COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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December 29, 2015

MEMORANDUM

TO: The Honorable Walter A. Stosch
Co-Chairman, Senate Finance Committee

The Honorable Charles J. Colgan
Co-Chairman, Senate Finance Committee

The Honorable S. Chris Jones
Chairman, House Appropriations Committee

Daniel S. Timberlake
Director, Virginia Department of Planning and Budget

Karen S. Rheuban, M.D.
Chair, Board of Medical Assistance Services

FROM: Cynthia B. Jones

SUBJECT: Report on Pharmacy Liaison Committee and Drug Utilization Review Board

Item 307(M) of the 2014 Appropriation Act requires the Department of Medical Assistance Services to report annually on the activities of its Pharmacy Liaison Committee and the Drug Utilization Review Board and actions taken to ensure cost-effective delivery of pharmacy services. The Appropriation Act further requires DMAS to report on the activities of these Committees to the Board of Medical Assistance Services, the Department of Planning and Budget, and the Chairmen of the House Appropriations and Senate Finance Committees by December 15 of each year.

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

CBJ/

Enclosure

cc: 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.

The Medicaid program, signed into law by President Lyndon B. Johnson on July 30, 1965, celebrates its 50th year in 2015.

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
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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 2015

Report Mandate

The 2015 Appropriation Act, Item 301 (M), requires:

> 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 301 (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

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 2015

A. Criteria Reviews and Updates

The DUR Board met on August 20, 2015, and November 12, 2015. At both meetings, 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 2015, the DUR Board reviewed and approved criteria for 39 new drugs, including:

- Contrave® (Anti-obesity)
- Esbriet® (Idiopathic Pulmonary Fibrosis Agent)
- Ofev® (Idiopathic Pulmonary Fibrosis Agent)
- Lynparza™ (Antineoplastic)
- Soolantra® (Rosacea Agent)
- Tybost® (Cytochrome P450 Inhibitor)
- Evotaz™ (Antiviral)
- Prezcobix™ (Antiviral)
- Vitekta® (Antiviral)
- Farydak® (Antineoplastic)
- Ibrance® (Antineoplastic)
- Lenvima™ (Antineoplastic)
- Corlanor® (Antianginal)
- Jadenu™ (agent to treat metallic poison)
- Natpara® (Parathyroid hormone)

- Orkambi™ (Cystic Fibrosis-CFTR Potentiator & Corrector Combination)
- Saxenda® (Anti-obesity)
- Rasuvo® Autoinjector (Rheumatoid Arthritis Agent)
- Trulicity™ Pens (Hyperglycemic Agent)
- Harvoni® Tablet (Antiviral)
- Akynzeo® (Antiemetic)
- Belsomra® (oral orexin receptor antagonist – sleep aid)
- Mircera® (Hematopoietic)
- Incruse® Ellipta® Inhaler (Anticholinergic Bronchodilator)
- Arnuity™ Ellipta Inhaler (Antiasthmatic)
- Viekira Pak™ (Antiviral)
- Afrezza Inhaler® (Antidiabetic)
- Savaysa® (Anticoagulant)
- Movantik® (Opioid Antagonist)
- Cosentyx® (Antipsoriatic Agent)
- Glyxambi® (Antidiabetic Agent)
- Otezla® (Phosphodiesterase Inhibitor)
- Toujeo® (Antidiabetic Agent)
- Natesto™ nasal gel (Testosterone)
- Cresemba® (Antifungal)
- Cholbam® (Bile Acid)
- Entresto™ (Cardiovascular Agent)
- Stiolto™ Respimat (Chronic Obstructive Pulmonary Agent)
- Odomzo® (Antineoplastic)

Reviewed and approved criteria for existing drugs. In 2015, 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) Anti-obesity agents; (7) Antineoplastics; (8) Antiinfectives; and (9) Biologics.

Updated existing criteria. In 2015, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Anti-obesity;
- Anti-neoplastics;
- Antivirals;
- Atypical Antipsychotics;
- Antianginals;
- Cardiovascular;
- Auto-immune;
- Hematologicals;
- Endocrine;
- Pulmonary;
- Anti-infectives;
- Biologicals; and,
- Heavy Metal Chelators.

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 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 pharmacies and/or providers. The educational letters ("patient profile letters") are customized to each identified case.

Between January 2015 and September 2015, the DUR Board retrospectively reviewed patient profiles and mailed letters on the following topics:

- Polypharmacy (defined below);
- Re-review on the interventions from April 2014 RetroDUR topic, Anticonvulsant Management
- Re-review on the interventions from May 2014 RetroDUR Polypharmacy review;
- Re-review on the interventions from June 2014 RetroDUR topic, Stroke Prevention;
- Polypharmacy (defined below);
- Re-review on the interventions from July 2014 RetroDUR topic, Osteoporosis Management; and
- Re-review on the interventions from July 2014 RetroDUR topic, Inappropriate Use of Pancreatic Enzymes.

Providers and pharmacists are asked to respond to the educational letters to formally acknowledge that they received and reviewed the patient profile letter. Potential responses providers and pharmacists 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 and/or pharmacists; the DUR Board conducts re-reviews based on claims data to assess whether providers and pharmacists 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**) provide 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. More recently, the DUR Board approved a 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.

The SA criteria for the antipsychotic drugs for members under the age of eighteen (18) are:

1) The drug must be prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation AND,
2) The member must have an appropriate diagnosis, as indicated on the attached SA form AND,
3) The member must be participating in a behavioral management program AND,
4) A written, informed consent for the medication must be obtained from the parent or guardian.

A pediatric psychiatrist was contracted to review SA requests for the antipsychotics in children that do not meet the approved criteria and provide peer to peer consultations with the prescribing providers. For requests that do not meet the criteria, the SA contractor may authorize a SA for a period of 30 days so that the child may receive the medication while requests are reviewed

According to reports provided by our contractor, as of August 2015, there are 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.

B. Service Authorizations

During 2015, 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:

- Contrave® (naltrexone/bupropion)
- Esbriet® (pirfenidone)
- Ofev® (nintedanib)
- Lynparza™ (olaparib)
- Soolantra® (ivermectin)
- Farydak® (panobinostat)
- Ibrance® (palbociclib)
- Lenvima™ (lenvatinib)
- Jadenu™ (deferasirox)
- Natpara® (parathyroid hormone)
- Zykadia™ (ceritinib)
- Odomzo® (sonidegib)

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 addition, the Board identified several issues and requested the following information:

- A list of all the ingredients in the topical baclofen compounded claims from the initial report.
- The names of the pharmacies compounding Cubicin® and a list of additional ingredients in the Cubicin® compounded claims.
- Details for a hydromorphone compounded claim.
- Published evidence regarding the use of ketamine in topical compounded medications for further discussion about the appropriateness.
- Published evidence regarding the use of oxytocin in compounded medications for further discussion about the appropriateness.

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 October 13, 2015, to discuss Virginia Medicaid's proposed new pharmacy reimbursement methodology. DMAS shared with the Committee a 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 implementation of the Provider Enrollment Requirement requiring all ordering, rendering, prescribing providers to enroll with Virginia Medicaid.

2. Plans to replace the current Medicaid Management Information System (MMIS) with a Medicaid Enterprise System (MES) in 2018. The proposed plan has pharmacy services being provided by a pharmacy benefit manager (PBM).

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
Vacant	Nurse
Sandra Dawson	Pharmacist
Jonathan Evans	Physician
Avtar Dhillon	Physician
Bill Rock, Vice Chairman	Pharmacist
Jamie Haight	Pharmacist
Michele Thomas	Pharmacist
Rhonda Bass	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