COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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January 10, 2014

MEMORANDUM

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

The Honorable Lacey E. Putney
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 2013 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

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

December 2013

Report Mandate

The 2013 Appropriation Act, Item 307 (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 307 (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 composed 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 2013

A. Criteria Reviews and Updates

The DUR Board met three times in 2013 (March, May, and September) and is scheduled to meet in December. During these 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 2013, the DUR Board reviewed and approved criteria for 56 new drugs, including:

- Surfaxin® (Lung surfactant)
- Ultresa ™ (Pancreatic enzymes)
- Cyclokapron® (Antifibrinolytic agent)
- Xeljanz ® (Janus kinase inhibitor)
- Linzess™ (Irritable bowel agent)
- Synribo™(Antineoplastic)
- Pliaglis® (Topical local anesthetic)
- Giazo™ (Antiinflammatory)
- Vascepa ™ (Lipotropic) (Antihyperglycemic);
- Ilevro™ (Ophthalmic antiinflmmatory) (Antineoplastic);
- Eliquis® (Direct Factor XA inhibitor) (Antineoplastic);
- Quillivant XR™ (CNS stimulant);
- Oxtellar XR™ (Anticonvulsant)
- Jetrea® (Ophthalmic proteolytic enzyme agent)
- Cometriq™ (Antineoplastic)
- Juxtpid™ (Antihyperlipidemic)
- Gattex® (Glucagon-like peptide-2 analog)
- Uceris™ (Glucocorticoid)Nesina™ (Antihyperglycemic)
- Kazano™ (Antihyperglycemic)Oseni™ (Antihyperglycemic)
- Auvi-Q™ (Anaphylaxis therapy agent)
- Iclusig® (Antineoplastic)
- Lotemax ® (Ophthalmic antiinflammatory)
- Onmel™ (Antifungal)
- Flucelvax®(Influenza vaccine)
- Abilify Maintena™ (Antipsychotic)
- Kadcyla™ (Antineoplastic)
- Fulyzaq™ (Antidiarrheal)
- Kynamro™ (Antihyperlipidemic)
- Pomalyst® (Antineoplastic)
- Prezista® (Antiviral)
- Ravicti™ (Ammonia inhibitor)
- Rebif Rebidose® (Multiple sclerosis agent)
- Signifor® (Somatostatic agent)
- Viramune XR® (Antiviral)
- Cystaran™ (Ophthalmic)
- Procysbi™ (Nephropathic agent)

- Invokana™ (Antihyperglycemic)
- Simbrinza™ (Miotic)
- Diclegis® (Antiemetic)
- Namenda XR™ (NMDA receptor antagonist)
- Afinitor Disperz® (Antineoplastic)
- Simponi® (Antiinflammatory tumor necrosis factor inhibitor)
- Tafinlar® (Antineoplastic)
- Belviq® (Antiobesity serotonin 2C receptor agonist)
- Doryx® (Antibiotic)
- Mekinist™ (Antineoplastic)
- Suprax® (Antibiotic)
- Revlimid® (Antineoplastic)
- Liptruzet™ (Antihyperlipidemic)
- Osphena™ (Selective estrogen receptor modulator)
- Sirturo™ (Antitubercular antibiotic)
- Tecfidera™ (Multiple sclerosis agent)
- Tobi Podhaler® (Aminoglycoside)
- Vecamyl™ (Antihypertensive)

Reviewed and approved criteria for existing drugs. In 2013, 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) Genitourinary agents; (7) Anticoagulants; (8) Antineoplastics; (9) Antiinfectives; and (10) Biologics.

Updated existing criteria. In 2013, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Antihyperglycemics
- Antiasthmatics
- Anticonvulsants
- Atypical Antipsychotics
- Analgesics
- Endocrine
- Anticoagulants
- Antibiotics
- Biologicals
- Antidepressants

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, 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., potential 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 2013 and September 2013, the DUR Board retrospectively reviewed patient profiles and mailed letters on the following items:

- Review on profiles for Diabetes Disease Management;

