COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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December 15, 2010

MEMORANDUM

TO: The Honorable Charles J. Colgan
Chairman, Senate Finance Committee

The Honorable Lacey E. Putney
Chairman, House Appropriations Committee

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

Monroe E. Harris, Jr., D.M.D.
Chairman, Board of Medical Assistance Services

FROM: Gregg A. Pane, MD, MPA

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

Item 297(H) of the 2010 Appropriations 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 Appropriations 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.

GAP/

Enclosure

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

Report on Pharmacy Liaison Committee and Drug Utilization Review Board

Virginia Department of Medical Assistance Services
December 2010

I. AUTHORITY FOR REPORT

Item 297(H) of the 2010 Appropriations Act directs the Department of Medical Assistance Services (DMAS) to implement continued enhancements to the prospective drug utilization review (ProDUR) program. DMAS is directed to continue the ProDUR Committee and the Pharmacy Liaison Committee (PLC) in order to promote the implementation of cost effective initiatives within the Medicaid pharmacy program. The Appropriations 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.

II. BACKGROUND

A. Role of the 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.

III. KEY DUR BOARD ACTIVITIES IN 2010

A. Criteria Reviews and Updates

The DUR Board met four times in 2010 (January, March, May, and August). During these meetings, the DUR Board approved criteria 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 2010, the DUR Board reviewed and approved criteria for eight new drugs, including:

- Fanapt® (Atypical Antipsychotic);
- Multaq® (Antiarrhythmic);
- Victoza® (Antihyperglycemic);
- Ampyra® (Neuromuscular agent);
- Dulera ® (Antiasthmatic);
- Jalyn™ (Benign Prostatic Hypertrophy agent);
- Natazia™ (Oral Contraceptive);
- Sabril® (Anticonvulsant).

Reviewed and approved criteria for existing drugs. In 2010, 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; and (6) Genitourinary agents.

Updated existing criteria. In 2010, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Benign Prostastic Hypertrophy Agents;
- Antiarrhythmics;
- Oral Contraceptives;
- Antihyperglycemics;
- Neuromuscular agents;
- Antiasthmatics;
- Anticonvulsants; and,
- Atypical Antipsychotics.

B. Cost and Utilization Reports Reviewed

In addition to reviewing clinical criteria, during the 2010 DUR Board meetings, the Board reviewed quarterly cost and utilization reports prepared by the program contractors (First Health

Services Corporation and ACS State Healthcare).[1] The DUR Board also reviewed ProDUR program cost savings reports and summaries of ProDUR alerts.

In May 2010, the DUR Board reviewed member adherence with warfarin and atypical antipsychotic (AAP) polypharmacy. The warfarin adherence report identified 498 members who were potentially non-compliant with their warfarin regimen with a medication possession ratio (MPR) < 80%. The atypical antipsychotic (AAP) polypharmacy report identified 4,880 members ≤ 18 years old prescribed AAPs. Of which, 23 members were on three (3) or more AAPs. The utilization reports were based on claims data from September 24, 2009 to April 23, 2010.

In August 2010, the Board reviewed an Underutilization Report, which identified an extensive list of opportunities to improve recipients' medication management. These criteria utilize nationally recognized clinical practice guidelines that represent evidence based best practices. The report reflects the latest claims data from July 2010. The actual time frame of the extraction is dependent upon the disease, prevention intervention or medication specifics being studied. For example, the underutilization of influenza vaccination captures information related to the immunizing season for the last year. A rule regarding myocardial infarction (MI) looks back for the last two years.

The report lists the candidates, exceptions and a ratio. The candidates include all recipients with the targeted disease or drug. The exceptions include all recipients with the targeted disease or drug who have the issue identified. The ratio is the exception divided by the candidates. Generally, it is most useful to further study those with higher ratios, as the volume of recipients is higher. However, for critical issues a lower ratio may be deemed important for study.

C. 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 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 2010 and August 2010, the DUR Board retrospectively reviewed patient profiles and mailed letters on the following items:

- Polypharmacy (defined below);
- Re-review profiles for the January 2009 review of medication non-adherence with statin therapy;

[1] First Health Services Corporation's contract expired June 27, 2010 and ACS became the new contractor effective June 28, 2010.

