

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

2011

REPORT TO THE GOVERNOR AND LEGISLATURE

TABLE OF CONTENTS

	<u>PAGE</u>
I. INTRODUCTION	3
II. DRUG UTILIZATION REVIEW (DUR) INTERVENTIONS	4
III. DUR BOARD	5
IV. DUR BOARD ACTION	6
V. TOPICS CONSIDERED BY THE DUR BOARD	15
VI. ASSESSMENT OF IMPACT AND COST SAVINGS	18
VII. EDUCATIONAL PROGRAM	21
VIII. PROGRAM ENHANCEMENTS	22
IX. FUTURE ENHANCEMENTS	23
X. CONCLUSION	24
ATTACHMENT A	25
• Glossary of terms	
• Definitions	
ATTACHMENT B	28
• NYS Social Services Law §369-bb	
ATTACHMENT C	31
• DUR Board Membership and Support Staff	

I. INTRODUCTION

Drug Utilization Review (DUR) programs serve to ensure that prescriptions for outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical consequences. 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 over periods of time. While improved patient care and provider education are the primary goals of DUR, significant cost savings have been realized as a result of these programs.

The benefits of DUR are:

- improved health of Medicaid recipients
- better coordinated health care for recipients
- better informed Medicaid physicians who may then prescribe drugs more appropriately
- reduced hospital admissions
- reduced Medicaid drug costs

The two components of the New York State DUR program are Retrospective DUR (RetroDUR) and Prospective DUR (ProDUR). In January 1993, in accordance with the federal Omnibus Reconciliation Act of 1990 (OBRA'90), 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.

While the ProDUR and RetroDUR programs work cooperatively, each seeks to achieve better patient care through different mechanisms. The ProDUR program allows pharmacy providers to perform on-line, real-time eligibility verifications and assists these providers at the point-of-sale in serving their Medicaid patients by helping to avoid drug-induced illnesses and adverse reactions/interactions. Under the RetroDUR program, a review of a patient's most recent drug utilization is performed after the medication has been dispensed. In 2011, the RetroDUR Program reviewed 2,000 Medicaid beneficiary cases per month.

The DUR Program is under the administration of the Office of Health Insurance Programs, New York State Department of Health (the Department). Data reporting and accompanying analysis and meeting information represented in this report is based on Federal Fiscal Year October 1, 2010 through September 30, 2011.

II. DRUG UTILIZATION REVIEW (DUR) 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. RetroDUR identifies patients whose pharmaceutical therapies place them at high risk for adverse drug-induced conditions or exacerbate illnesses. If it is suspected that the patient has received inappropriate drug therapy, an intervention letter 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 alerting prescribers to potential problems through interventions and by providing providers with clinical educational materials. In certain cases, RetroDUR can result in a referral to the Recipient Restriction Program which requires a patient to use one or more designated primary providers.

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.

The New York State Department of Health (DOH) implemented a Pro-DUR program that allows the pharmacy community to submit transactions in an online real-time environment. In order to receive payment for services rendered, all pharmacies must submit their transactions through the online ProDUR system. A feature of the ProDUR program is the Electronic Claim Capture and Adjudication (ECCA) of claims. This program will check all prescription drugs paid by Medicaid for the member over the past 90 days and alert the pharmacists to possible medical problems associated with dispensing the new drug.

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 (the 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 roster of DUR Board members is contained 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 patients.

IV. DUR BOARD ACTION

Palivizumab

Palivizumab is an intramuscular (IM) injection used as prophylaxis for respiratory syncytial virus (RSV). It is used in certain high-risk children with histories of prematurity (≤ 35 weeks gestational age), chronic lung disease (CLD) (formerly known as bronchopulmonary dysplasia), and hemodynamically significant congenital heart disease (CHD). Palivizumab neutralizes RSV, inhibiting its fusion activity and therefore inhibiting RSV replication, but should not be used for the treatment of RSV disease.

RSV is a leading cause of bronchiolitis and pneumonia in infants. RSV is self-limiting in otherwise healthy individuals, but it can cause serious complications in babies born prematurely who are less than six months of age during RSV season, and in infants and children with comorbid conditions such as CLD, congenital heart disease (CHD) and immunodeficiency.

