

**NEW JERSEY DRUG UTILIZATION REVIEW BOARD
ANNUAL REPORT**

JULY 1, 2003 THROUGH JUNE 30, 2004

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I. Acknowledgements

The Drug Utilization Review process for SFY 04 was made possible by the hard work and commitment of the following members of the New Jersey Drug Utilization Review Board:

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In addition, the following State staff were responsible for assisting the drug utilization review process:

Patricia F. Hafitz, R.Ph., Pharmaceutical Consultant, Office of Utilization Management, Division of Medical Assistance and Health Services.

Robert Kocsardy, R.Ph., Pharmaceutical Consultant, Office of Utilization Management, Division of Medical Assistance and Health Services. Special thanks are added to the record in appreciation for his educational presentations.

Joseph B. Martinez, R.Ph., Chief of Pharmaceutical Services, Office of Utilization Management, Division of Medical Assistance and Health Services.

Kathleen M. Mason, Assistant Commissioner, Senior Benefits and Utilization Management, Department of Health and Senior Services; ex-officio, NJ Drug Utilization Review Board

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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 December 1st of each calendar year to provide an annual report, with copies to the federal 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, 2003 and ending June 30, 2004.

It is important to note that requirements for the Drug Utilization Review (DUR) annual report submitted to the federal 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 for the federal DUR report.

The NJDURB met quarterly during SFY 04. The State's Mandatory Generic Program was implemented in early SFY 04, and after discussion about the difficulty encountered by the mentally ill population, the Board recommended that atypical antipsychotics and antidepressants be excluded from the generic substitution program. The "off-label" use of medications was also discussed in depth, and the Board concurred that there was enough documentation available to recommend that the State provide coverage for several products being used "off-label". Several protocols were recommended, as well as additions to the State's drug-drug interaction edit. The Board also continued to oversee retrospective projects dealing with antihypertensive, antiretroviral and antidiabetic medications, warfarin, corticosteroid inhalers and osteoporosis. SFY 05 will provide the Board with the opportunity to review and make recommendations in regard to several categories of medications with high rates of utilization, including hematopoietic agents, narcotics, antiretrovirals, and proton pump inhibitors. New drugs scheduled for release during SFY 05 will provide opportunities for Board discussion about diabetes, asthma and other disease management, and "off-label" use of medication will continue to require review. An update on Medicare Part D (due for implementation in SFY 06), will be included at each quarterly meeting in SFY 05, so the Board will be kept apprised of the latest developments and their impact on Medicaid and PAAD beneficiaries.

The NJDURB in SFY 04 spent \$63,286. The 9 educational lectures sponsored by the Board included the topics of drug interactions, HIV, infectious hepatitides, liver function tests and renal function tests. The number of claims posting a severe drug-drug interaction decreased from 26,322 last year to 16,116 this year, and it is likely that prescribers and pharmacists are becoming more aware of drug interactions through educational programs including those sponsored by the NJDURB.

As part of Prospective Drug Utilization Review (PDUR), the edits recommended by the NJDURB which deny a claim from being processed serve to prevent adverse reactions, unnecessary prescriptions and duplicate therapies, thereby protecting the patient as well as preventing fraud, waste and abuse. Pharmacists who receive clinical denials are believed to be interacting with their patients and prescribers, and are in fact, changing prescribing habits, and ultimately containing expenditures. A claim denied initially which does not reappear for future payment is considered to have been an avoidance of

inappropriate expenditure. The Unisys cost avoidance reports (appendix B) for SYF 04 indicate likely cost savings to the State averaging nearly \$3.2 million per month for Medicaid and PAAD combined.

The cost of administering the Medical Exception Process (MEP) through First Health Clinical Services (FHCS) for the period of July 1, 2003 through June 30, 2004 was \$8,414,881.88.

III. Background

The NJDURB is responsible for specific processes involving prospective and retrospective components of the DUR process. Both of these processes are intended to improve quality of care. PDUR consists of interventions performed by a pharmacist prior to a drug being dispensed to a State beneficiary. These interventions involve consultations with the patient and physician regarding proper 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. This may serve useful in assisting the State and/or the prescriber in evaluating their prescribing patterns. Based on this information, the Board is responsible for performing certain educational outreach activities to bring about changes in these patterns to encourage proper drug utilization.