- Review for the FDA's warning to healthcare professionals that manufacturers of metoclopramide must add a boxed warning to their drug labels about the risk of its long-term or high-dose use;
- Re-review profiles for the February 2009 review of medication non-adherence with statin therapy;
- Beer's List Criteria review;
- Re-review on the interventions from the March 2009 RetroDUR review of medication adherence with antiretrovirals and antiepileptic agents;
- Polypharmacy (defined below);
- Review profiles for Metabolic Monitoring in adult patients on Atypical Antipsychotics;
- Re-review profiles for the May 2009 Beers Criteria review (defined below);
- Review profiles for Metabolic Monitoring in Children and Adolescents on Atypical Antipsychotics;
- Re-review profiles for the June 2009 RetroDUR review of acetaminophen overutilization;
- Polypharmacy (defined below)
- Beer's List Criteria;
- Re-review profiles for the August 2009 RetroDUR review of medication adherence with long-acting bronchodilator therapy in patients with chronic obstructive pulmonary disease (COPD);
- Review profiles for the therapeutic duplication of serotonergic agents;
- Re-reviews on the interventions from the September 2009 RetroDUR polypharmacy review.

Providers and pharmacists can 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. Of the 647 re-review profiles between January 2010 and August 2010, 245 (38.0 percent) showed no change in therapy while 402 (62.0 percent) showed that their therapy had been changed or discontinued.

A RetroDUR response rate is calculated by dividing the number of responses received by the number of patient profile letters that were mailed. Between September 2009 and May 2010,

2,412 letters were mailed to providers and pharmacists and 405 responded. This equates to a 17 percent RetroDUR response rate.

Often the goal of the RetroDUR program is not to change the prescribers 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 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, two major classes of drugs, benzodiazepines and barbiturates (sedatives), are excluded by Medicare, but are covered by Medicaid. Additionally, 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.

In April 2010, the DUR Board retrospectively reviewed medications on the "Beers List," to evaluate the use of certain medications in elderly patients covered by Medicaid. Based on their review, the DUR Board discovered that:

- 42 percent of the interventions involved the use of benzodiazepines or barbiturates that are inappropriate to use in older adults at any dosage;
- 51 percent of the interventions involved the use of benzodiazepines that are not recommended in patients with certain medical conditions; and
- 7 percent involved the inappropriate use of the over-the-counter antihistamine, diphenhydramine, as a sedative-hypnotic.

Inappropriate use of these medications can lead to prolonged sedation and an increased incidence of falls and fractures in older adults. There were re-review profiles for May 2009 Beers Criteria review in January 2010. These profiles were for patients whose prescribers received letters regarding the inappropriate use of benzodiazepines, barbiturates, and certain OTC medications in older adults. Of the 79 re-review profiles, 46 (58 percent) showed no change in therapy while 33 (41 percent) showed that their therapy had been changed or discontinued.

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.

During meetings in March, May, and August 2010, the DUR Board reviewed drug claims for polypharmacy. There were 174 and 24 letters sent to prescribers for the December 2009 review and re- review, respectively. In addition, there were 214 letters sent to prescribers for the March review and 74 letters sent to prescribers for September 2009 re-reviews in May 2010. The intent of the review was to evaluate patients: (1) who receive more than nine unique prescriptions in a 34-day period, and (2) whose prescriptions were written by 3 or more prescribers and filled at 3 or more pharmacies. Since the polypharmacy review was incorporated into the existing RetroDUR program in August 2005, approximately 14,000 patient medication profiles have been reviewed for polypharmacy and a total of 1,450 intervention letters have been sent to prescribers.

The overall prescriber response rate for the polypharmacy RetroDUR program is 24 percent; of those responding, 56 percent indicated that they find the information useful and plan to monitor, alter, or discontinue the treatment regimen.

IV. COSTS AVOIDED AS A RESULT OF DRUG UTILIZATION REVIEWS

Drug utilization review programs should be viewed as a quality of care initiative rather than an actual cost containment program. 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.

Due to a change in the contractor responsible for the administration of the DUR program, FY 2010 cost savings for these programs were not available at the time this report was written. However, DMAS is working with ACS, the new contractor, to develop a methodology to calculate cost savings realized by the drug utilization review program.

V. OTHER MEDICAID PHARMACY INITIATIVES REVIEWED BY THE DUR BOARD

A. Behavioral Pharmacy Management System

Since April 2005, DMAS, in partnership with the Department of Behavioral Health and Development Services, contracted with Eli Lilly and Company to implement Comprehensive Neuroscience's (CNS) Behavioral Pharmacy Management (BPM) Program. This contract was terminated in March 2010. DMAS, in anticipation of the termination, began integrating aspects of the BPM Program into both the prospective and retrospective review processes of the Drug Utilization Review (DUR) program beginning in 2007. Consequently, the DUR Board implemented drug utilization review edits that address situations in which potential medication problems may arise, such as early refills and therapeutic duplication for drugs for behavioral health medications.

