

MEDICAID DRUG UTILIZATION REVIEW PROGRAM

**ANNUAL REPORT
OF THE
NEW YORK STATE
DRUG UTILIZATION REVIEW BOARD**

2008

REPORT TO THE GOVERNOR AND LEGISLATURE

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I. INTRODUCTION

Drug Utilization Review programs (DUR programs) help ensure that prescriptions for outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical consequences. This objective is consistent with New York's Medicaid's goal of assuring beneficiaries access to cost-effective, high quality health care.

DUR programs use professional medical protocols, computer technology, and data processing to assist in the management of data regarding the prescribing of medicines and the dispensing of prescriptions.

The benefits of DUR include:

- Improved health and quality of life
- Reduced drug and medical costs
- Reduced hospital admissions
- Reduced drug diversion
- Better coordinated health care
- Informed providers who prescribe drugs more appropriately

DUR programs help to ensure that the patient receives the right medicine at the right time, in the correct dose, and dosage form. While improved patient care and provider education are the primary goals of DUR, significant cost savings have been realized as a result of its implementation. Prospective Drug Utilization Review (ProDUR), which occurs at the time the prescription is filled, and Retrospective Drug Utilization Review (RetroDUR), which occurs after the claim is paid, work in concert to achieve better patient care.

In January 1993, in accordance with the federal Omnibus Reconciliation Act of 1990 (OBRA), New York implemented RetroDUR for Medicaid beneficiaries. Eighteen months later, in June 1994, New York implemented an electronic, on-line ProDUR system. The use of a ProDUR system became mandatory for all pharmacies participating in New York Medicaid in March 1995. Infusion pharmacies are exempt from the ProDUR on-line requirements, because they do not service typical ambulatory pharmacy patients.

During 2007-2008, the DUR Program underwent significant changes. Administration of the program was transferred from the Office of the Medicaid Inspector General (OMIG) to the Department of Health's (the Department) Office of Health Insurance Programs. Case reviews that were formerly conducted by OMIG staff are now conducted by the University of Massachusetts Medical College's Clinical Pharmacy Services Program through a subcontract administered by the State University of New York (SUNY) and a Memorandum of

Understanding between the Department and SUNY. In April 2008, the number of cases reviewed increased from 1,000 to 2,000 cases per month.

II. DRUG UTILIZATION REVIEW INTERVENTIONS

A. RetroDUR

Under RetroDUR, predetermined criteria are used to generate case reviews of selected Medicaid patients from paid prescription drug claim data. In particular, the patient's most recent drug utilization is examined for safety and appropriateness of therapy. If it is suspected that the patient has received inappropriate drug therapy, an alert is sent to prescribers and pharmacists detailing potential drug therapy problems due to therapeutic duplication, drug-to-disease contraindications, drug-to-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy reactions and/or clinical abuse/misuse. RetroDUR is designed to improve prescribing trends by educating prescribers and alerting them to potential problems. In extreme cases, RetroDUR can result in a referral to the Recipient Restriction Program which limits a beneficiary's access to one pharmacy.

Since the inception of RetroDUR in 1993, the Department has used the services of a software vendor and the Drug Utilization Review Board (DUR Board) to develop a drug monitoring and decision support system that identifies patients whose pharmaceutical therapies place them at high risk for adverse drug-induced conditions or exacerbates illnesses.

B. ProDUR

ProDur allows pharmacists to perform on-line, real-time eligibility verifications and Electronic Claims Capture (ECC), and alerts the pharmacist at the point of sale of potential drug-induced illnesses and adverse drug reactions and interactions.

ProDUR uses a national standard for DUR message transmission of on-line pharmacy claims developed by the National Council for Prescription Drug Programs (NCPDP). Adaptation of this standard was modified subject to the approval of NCPDP to meet New York Medicaid's unique needs.

An important feature of ProDUR is that it allows pharmacists to submit claims electronically through a process known as ECC. ECC offers numerous benefits over submitting claims on paper or magnetic media. When claim information is submitted electronically, the manual processing associated with claim forms and magnetic media is no longer required, claim preparation time is reduced, and pharmacies know the claim has been accepted shortly after it is transmitted. ECC also allows individual claims within an electronic submission to be rejected without causing the entire submission to be denied. Actual on-line

adjudication for pharmacy claims commenced in November 2002 as part of the phase-in of components of the Replacement Medicaid System for New York State.

