New Jersey Drug Utilization Review Board Annual Report

July 1, 2019 through June 30, 2020

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I. Acknowledgements

The Prospective Drug Utilization Review (PDUR) process for State Fiscal Year (SFY) 2020 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 Judith Barberio, A.P.N., C., Ph.D. Linda Gochfeld, M.D. Linda G. Gooen, Pharm.D., M.S., CCP, BCGP, FASCP Steven Matthew Marcus, M.D. Sandra Moore, Pharm.D. Eileen Moynihan, M.D. Kristine M. Olson, M.S., R.N., A.P.N.,C Jay R. Schafer, R.Ph.

In addition, the following State and DXC Technology professional staff supported the activities of the Drug Utilization Review Board:

Thomas Lind, MD, Medical Director, New Jersey Department of Human Services, Division of Medical Assistance and Health Services.

Zankhana Desai R.Ph. Chief, Pharmaceutical Services DHS Medicaid/PAAD/SG/ADDP programs

Elizabeth Bailey, PharmD, CCP Regional Pharmaceutical Consultant PAAD/Senior Gold Program/Division of Aging Services

Sam Emenike, Pharm.D., Clinical Specialist, DXC Technology.

Dalia Hanna, Pharm.D., PMP, Medical Exceptions Process Program Manager, DXC Technology.

Edward J. Vaccaro, R.Ph., Consultant Pharmacist, DXC Technology.

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 are required to provide an annual report, with additional copies provided 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 Drug Utilization Review (DUR) activities identified by the New Jersey Drug Utilization Review Board (NJDURB) for the period beginning July 1, 2019 and ending June 30, 2020.

Please 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 for the federal DUR report.

The NJDURB was scheduled to meet on a quarterly basis during State Fiscal Year (SFY) 2020, but because of the COVID-19 Pandemic, it did not meet in April 2020.

The Board reviewed and discussed drug utilization data for several different drug classes, as well as individual drugs of interest. Several prior authorization/clinical initiatives and outcomes were reviewed. The NJDURB spent \$6,365 in SFY 2020.

As part of the Prospective Drug Utilization Review (PDUR) process, a process that allows interventions by the State prior to medications being dispensed by pharmacies, recommendations made by the NJDURB are intended to prevent adverse drug events and the overutilization/underutilization of medications protecting the patient, and preventing fraud, waste and abuse. These interventions offer pharmacists additional information and the opportunity to consult with patients and prescribers. The PDUR program has clearly demonstrated its ability to influence, and in some cases dramatically change, prescribing patterns, ultimately encouraging appropriate drug utilization, improved health outcomes, and the avoidance of unnecessary drug costs.

An estimated **\$7,708,851** in fee-for-service (FFS) drug expenditures were cost avoided by the administration of a Medical Exception Process (MEP). The MEP is a prior authorization process based on clinical standards related to pharmaceutical care. The estimated cost savings is based on a review of drug utilization during the sixty-day period immediately following the denial of a pharmacy service due to a PDUR intervention. An estimated \$5,695,817 in drug expenditures were cost-avoided by Medicaid and an estimated \$2,013,034 were cost-avoided by pharmacy benefit programs administered by the New Jersey Department of Health. The MEP is tailored to meet the individual needs of each State-sponsored pharmacy benefit program.

The savings are a value-added benefit resulting from the PDUR process. The State creates PDUR standards for drug-drug interactions, duplication of drug therapies, and maximum daily doses among others to identify possible conflicts and to encourage appropriate prescribing and/or drug utilization.

The cost of administering the MEP through DXC Technology for the period of July 1, 2019 through June 30, 2020 was \$1,432,000.

III. Background

The NJDURB is responsible for reviewing and recommending drug utilization protocols for medications provided by, both the FFS and managed care NJ Family Care (NJFC) Programs, the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Program, the Senior Gold Prescription Discount (Senior Gold) Program, as well as the Aids Drug Distribution Program (ADDP).

