New Jersey Drug Utilization Review Board
Annual Report

July 1, 2007 through June 30, 2008

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I. Acknowledgements

The drug utilization review process for State Fiscal Year (SFY) 2008 was made possible by the hard work and commitment of the following members of the New Jersey Drug Utilization Review Board:

David Ethan Swee, M.D., Chairman

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In addition, the following employees assisted the drug utilization review process:

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Robert Kocsardy, R.Ph., Pharmaceutical Consultant, Office of Utilization Management, Division of Medical Assistance and Health Services, NJ Department of Human Services. Special thanks are added to the record in appreciation for his continuing education presentations throughout the State of New Jersey.

Samuel Emenike, Pharm.D., Clinical Specialist, Unisys.

Dalia Hanna, Pharm.D., Medical Exceptions Process Program Manager, Unisys.

Pinali Patel, Pharm.D., Pharmaceutical Consultant, Unisys.
II. Executive Summary

In accordance with Public Law 1998, chapter 41, the State of New Jersey Department of Human Services and the Department of Health and Senior Services are required by the December 1st of each calendar year to provide an annual report, with copies to the United States Department of Health and Human Services, the Governor, the Legislature, the New Jersey Pharmacists Association and the Medical Society of New Jersey. The report includes a description of the highlights and opportunities identified by the New Jersey Drug Utilization Review Board (NJDURB) for the period beginning July 1, 2007 and ending June 30, 2008.

It is important to note that requirements for the Drug Utilization Review (DUR) annual report submitted to the United States Department of Health and Human Services by the New Jersey Division of Medical Assistance and Health Services (DMAHS) differ from those indicated by Public Law 1998, chapter 41 (Appendix A). Information included in this annual report will serve as input to the federal DUR report.

The NJDURB met quarterly during SFY 2008. The Board reviewed and discussed utilization data for a number of different drug classes as well as individual drugs of interest. Several prior authorization protocols were recommended, as well as additions to the State’s drug-drug interaction and duration edit. The Board also continued to oversee retrospective projects dealing with antihypertensive, antiretroviral and anti-diabetic medications. The “off-label” use of medication will continue to require review, as well as over-the-counter (OTC) medications.

The NJDURB in SFY 2008 spent $9,100. There were educational lectures presented that included the topics of diabetes, hypertension, mental health, AIDS-HIV, drug interactions and pharmacy errors.

As part of Prospective Drug Utilization Review (PDUR), the edits recommended by the NJDURB that deny a claim from being processed, serve to prevent adverse reactions and duplicate therapies, thereby protecting the patient as well as preventing fraud, waste and abuse. Upon receipt of clinical denials, pharmacists have an opportunity to interact with their patients and respective prescribers, and are in fact, changing prescribing habits, and ultimately controlling utilization and improving outcomes. The report sample in Appendix B for SFY 2008 indicates likely savings to the State averaging nearly $6.5 million per month for all populations combined prior to considering the cost of administering the Medical Exceptions Process (MEP). The savings reflect the DUR process. The State created DUR edits such as drug-drug interactions, duplication of therapies, and maximum daily doses to identify possible conflicts and ultimately hinder inappropriate prescribing.

The cost of administering the MEP through Unisys for the period of July 1, 2007 through June 30, 2008 was $5,922,611.
III. Background

The NJDURB is responsible for reviewing and recommending specific processes for prospective and retrospective components of the DUR process. These processes are intended to improve quality of care.

Prospective drug utilization review (PDUR) consists of interventions performed by a pharmacist prior to a drug being dispensed to a Medicaid, Pharmaceutical Assistance to the Aged and Disabled (PAAD), Senior Gold, or AIDS Drug Distribution Program (ADDP) client who receives a drug benefit through these fee for service (FFS) programs. These interventions involve consultations with the patient and physician regarding drug utilization, including the potential for severe drug-drug interactions, exceeding maximum daily dosage, possible therapeutic duplication, and exceeding duration of medication use.

Retrospective Drug Utilization Review (RDUR) evaluates these same criteria. However, such reviews are performed on a beneficiary’s drug claim history after medications have been dispensed. The process is useful to the State and/or the prescriber in evaluating prescribing patterns. Based on this information, to assure continuous quality assurance, the Board is responsible for performing certain educational outreach activities to bring about changes in these patterns to encourage clinically appropriate drug utilization.

