Report on Pharmacy Liaison Committee and Drug Utilization Review Board

Virginia Department of Medical Assistance Services
December 2008

I. AUTHORITY FOR REPORT

Item 306(I) of the 2008 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 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 or claims will be denied.

Unlike the ProDUR program which is prospective in nature, the RetroDUR program is a retroactive 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 and requests the generation of educational intervention letters in appropriate circumstances.

B. New DUR Board Member Selected in 2008

In 2008, DMAS filled one vacancy on the DUR Board due to conflict of interest. Jennifer Edwards, Pharm.D., resigned to accept a seat on the Virginia Board of Pharmacy. Jamie Haight, R.Ph., a retail pharmacist with Walgreens Company, was selected for the DUR Board.

III. KEY DUR BOARD ACTIVITIES IN 2008

A. Criteria Reviews and Updates

The DUR Board met two times in 2008 (April and August). During these meetings, the DUR Board approved criteria for new drugs, revised and approved criteria for existing drugs, and updated existing criteria. Anytime the DUR Board approves new criteria or revises criteria, the criteria are integrated into both the ProDUR and the RetroDUR programs. Criteria reviewed in 2008 are summarized below.

Criteria for new drugs. In 2008, the DUR Board reviewed and approved criteria for 11 new drugs, including:

- Nebivolol (Blood pressure drug);
- Etravirine (Antiretroviral);
- Raltegravir (Antiretroviral);
- Formoterol (Pulmonary drug);
- Arformoterol (Pulmonary drug);
- Maraviroc (Antiretroviral);
- Levocetirizine (Antihistamine);
- Lisdexamfetamine (CNS stimulant);
- Ciclesonide (Nasal Anti-inflammatory steroid);
- Olopatadine (Nasal Antihistamine); and
- Desvenlafaxine (Antidepressant)

Revised and approved criteria for existing drugs. In 2008, the DUR Board reviewed and approved criteria for (1) Anti-emetics (agents for nausea and vomiting); (2) Anti-migraine agents; and (3) Narcotics.

Updated existing criteria. In 2008, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Antidepressants;
- Antihypertensives;
- Bronchial Dilators;
- Antiviral agents;
- Antihistamines;
- CNS Stimulants; and
- Glucocorticoids

B. Cost and Utilization Reports Reviewed

In addition to reviewing clinical criteria, during the 2008 DUR Board meetings, the Board reviewed quarterly cost and utilization reports prepared by the program contractor (First Health Services Corporation). The DUR Board also reviewed ProDUR program cost savings reports and summaries of ProDUR alerts.

In April 2008, the DUR Board reviewed FDA Public Health Advisory – Byetta; high dose methadone utilization; prolonged use of low molecular weight heparins; glucose monitoring in patients with severe mental illness; and patients with atrial fibrillation without thrombolytic therapy. The utilization reports were based on data from April 1, 2007 to September 30, 2007.

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). After the DUR Board decides which drug classes they want to evaluate, the appropriate claims data are extracted. Then an expert panel of reviewers evaluates a sample of the 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 October 2007 and December 2008, the DUR Board retroactively reviewed patient profiles and mailed letters on the following items:

- Criteria for the narcotic therapeutic class and new drugs approved by the Board at the August 2007 meeting;
- Re-review of Non-compliance with Lipotropic (cholesterol) therapy in post-myocardial infarction patients;
- Beer's List Criteria (defined below);
- Re-review of Acetaminophen (analgesic) overutilization;
- Polypharmacy (defined below);
- The absence of antithrombic therapy in patients with atrial fibrillation;
- The empiric use of antibiotics in upper respiratory infections;
- Re-review for the FDA warning regarding the safety of sedative-hypnotics;
- FDA Warning regarding the risk of severe musculoskeletal pain associated with bisphosphonates;
- Re-review for the FDA warning regarding the potential safety issue related to rosiglitazone (diabetic drug) and the increased risk of heart attack and other heart-related deaths;
- Re-review of new drug and therapeutic class criteria;
- Diabetic care in mental illness patients;
- Iron supplementation in Epoetin (blood cell stimulator) Therapy; and

- Re-review of DUR criteria violations for Growth Hormones, Hepatitis C Agents, Low Molecular Weight Heparins and Antiretroviral Agents

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 1,096 re-reviews profiles between October 2007 and August 2008, 543 (49.5 percent) showed no change in therapy while 553 (50.5 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 October 2007 and June 2008, 901 letters were mailed to providers and pharmacists and 240 responded. This equates to a 27 percent RetroDUR response rate.

Often the goal 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 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 risk than benefit. For a wide variety of individual reasons, the medications listed tend to cause side effects in the elderly due to the physiologic changes of 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, so they are still 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 May 2008, the DUR Board retroactively reviewed medications on the "Beers List," to evaluate the current use of certain medications in elderly patients covered by Medicaid. Based on their review, the DUR Board discovered that:

- 39 percent of the inappropriate use criteria interventions involved the use of benzodiazepines in doses that exceeded the recommended maximum for older adults;
- 46 percent of the interventions involved the use of benzodiazepines or barbiturates that are inappropriate to use in older adults at any dosage;
- 6 percent of the interventions involved the use of benzodiazepines that are not recommended in patients with certain medical conditions; and
- 9 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 also re-review profiles for October 2007 Beers Criteria review. 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 158 re-reviews profiles, 93 (59 percent) showed that their therapy had been discontinued. The remaining 65 (41 percent) of respondents reviewed the evaluation but did not change current therapy.