The Board was asked to consider information regarding study results including dosing and indications. The Board was also asked to consider the potential variability of the respiratory syncytial virus (RSV) season, and the importance of avoiding delays in or disruption of dosing schedules. Testimony addressed concerns with the differences in the risk factors, age of use, and number of doses recommended in the new guidelines.

The Board was presented with a comparison of the 2006 and 2009 American Academy of Pediatrics (AAP) palivizumab guidelines. The DUR Board discussed the major differences between the 2006 and 2009 palivizumab guidelines. Points of discussion focused on the age during the RSV season and number of doses recommended for those with a gestational age between 32 weeks and 34 weeks 6 days.

The DUR Board took the following action(s) regarding palivizumab guidelines:

- Follow the American Academy of Pediatrics 2009 palivizumab guidelines with the exception of the 32 - 34 week 6 day gestational age infants, for which up to 5 doses may be considered.

Pegylated Interferons

Peginterferon alpha coupled with ribavirin is the treatment of choice for Hepatitis-C as indicated by The American Association for the Study of Liver Diseases (AASLD) as well as the American Gastroenterology Association (AGA).

Hepatitis-C is manifested as one of several distinct genotypes. Utilization within the Medicaid program recommends combination therapy with peginterferon alpha and ribavirin as the treatment of choice. HCV genotyping should be performed before starting in order to determine treatment duration and likelihood of response; liver biopsy is also recommended, unless contraindicated, to help guide the decision of whether or not to start treatment. Based on the prevalence of genotype 1 in the U.S., the majority of patients treated for chronic hepatitis C would be expected to receive therapy for a maximum of 48 weeks. Though not explicitly stated in product labeling, there is some evidence supporting clinical guidelines to consider extending treatment to 72 weeks for patients with genotype 1 that demonstrate a delayed virologic response with undetectable HCV RNA at week 24.

The DUR Board was asked to consider information regarding pegylated interferons including hepatitis-C virus (HCV) treatment guidelines, indications, adverse events, and information regarding dosing and administration.

The DUR Board discussed pegylated interferons and the recommendation for quantity, frequency, and duration limits. The discussion focused on obtaining genotypes and requiring the recommended testing at the appropriate intervals to ensure proper length of therapy.

The DUR Board took the following action(s) regarding pegylated interferons:

- Duration limits will be instituted for pegylated interferons to ensure appropriate utilization. Prior authorization will be required for the initial 14 weeks of therapy to determine the appropriate duration of therapy based on genotype.
- Further documentation required for the continuation of therapy at weeks 14 and 26:
 1. After 12 weeks of therapy obtain a quantitative HCV RNA. Continuation is supported if the patient has an undetectable HCV RNA or at least a 2 log decrease compared to baseline.
 2. After 24 weeks of therapy obtain a HCV RNA. Continuation for genotype 1 and 4 is supported if the patient has an undetectable HCV RNA.

Propoxyphene

Propoxyphene received FDA approval in 1957 for treatment of mild to moderate pain. Propoxyphene/Acetaminophen (APAP) received approval from the FDA in 1972 for the same indication. Propoxyphene is considered a weak opiate agonist and is currently indicated for the treatment of mild to moderate pain both alone and in combination with APAP. Propoxyphene products have been a part of clinical practice for decades, but use had slowly declined, likely due to increasing

concerns over safety and efficacy. Still, two different brands were among prescriptions filled in the US in 2010.

A propoxyphene utilization review was presented at which the Board was informed of the recent FDA warnings and recommendations and the black box warning associated with the risk of serious life-threatening adverse events including death. Discussion included the potential public health concerns associated with use of this drug. The Board was also provided with NYS Medicaid claims utilization information regarding propoxyphene containing products.

The DUR Board discussed propoxyphene containing products regarding quantity/frequency/duration limits and inclusion in the Clinical Drug Review Program (CDRP). The discussion focused on the black box warning and the FDA's request for a voluntary recall and that propoxyphene should no longer be prescribed or dispensed due to the potential for life threatening events associated with a single dose.

The DUR Board took the following action(s) regarding propoxyphene:

- FDA recommendations should be followed and propoxyphene should not be prescribed or dispensed.
- In the event the State is required to continue propoxyphene reimbursement, propoxyphene meets the criteria for inclusion into the CDRP.
- Recommended that the Medicaid Pharmacy and Therapeutics Committee consider propoxyphene for inclusion into the CDRP.
- Propoxyphene limited to a maximum of 30 dosage units over a maximum of a 5 day period with no refills, with a frequency limit of 180 days.

