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December 1, 2009

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

Robert D. Voogt, Ph.D., C.R.C.
Chairman, Board of Medical Assistance Services

FROM: Patrick W. Finnerty

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

Item 306(I) of the 2009 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. I have enclosed for your review the report for 2009.

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

PWF/

Enclosure

Cc: The Honorable Marilyn B. Tavenner, Secretary of Health and Human Resources

Report on Pharmacy Liaison Committee and Drug Utilization Review Board

Virginia Department of Medical Assistance Services
December 2009

I. AUTHORITY FOR REPORT

Item 306(I) of the 2009 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 or claims 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 and requests the generation of educational intervention letters in appropriate circumstances.

B. DUR Board Member Retired in 2009

In 2009, James Evans, M.D., retired from the Department of Behavioral Health and Developmental Services (DBHDS formerly DMHMRSAS), leaving a vacancy on the DMAS DUR Board. To date, a replacement has not been confirmed.

III. KEY DUR BOARD ACTIVITIES IN 2009

A. Criteria Reviews and Updates

The DUR Board met three times in 2009 (May, August, and October). 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. Specifics are provided below.

Criteria for new drugs. In 2009, the DUR Board reviewed and approved criteria for 15 new drugs, including:

- Kapidex (Gastrointestinal drug);
- Trilipix (Lipotropic);
- Sancuso (Antiemetic);
- Aloxi (Antiemetic/Antivertigo);
- Rapaflo(Benign Prostatic Hypertrophy agent);
- Toviaz (Urinary Antispasmodic);
- Uloric (Hyperuricemia agent);
- Adcirca (Pulmonary Antihypertensive);
- Effient (Platelet Aggregation Inhibitor);
- Nucynta (Analgesic);
- Savella (Fibromyalgia agent);
- Vimpat (Anticonvulsant);
- Saphris (Antipsychotic);
- Intuniv (Psychostimulant Antidepressant); and,
- Onglyza (Antihyperglycemic).

Reviewed and approved criteria for a new drug class. In 2009, the DUR Board reviewed and approved criteria for Fibromyalgia agents.

Updated existing criteria. In 2009, the DUR Board reviewed and updated existing criteria for the following therapeutic classes:

- Gastrointestinal Drugs;
- Lipotropics;
- Antiemetics;
- Antiemetic/Antivertigo;
- Benign Prostastic Hypertrophy Agents;

- Urinary Antispasmodic;
- Hyperuricemia Agents;
- Pulmonary Antihypertensives;
- Platelet Aggregation Inhibitors;
- Analgesics;
- Anticonvulsants; and,
- Atypical Antipsychotics.

B. Cost and Utilization Reports Reviewed

In addition to reviewing clinical criteria, during the 2009 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 May 2009, the DUR Board reviewed: Omnaris – duration of use in children; narcotic use in patients without a diagnosis of cancer; percentage of all patients on behavioral health medications; and children taking atypical antipsychotics. The utilization reports were based on data from January 1 2008 to February 28, 2009.

In August 2009, the Committee evaluated a preliminary review of Virginia Medicaid claims data that revealed a number of recipients under the age of six are receiving atypical antipsychotics. Based on the findings of this review, the Committee recommended a retrospective drug utilization review (RetroDUR) of atypical antipsychotics in children less than six years old for the period of June 1, 2009 to August 31, 2009 be conducted. At the October 2009 meeting, the DUR Board discussed the results of this review and expressed concerns about the use of these medications in this patient population. The Board concluded it needed additional information from the prescribers of these medications and requested lettering the ninety one (91) prescribers in an effort to understand the use of atypical antipsychotics in this age group. Once the completed response forms from the prescribers are received, the Board will meet to further discuss this issue.

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 January 2009 and August 2009, the DUR Board retrospectively reviewed patient profiles and mailed letters on the following items:

- Non-adherence with statin therapy, Part I, to reduce cholesterol levels;
- Re-review profiles for the April 2008 Beers Criteria review (defined below);
- Non-adherence with statin therapy, Part II, with another set of recipients who are potentially non-compliant with their statin therapy using the medication possession ratio (MPR) approach;
- Re-review profiles for the two May 2008 RetroDUR reviews (diabetic care in mental illness patients and iron supplementation during epoetin therapy);
- Reviews of medication adherence with two more classes – antiretrovirals and antiepileptics;
- Re-review profiles for the June 2008 RetroDUR review of patients with a diagnosis of asthma who were chronically using a beta agonist inhaler and not using an inhaled corticosteroid (ICS);
- Polypharmacy (defined below);
- Re-review for March 2008 polypharmacy review;
- Beer's List Criteria;
- Review looking for therapeutic duplication alerts for muscle relaxants, NSAIDs, and pregabalin with gabapentin;
- Review of the drug interaction between amiodarone and doses of simvastatin greater than 20 mg per day based on the August 2008 warning from the FDA;
- Re-review profiles for the October 2008 review of Beer's Criteria;
- Review to identify patients taking total daily doses of acetaminophen greater than the recommended maximum daily dose of 4 grams;
- Re-review for the November 2008 polypharmacy review;
- Review which looked at patients with chronic obstructive pulmonary disease (COPD) and their adherence to their long-acting bronchodilator (LABD) therapy;
- Re-review profiles for the September 2008 review of medication non-adherence with beta blocker therapy.

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 890 re-reviews profiles between October 2008 and August 2009, 552 (62.0 percent) showed

no change in therapy while 338 (38.0 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 October 2008 and July 2009, 1,027 letters were mailed to providers and pharmacists and 255 responded. This equates to a 25 percent RetroDUR response rate.

Often the goal 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, 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 2009, 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:

- Forty percent (40%) of the inappropriate use criteria interventions involved the use of benzodiazepines in doses that exceeded the recommended maximum for older adults;
- Twenty-nine percent (29%) of the interventions involved the use of benzodiazepines or barbiturates that are inappropriate to use in older adults at any dosage;
- Nine percent (9%) of the interventions involved the use of benzodiazepines that are not recommended in patients with certain medical conditions;
- Nineteen percent (19%) involved the inappropriate use of the over-the-counter antihistamine, diphenhydramine, as a sedative-hypnotic; and,
- Two percent (2%) involved the prolonged use of inappropriate laxatives in older adults.

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 April 2008 Beers Criteria review in January 2009. 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 124 re-review profiles, 73 (59 percent) showed no change in therapy while 51 (41 percent) showed that their therapy had been discontinued. There were also re-review profiles for October 2008 Beers Criteria review in June 2009. Of the 165 re-reviews profiles, 124 (75 percent) continued to remain on their original 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 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 May and August 2009, the DUR Board reviewed drug claims for polypharmacy. There were 110 and 42 letters sent to prescribers for the December review and re- review, respectively. In addition, there were 68 and 28 letters sent to prescribers for the April review and re-review, 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 12,000 patient medication profiles have been reviewed for polypharmacy and a total of 1,238 intervention letters have been sent to prescribers.

The overall prescriber response rate for the polypharmacy RetroDUR program is 43 percent; of those responding, 89 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 DBHDS, and in consultation with the Psychiatric Society of Virginia. DMAS agreed to one-year extensions in 2007, 2008, and 2009. The current contract expires in February 2010.

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 Program 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, starting in 2007, DMAS began rolling the BPM Program, to the extent possible, into the DUR process. In 2009, the DUR Board reviewed the percentage of all patients on behavioral health medications; children taking atypical antipsychotics; and, antipsychotic medication utilization in children ages 0 to 5. The integration of the BPM Program into the DUR program continues to be a priority of the DUR Board.

B. Dose Optimization and Maximum Quantity Limits Program

In 2009, 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 2009, DMAS expanded the dose optimization program by adding several strengths of antidepressants, antipsychotics, and ADHD agents. The DUR Board approved the addition of a new anti-nausea medication to the maximum quantity limits program. Between January 2009 and September 2009, total savings for the dose optimization and maximum quantity programs was $3.5 million. This figure exceeds projected annual savings of $2.1 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).

On November 9, 2009, the PLC convened to discuss proposals for the cost effective delivery of pharmacy services. Topics discussed also included the impact of Federal Health Care Reform and the First Data Bank AWP "rollback" court settlement. In addition, DMAS staff provided updates on pharmacy initiatives implemented since the last PLC meeting including:

- tamper resistant prescription pads;
- dose optimization and maximum quantity limits;
- national provider identification;
- specialty drug program; and,
- electronic prescribing.

Additional information on the Specialty Drug Program and electronic prescribing can be obtained from DMAS' 2009 annual reports to the Virginia General Assembly which can be accessed at www.dmas.virginia.gov/ab-studies_reports.htm.

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

2009 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 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.