The NJDURB is responsible for recommending DUR standards to avoid drug-related issues such as duplication of therapy, inappropriate dosing, drug-drug interactions, drug-disease contraindications, and inappropriate therapeutic usage. The Commissioners of the Department of Human Services and the Department of Health and Senior Services then consider these standards for approval. These standards are maintained through the State’s point-of-sale (POS) claims processing system.
IV. Findings

A. Overview of Activities and Interventions and Impact on Quality of Care

Highlights of Board Activities During SFY 2008 include:

- A Recommendation was made to the State to extend coverage to include OTC smoking cessation products in addition to the already covered prescription pharmaceuticals. The Board also proposed that coverage of the OTC smoking cessation patches be covered for patients 13 years of age and older. Most clinical literature supports the use of smoking cessation patches in this age group attempting to quit.

- The Board approved the Selzentry® (maraviroc) Protocol that will allow the State to monitor and ensure this new therapy is being utilized appropriately and resistance due to inappropriate use is minimized. Maravoric, a recently FDA-approved medication, is used for patients infected with HIV. The medication inhibits the interaction of HIV-1 gp120 and the CCR5 receptor which is necessary for the virus to gain entry into the cell for viral replication. Prior to initiating treatment with maravoric health care providers must obtain a tropism test to determine if the CCR5 co-receptor is present and the CXCR4 co-receptor is not. The results of the assay will determine if this therapy is appropriate for a particular patient. Medicare and Medicaid will cover the cost of the tropism test to ensure that treatment is available to those who will benefit from maravoric therapy.

- The Board approved the Isentress® (raltegravir) Protocol, a new FDA approved medication used for the treatment of HIV-1 infection. Its mechanism of action is inhibition of HIV-1 integrase, which is necessary for viral replication. Raltegravir should only be used in adult patients who are treatment experienced who show resistance to other antiretroviral agents. The protocol will ensure that this pharmaceutical will be utilized appropriately in HIV patients.

- The Board approved the Intelence® (etravirine) Protocol, a new FDA approved non-nucleoside reverse transcriptase inhibitor (NNRTI). This pharmaceutical needs to be used in combination with other antiretroviral agents in treatment of experienced patients.

- The protocol for treatment of chronic hepatitis C virus was approved by the Board. This is to ensure FDA approved therapies are utilized appropriately in patients requiring these pharmaceuticals. Clinical information will be required from prescribers prior to the approval of these pharmaceuticals.

All the recommendations made by the Board in SFY 2008 were accepted by the Commissioner of the Department of Human Services and the Commissioner of the Department of Health and Senior Services.
B. Assessment of Costs

Training
Accredited continuing education programs for physicians and pharmacists were provided by the NJDURB in conjunction with DMAHS. There was no financial assistance provided by the private entities. Subjects covered were drug interactions, renal function and failure, and diabetes and the use of antipsychotics. The overall administrative cost for the DURB was $9,100.

Drug Utilization
The specific therapeutic class with highest volume of claims, 73,239 approved by Unisys in SFY 2008 was for pain medications. Other top categories approved by Unisys included gastrointestinal medications and sedative/hypnotics with a claim volume of 37,200 and 22,612 approvals respectively. The top three therapeutic categories denied by Unisys included gastrointestinal medications, pain medications, and nutritionals with claim volumes of 9,975; 5,059; and 3,147 denials respectively. Major reasons for review and denial were multiple prescribers, dosage and duration of therapy above established DUR standards, clinical criteria not met, inappropriate diagnosis, and other drug causing a drug-drug interaction.

The PDUR program utilized by the State in SFY 2008 is supported by various edit tables designed to provide maximum discretion to the State in applying PDUR edits. These tables include standards for individual Generic Code Numbers or Specific Therapeutic Class, minimum age, maximum age, approved standards based on relationships between a claim’s reported metric quantity and days supply, effective date and ability to immediately deny claims or override with prior authorization or allow a 30 day supply of drug to be dispensed to allow for interventions with the physician to take place. As part of PDUR, the edits recommended by the DURB which block a claim from being processed prevent adverse reactions, unnecessary prescriptions and duplicate therapies, thus protecting the patient as well as preventing fraud, waste and abuse.

Medical Exception Process
The cost of administering the MEP through Unisys for SFY 2008 was $5,922,611.
C. Recommendations

In order to improve the State’s DUR program, it is recommended that the Board be provided the opportunity to continuously discuss and recommend the use of over the counter medications. The NJDURB and its expertise can assist the State in better managing the funds appropriated for Medicaid, PAAD, Senior Gold, and ADDP beneficiaries by recommending strategies and approving protocols that ensure appropriate drug utilization, prevent abuse, and deter fraud. Educational programs sponsored by the Board should focus on promoting clinically appropriate utilization of medication and simultaneously promote cost-effectiveness.
### V. Acronyms

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VI. Appendices

Appendix A


§ 30:4D-17.6. Definitions

As used in this act:

“Beneficiary” means a person participating in a State pharmaceutical benefits program.