(Note: Propoxyphene was eventually removed from the U.S. market.)

Proton Pump Inhibitors

Proton Pump Inhibitors (PPIs) are a widely prescribed class of drugs in the United States for gastrointestinal-related disorders. Recently there have been concerns regarding potential safety risks related to long-term/overuse, most notably increased risk of fractures and infections.

The American College of Gastroenterology's (ACG) 2005 guidelines for treatment of GERD state that PPIs are the most effective at providing rapid relief of Gastroesophageal Reflux Disease (GERD) symptoms and at healing esophagitis associated with GERD. Patients with mild/moderate GERD (nonerosive) should be limited to short-term treatment (4-8 weeks) of PPIs, while severe or chronic cases of GERD typically require long-term or continuous therapy. Per the American Gastroenterology Association's 2008 Medical Position Statement on GERD, continuous treatment is recommended in order to prevent

relapse and to maintain a healed mucosa. Patients not continued on long-term therapy have high recurrence rates of erosive esophagitis and heartburn. An exact definition of “long-term” is not specified, however, the lowest effective dose should be used.

The Board was presented with information regarding proton pump inhibitors (PPIs) including indications, safety issues, adverse events, dosing and administration and appropriate duration of therapy based on diagnosis. The Board was provided information from studies demonstrating the high incidence of inappropriate utilization of PPIs nationwide. The Board was also provided with NYS Medicaid claims utilization information specifically related to potential overutilization of PPIs. Prior authorization requirements from comparator State Medicaid programs were also reviewed.

The DUR Board discussed proton pump inhibitors with regard to appropriate quantity and treatment duration for specific diagnoses. The discussion focused on overutilization.

The DUR Board took the following action(s) regarding proton pump inhibitors:

- Quantity, frequency, and duration limits will be instituted for proton pump inhibitors to ensure appropriate utilization.
- The duration and quantity limits will be based on FDA approved dosing and administration labeling as follows:
- Duration limits:
 1. Mild/moderate gastroesophageal reflux disease (GERD), acute healing of duodenal/gastric ulcers (including non-steroidal anti-inflammatory drug (NSAID) -induced): 60 days.
 2. Maintenance treatment of duodenal ulcers: 365 days.
 3. H. pylori: 14 days.
- Quantity limits:
 1. GERD, erosive esophagitis, healing and maintenance of duodenal/gastric ulcers (including NSAID-induced), prevention of NSAID-induced ulcers: once daily dosing (30 units every 30 days).
 2. Hypersecretory conditions, Barrett's esophagitis, H. pylori, refractory GERD: twice daily dosing (60 units every 30 days).

Miscellaneous Antibiotics (extended-release amoxicillin and delayed-release doxycycline)

Amoxicillin extended-release was approved by the FDA for the treatment tonsillitis and/or pharyngitis secondary to *Streptococcus Pyogenes*. Penicillin VK or amoxicillin are the standard of therapy for the treatment of Streptococcal pharyngitis.

Encouraging the use of amoxicillin *regular-release* dosed according to guidelines or clinical literature is safe, efficacious, and cost-effective. At the time of the report to the DUR Board, no other clinical trials had been published on the effectiveness of amoxicillin extended-release. Furthermore, no clinical trials compared amoxicillin extended-release to amoxicillin.

The DUR Board was provided with a general overview of extended-release amoxicillin including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, and the availability of more cost effective products of equal efficacy.

The DUR Board discussed utilization of extended-release amoxicillin in relation to the lone indication for the treatment of *S. Pyogenes* and initial use of equipotent, more cost effective non-extended-release amoxicillin and/or penicillin. The Board also discussed the need to ensure appropriate duration of therapy when extended-release amoxicillin is prescribed.