In addition, the DUR has been closely monitoring the utilization of atypical antipsychotics in children less than six years old. In August 2009, the Board evaluated a preliminary review of Virginia Medicaid claims data that revealed a number of recipients under the age of six are receiving atypical antipsychotics.

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. The DUR Board requested a RetroDUR review of these cases to determine if there is cause for concern. Intervention letters were sent to prescribers of these agents in children under 6 years of age. A survey sheet was enclosed that requested feedback on the following: specific diagnosis that was being treated; had the patient received a psychiatric consult if the prescriber was not a psychiatrist or behavioral health specialist; and was the patient being monitored for metabolic syndrome by checking weight, glucose levels and lipid panels at the recommended intervals.

Intervention letters were sent to 90 prescribers regarding 157 patients. If no response was received after two weeks, the prescribers were contacted by telephone. A response rate of 71% was obtained from the prescribers. The majority of the patients were being treated for extreme behaviors such as aggression related to autism or oppositional defiant disorder. In addition, many of them also had a diagnosis of ADHD. Eighty-one percent (81%) of the prescribers that responded indicated they monitor for metabolic syndrome and another three percent indicated they plan to do so.

At the DUR Board's May 2010 meeting, the members agreed that a clinical service authorization is warranted for the use of these drugs in children less than 6 years old. The Board is in the process of finalizing the criteria that will be used to determine the service authorization. In addition, DMAS is investigating a collaborative agreement with Virginia Commonwealth University's Department of Psychiatry as well as other contractors to administer the service authorization process.

During 2010, the Board continued to monitor all children under 6 who are new to atypical antipsychotic therapy on a quarterly basis, as well as, perform interventions specifically targeting metabolic monitoring in both children and adults.

B. Dose Optimization and Maximum Quantity Limits Program

In 2010, DMAS continued to update the enhanced ProDUR programs (dose optimization and maximum quantity limits). Both the dose optimization and maximum quantity programs ensure that recipients have a 34-day supply of a medication with reasonable dispensing quantities.

The dose optimization program identifies high cost products where all strengths have the same unit cost and the standard dose is one tablet per day. By providing the highest strength daily dose, the number of units in a 34-day supply will be minimized. This program does not require "pill splitting" due to the potential medical risks and burden on recipients and pharmacy providers.

Establishing maximum quantity limits involves identifying high cost products where a 34-day supply is defined by a set number of tablets. This strategy establishes quantity limits based on commonly acceptable clinical dosing practices.

The dose optimization program currently focuses on antidepressants, antipsychotics and ADHD agents. Maximum quantity limits focuses on anti-emetics (anti-nausea/vomiting), anti-migraine agents, and narcotics. For cost savings and quality of care purposes, DMAS continually reviews opportunities to include new drugs and drug classes in the dose optimization and maximum quantity programs.

In January 2010, DMAS expanded the maximum quantity limits program by adding Sancuso® (granisetron) transdermal systems. In April 2010, the DUR Board approved the addition of Suboxone® tablets (buprenorphine and naloxone); Subutex® tablets (buprenorphine), and Lidoderm® 5% topical patches to the maximum quantity limits program and expanded the dose optimization program by adding several new drugs and drug strengths including Aciphex®, Avinza®, Byetta®, Daytrana®, Effexor® XR, Elidel®, Enbrel®, Focalin® XR, Janumet®, Januvia®, Kadian®, Metadate® CD, Nexium®, Oxycontin®, Prevacid®, Prilosec® OTC, Protonix®, Protopic®, Provigil®, Ritalin® LA, Seroquel® XR, Victoza®, and Vyvanse®. Between January 2010 and April 2010, total savings for the dose optimization and maximum quantity programs was $2.4 million.

VI. PHARMACY LIAISON COMMITTEE 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 is scheduled to meet on December 1, 2010, to discuss initiatives for the promotion of cost-effective services delivery.

VII. ACKNOWLEDGEMENTS

DMAS 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.

ATTACHMENT A

2010 Appropriations Act, Item 297(H)

The Department of Medical Assistance Services shall implement continued enhancements to the prospective drug utilization review (pro-DUR) program. The Department shall continue the Pharmacy Liaison Committee and the pro-DUR Committee. The department shall continue to work with the Pharmacy Liasion Committee to implement initiatives for the promotion of cost-effective services delivery as may be appropriate. The department shall report on Pharmacy Liaison Committee's and the pro-DUR Committee's activities to the Board of Medical Assistance Services and the Chairmen of the House Appropriations and Senate Finance Committees, and the Department of Planning and Budget no later than December 15 of each year of the biennium.