III. DUR BOARD

Pursuant to NYS Social Services Law §369-bb (Attachment B), the DUR Board was created in 1992 to establish and implement medical standards and criteria for RetroDUR and ProDUR. Board members are appointed by the Commissioner of Health (Commissioner) and serve three-year terms. In accordance with State law, the DUR Board is comprised of 13 health care professionals actively practicing in New York including: five physicians, one of whom has a specialty in mental health; five pharmacists, two persons with expertise in drug utilization review; and one State-employed designee of the Commissioner. Board membership represents the geographic diversity of the State. A list of DUR Board members can be found in Attachment C.

As specified by law, the DUR Board is responsible for a wide range of duties including but not limited to the establishment and implementation of medical standards and criteria for RetroDUR and ProDUR and the development, selection, application, and assessment of educational interventions for physicians, pharmacists, and recipients that improve care.

In 2008, potential physician and pharmacist DUR Board candidates were identified and vetted by the Department and appointed by the Commissioner. These actively-practicing appointees include a psychiatrist; pediatrician; AIDS specialist; internist; pharmacists practicing in chain, independent, and institutional pharmacies; and pharmacists from academia with expertise in pharmacology and drug utilization review. The Commissioner's designee was also appointed to the Board during this report period.

IV. ASSESSMENT OF IMPACT AND COST SAVINGS

The *Guidelines for Estimating the Impact of Medicaid DUR* (Guidelines) were published in 1994 by the U.S. Department of Health and Human Services (HHS) to enable states to prepare the annual report required by the federal government. Developed by a panel of advisors having extensive experience in both DUR and program evaluation studies, these Guidelines produce estimates of the cost savings associated with DUR programs and help DUR programs analyze and improve operations.

The Guidelines state the DUR Program should:

- Review a single target drug or drug class
- Examine interventions separately, even if two interventions target the same drug or drug class
- Select recipients using the target drug before the intervention and track over time
- Select a group of patients at risk of inappropriate use of the target drug and monitor their experience
- Organize possible effects into three levels:
 1. a pre-period that is immediately prior to the DUR intervention
 2. a time period that includes and immediately surrounds the intervention with alert letters sent to providers explaining the therapeutic problems
 3. a post-period interval during which any effects of the intervention are likely to occur

Medicaid's DUR vendor, Health Information Design (HID), adheres to the recommendations in the Guidelines and uses database criteria in all computations and reports. HID uses pharmacy claim dollar amounts as well as medical claim dollar amounts in their assessments. HID follows the Guidelines' recommendations by using before and after intervention comparison groups.

The method used by the Department to determine RetroDUR drug savings is case comparison of Medicaid drug expenditures in the three-month period immediately prior to and after the mailing of a prescriber intervention alert letter. The expenditures are compared to a control group who received no DUR interventions. The savings realized under the RetroDUR program may fluctuate from year to year because of the differences in selected review criteria. Using this method, DUR programs resulted in savings as described in the following sections.

A. Retrospective Drug Utilization Review (RetroDUR) Savings

As previously described in this report, the DUR Program provides an important quality assurance service to Medicaid enrollees. Enrollees identified by this program are at an increased risk of dangerous side effects or drug-induced issues. RetroDUR activities alert providers to therapy risks, and in many cases providers will discontinue unnecessary medications, reduce quantities of medications prescribed, or change to a safer therapy profile. Reductions in medication expenses as well as decreases in acute care, emergency room visits, and hospitalizations are sources of savings realized because of RetroDUR.

During this report period, 16,387 high risk profiles* were reviewed resulting in multiple cases being selected for provider alerts.

| | |
|------------------------------|-----|
| Drug-to-Drug Conflicts | 28% |
| Over-utilization of Therapy | 27% |
| Clinical Appropriateness | 23% |
| Drug-to-Disease Interactions | 20% |
| Under-utilization of Therapy | 2% |

***A profile may result in multiple alert letters**

During the reporting period, 25,686 alert letters were sent to providers including 23,356 to prescribers and 2,330 to pharmacies. These letters contain the patient's profile as well as a provider response form that may be returned to the Department. Average provider response rate was 32 percent. Drug savings realized through RetroDUR interventions for this review period amounted to \$10,087,872.

