometyx® (Antineoplastic)
- Probuphine® (Partial opioid agonist)
- Onzetra XSail® (5-HT1B/1D agonist (triptans)
- Xtampza ER® (Opioid analgesic)
- Nuplazid® (Atypical antipsychotic)
- Kybella® (Cytolytic agent)
- Tecentriq® (Monoclonal antibody/programmed death ligand-1 (PD-L1) blocker)
- Bevespi® (Chronic Obstructive Pulmonary Disease Agent)
- Venclexta® (Antineoplastic)
- Xiidra® (Lymphocyte function-associated antigen-1 (LFA-1) antagonist)
- Zurampic® (Uric acid transporter 1 (URAT1) inhibitor)
- Exondys 51® (Antisense oligonucleotide)

Reviewed and approved criteria for existing drugs. In 2016, the DUR Board reviewed and approved criteria for (1) Endocrine and Metabolic agents; (2) Immunologic agents; (3) Respiratory agents; (4) Cardiac agents; (5) Central Nervous System agents; (6) Antineoplastics; (7) Antiinfectives; and (8) Biologics.

Updated existing criteria. In 2016, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Anti-neoplastics;
- Antivirals;

- Atypical Antipsychotics;
- Cardiovascular;
- Auto-imune;
- Hematologicals;
- Endocrine;
- Pulmonary;
- Anti-infectives;
- Biologicals;
- Opioid Antagonist;
- Opioids; and
- Stimulants.

B. RetroDUR Program Activities

1. RetroDUR Reviews

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 identified. An expert panel of reviewers evaluates the claims data to identify potentially problematic prescribing practices. When problematic practices (e.g., risk to patient health or safety) are noted, the reviewer requests that the program contractor send educational intervention letters to providers. The educational letters ("patient profile letters") are customized to each identified case.

Between January 2016 and November 2016, the DUR Board retrospectively reviewed patient profiles and mailed letters on the following topics:

- Polypharmacy (defined below)
- Beer's List Criteria (defined below)
- Asthma Disease Management
- Metabolic Monitoring in Patients Receiving Atypical Antipsychotics
- Treatment of Chronic Non-Cancer Pain with Opiates
- Chronic Obstructive Pulmonary Disease
- Diabetes Management
- Short Acting Opiates
- Anxiolytics/Sedative Hypnotics
- Drugs of Abuse and Naloxone
- Attention Deficit/Hyperactivity Disorder (ADHD) Medication Management
- Drugs Dispensed with no Apparent Indication

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 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. 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 current treatment regimen.

2. Beers List Criteria

The 2003 Virginia General Assembly passed legislation that required DMAS to review its elderly long-term care enrollees for inappropriate use of medications as defined by Dr. Mark Beers. The **Beers Criteria** (or **Beers List**) provides a list of medications that are generally considered inappropriate when given to elderly people because these medications may pose more risks than benefits. For a wide variety of reasons, the medications listed tend to cause side effects in the elderly due to the physiologic changes associated with aging. Dr. Beers has published several articles describing the inappropriate use of various medications in older adults.

With the implementation of Medicare Part D, Medicaid no longer covers the majority of the medications on the "Beers List" for dual eligibles (Medicaid enrollees who are also Medicare eligible). However, Medicare Part D does not cover over-the-counter (OTC) medications. Consequently, OTC medications, such as antihistamines and decongestants, are included in the Beers criteria.

3. Polypharmacy

Polypharmacy occurs when patients receive multiple prescriptions from multiple prescribers and have their prescriptions filled at multiple pharmacies. Polypharmacy may occur when patients lack a primary care physician and/or a single pharmacy to coordinate and optimize their medication regimen. Polypharmacy can be problematic because it places patients at an increased risk of adverse medication-related events. This is often seen in older adults because this segment of the population often experiences the greatest number of co-morbid diseases that require multiple prescribers and medications.

DMAS has seen a decline in polypharmacy criteria violations since Medicare Part D (which focused on older adults) was implemented. Polypharmacy, however, still exists in the remaining population and prescribers seem receptive to the information they receive.

