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Department of Medical Assistance Services

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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

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

FROM: Cynthia B. Jones Cynthia B. Jones

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

Item 297(H) of the 2011 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.

CBJ/

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
Due December 2011
Submitted March 2012

I. AUTHORITY FOR REPORT

Item 297(H) of the 2011 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 15th 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 2011

A. Criteria Reviews and Updates

The DUR Board met three times in 2011 (March, May, and September) and is scheduled to meet in November. 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 2011, the DUR Board reviewed and approved criteria for 25 new drugs, including:

- Butrans® (Analgesic);
- Cycloset® (Antihypertensive);
- Egrifta® (Endocrine);
- Ella® (Oral Contraceptive);
- Latuda ® (Atypical Antipsychotic);
- Pradaxa™ (Anticoagulant);
- Amturnide™ (Antihypertensive);
- Edarbi® (Antihypertensive);
- Caprelsa ™ (Antineoplastic)
- Daliresp™ (Antiasthmatic)
- Dificid ™ (Antibiotic)
- Edurant™ (Antiviral)
- Fluzone ™ (Vaccine)
- Horizant ™ (CNS Drug)
- Incivek ™ (Antiviral)
- Mononine ™ (Blood Factor)
- Nulojix ™ (Immunosuppressant)
- Phoslyra ™ (Electrolyte Depleter)
- Sprix ™ (Analgesic)
- Tradjenta ™ (Hypoglycemic)
- Viibryd ™ (Antidepressant)
- Victrelis™ (Antiviral)
- Xarelto™ (Anticoagulant)
- Zutripro ™ (Cough/Cold Preparation)
- Zytiga ™ (Antineoplastic)

Reviewed and approved criteria for existing drugs. In 2011, 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; (10) Biologics; and (11) Blood Factors.

Updated existing criteria. In 2011, 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;
- Atypical Antipsychotics;
- Analgesics;
- Endocrine;
- Anticoagulants;
- Antibiotics;
- Biologicals;
- Blood Factors
- Antidepressants; and,
- Antitussives.

B. Cost and Utilization Reports Reviewed

In addition to reviewing clinical criteria, during the 2011 DUR Board meetings, the Board reviewed quarterly cost and utilization reports prepared by the program contractor, ACS State Healthcare. The DUR Board also reviewed ProDUR program cost savings reports and summaries of ProDUR alerts.

In November 2010, the DUR Board reviewed member utilization of Synagis®. Synagis® was licensed in June 1998 by the United States Food and Drug Administration (FDA) for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients who are at increased risk of severe disease. The American Academy of Pediatrics (AAP) has published specific guidelines for the use of Synagis®. A report containing monthly Virginia Medicaid claims data from October 2009 to September 2010 showed total claims paid was $4,572,520 and that Synagis® ranked number one in its Generic Therapeutic Class. According to this report, 80 recipients received Synagis® in April 2010, three in May 2010, and 17 in September 2010 - months that are outside the Centers for Disease Control's (CDC) established season for Synagis® administration. After reviewing the utilization, the DUR Board requested that the AAP guidelines for Synagis ®use be reviewed and discussed during its next meeting in an effort to determine if the current utilization was appropriate. At the March 2011 DUR Board meeting, the Board voted that Synagis® must have prior authorization for all members utilizing the current American Academy of Pediatrics guidelines. And effective July 2011, the Department of Medical Assistance Services required prescribing providers to complete a service authorization (SA) for the use of Synagis®.

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 2011 and September 2011, the DUR Board retrospectively reviewed patient profiles and mailed letters on the following items:

- Review on profiles for Proton Pump Inhibitors BID Dose Optimization Part 1;
- Review on profiles for Proton Pump Inhibitors BID Dose Optimization Part 2;
- Review on profiles for Proton Pump Inhibitors BID Dose Optimization Part 3;
- Polypharmacy (defined below);
- Re-review profiles for the July 2010 review of medications with Abuse Potential;
- Re-review on the interventions from July 2010 RetroDUR Polypharmacy Review;

- Beer's List Criteria review;
- Re-review profiles for the August 2010 RetroDUR review of Beta Blocker underutilization after Myocardial Infarction;
- Re-reviews were performed on the Influenza Vaccination underutilization intervention from the September 2010 review;
- Review for HIV patients and lettered their prescribers on strategies to achieve treatment goals and enhance the effectiveness of Antiretroviral Therapy (ART);
- Re-review profiles for the October 2010 Beers Criteria review (defined below); and,
- Polypharmacy (defined below).

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 2,020 re-review profiles between January 2011 and September 2011, 1,141 (57.0 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 January 2011 and May 2011, 2,681 letters were mailed to providers and pharmacists and 422 responded. This equates to a 16 percent RetroDUR response rate.

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 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.

During the March 2011 meeting, the DUR Board discussed the November 2010 retrospective review of 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:

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

In May 2011, 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:

- 31 percent of the interventions involved the use of benzodiazepines or barbiturates that are inappropriate to use in older adults at any dosage;
- 14 percent of the interventions involved the use of benzodiazepines that are not recommended in patients with certain medical conditions; and
- 25 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. A re-review of the April 2010 Beers Criteria profiles was conducted in October 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 298 profiles re-reviewed, 133 (45 percent) showed that their therapy had been changed or discontinued while 165 (55 percent) showed no change in 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 March, May, and September 2011, the DUR Board reviewed drug claims for polypharmacy. There were 249 letters sent to prescribers regarding 106 patients for the July 2010 review. Of the original 106 patients, 91 (86%) were discontinued on therapy according to the re- review in March 2011. In addition, there were 556 letters sent to prescribers concerning 247 patients for the April 2011 review. 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 17,000 patient medication profiles have been reviewed for polypharmacy and a total of 2,087 intervention letters have been sent to prescribers.

The overall prescriber response rate for the July 2010 intervention was 10%; of those responding, 5 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. Atypical Antipsychotic Use in Children Under the Age of Six (6)

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 2 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.

During 2010, the Board voted to implement an edit and requested additional information from the Department of Medical Assistance Services (DMAS) related to how the edit would be implemented.

Effective December 1, 2011, DMAS will require specific clinical criteria for atypical antipsychotics prescribed to new patients under the age of 6 who are enrolled in the fee-for-service Virginia Medicaid program. In consultation with the DUR Board, DMAS has established Service Authorization (SA) criteria.

VI. 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 December 1, 2010 and July 19, 2011 to discuss proposals for the cost effective delivery of pharmacy services. Topics discussed also included the impact of Federal Health Care Reform and the pharmacist reimbursement for the administration of influenza vaccines. In addition, DMAS staff provided updates on pharmacy initiatives recently implemented including:

- Clinical edits for Synagis® and atypical antipsychotics in children under the age of six which will require prescribing providers to submit service authorizations for these medication;
- Replacement source for average wholesale price (AWP);
- Contractor changes for rebate, pharmacy services and fiscal agent vendors.

As a result of these discussion, DMAS implemented system changes effective October 17, 2011 which will allow pharmacists to submit claims for influenza vaccines for Medicaid recipients age 21 and older through the point-of-sale (POS) claims processing system.

VII. 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.

ATTACHMENT A

2011 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 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.