An additional \$21,685,847 in savings was also achieved from avoiding medical costs associated with adverse drug events. This savings was determined by tracking RetroDUR cases and comparing medical costs incurred after intervention letters were sent to prescribers, with the medical costs incurred during the same period for a comparison group with no interventions. This comparative study examined each recipient's claims record and calculated the difference in medical expenditures.

B. Prospective Drug Utilization Review (ProDUR) Savings

The ProDUR/ECC system maintains an on-line record of every Medicaid recipient's drug history for at least a 90-day period. The pharmacist enters information regarding each prescription and that information is automatically compared against such information as previously dispensed drugs, duplicate prescriptions, drug-to-drug interactions, over and under dosage and drug-to-disease alerts. If the verification process detects a potential problem, the pharmacist receives an on-line warning or rejection message. The pharmacist can then take the appropriate action, such as contacting the prescribing physician to discuss the matter. The outcome might be that the drug is not dispensed, the dosage is reduced, or a change is made to a different medication.

The Department estimates that ProDUR generates an average of \$2,351,792 in gross drug savings per week due to the avoidance of therapeutic duplications and drug-to-drug interactions. This cost savings is determined by an examination of the weekly ProDUR reject/override report that indicates the number of times a pharmacist chose to override the DUR rejection message and dispense the medication. The Department is then able to determine the number of times drugs were not provided and the approximate cost of the drugs that were not dispensed. The total of these transactions is the weekly cost avoidance. For

this reporting period, there were 1,548,015 net on-line claim rejects resulting in annual savings of \$122,293,185.

V. PROGRAM ENHANCEMENTS AND SUGGESTIONS FOR IMPROVEMENT

Several enhancements were made to both ProDUR and RetroDUR during the FFY 2008/09 reporting period. These improvements, which were both programmatic and systemic, include the following:

A. Program Enhancements

- Increased clinical case reviews from 1,000 to 2,000 prioritized RetroDUR cases monthly in April 2008 for Medicaid patients potentially at risk of adverse drug outcomes.
- Collaborated with the New York State Office of Mental Health to improve prescribing practices related to antipsychotic medications.
- Examined drug claims of special populations, including enrollees with HIV/AIDS and asthma to identify medication trends and develop interventions that support appropriate prescribing.
- Extracted and analyzed Medicaid data from multiple databases, including HID, the Medicaid Data Mart and Medicaid's claims processing system (eMedNY), to identify and prioritize populations for current and future drug-disease initiatives.
- Reviewed and implemented RetroDUR review criteria for drugs added to the Medicaid List of Reimbursable Drugs.
- Detected potential Medicaid fraud cases through the DUR systems and referred these cases for further investigation.
- Created the DUR Program site on the Department's Web site at http://nyhealth.gov/health_care/medicaid/program/dur/index.htm .

B. System Enhancements

- Initiated system evolution discussions to modify ProDUR reporting to enable easier and more flexible user access.
- Reviewed and implemented ProDUR and RetroDUR criteria that reduce false positive alerts.
- Updated criteria exceptions to detect occurrences of drug misuse and to help ensure positive outcomes.
- Updated clinical criteria for RetroDUR systems.

C. Future Enhancements

- The Department will continue its effort to allow physicians to access a modified patient medical and drug history on-line prior to prescribing.
- The Department will expand its DUR activities to support programs that improve prescribing practices and improve patient medication compliance and adherence including the Prescriber Education Program, the Psychiatric Services and Clinical Knowledge Enhancement System (PSYCKES), and the Medicaid Medication Therapy Management Program (MTM).
- The Department will seek the advice of the DUR Board to implement clinically appropriate limitations on the frequency, quantity, and duration of drug therapy.
- The Department will seek the advice of the DUR Board to implement clinically appropriate medication step therapy.
- The Department will develop a reporting mechanism that supports the exchange of information between the DUR Board and the Medicaid Pharmacy and Therapeutics Committee.

VI. Conclusion

The DUR Program has proven to be a valuable tool in New York State's efforts to protect and improve the health of Medicaid enrollees. The Department will continue to work with the new DUR Board to develop and implement medication management programs that improve patient outcomes and reduce unnecessary medication costs.