“Compendia” means those resources widely accepted by the medical professions in the efficacious use of drugs which is based on, but not limited to, these sources: the “American Hospital Formulary Services Drug Information,” the “U.S. Pharmacopeia-Drug Information,” the “American Medical Association Drug Evaluation,” and the peer-reviewed medical literature, and information provided from the manufacturers of drug products.

“Criteria” means those explicit and predetermined elements that are used to assess or measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.

“Department” means the Department of Human Services.

“Drug Interactions” means the occurrence when two or more drugs taken by a recipient lead to clinically significant toxicity that is characteristic of one or any of the drugs present or that leads to the interference with the effectiveness of one or any of the drugs.

“Drug-disease contraindication” means the occurrence when the therapeutic effect of a drug is adversely altered by the presence of another disease or condition.

“Intervention” means a form of educational communication utilized by the Board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices.

“Medicaid” means the program established pursuant to P.L.1968, c. 413 (C.30:4D-1 et seq.).
“Over-utilization or under-utilization” means the use or non-use of a drug in quantities such that the desired therapeutic goal is not achieved.

“PAAD” means the program of pharmaceutical assistance to the aged and disabled established pursuant to P.L.1975, c. 194 (C.30:4D-20 et seq.).

“Prescriber” means a person authorized by the appropriate State professional and occupational licensing board to prescribe medications and devices.

“Prospective drug utilization review” means that part of the drug utilization review program that occurs before the drug is dispensed and is designed to screen for potential drug therapy problems based on knowledge of the patient, the patient’s continued drug use and the drug use criteria and standards developed by the board.

“Retrospective drug utilization review” means that part of the drug utilization review program that assesses or measures drug use based on an historical review of drug data against criteria and standards developed by the Board on an ongoing basis with professional input.

“Standards” means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the beneficiary database.

“State pharmaceutical benefits program” means the following programs: Medicaid, PAAD, Senior Gold, the AIDS drug distribution program, and any other State and Federally funded pharmaceutical benefits program.

“Therapeutic appropriateness” means drug prescribing and dispensing based on rational drug therapy that is consistent with the criteria and standards developed pursuant to P.L.1993, c.16 (C.30:4D-17.16 et seq.) and section 2 of P.L.1998, c. 41 (C.30:4D-17.17a).

“Therapeutic duplication” means the prescribing and dispensing of the same drug or of two or more drugs from the same therapeutic class when overlapping time periods of drug administration are involved and when the prescribing or dispensing is not medically indicated.


§ 30:4D-17.17a. Drug Utilization Review Board

a. There is established the Drug Utilization Review Board in the department to advise the department on the implementation of a drug utilization review program pursuant to P.L. 1993, c. 16 (C. 30:4D-17.16 et seq.) and this section. The board shall establish a Senior Drug Utilization Review Committee to address the specific prescribing needs of the elderly and an AIDS/HIV Drug Utilization Review Committee to address the
specific prescribing needs of persons with AIDS/HIV, in addition to such other committees as it deems necessary. It shall be the responsibility of each committee to evaluate the specific prescribing needs of its beneficiary population, and to submit recommendation to the board in regard thereto.

The Board shall consist of 17 members, including the Commissioners of Human Services and Health and Senior Services or their designees, who shall serve as nonvoting ex officio members, and 15 public members. The public members shall be appointed by the Governor with the advice and consent of the Senate. The appointments shall be made as follows: six persons licensed and actively engaged in the practice of medicine in this State, including one who is a psychiatrist and at least two who specialize in geriatric medicine and two who specialize in AIDS/HIV care, one of whom is a pediatric AIDS/HIV specialist, four of whom shall be appointed upon the recommendation of the Medical Society of New Jersey and two upon the recommendation of the New Jersey Association of Osteopathic Physicians and Surgeons; one person licensed as a physician in this State who is actively engaged in academic medicine; four persons licensed in and actively practicing or teaching pharmacy in this State, who shall be appointed from a list of pharmacists recommended by the New Jersey Pharmacists Association, the New Jersey Council of Chain Drug Stores, the Garden State Pharmacy Owners, Inc., the New Jersey Society of Hospital Pharmacists, the Academy of Consultant Pharmacists and the College of Pharmacy of Rutgers, The State University; one additional health care professional; two persons certified as advanced practice nurses in this State, who shall be appointed upon the recommendation of the New Jersey State Nurses Association; and one member to be appointed upon the recommendation of the Pharmaceutical Research and Manufacturers of America.