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 is 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 April and August 2008, the DUR Board reviewed drug claims for polypharmacy. There were 42 and 28 letters sent to prescribers for the April and August reviews respectively. 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 9,000 patient medication profiles have been reviewed for polypharmacy and a total of 1,032 intervention letters have been sent to prescribers.

The overall prescriber response rate for the polypharmacy RetroDUR program is 27 percent; of those responding, 60 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 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.

V. OTHER MEDICAID PHARMACY INITIATIVES REVIEWED BY THE DUR BOARD

A. Behavioral Pharmacy Management System

In April 2005, DMAS signed a two-year contract with Eli Lilly and Company to implement Comprehensive Neuroscience's (CNS') BPM Program. DMAS did so in partnership with DMHMRSAS, and in consultation with the Psychiatric Society of Virginia. In 2007, DMAS agreed to a one-year extension, and then in February 2008, DMAS agreed to another one-year extension, which extends the BPM program through the end of February 2009.

The BPM Program provides a retrospective review of behavioral pharmacy claims and delivers an intervention to Medicaid providers whose prescribing patterns fall outside nationally-recognized prescribing guidelines. The intervention consists of an informational mailing, including a cover letter, a prescriber summary report, psychotropic drug histories for the physician's patients, and a form on which the physician can provide feedback to the BPM Program. On a monthly basis, the BPM Program alternates mailings to prescribers of children and adults. The BPM Program is designed to optimize therapeutic outcomes of pharmacological treatment, ensure appropriate use of psychotropic medications, reduce the risk of adverse events, and improve the cost-effectiveness and quality of treatment received by patients with mental illness.

Based on preliminary data, there is no current evidence that overall expenditures for psychotropics have slowed in Virginia since the BPM intervention began. However, there is evidence that the total behavioral pharmacy costs for targeted patients (those patients whose physicians received an intervention from CNS) is decreasing.

Unlike the BPM Program, as part of the drug utilization review process, the DUR Board reviews (on a rotating basis) all drug classes, not just behavioral health drugs. The DUR Board develops

drug utilization review edits that address situations in which potential medication problems may arise, such as early refills and therapeutic duplication. Some of these edits overlap with the quality indicators included in the BPM Program. Therefore, DMAS has rolled the BPM Program, to the extent possible, into the DUR process. In 2007, DMAS took the first steps to integrate the two programs. Specifically, two members from the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS) were selected to serve on the DUR Board (James Evans, M.D., a psychiatrist, and Michele Thomas, Pharm.D.). Furthermore, CNS began attending DUR Board meetings to provide updates on the BPM program. The integration of this program into the DUR program will continue to be a priority of the DUR Board.

B. Dose Optimization and Maximum Quantity Limits Program

DMAS has now implemented the second phase of the ProDUR enhancements - dose optimization and maximum quantity limits. The original phase, which began on July 1, 2007, was a soft edit period during which the pharmacy providers only received a message that the claim exceeded the quantity limit. On January 1, 2008, claim denials began at point of sale for both dose optimization and maximum quantity limits when dispensing is outside of guidelines. Claims denials with prior authorization are utilized for the dose optimization program, and claims denials with no prior authorizations are utilized for the maximum quantity limits program. These enhanced programs consist of ensuring 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. DMAS continues to review the list of drug classes for opportunities to include new classes for cost savings and quality of care purposes. In May 2008, several strengths of antidepressants, antipsychotics and ADHD medications were added to the dose optimization program to further strengthen the savings. The total savings from January 2008 through August 2008 is $3,017,733. This already exceeds the projected annual savings of $2.1 million.

VI. PHARMACY LIAISON COMMITTEE ACTIVITIES

The Pharmacy Liaison Committee is comprised of appointed members who meet periodically to discuss pertinent Medicaid pharmacy issues and the impact on the pharmacy community. The Pharmacy Liaison Committee (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 Pharmacy Liaison Committee did not formally meet in 2008 due to the implementation schedule for key State and federal pharmacy initiatives and the involvement of DMAS pharmacy staff and Pharmacy Liaison Committee members in numerous public-private sector workgroups. State pharmacy initiatives, such as Dose Optimization and Maximum Quantity Limits, and Specialty Pharmacy, as well as federal mandates for the use of Tamper-Resistant Prescription Pad and National Provider Indentification numbers were addressed at the September 27, 2007 Pharmacy Liaison Committee meeting. The proposed Specialty Pharmacy program was the subject of several Pharmacy Liaison Committee meetings in 2006 and 2007 which culminated with the final design of the Specialty Program implemented on July 1, 2008. All of these pharmacy initiatives were implemented in 2008 along with an additional federal mandate for the use of NDC codes on drugs administered in an outpatient setting. DMAS plans to schedule formal meetings with the Pharmacy Liaison Committee in 2009.

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

2008 Appropriations Act, Item 306(I)

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 Liaison 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.