The DUR Board took the following action(s) regarding extended-release amoxicillin:

- Step therapy will be applied for Moxatag® (extended-release amoxicillin) for patients that have not attempted to use a more cost effective immediate-release amoxicillin first.
- Quantity limit: 10 tablets

According to DRUGDEX®, an official compendia, doxycycline is principally used in the treatment of infections caused by susceptible *Rickettsia*, *Chlamydia*, and *Mycoplasma*; as an alternative to mefloquine for malaria prophylaxis; treatment for syphilis, uncomplicated *Neisseria gonorrhoeae*, *Listeria*, *Actinomyces israelii*, and *Clostridium* infections in penicillin-allergic patients; used for community-acquired pneumonia and other common infections due to susceptible organisms; anthrax due to *Bacillus anthracis*, including inhalational anthrax (postexposure); treatment of infections caused by uncommon susceptible gram-negative and gram-positive organisms including *Borrelia recurrentis*, *Ureaplasma urealyticum*, *Haemophilus ducreyi*, *Yersinia pestis*, *Francisella tularensis*, *Vibrio cholerae*, *Campylobacter fetus*, *Brucella* spp, *Bartonella bacilliformis*, and

Calymmatobacterium granulomatis, Q fever, Lyme disease; treatment of inflammatory lesions associated with rosacea; intestinal amebiasis; severe acne.

Tetracyclines as a class of antibiotics all share a side effect profile that includes nausea and gastrointestinal upset. Doxycycline hyclate is the oldest formulation of this drug available on the market. Due to gastrointestinal side effects, a monohydrate formulation of doxycycline was devised to reduce side effects. Most recently, doxycycline delayed-release capsule, an enteric coated formulation of doxycycline hyclate, was approved for the treatment of a variety of susceptible infections in adults and children (≥ 8 years and 45 kg). In 2005, a bioequivalent tablet (Doryx® tablets) formulation replaced the capsule formulation. In addition, two companies presently have generic doxycycline delayed-release (DR) formulations FDA approved.

The DUR Board was provided with a general overview of delayed-release doxycycline including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, and the availability of more cost effective products of equal efficacy.

The DUR Board discussed utilization of delayed-release doxycycline in relation to initial use of equipotent, more cost effective non-delayed-release doxycycline. The Board also discussed quantity, frequency and duration limits for the treatment of acute infections with delayed-release doxycycline.

The DUR Board took the following action(s) regarding doxycycline delayed-release

- Step therapy applied for delayed-release doxycycline for patients that have not attempted to use a more cost effective immediate-release doxycycline first.
- Quantity limit equal to or less than 28 units

Non-Benzodiazepine Sedative Hypnotics (NBSHs)

Insomnia is defined by both the International Classification of Diseases ICD-10 and Diagnostic and Statistical Manual of Mental Disorders DSM-IV as difficulty initiating or maintaining sleep or subjective feelings of non-refreshing/restorative sleep for a period of one month or longer. NBSHs are FDA-approved for treatment of insomnia. Prior to 2005, FDA class labeling for hypnotic drugs advised short-term treatment courses but currently does not address treatment durations. Ramelteon, eszopiclone, and controlled-release zolpidem are the only NBSHs approved for long-term (up to 6 months) use for the treatment of insomnia. Robust safety and efficacy data of NBSHs for use longer than that noted in their package inserts is currently lacking; however, some studies support the use of eszopiclone, zaleplon, and ramelteon for up to 12 months.

The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations. The Board was also provided with NYS Medicaid claims utilization information including quantity dispensed, frequency of dispensing, duration of therapy, and the association with additional factors including potential over-utilization and misuse.

The DUR Board discussed utilization of non-benzodiazepine sedative hypnotics in relation to quantity and duration limits based on Food and Drug Administration (FDA) labeling and use supported by Compendia. The Board also discussed distributing education materials to providers regarding safety concerns related to proper monitoring of patients initiating treatment with these medications.

The DUR Board took the following action(s) regarding Non-Benzodiazepine Sedative Hypnotics:

Duration limit equivalent to the maximum recommended duration per Compendia sources:

- 360 days for immediate-release zolpidem products.
- 180 days for eszopiclone and ramelteon products.
- 168 days for extended-release zolpidem products.
- 30 days for zaleplon products.

Frequency limit, based on recommended maximum daily doses:

- 30 dosage units per prescription dispensing; 1 dosage unit per day for a maximum of 30 days for non-zaleplon-containing NBSHs.
- 60 dosage units per prescription dispensing; 2 dosage units per day for a maximum of 30 days for zaleplon-containing NBSHs.
- A first-fill duration and quantity limit for each NBSH of 10 days for a maximum of 10 dosage units for patients naïve to the prescribed NBSH (exception for zaleplon-containing products is 10 days for a maximum of 20 dosage units).