Each member of the board shall have expertise in the clinically appropriate prescribing and dispensing of outpatient drugs.

b. All appointments to the board shall be made no later than the 60th day after the effective date of this act. The public members shall be appointed for two-year terms and shall serve until a successor is appointed and qualified, and are eligible for reappointment; except that of the public members first appointed, eight shall be appointed for a term of two years and five for a term of one year.

c. Vacancies in the membership of the board shall be filled in the same manner as the original appointments were made but for the unexpired term only. Members of the board shall serve with compensation for the time and expenses incurred in the performance of their duties as board members, as determined by the Commissioners of Human Services and Health and Senior Services, and subject to the approval of the Director of the Division of Budget and Accounting in the Department of the Treasury.

d. The board shall select a chairman from among the public members, who shall serve a one-year term, and a secretary. The chairman may serve consecutive terms. The board shall adopt bylaws. The board shall meet at least quarterly and may meet at
other times at the call of the chairman. The board shall in all respects comply with the provisions of the “Open Public Meetings Act,” P.L. 1975, c. 231 (C. 10:4-6 et seq.). No motion to take any action by the board shall be valid except upon the affirmative vote of a majority of the authorized membership of the board.

e. The duties of the board shall include the development and application of the criteria and standards to be used in retrospective and prospective drug utilization review. The criteria and standards shall be based on the compendia and developed with professional input in a consensus fashion. There shall be provisions for timely reassessments and revisions as necessary and provisions for input by persons acting as patient advocates. The drug utilization review standards shall reflect the local practices of prescribers, in order to monitor:

(1) therapeutic appropriateness;
(2) over-utilization or under-utilization;
(3) therapeutic duplication;
(4) drug-disease contraindications;
(5) drug-drug interactions;
(6) incorrect drug dosage;
(7) duration of drug treatment; and
(8) clinical drug abuse or misuse.

The board shall recommend to the department criteria for denials of claims and establish standards for a medical exception process. The board shall also consider relevant information provided by interested parties outside of the board and, if appropriate, shall make revisions to the criteria and standards in a timely manner based upon this information.

f. The board, with the approval of the department, shall be responsible for the development, selection, application, and assessment of interventions or remedial strategies for prescribers, pharmacists and beneficiaries that are educational and not punitive in nature to improve the quality of care, including:

(1) Information disseminated to prescribers and pharmacists to ensure that they are aware of the duties and powers of the board;
(2) Written, oral or electronic reminders of patient-specific or drug-specific information that are designed to ensure prescriber, pharmacist, and
beneficiary confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care;

(3) The development of an educational program, using data provided through drug utilization review as a part of active and ongoing educational outreach activities to improve prescribing and dispensing practices as provided in this section. These educational outreach activities shall include accurate, balanced and timely information about drugs and their effect on a patient. If the board contracts with another entity to provide this program, that entity shall publicly disclose any financial interest or benefit that accrues to it from the products selected or used in this program;

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

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

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

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


§ 30:4D-17.18. Responsibilities of department The department shall be responsible for:


b. The implementation of a drug utilization review program, subject to the approval of the Commissioner of Health and Senior Services, to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes, including the approval of the provisions of any contractual agreement between the State pharmaceutical benefits program and other entities processing and reviewing drug claims and profiles for the drug utilization review program.

The program shall include both retrospective and prospective drug utilization review. Retrospective drug utilization review shall include an analysis of drug claims processing data in order to identify patterns of fraud, abuse or gross overuse, an inappropriate or medically unnecessary care, and to assess data on drug use against standards that are based on the compendia and other sources. Prospective drug utilization review shall include a review conducted by the pharmacist at the point-of-sale.

d. (Deleted by amendment, P.L. 1998, c. 41).

e. The submission of an annual report, which shall be subject to public comment prior to its issuance, to the Federal Department of Health and Human Services by December 1st of each year. The annual report shall also be submitted to the Governor, the Legislature, the New Jersey Pharmaceutical Association and the Medical Society of New Jersey by December 1st of each year. The report shall include the following information:

(1) An overview of the activities of the board and the drug utilization review program;

(2) Interventions used and their ability to improve the quality of care; however, this information shall not disclose the identifies of individual prescribers, pharmacists, or beneficiaries, but shall specify whether the intervention was a result of under-utilization or over-utilization of drugs;

(3) The costs of administering the drug utilization review program;

(4) Any cost impact to other areas of the State pharmaceutical benefits program resulting from the drug utilization review program, such as hospitalization rates or changes in long-term care;

(5) A quantitative assessment of how drug utilization review has improved beneficiaries’ quality of care;

(6) A review of the total number of prescriptions and medical exception requests reviewed by drug therapeutic class;