ATTACHMENT A

DEFINITIONS

1. **Drug-to-Disease Interaction** – The potential for or the occurrence of an undesirable alteration of the therapeutic effect of a given prescription.
 - A. **Latrogenic Effect** – The potential of a drug causing an undesirable effect or disease state.
 - B. **Exacerbation Effect** – The potential of a drug making an existing disease state worsen.
2. **Drug Interaction** – The potential for or occurrence of an adverse effect as a result of using two or more drugs together.
3. **Over-utilization** – The use of a drug in quantities exceeding published standards that puts the recipient at risk of an adverse medical result.
4. **Under-utilization** – The use of a drug in insufficient quantity to achieve a desired therapeutic goal.
5. **Duration** – The use of a drug for a period that exceeds published standards for achieving a desired therapeutic goal.
6. **Duplication** – The prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program cost without additional therapeutic benefit.
7. **Clinical Appropriateness** – Patients who are taking certain medications that are considered national standard therapy for certain medical conditions or diseases.
8. **Criteria** – The expected levels of achievement of specifications against which performance can be assessed.
9. **Contraindication** – A specific situation in which a drug should NOT be used, because it may be harmful to the patient.

GLOSSARY OF TERMS

| | |
|----------------|--|
| CMS | Centers for Medicare and Medicaid Services - The federal agency that administers the Medicare Program and works with the states to administer the Medicaid Program. |
| DOH | Department of Health |
| DUR | Drug Utilization Review |
| DURB | Drug Utilization Review Board |
| ECC | Electronic Claims Capture – In order to receive payment for service rendered, all pharmacies must submit their transactions through the on-line DUR program. This program can also capture claims electronically and transmit them to the fiscal agent for adjudication. |
| HID | Health Information Design |
| HIPPA | Health Insurance Portability and Accountability Act of 1996 |
| NCPDP | National Council for Prescription Drug Programs |
| OMH | Office of Mental Health |
| PSYCKES | Psychiatric Services and Clinical Knowledge Enhancement System |
| SURS | Surveillance Utilization Review Subsystem |

ATTACHMENT B

NYS SOCIAL SERVICES LAW §369-bb

§ 369-bb. Drug utilization review board. 1. A thirteen-member drug utilization review board is hereby created in the department. The board is responsible for the establishment and implementation of medical standards and criteria for the retrospective and prospective DUR program.

2. The members of the DUR board shall be appointed by the commissioner and shall serve a three-year term. Members may be reappointed upon the completion of other terms. The membership shall be comprised of the following:

(a) Five persons licensed and actively engaged in the practice of medicine in the state, at least one of whom shall have expertise in the area of mental health, who shall be selected from a list of nominees provided by the medical society of the state of New York and other medical associations.

(b) Five persons licensed and actively practicing in community pharmacy in the state who shall be selected from a list of nominees provided by pharmaceutical societies/associations of New York state.

(c) Two persons with expertise in drug utilization review who are either health care professionals licensed under Title VIII of the education law or who are pharmacologists.

(d) One person from the department of social services (commissioner or designee).

3. The appointed members to the board, or its agents shall have no sanctions against them by medicare or medicaid.

4. The appointments to this board shall be made so that the length of the terms are staggered. In making the appointments, the commissioner shall consider geographic balance in the representation on the board.

5. The DUR board shall elect a chairperson from among its members who shall serve a one-year term as chairperson. The chairperson may serve consecutive terms.

6. Members of the DUR utilization review board and all its employees and agents shall be deemed to be an "employee" for purposes of section seventeen of the public officers law.

7. The department shall provide administrative support to the DUR board.

8. The duties of the DUR board are as follows:

(a) The development and application of the predetermined criteria and standards to be used in retrospective and prospective DUR that ensure that such criteria and standards are based on the compendia and that they are developed with professional input in a consensus fashion with provisions for timely revisions and assessments as necessary. Further, that the DUR standards shall reflect the appropriate practices of physicians in order to monitor:

- (i) Therapeutic appropriateness;
- (ii) Overutilization or underutilization;
- (iii) Therapeutic duplication;
- (iv) Drug-disease contraindications;
- (v) Drug-drug interactions;
- (vi) Incorrect drug dosage or duration of drug treatment; and
- (vii) Clinical abuse/misuse.