A letter to providers regarding use of NBSHs pertaining to first-fill duration and the maximum applicable quantity and duration limits.

Central Nervous System (CNS) Stimulants

Central nervous system stimulants are indicated for the treatment of attention deficit hyperactivity disorder (ADHD), excessive somnolence associated with narcolepsy, obstructive sleep apnea/hypopnea disorder (OSAHS) and shift work sleep disorder (SWSD).

The use of CNS stimulants has been gaining popularity with an increase in diagnoses of Attention-deficit/Hyperactivity Disorder (ADHD) and a growing number of persons seeking prescription drugs for improvement in memory,

cognitive focus, or attention span (also known as neuro-enhancement). ADHD may continue on from childhood to adulthood in a majority of patients. These medications have potential for adverse events/sudden death and the risk for abuse, misuse, and/or diversion.

The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations associated with the Attention Deficit Disorder and sleep disorders. The Board was also provided with NYS Medicaid claims utilization information specifically related to age, quantity dispensed, frequency of dispensing, duration of therapy, and the association with additional factors including potential over-utilization and misuse.

The DUR Board discussed the use of CNS stimulants in relation to the use within evidence-based daily dosages and frequency as determined by (FDA) labeling. The Board also discussed issues with CNS stimulants based on age, safety and public health concerns, potential for illicit use and diversion, and use inconsistent with approved indications.

The DUR Board took the following action(s) regarding CNS stimulants:

Quantity limits based on a daily dosage as determined by FDA labeling.

- Quantity limits for patients less than 18 years of age to include:
 1. Short-acting CNS stimulants; not to exceed 3 dosage units daily with a maximum of 90 days per strength (for titration).
 2. Long-acting CNS stimulants; not to exceed 1 dosage unit daily with a maximum of 90 days.
- Quantity limits for patients 18 years of age and older to include:
 1. Short-acting CNS stimulants; not to exceed 3 dosage units daily with a maximum of 30 days.
 2. Long-acting CNS stimulants; not to exceed 1 dosage unit daily with a maximum of 30 days.
 3. Diagnosis requirement for patients age 18 and older requesting greater than a 30-day supply.

Central Nervous System Stimulants should be brought to the New York State Pharmacy and Therapeutics Committee to be considered for inclusion in the Clinical Drug Review Program for patients 18 years and older.

Anabolic Steroids

Testosterone agents are primarily used clinically for testosterone replacement in adult male hypogonadism. The American Association of Clinical Endocrinologists (AACE) published clinical practice guidelines for the evaluation and treatment of hypogonadism in adult males in 2002, while the Endocrine Society published the most recent clinical guidelines for testosterone therapy in adult men with androgen deficiency in 2010.

None of the available testosterone agents or synthetic derivatives are currently FDA-approved for erectile dysfunction (ED). Testosterone replacement therapy for hypogonadism is the most common medical use of anabolic steroids but should only be initiated in men with significant symptoms and confirmed low testosterone concentrations (evidence of being tested at least twice prior to initiation of treatment).

The DUR Board was provided with a general overview of the drug class including the indications, accepted uses and clinical considerations associated with hypogonadism. The Board was also provided with NYS Medicaid claim utilization information, including quantity per claim, frequency of refills, and the association with additional factors including potential over-utilization and misuse.

The DUR Board discussed the use of anabolic steroids in relation to duration limits based on documented diagnosis and approved FDA labeled daily dosing. The Board also discussed the history and potential for abuse, diversion, and illegal use, as well as use inconsistent with approved indications and documented safety and public health concerns pertaining to anabolic steroids.

The DUR Board took the following action(s) regarding Anabolic Steroids:

Limitations for anabolic steroid products based on approved FDA labeled daily dosing and documented diagnosis not to exceed a 90-day supply (30-day supply for oxandrolone):

- Initial duration limit of 3 months (for all products except oxandrolone), requiring documented follow-up monitoring for response and/or adverse effects before continuing treatment.
- Duration limit of 6 months for delayed puberty.
- Duration limit of 1 month for all uses of oxandrolone products.

Anabolic steroids should be brought to the New York State Pharmacy and Therapeutics Committee to be considered for inclusion in the Clinical Drug Review Program.