(7) An assessment of the impact of the educational program established pursuant to subsection f. of section 2 of P.L. 1998, c. 41 (C.30:4D-17.17a) and interventions on prescribing or dispensing practices, total program costs, quality of care and other pertinent patient patterns; and

(8) Recommendations for improvement of the drug utilization review program.

f. The development of a working agreement between the board and other boards or agencies, including, but not limited to: the Board of Pharmacy of the State of New Jersey and the State Board of Medical Examiners, in order to clarify any overlapping areas of responsibility.

g. The establishment of an appeal process for prescribers, pharmacists and beneficiaries pursuant to P.L. 1993, c. 16 (C.30:4D-17.16 et seq) and section 2 of P.L. 1998, c. 41 (C.30:4D-17.17a).
h. The publication and dissemination of medically correct and balance educational information to prescribers and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among prescribers, pharmacists and beneficiaries, including:

(1) potential or actual reactions to drugs;
(2) therapeutic appropriateness;
(3) over-utilization or under-utilization;
(4) appropriate use of generic drugs;
(5) therapeutic duplication;
(6) drug-disease contraindications;
(7) drug-drug interactions;
(8) incorrect drug dosage or duration of drug treatment;
(9) drug allergy interactions; and
(10) clinical abuse or misuse.

i. the development and publication, with the input of the Board of Pharmacy of the State of New Jersey, of the guidelines to be used by pharmacists, including mail order pharmacies, in their counseling of beneficiaries.

j. The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the drug utilization review program, that identifies individual prescribers, pharmacists, or beneficiaries. The board may have access to identifying information for purposes of carrying out intervention activities, but the identifying information may not be released to anyone other than a member of the board, except that the board may release cumulative non-identifying information for purposes of legitimate research. The improper release of identifying information in violation of this act may subject that person to criminal or civil penalties.

k. The determination of whether nursing or long-term care facilities under 42 CFR 483.60 are exempt from the provisions of this act.

l. The establishment of a medical exception process by regulation.
m. The provision of such staff and other resource as the board requires.

HISTORY: L. 1993, c. 16, § 3; amended 1998, c. 41, § 3.

§ 30:4D-17.18a. Rules, regulations

The Commissioner of Human Services, pursuant to the “Administrative Procedure Act,” P.L.1968, c. 410 (C.52:14B-1 et seq.), and subject to the approval of the Commissioner of Health and Senior Services as appropriate, shall adopt rules and regulation to effectuate the purposes of P.L.1993, c. 16 (C.30:4D-17.16 et seq.) and section 2 of P.L.1998, c. 41 (C.30:4D-17.17a); except that, notwithstanding any provision of P.L.1968, c. 410 (C.52.14B-1 et seq.) to the contrary, the Commissioner of Human Services, subject to the approval of the Commissioner of Health and Senior Services, may adopt, immediately upon filing with the Office of Administrative Law, such regulations as the commissioner deems necessary to implement the provisions of P.L.1993, c. 16 (C.30:4D-17.16 et seq.) and section 2 of P.L.1998, c. 41 (C.30:4D-17.17a), which shall be effective for a period not to exceed six months and may thereafter be amended, adopted, or re-adopted by the Commissioner of Human Services, subject to the approval of the Commissioner of Health and Senior Services, in accordance with the requirements of P.L.1968, c. 410 (C.52:14B-1 et seq.).

## Appendix B

**Unisys Cost Avoidance Reports**

Claims represented in this report did not reappear for future payment and are considered an avoidance of inappropriate expenditure

**July 2007-September 2007**

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Cost savings identified in this report reflect costs for DUR claims denied by a DUR edit for which no future paid claims were identified for the 60 day period following the date of denial

This report has been unduplicated by claim and edit

**Description of Edits**

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- 404 Duration Exceeded
- 405 Possible Therapeutic Class Duplication
- 417 Generic Substitution Required
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- 449 “Inappropriate Narcotic Use”
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- 537 Daily Drug Quantity Exceeded
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Appendix B
Unisys Cost Avoidance Reports
Claims represented in this report did not reappear for future payment and are considered an avoidance of inappropriate expenditure

October 2007-December 2007

<table>
<thead>
<tr>
<th>Edit</th>
<th>FFS Medicaid</th>
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<th>Senior Gold</th>
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<th>Grand Total</th>
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Total  $13,257,534  $4,612,183  $2,384,448  $630,503  $244,727  $701  $21,130,096

Cost savings identified in this report reflect costs for DUR claims denied by a DUR edit for which no future paid claims were identified for the 60 day period following the date of denial

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Description of Edits

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January 2008-March 2008

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<table>
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