(b) The development, selection, application, and assessment of interventions or remedial strategies for physicians, pharmacists, and

recipients that are educational and not punitive in nature to improve the quality of care including:

(i) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the board's duties and powers;

(ii) Written, oral, or electronic reminders of patient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(iii) Use of face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention;

(iv) Intensified reviews or monitoring of selected prescribers or pharmacists;

(v) The creation of an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices as provided in this subdivision. (This may be done directly or through contract with other entities);

(vi) The timely evaluation of interventions to determine if the interventions have improved the quality of care; and

(vii) The review of case profiles prior to the conducting of an intervention.

(c) The publication of an annual report which shall be subject to the department's comment prior to its issuance to the federal department of health and human services by December first of each year. The annual report also shall be submitted to the governor and the legislature before December first of each year. The report shall include the following information: (i) A description of the activities of the board, including the nature and scope of the prospective and retrospective drug use review programs;

(ii) A summary of the interventions used;

(iii) An assessment of the impact of these educational interventions in quality of care;

(iv) An estimate of the cost savings generated as a result of such program; and

(v) Recommendations for program improvement.

(d) The development of a working agreement for the DUR board with related boards or agencies, including, but not limited to: the board of pharmacy, the board of medicine, the SURS staff, and staff of the department of health and the office of mental health, in order to clarify the areas of responsibility for each where such areas may overlap.

(e) The establishment of a process where physicians or pharmacists will have the opportunity to submit responses to the DUR educational letters.

(f) The publication and dissemination of educational information to physicians and pharmacists on the DUR board and the DUR program to include information on:

(i) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients;

(ii) Potential or actual severe/adverse reactions to drugs;

(iii) Therapeutic appropriateness;

(iv) Overutilization or underutilization;

(v) Appropriate use of generics;

- (vi) Therapeutic duplication;
- (vii) Drug-disease contraindications;
- (viii) Drug-drug interactions;
- (ix) Incorrect drug dosage/duration of drug treatments;
- (x) Drug allergy interactions; and
- (xi) Clinical abuse/misuse.

(f) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed or analyzed by the DUR board, staff to the board, or contractors to the DUR program, that identifies individual physicians, pharmacists, or recipients. The board may have access to identifying information for purposes of carrying out intervention activities, but such identifying information may not be released to anyone other than a member of the DUR board or the department and its agents.

(h) The improper release of identifying information in violation of this article may subject that person to criminal or civil penalties.

(i) The board may release cumulative non-identifying information for purposes of legitimate research.

9. The relationship of the DUR board to the department is as follows:

(a) The department shall monitor the DUR board's compliance to federal and state statute and regulation.

(b) The DUR board shall serve at the discretion of the commissioner.

© The department shall have authority on all fiscal matters relating to the DUR program.

(d) The department shall have authority on all administrative matters relating to the administration of the medical assistance program within the DUR program.

(e) The DUR board shall have responsibility for all medical matters relating to the DUR program.

(f) The DUR board may utilize medical consultants and review committees as necessary, subject to department approval.

ATTACHMENT C

FFY 2008/09 New York State Medicaid Drug Utilization Review (DUR) Board

Joseph Paladino, Pharm.D, Chair (DUR Expert)
Leigh Briscoe-Dwyer, Pharm.D, Vice-Chair, BCPS, CGP
David Lehmann, M.D., Pharm.D. (Internal Medicine)
Anita Radix, M.D. (Infectious Disease)
John McIntyre, M.D. (Psychiatry/Mental Health)
Colleen Mattimore, M.D. (Pediatrics)
Marc L. Speert, R.Ph.
Benedict Ho, R.Ph.
Seana O'Mara, Pharm.D.
Samir Shah, R.Ph.
Jadwiga Najib, Pharm.D. (DUR Expert)
John F. Naioti, Jr., R.Ph. (Commissioner's Designee)

Department of Health DUR Support Staff

Linda J. Jones, R.N., Director, Medicaid Pharmacy Program
Carol Lindley, DUR Supervisor
John F. Naioti, Jr., R.Ph., DUR Manager
Daniel McNamara, R.Ph., Pharmacist Consultant
Jean Osterholt, Health Program Administrator Trainee