- Re-review on the interventions from November 2011 RetroDUR Beer's List Criteria review;
- Beer's List Criteria review;
- Re-review on the interventions from December 2011 RetroDUR Osteoporosis review;
- Polypharmacy (defined below);
- Re-review on the interventions from January 2012 RetroDUR Polypharmacy review;
- Review on profiles for psychotropic medication utilization in children and adolescents;
- Re-review on the interventions from February 2012 RetroDUR review for multiple prescribers of benzodiazepines and opiods;
- Review on profiles for Anticonvulsants: Drug Usage and Evaluation;
- Re-review on March 2012 Beer's List Criteria review;
- Review on profiles for Asthma Disease Management;
- Re-review on April 2012 RetroDUR Polypharmacy review;
- Polypharmacy (defined below);
- Re-review on the interventions from May 2012 RetroDUR Gastrointestinal agents DUE review;
- Beer's List Criteria review;
- Re-review on interventions from June 2012 RetroDUR review for atypical antipsychotics: coordination of care;
- Review on profiles for Prevention of the treatment of migraines;
- Re-review on July 2012 RetroDUR Polypharmacy review;
- May 2013 – pending information from Xerox;
- June 2013 – pending information from Xerox;
- July 2013 – pending information from Xerox;
- August 2013 – pending information from Xerox; and
- September 2013 – pending information from Xerox

Providers and pharmacists are asked 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).

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

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. By identifying patients with potential coordination of care issues and notifying prescribers involved in their care, patient outcomes should be improved.

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.

IV. OTHER MEDICAID PHARMACY INITIATIVES REVIEWED BY THE DUR BOARD

A. Atypical Antipsychotic Use in Children Under the Age of Six (6)

Atypical antipsychotic agents are not FDA approved for the use in children under the age of 6 years with the exception of risperidone for the treatment of irritability in autistic disorder. However, across the nation the utilization of these agents in children with severe mental health conditions is rising. 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. During 2011, the DUR Board decided to implement a Service Authorization (SA) requirement for the use of atypical antipsychotics in children under the age of six years of age based on the following criteria:

- **a.** The drug must be prescribed by a pediatric psychiatrist or pediatric neurologist or the prescriber must supply proof of a psychiatric consultation AND,
- **b.** The recipient must have an appropriate diagnosis AND,
- **c.** The recipient must be participating in a behavioral management program AND,
- **d.** Written, informed consent for the medication must be obtained from the parent or guardian.

A pediatric psychiatrist was contracted to review service authorization requests for the antipsychotics in children under the age of six 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. At the implementation of the SA requirement in December 2011, there were 129 children under the age of six receiving an atypical antipsychotic. According to reports provided by our contractor, as of March 2013, there are 51 children on atypical antipsychotic medications – approximately a 60% reduction in the number of children on these drugs.

B. Service Authorizations

During 2013, 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:

Elelyso® (taliglucerase)
Eylea® (aflibercept)
Ferriprox® (deferipone)
Fulyzaq™ (crofelemer)
Kalydeco™ (ivacaftor)
Korlym™ (mifepristone)
Potiga™ (ezogabine)
Ravicti™ (glycerol phenylbutyrate)
Signifor® (pasireotide)
Tafinlar® (dabrafinib mesylate)
Mekinist™ (trametinib)
Revlimid® (lenalidomide)

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 August 8, 2013 to discuss proposals for the cost effective delivery of pharmacy services. Topics discussed also included an update on the possibility of Medicaid expansion as a result of the Affordable Care Act (ACA) including the assignment of foster children and dual eligible members into managed Medicaid. In addition, DMAS staff provided updates on pharmacy initiatives recently implemented including:

1. The implementation of the Provider Enrollment Requirement which requires all rendering, ordering and providers to be enrolled with Virginia Medicaid,
2. The continued exclusion of Mental Health Drugs from the Preferred Drug List (PDL),
3. DMAS contracting with Myers and Stauffer to conduct a Cost of Dispensing Survey for pharmacy providers,
4. Concerns with drug claims submitted by 340B Contract Pharmacies, and
5. The increase in the number of ProDUR Messages returned to pharmacies submitting pharmacy claims through point-of-sale (POS).

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 their collection, analysis, and reporting of the claims data for the DUR Program.

VII. DUR BOARD MEMBERS

NAME	PROFESSION
Randy Ferrance, Chairman	Physician
Jane Settle, Vice Chairman	Nurse
Cindy Fagan	Nurse
Sandra Dawson	Pharmacist
Jonathan Evans	Physician
Avtar Dhillon	Physician
Bill Rock	Pharmacist
Jamie Haight	Pharmacist
Michele Thomas	Pharmacist
Rhonda Bass	Physician
Vacant	Pharmacist
Vacant	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. Macauley	Community Pharmacy (EPIC)
Anne Leigh Kerr	Pharmaceutical Research & Manufacturers of America
Tim Mussleman	Virginia Pharmacists Association