V. TOPICS CONSIDERED BY THE DUR BOARD

New York State Medicaid Utilization Threshold Program

The Board was presented with a New York State Medicaid Utilization Threshold Program overview. The DUR Board was provided information on the modernization of the thresholds, the impact of the modernization, and next steps. The Board was also provided a monthly breakdown on overrides and communications.

New York State Medicaid Prescriber Education Program (NYSMPEP)

The New York State Medicaid Prescriber Education Program (NYSMPEP) is a partnership between the New York State Department of Health and several State University of New York (SUNY) academic institutions. The Board was presented with an update of the New York State Medicaid Prescriber Education Program. The DUR Board was provided with a detailed description of the NYSMPEP and the development of the Drug Information Response Center. The Drug Information Response Center is an interactive web/telephony site at which clinical pharmacists are available to provide timely in-depth drug information responses as questions arise from their interactions with prescribers. Points of discussion included identification of prescriber education topics, module development, current modules that have been implemented and modules still in development.

The Board was provided with information regarding NYSMPEP personnel updates, including the status of current and imminent planned statewide geographical rollouts for the academic educators. The Board was also updated on strategies to strengthen ties between individual prescribers, how the Drug Information Resource Center will be integrated into the NYSMPEP, and a status update of the multiple modules. The Medicaid Medical Director presented the Board with the clinical guidance document for the module relevant to treating type II diabetes, titled "Treating Type 2 Diabetes Mellitus: a New York State Medicaid Clinical Guidance Document".

DUR Retrospective Analysis

The Board was provided with an overview of the Clinical Drug Review Program (CDRP) drugs and drug classes that were previously addressed by the DUR Board and referred to the Pharmacy and Therapeutics (P&T) Committee for further evaluation. The DUR Board was provided a brief overview of the P&T Committee's recommendations in relation to the Commissioner's final determinations and implementation timelines. The Board received a post implementation analysis of the claims volume and prior authorization requests of Xyrem, Human Growth Hormone, and Topical Immunomodulators.

With regard to Xyrem, it was determined that utilization of the product had remained relatively stable since implementation to the CDRP. The majority of approved prior authorization requests in the sample timeframe required review by the Medical Director. In the final analysis, no changes were recommended and it was suggested to continue management under the CDRP.

Regarding Human Growth Hormone (HGH), the majority of prior authorization requests (96.8 percent) met all the established criteria upon the initial review. Two requests were reviewed by the Medical Director and approved. Since implementation to the CDRP, the overall market had declined by approximately 7.4 percent. In the category of 21 years of age and older, the market had declined by approximately 68.8 percent. The recommendation to the Board was to conduct an analysis to determine if a minimum age requirement is medically appropriate and to determine if the age requirement for CDRP should be reduced from 21 to 18 years of age.

With regard to Topical Immunomodulators, the majority of requests (85.6 percent) met established clinical criteria for prior authorization. The primary reason that a PA request did not meet all the clinical criteria for PA involved the provider utilizing the therapy for an unapproved FDA indication or compendia use. Utilization had declined post-implementation by 80.7 percent. The market had remained stable over time.

Psychiatric Services and Clinical Knowledge Enhancement System (PSYCKES) Update

A PSYCKES overview discussed the program's impact on improving the safety and quality of psychotropic medication management. PSYCKES Continuous Quality Improvement Quarterly Report for the third quarter of the year was presented. The discussion also included implementation status, project selections, feedback and prescribing trends noted within clinics in the project. Also presented were the support mechanisms utilized by the Office of Mental Health for the project, Phase II indicator sets for future projects, and how PSYCKES may be integrated with other State agency programs.

Retrospective Drug Utilization Review (RDUR) Overview

The Board was provided with a RetroDUR overview containing detailed information regarding the process, timeline, and the flow of information within the RDUR program. The Health Information Design role in the process was considered as well as the reports they provide. Also presented was an overview of the State University at Buffalo profile review process.

DUR Website Enhancements

The Board was presented with an overview of DUR website enhancements. The Board was provided screenshots of the website home page and links. The Board was also provided with information on future DUR links to be included on the Preferred Drug List.

Respiratory Syncytial Virus (RSV) Treatment Guidelines

Testimony addressed concerns with the differences in the risk factors and age of use published in the new guidelines. The Medicaid Medical Director presented an overview of the New York State Medicaid guidelines for palivizumab utilization for the 2011-2012 RSV season. The guidelines included information regarding groups at risk, seasonal dose limits, and additional criteria including chronological age.