III. COSTS AVOIDED AS A RESULT OF DRUG UTILIZATION REVIEWS

Drug utilization review programs should be viewed as a quality of care initiative rather than actual cost containment programs. Drug utilization review programs are valuable tools to monitor and guide healthcare management. Cost savings for drug utilization programs are essentially cost avoidance figures. For example, as part of the ProDUR program, the savings on a denied early refill claim is realized at point-of-sale, but is then lost if the patient returns the following week at the proper time for his/her refill. As part of the RetroDUR program, if a patient is no longer enrolled in Medicaid, the lack of drug usage is interpreted as a change in therapy and thus a cost savings. Therefore, use of such a calculation can lead to an inflated estimate of savings because the therapy may not have actually been changed.

IV. OTHER MEDICAID PHARMACY INITIATIVES REVIEWED BY THE DUR BOARD

A. Atypical Antipsychotic Use in Children Under the Age of Eighteen (18)

In 2010, the DUR Board decided to monitor all children under age 6 who were new to atypical antipsychotic therapy on a quarterly basis, which was later changed to a monthly basis. In 2011, the DUR Board voted and approved a service authorization (SA) requirement for the use of atypical antipsychotics in children under the age of six years of age based specific criteria. In 2014, the DUR Board approved a recommendation to extend the age range and require specific clinical criteria for atypical and typical antipsychotics prescribed to members ages six (6) to twelve (12) years who were enrolled in the fee-for-service Virginia Medicaid program. The DUR Board approved a another recommendation to require a SA for atypical antipsychotics prescribed to any member under the age of eighteen (18) years enrolled in Virginia Medicaid's fee-for-service program. This service authorization requirement was implemented on March 1, 2015.

In August 2015, there were 728 children under the age of eighteen (18) on antipsychotic medications – approximately a 16.7% reduction in the number of children on these drugs since the expansion of the SA requirement to include all members under the age of 18 years. As of August 2016, there were 731 children on antipsychotic medications demonstrating no significant increase.

B. Service Authorizations

During 2016, the Board recommended that DMAS require prescribing providers to submit a Service Authorization (SA) for the use of the following drugs based on the U.S. Food and Drug Administration (FDA) approved labeling:

- Alencensa® (alectinib HCL)
- Cotellic™ (cobimetnib)
- Lonsurf®(trifluridine/tipircil HCL)
- Ninlaro® (ixazomab citrate)
- Tagrisso™ (osimertinib mesylate)
- Cabometyx® (cabozantinib)

C. Dose Optimization

The intent of the dose optimization program is to use the optimum dose of a product to fill a prescription. The DUR Board continues to focus on reviewing clinically appropriate edits in terms of dose optimization and maximum quantities. An example of the dose optimization program is using one 10 mg Abilify® tablet instead of two 5mg Abilify® tablets to fill a prescription when once daily dosing is in the FDA approved labeling. The dose optimization program is not a pill-splitting policy. If the quantity submitted on the claim is over the established dose optimization limit, the claim rejects at point of sale. In order for patients to receive more than a 34-day supply for these drugs, it is necessary for the prescriber to complete a service authorization request. New additions to the dose optimization program effective November 1, 2016 include:

Drug Name (Strengths)	Generic Name	Dose Optimization
Latuda® (20, 40, 60, 120 mg)	Lurasidone HCl	1/day
Latuda® (80 mg)	Lurasidone HCl	2/day
Fanapt® (1, 2, 4, 6, 8, 10, 12 mg)	Iloperidone	2/day
Invega® (1.5, 3, 6, 9 mg)	Paliperidone	1/day
Saphris® (2.5, 5, 10 mg)	Asenapine maleate	2/day

D. Compounded Drug Claims Analysis

The Board reviewed a Compounded Drug Claims report and discussed the medical necessity of selected ingredients used in several claims.

In the fourth quarter of 2015, 1,420 claims for compounded prescriptions were submitted for payment of $228,498. A cost analysis of the bases and vehicles used in compounding was presented. Based on this review, the Board requested a more in-depth review of review of topical compounded preparations billed to Medicaid with the FDA approved indications and evidence of effectiveness for these products.

A six month utilization review of all compounded prescriptions was examined by the Board. The report included total prescriptions written, total payments, top 10 claims by expenditures, top 10 prescribers, top 10 pharmacies by claims count and payment. Cost comparisons of vehicles used in compounding products were also presented. The Board focused on topical compounded prescriptions and approved a recommendation for all ketamine containing products to deny at point of sale effective November 1, 2016. Ketamine is not FDA approved or Compendia supported for use as a compounded topical preparation. Furthermore, the American Academy of Neurology guidelines state that topical use of ketamine is not recommended.