The NJDURB is responsible for recommending DUR standards to avoid: duplication of therapy, inappropriate dosing, drug-drug interactions, drug-disease contraindications, inappropriate therapeutic usage and duration of therapy. 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 incorporated into the State's claims processing system for pharmaceutical services, which includes the point-of-sale (POS) claims processing system.

IV. Findings

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

During SFY 04, the Board

- discussed the *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*, published by the United States Department of Health and Human Services, and recommended that the following interactions be included in the State's drug-drug interaction edit; stavudine with zidovudine, stavudine with Combivir; stavudine with Trizivir; stavudine with zalcitabine; didanosine with zalcitabine; emtricitabine with lamivudine; emtricitabine with Combivir; emtricitabine with Trizivir; hydroxyurea as part of any antiretroviral regimen;
- reviewed the antiretroviral agent Reyataz and recommended that proton-pump inhibitors, erectile dysfunction drugs, rifampin, bepridil, indinavir, lovastatin, and simvastatin be included in the drug-drug interaction edit with Reyataz;
- recommended an authorization criteria protocol for Xolair;
- recommended that drugs used to treat erectile dysfunction be limited to four doses per month, with the addition of a drug-drug interaction standard for this category of drugs with nitrates;
- discussed Zelnorm, Provigil and Tarvil;
- discussed the off-label use of medications;
- discussed the maintenance use of Fuzeon; and
- recommended that antidepressant and antipsychotic drugs should be exceptions to the State's Mandatory Generic program.

The Warfarin/Antibiotic Retrospective Process (WARP), initiated March 1, 2001, continued as a regular activity in SFY 04. The process results in notification to the warfarin prescriber when a beneficiary on warfarin receives an antibiotic which can potentially interact with the warfarin. The notification recommends that the prescriber test their patient seven to ten days after initiating the antibiotic. This process is intended to heighten the awareness of this potentially life-threatening interaction, improve the quality of care for beneficiaries, and reduce the number of hospital admissions associated with this interaction. There were 14,751 letters sent to prescribers in SFY 04 notifying them of this serious drug-drug interaction as compared to 15,256 letters in SFY 03.

The Antiretroviral Adherence Intervention Project, started in February 2003, involves prescriber notification when a beneficiary fails to renew their prescription for antiretroviral therapy within a specified time frame that would indicate underutilization of the product. From July 1, 2003 to June 30, 2004 a total of 2,829 letters sent resulted in physicians stressing the importance of adherence to therapy to avoid viral resistance in 1,481 instances. Viral load and CD-4 count were measured 395 times as a result of non-adherence notification. According to an article on Medscape at <http://www.medscape.com/viewarticle/420932>, a study assessing the effects of different levels of adherence in patients receiving protease inhibitor therapy found that patients with adherence rates of 95% or better had significantly better virologic outcome (22% virologic failure) than patients with adherence rates of 80% or less (80% virologic failure). In addition, patients with adherence of 95% or better had fewer days in the hospital. Another study, available at http://www.medscape.com/viewarticle/410267_6, demonstrated an

almost linear relationship between adherence to HAART and the likelihood of achieving undetectable viremia. These studies are just part of the mounting evidence that demonstrates adherence to antiretroviral therapy has a strong impact on virologic response and emergence of viral resistance.

The Antihypertensive Therapy Intervention Project, started in April 2004, is designed to assist prescribers in the management of their hypertensive patients. When a beneficiary fails to renew their prescription for antihypertensive therapy within a specified time frame, it indicates possible underutilization of the medication, and may indicate a patient is having difficulty adhering to the prescribed therapy. Notification to the prescriber facilitates intervention and follow-up to improve compliance. For the 3-month period consisting of April, May and June 2004, a total of 13,227 letters sent to prescribers resulted in compliance being stressed to patient and/or caregiver in 2,035 instances, with written action plans given 118 times, and changes in therapy made 347 times. Controlling blood pressure in hypertensive patients is an important factor in reducing cardiovascular disease and the risk of stroke, coronary artery disease, and chronic renal disease according to an article published in *Journal of Clinical Hypertension* 5(2):127-132, 2003. This article, available at <http://www.medscape.com/viewarticle/452254>, also examines the issues which influence compliance, namely side effects, convenience, polypharmacy, and patient education. The results of a study done in the United Kingdom over a 26 month period found 7,741 newly diagnosed hypertensive patients who discontinued their medication had substantially higher health care costs from hospitalization and office visits than those patients who continued their treatment. Additionally, the Hypertension Optimal Treatment (HOT) study concluded that patients with lower blood pressures have significant improvement in quality of life.