VI. 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 that 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 patients 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:
 - a pre-period that is immediately prior to the DUR intervention.
 - a time period that includes and immediately surrounds the intervention with alert letters sent to providers explaining the therapeutic problems.
 - a post-period interval during which any effects of the intervention are likely to occur.

The New York State Medicaid 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 recommendations in the Guidelines 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.

The New York State Medicaid Drug Utilization Review (DUR) Program has two separate but complementary components, namely the Retrospective Drug Utilization Review (RetroDUR) Program and the Prospective Drug Utilization Review (ProDUR) Program.

The ProDUR Program is designed such that a pharmacy provider may enter information pertinent to a prescription at the point of sale, and that information is automatically compared against previously processed claim data such as 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 prescriber to discuss the matter. The outcome may be that the drug is not dispensed, the dosage is reduced, or a change is made to a different medication.

The cost of drugs not dispensed averaged \$647,778 in gross drug savings per week due to the avoidance of therapeutic duplications and drug-to-drug interactions. For 2011, there were 929,739 on-line claim rejects resulting in annual savings of \$33,684,444. These results demonstrate the success of the DUR Program in improving quality of care and patient safety and in helping to avoid prescription drug and medical costs associated with adverse drug events. As reported in the past, there were significant savings in the program's early refill edit as well. However, these savings were reported as part of the NYS Medicaid Redesign Team initiative and therefore will not be reported as a factor in cost avoidance for DUR for FFY2011.

Through RetroDUR, predetermined criteria are used to generate case reviews of selected Medicaid patients from paid prescription drug claim data. 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 the 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.

The RetroDUR Program is designed to improve prescribing trends by educating providers and alerting them to potential problems. The Department continues to use alert letters based on DUR Board approved criteria to inform prescribers of potential drug-related problems among their patients. FFY 2011 RDUR review volume is 2,000 cases per month, and cases are reviewed by pharmacist staff from the State University at Buffalo.

The Department's RetroDUR vendor, Health Information Designs, Inc. (HID), created 11,649 confirmed cases for clinical review resulting in 18,267 alert letters sent to providers. Approximately 24% of these providers voluntarily replied to our alert letters. In 2011, the RetroDUR Program saved an estimated \$16,085,629 as a direct result of reduced drug costs and an additional \$9,354,502 from avoiding medical costs associated with adverse drug events.

In 2011, total cost avoidance from prospective drug utilization review (ProDUR) (\$33,684,444), retrospective drug utilization review (RetroDUR) (\$16,085,629) and medical claims resulting from the Drug Utilization Review program (\$9,354,502) is estimated at \$59,124,575**.

** In previous years, these results were calculated in accordance with guidelines issued by the U.S. Department of Health and Human Services. In order to more closely estimate cost avoidance for the DUR Program, this annual report is using an average prescription cost calculated by using the net-net cost of medications rather than the previously used gross value. In other words, the cost of medications for this report is calculated with the inclusion of manufacturer rebates.

VII. EDUCATIONAL PROGRAM

Legislation governing the DUR program requires:

"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."

Informational letters are sent to targeted providers by the Medicaid Drug Utilization Review (DUR) Program in order to address specific clinical matters or to share relevant clinical information. The chart below lists the number and type(s) of clinical letters that were distributed to providers during the reporting period.

	Informational Letters sent to providers	
Topic	Quantity	Date Distributed
Vusion	380	July 13, 2010
Regranex	794	August 16, 2010
Oxycontin	1,576	August 31, 2010
Solaraze	469	October 31, 2010
Suboxone	396	February 4, 2011
Early Refill	440	March 24, 2011
Triptans	3,496	April 15, 2011
PPIs	1,639	June 6, 2011
Interferon	358	July 13, 2011

VIII. PROGRAM ENHANCEMENTS

Enhancements made during the FFY 2011 reporting period include the following:

- Expansion of an elective intern training program with the Albany College of Pharmacy and Health Sciences.
- Enhanced cooperative projects between the DUR program, the State University of New York, and the NYS Prescriber Education Program such as Diabetes Standards of Care.
- Video-conferencing of weekly meetings with the University of Buffalo clinical pharmacy staff in order to facilitate development of cooperative reports for the DUR program.
- Establishment of monthly status meetings with the State University of New York administrative staff in order to review the progress of ongoing projects and share information essential to the cooperative partnership.
- Utilization of an enhanced reporting process for the referral of suspected fraud and abuse to the Office of the Inspector General. DUR is mandated to report fraud whenever it is suspected.
- Inclusion of DUR Board recommendations into the Medicaid claims processing system through the application of updated technology.
- Expanded DUR program information through enhancements to the DUR web site at:
http://nyhealth.gov/health_care/medicaid/program/dur/index.htm.