The Board directed the Department of Medical Assistance Services (DMAS) to request safety and effectiveness documentation from providers prescribing these topical compounded products. Further claims analysis based on patient age, route of administration and pharmacy provider type will also be presented in the future.

E. Morphine Equivalent Dosing For Narcotics

The Board reviewed narcotic claims to determine if they exceed morphine equivalent dosing thresholds. Methodologies derived from the CMS recommendations for Medicare Part D sponsors were applied to the analysis. The Department's contractor sent notification letters to prescribers with patients exceeding the 120 Morphine Equivalent Dose (MED) threshold during the time period of January thru May 2016 either as a single prescription or a combination of 2 or more prescriptions. The purpose of these intervention letters was to assist prescribers in patient care management and to inform prescribers of new service authorization criteria for short and long acting opioids effective July 1, 2016.

F. Synagis Utilization

The Board evaluated the use and ages of the members receiving Synagis for the 2015-16 respiratory syncytial virus (RSV) season. The safety and efficacy of Synagis in pediatric patients greater than 2 years of age has not been established although Synagis is sometimes used in older patients who are seriously ill and at risk of RSV infections. The RSV season for Virginia is defined as October 1 through March 31. In July 2011, an edit requiring a service authorization (SA) for Synagis was implemented in accordance with the guidelines developed by the American Academy of Pediatrics. The purpose of this activity was to evaluate the use and ages of the members receiving Synagis for the 2015-16 RSV season. The service authorization continues to work effectively to monitor that FDA approved indications for treatment are followed. The range of ages of the Synagis recipients has reduced considerably from a maximum age of 22 years in the 2010-11 season to a maximum age of 11 years during our most recent 2015-16 season.

G. Concurrent Use Of Opioids In Members Being Treated For Opioid Addiction

Opioid abuse continues to be a challenge in the Medicaid population, with states opting to pay for opioid dependence treatment medications. The Board reviewed an analysis of utilization of buprenorphine agents for opioid addiction. In the first quarter of 2016, there were 1068 claims ($210,408) for buprenorphine agents. Of these prescriptions, 7 patients were identified with concurrent therapy of a narcotic antagonist and an opioid and/or benzodiazepine. The 29 prescribers identified will be contacted by intervention letters.

V. PHARMACY LIAISON COMMITTEE (PLC) ACTIVITIES

The 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 June 21, 2016, to discuss Virginia Medicaid's proposed new pharmacy reimbursement methodology. DMAS shared with the Committee its timeline for implementing a new pharmacy reimbursement methodology based on the National Average Drug Acquisition

Cost (NADAC) plus a professional dispensing fee. In addition, DMAS staff provided updates on pharmacy initiatives recently implemented including:

1. The Agency's procurement activities for a pharmacy benefit manager (PBM) for the fee-for-service program. DMAS staff informed the Committee that the PBM Request for Proposals (RFP) was published on June 16, 2016.

2. DMAS' Substance Use Disorder (SUD) Program. The 2016 Appropriation Act included funding for a new program establishing Medicaid benefits for substance abuse disorder treatment. The budget includes $11 million in general funds and $11 million in federal matching funds over the biennium to implement a comprehensive Medicaid benefit package for substance abuse disorder (addiction) treatment for **current** Medicaid members. The program creates a fully integrated physical and behavioral health continuum of care through Managed Care Plans and is scheduled to go live April 2107.

3. Medicaid Managed Long Term Services and Support (MLTSS) RFP. MLTSS is a new statewide Medicaid managed care program that will serve approximately 212,000 individuals with complex care needs, through an integrated delivery model, across the full continuum of care. MLTSS will include all aged, blind and disabled (ABD) populations, dual eligibles and LTSS populations. Care management is at the heart of the MLTSS high-touch, person-centered program design. MLTSS focuses on improving quality, access and efficiency. MLTSS is proposed to launch July 2017 and enrollment into MLTSS is required for qualifying populations. The MLTSS RFP was published on April 29, 2016 and will be implemented in phases across the state with a completion date of January 2018.

VI. 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 Xerox State Healthcare, fiscal agent for Virginia Medicaid, for its collection, analysis, and reporting of the claims data for the DUR Program.

VII. 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
Vacant	Pharmacist
Michele Thomas	Pharmacist
Vacant	Physician
Wendy Nash	Pharmacist
Seth Brant	Physician
Vacant	Pharmacist

VIII. 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
Tim Musselman	Virginia Pharmacists Association