The Antidiabetic Medication Adherence Intervention Project, started May 2004, is designed to assist prescribers in the management of their diabetic patients. When a beneficiary fails to renew their prescription for antidiabetic therapy within a specified time frame, it indicates possible underutilization of the medication, and may indicate that a patient is having difficulty adhering to the prescribed therapy. Notification to the prescriber facilitates intervention and follow-up to improve compliance. For the two month period of May and June 2004, a total of 4,967 letters sent to prescribers resulted in compliance being stressed to the patient and/or caregiver in 751 instances, with a written action plan given 53 times, and therapy being changed in 149 instances. The complications of diabetes, namely retinopathy, nephropathy, and neuropathy can be devastating in terms of morbidity, mortality and health care costs. When a patient's blood glucose levels are maintained as close as possible to normal, these complications can be delayed and/or slowed. The most compelling evidence of this came out of the Diabetes Control and Complications Trial (DCCT), available at <http://www.medscape.com/viewarticle/470738>, a trial involving 1,441 subjects with type 1 diabetes. Another study, done in Hong Kong, available at <http://www.edscape.com/viewarticle/465932>, included patients with type 1 and type 2 diabetes, and found that patients defined to be non-compliant with their therapy had received inadequate information regarding management of their disease and the risk of complications. Intervention with these patients succeeded in improving their compliance and glycemic control.

B. Assessment of Costs

Expenditures for SFY 04 for the NJDURB totaled \$63,286. This is a reduction over prior years due to the fact that there were seven Board member positions not filled, and to a greater extent, thanks to Mr. Robert Kocsardy who provided his services as lecturer for the educational forums for no additional cost. It is important to note that although severe drug-drug interactions were identified on 16,116 claims in SFY 04, a decrease from 26,322 in SFY 03, FHCS was contacted by pharmacists regarding severe drug-drug interactions claims 4,668 times, an increase from 2,517 in SFY 03. Pharmacists resolved 11,448 severe drug-drug interactions with patients and prescribers without the involvement of FHCS. Educational programs, including those sponsored by the NJDURB, have succeeded in increasing awareness about drug interactions among prescribers and pharmacists.

The specific therapeutic class with the highest volume of claims reviewed by FHCS in SFY 04 was narcotic analgesics. 65,311 claims were reviewed with 61,697 approvals, and 3,614 denials. The major reason for approval was for prescribing of multiple narcotics. 55,143 claims were reviewed for agents that reduce gastric acid secretion with 50,614 approvals and 4,529 denials. The major reason for review and approval was dosage and duration of therapy above established DUR standards. Drugs to treat ADD, ADHD and narcolepsy were reviewed 52,674 times with 52,362 approvals and 312 denials; the major reason for approval was appropriate diagnosis. NSAIDs and cyclooxygenase inhibitors accounted for 28,757 reviews with 23,401 approvals and 5,356 denials; and lipotropics accounted for 22,346 reviews with 21,696 approvals and 650 denials. The major reason for approval in these two categories was discontinuation of another drug which was causing a drug-drug interaction.

The PDUR program utilized by the State in SFY 04 is supported by various edit tables designed by the State 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 the ability to immediately deny claims or override with PA or allow a 30 day supply of drug to be dispensed to allow for MEP 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. Pharmacists who receive clinical denials are believed to be interacting with their patients and prescribers, and are in fact, changing prescribing habits, and ultimately containing expenditures. A claim denied initially which does not reappear for future payment is considered to have been an avoidance of inappropriate expenditure. The Unisys cost avoidance reports for SYF 04 indicate likely savings to the State averaging nearly \$3.2 million per month for Medicaid and PAAD combined.

There were 63,847 retrospective interventions performed in SFY 04. These retrospective projects are designed to provide intervention that potentially reduces hospitalization rates. In 2002, an analysis of the WARP by PRONJ, estimated avoided hospitalizations yielded

annual savings of \$471,889. The Steroid as Regular Therapy in Early Asthma (START) study, spanning 3 years and 31 countries, found that patients receiving inhaled budesonide experienced 69% fewer hospital days, and 76% fewer emergency department visits. Other studies have demonstrated that patients with adherence rates of 95% or better with Protease Inhibitor therapy had fewer days in the hospital as a consequence of HIV. A study done in the United Kingdom found that patients who discontinued their antihypertensive therapy had substantially higher health care costs from hospitalizations and office visits than those patients who continued their treatment. The results of the DCCT provide compelling evidence of how the complications of diabetes can be delayed and/or slowed when a patient's blood glucose levels are maintained as close to normal as possible.