IX. FUTURE ENHANCEMENTS

- Commencement of a proposed elective intern training program with the University of Buffalo and Creighton University.
- Incorporation of a SUNY faculty position to serve as a liaison between SUNY and DOH. This liaison will assist in combining the intellectual assets of both programs and developing the most effective means of collaboration between the two entities.
- Review and implementation of ProDUR and RetroDUR criteria that reduce false positive alerts.
- Utilization of updated claim technology to examine effectiveness of DUR program interventions and system edits.
- Expanded use of visual/projection aids at DUR Board meetings to provide a more enhanced understanding of presentations and a more efficient decision making process.
- Customization of criteria exceptions to enhance detection of occurrences of drug misuse and to help ensure positive outcomes.
- Ongoing update of clinical criteria for RetroDUR systems.
- Updating of the clinical editing system, allowing the implementation of DUR Board recommendations and DoH policy enhancements into the ProDUR system.

X. CONCLUSION

The DUR Program has proven to be a valuable program in the efforts of New York State to protect and improve the health of Medicaid patients. The New York State Health Department will continue to work with the Drug Utilization Review Board to develop and implement medication management processes that improve patient outcomes and reduce unnecessary medication costs.

ATTACHMENT A

GLOSSARY OF TERMS

CDRP	Clinical Drug Review Program
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 ProDUR process. This process can also capture claims electronically and transmit them to the fiscal agent for adjudication.
HID	Health Information Designs, Inc.
HIPAA	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

DEFINITIONS

Clinical Appropriateness – When the expected health benefit exceeds negative consequences by a sufficient margin.

Clinical Drug Review Program (CDRP) - The New York State Medicaid Pharmacy Program aimed at ensuring that specific drugs are utilized in a medically appropriate manner. Under the CDRP, certain drugs require prior authorization because there may be specific safety issues, public health concerns, the potential for fraud and abuse or the potential for significant overuse and misuse.

Contraindication – A specific situation in which a drug should NOT be used because it may be harmful to the patient.

Criteria – The expected levels of achievement of specifications against which performance can be assessed.

Drug Interaction – The potential for or occurrence of an adverse effect as a result of using two or more drugs together.

Drug-to-Disease Interaction – The potential for or the occurrence of an undesirable alteration of the therapeutic effect of a given prescription.

Exacerbation Effect – The potential of a drug making an existing disease state worsen.

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.

Duration – The use of a drug for a period that exceeds published standards for achieving a desired therapeutic goal.

Iatrogenic Disorder – Any adverse mental or physical condition induced in a patient by effects of treatment by a physician or surgeon.

Over-utilization – The use of a drug in quantities exceeding published standards that may place a patient at risk of an adverse medical result.

Prospective DUR (ProDUR) - That part of the drug utilization review program that is to occur before the drug is dispensed that is designed to screen for potential drug therapy problems based on explicit and predetermined standards.

Retrospective DUR (RetroDUR) - That part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards on an ongoing basis with professional input.

Under-utilization – The use of a drug in insufficient quantity to achieve a desired therapeutic goal.

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

2011 New York State Medicaid Drug Utilization Review (DUR) Board

Leigh Briscoe-Dwyer, Pharm.D. , BCPS, CGP, Chair
Seana O'Mara, Pharm.D. , Vice-Chair
Joseph Paladino, Pharm.D. , (DUR Expert)
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.
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

Janet Z. Elkind, Assistant Division Director, Medicaid Pharmacy Program
John F. Naioti, Jr., R.Ph., DUR Manager
Anthony Merola, R.Ph.
Daniel P. McNamara, R.Ph.
Robert L. Correia, Pharm.D.
Judith L. Barrett, R.Ph.
Monica M. Toohey, R.Ph.
Jean E. Osterholt, Health Program Administrator