The cost of administering the Medical Exception Process through FHCS for the period of July 1, 2003 through June 30, 2004 was \$8,414,881.88.

C. Recommendations

In order to improve the State's DUR program, it is recommended that appointments for the vacant seats on the NJ Drug Utilization Review Board be expedited. The process for members to be appointed is lengthy and has left expired terms unfilled for long periods of time. The Board will need to evaluate issues that affect the benefits of the Aged, Blind and Disabled population that will be carved out of managed care in 2005, and enrolled in Medicare Part D in 2006.

Educational programs sponsored by the Board should focus on promoting proper utilization of medications, and specifically target categories of drugs that have high rates of utilization, such as narcotics, antipsychotics, and gastric acid suppressants. The Board will also need to continue to discuss the "off-label" use of medication.

Acronyms

ADD	Attention Deficit Disorder
ADHD	Attention Deficit Hyperactivity Disorder
ADDP	AIDS Drug Distribution Program
DCCT	Diabetes Control and Complications Trial
DMAHS	Division of Medical Assistance and Health Services
DUR	Drug Utilization Review
DURB	Drug Utilization Review Board
FHCS	First Health Clinical Services
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
MEP	Medical Exception Process
NJDURB	New Jersey Drug Utilization Review Board
NSAID	Non-steroidal anti-inflammatory drugs
PA	Prior Authorization
PAAD	Pharmaceutical Assistance to the Aged and Disabled
PDUR	Prospective Drug Utilization Review
POS	Point of Sale
PRONJ	Peer Review Organization of New Jersey
RDUR	Retrospective Drug Utilization Review
SFY	State Fiscal Year
START	Inhaled Steroid as Regular Therapy in Early Asthma
WARP	Warfarin/Antibiotic Retrospective Process

VI. Appendices

Appendix A

P.L. 1998, Chapter 41, approved June 30, 1998, as amended and supplemented

§ 30:4D-17.16. Definitions

As used in this act:

"Beneficiary" means a person participating in a State pharmaceutical benefits program.

"Board" means the Drug Utilization Review Board established pursuant to section 2 of P.L.1998, c. 41 (C.30:4D-17.17a) in connection with State pharmaceutical benefits programs.

"Compendia" means those resources widely accepted by the medical profession 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 Evaluations," 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.).

"Overutilization or underutilization" 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 medication 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 use

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, 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.

HISTORY: L. 1993, c. 16, §1; amended 1998, c. 41, § 1.

§ 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 recommendations 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 who 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, 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) overutilization or underutilization;
- (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 discussion 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.

HISTORY: L. 1998, c. 41, § 2; amended 2003, c. 262.

§ 30:4D-17.18. Responsibilities of department

The department shall be responsible for:

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

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, and 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.

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

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 1

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 1 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 identities of individual prescribers, pharmacists, or beneficiaries, but shall specify whether the intervention was a result of underutilization or overutilization 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 balanced 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) overutilization or underutilization;
 - (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 nonidentifying 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 resources 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 regulations 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.).

HISTORY: L. 1998, c. 41, § 4.

Appendix B

Unisys Cost Avoidance Reports

July 03

EDIT	GA	MCAID	CF	ADDP	PAAD	GRAND TOTAL
403	\$3,493.83	\$60,374.33	\$0.00	\$1,020.65	\$135,224.41	\$200,113.22
404	\$5,783.88	\$62,637.32	\$0.00	\$880.84	\$101,951.14	\$171,253.18
405	\$30,254.41	\$317,196.94	\$0.00	\$3,340.73	\$271,472.07	\$622,264.15
535	\$11,810.25	\$181,455.73	\$0.00	\$2,093.04	\$142,806.65	\$338,165.67
537	\$73,676.45	\$1,038,308.06	\$0.00	\$71,352.47	\$659,007.72	\$1,842,344.70
869	\$4,222.91	\$26,364.89	\$0.00	\$550.17	\$32,515.79	\$63,653.76
877	\$0.00	\$20.89	\$0.00	\$0.00	\$0.00	\$20.89
916	\$715.60	\$8,131.34	\$0.00	\$56.63	\$7,315.24	\$16,218.81
TOTAL	\$129,957.33	\$1,694,489.50	\$0.00	\$79,294.53	\$1,350,293.02	\$3,254,034.38

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- 2) ABSENCE OF PAYMENT FOR A SINGLE DUR CLAIM IS REFLECTED IN THE COST SAVINGS
- 3) THIS REPORT HAS BEEN UNDUPLICATED BY CLAIM AND EDIT
- 4) COST SAVINGS MAY VARY DUE TO THE ALLOWANCES FOR 100 DAYS SUPPLY, CHANGES IN DRUG THERAPY INVOLVING THE PRESCRIBING OF A DIFFERENT DRUG, AND CHANGES IN DRUG UTILIZATION

Edit 403/404 duration of use standard exceeded
 Edit 405 duplication of therapy
 Edit 535/535 recommended maximum daily dosage exceeded
 Edit 869/877
 and 916 drug-drug interaction

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October-03	403	\$2,172.97	\$55,142.30	\$0.00	\$622.09	\$122,371.91	\$180,309.27
	404	\$4,097.19	\$65,235.25	\$0.00	\$653.34	\$108,233.38	\$178,219.16
	405	\$38,941.30	\$350,346.71	\$0.00	\$8,138.53	\$262,761.26	\$660,187.80
	535	\$14,841.67	\$181,850.01	\$0.00	\$6,868.72	\$125,574.55	\$329,134.95
	537	\$105,733.88	\$1,383,123.17	\$0.00	\$148,335.08	\$578,799.74	\$2,215,991.87
	869	\$14,393.98	\$34,466.09	\$0.00	\$5,623.45	\$30,692.36	\$85,175.88
	877	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
	916	<u>\$958.68</u>	<u>\$10,994.81</u>	<u>\$0.00</u>	<u>\$1,939.40</u>	<u>\$7,549.14</u>	<u>\$21,442.03</u>
TOTAL		\$181,139.67	\$2,081,158.34	\$0.00	\$172,180.61	\$1,235,982.34	\$3,670,460.96

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JANUARY 2004							
	EDIT	GA	MCAID	CF	ADDP	PAAD	GRAND TOTAL
	403	\$3,303.71	\$48,198.69	\$0.00	\$301.32	\$124,539.43	\$176,343.15
	404	\$2,851.76	\$44,468.26	\$0.00	\$488.65	\$77,440.36	\$125,249.03
	405	\$22,964.60	\$241,795.26	\$0.00	\$3,252.03	\$196,301.35	\$464,313.24
	535	\$14,935.07	\$156,300.47	\$0.00	\$3,189.47	\$109,531.13	\$283,956.14
	537	\$87,409.24	\$1,153,564.17	\$0.00	\$46,836.84	\$464,165.86	\$1,751,976.11
	869	\$7,769.58	\$31,512.12	\$0.00	\$6,442.99	\$26,764.55	\$72,489.24
	877	\$0.00	\$20.44	\$0.00	\$0.00	\$0.00	\$20.44
	916	\$709.45	\$11,088	\$0.00	\$1,352.81	\$7,315.24	\$20,465.77
	TOTAL	\$139,943.41	\$1,686,947.68	\$0.00	\$61,864.11	\$1,006,057.92	\$2,894,813.12

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								APRIL 2004
	EDIT	GA	MCAID	CF	ADDP	PAAD	GRAND TOTAL	
	403	\$0.00	\$55,463.89	\$0.00	\$1,576.95	\$122,677.76	\$179,718.60	
	404	\$0.00	\$58,678.72	\$0.00	\$368.21	\$80,031.59	\$139,078.52	
	405	\$0.00	\$355,440.24	\$0.00	\$4,954.10	\$256,493.63	\$616,887.97	
	535	\$0.00	\$144,582.91	\$0.00	\$3,639.39	\$109,556.71	\$257,779.01	
	537	\$0.00	\$1,019,929.98	\$0.00	\$43,058.90	\$571,205.99	\$1,634,194.87	
	869	\$0.00	\$31,377.94	\$0.00	\$5,313.62	\$28,472.99	\$65,164.55	
	877	\$0.00	\$0.00	\$0.00	\$0.00	\$9.81	\$9.81	
	916	\$0.00	\$9,250	\$0.00	\$0.00	\$5,188.58	\$14,438.42	
TOTAL		\$0.00	\$1,674,723.52	\$0.00	\$58,911.17	\$1,173,637.06	\$2,907,271.75	

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