Effective July 1, 2011, managed care organizations (MCOs) participating in NJFC became responsible for coverage and reimbursement for pharmacy benefits, with the exception of methadone prescribed for the treatment of substance use disorders. On July 1, 2014, DMAHS transitioned drug benefit responsibilities, including drugs covered by Medicaid Long-Term Services and Supports (MLTSS), from NJFC FFS to the NJFC managed care programs, with the exception of medications dispensed to certain long-term-care clients, State institutional clients, and beneficiaries transitioning from FFS to managed care.

Beginning July 1, 2019, DMAHS implemented a High-Cost Drugs Risk Corridor program for the non-dual eligible/non-Managed Long-Term Services and Supports (MLTSS) populations to mitigate the unpredictable catastrophic claim risks associated with a predefined list of high cost drugs. All Managed Care Organizations (MCOs) are required to participate in this Risk Corridor program. A risk corridor payment or recoupment amount is determined by DMAHS and paid as a lump sum by DMAHS or the MCO, respectively, based on the difference between the actual incurred costs and the predetermined benchmark for the MCO's risk corridor eligible claims. The NJDURB has been engaged in developing drug protocols for these high-cost drugs to ensure consistency when MCOs determine medical necessity.

Final details regarding the Morphine Milligram Equivalents (MMEs) protocols approved by the Department of Health and Human Services are being shared as part of this Summary. The State's MME protocols encourage prescribers of opioid medications to closely consider the addiction potential of opioid medications and to use MMEs as a useful guide when initially prescribing or re-assessing the clinical needs of State beneficiaries receiving pharmacy benefits. A MME is assigned to opioid medications to represent their relative potency compared to 30mg of morphine.

DMAHS, with the support of the NJDURB, established a MME daily dosage not to exceed 50 MMEs for an opioid naïve patient and a MME daily dosage not to exceed 120 MMEs for an opioid tolerant patient. Exclusions from the protocol include patients diagnosed with cancer or sickle cell anemia, as well as hospice patients and patients receiving palliative end of life care. The protocol also requires prior authorization for the concomitant use of opioids and benzodiazepines.

A concern of the NJDURB is access to prescribed medications during the State's Public Health Emergency (PHE) due to COVID-19. DMAHS made accommodations in the State's Point-of-Sale (POS) claims processing system for all State pharmacy benefit programs allowing the dispensing of a ninety (90) days' supply of maintenance medications, other than controlled dangerous substances, and early prescription refills.

In accordance with section 1927(g) of the SSA and 42 CFR part 456 subpart K (also referred to as the final managed care rule that became effective on July 1, 2017), the MCOs establish and maintain drug utilization review (DUR) programs that are consistent with the FFS DUR program satisfying minimum requirements for prospective and retrospective DUR, as described in Section 1927(g) of the Social Security Act, amended by the Omnibus Budget Reconciliation Act (OBRA) of 1990. To support the MCO DUR program, the DMAHS provides its expertise for developing drug protocols and assists the MCO in analyzing drug utilization.

DUR standards encourage proper drug utilization by ensuring compliance, minimizing potential fraud, waste, and abuse, and taking into consideration both the quality and cost of the pharmacy benefit. Prospective and retrospective DUR standards established by managed care organizations are consistent with standards established by the New Jersey Drug Utilization Review Board (DURB). These standards include therapeutic duplication, drug-drug interactions, maximum daily dosage and therapy duration. In addition, the Board works with the MCOs to develop measures to ensure consistency among DUR protocols used to prior authorize prescription drugs.

The recommendations of the Board pertaining to NJFC FFS and MCO utilization management, as well as pharmacy benefit programs administered by the Department of Health, were reviewed and approved by both the Commissioner of Health and the Commissioner of Human Services.

Critical to the FFS PDUR program is the State's Medical Exception Process (MEP). As mentioned earlier, the MEP is a prior authorization process which functions within the framework of DUR standards recommended by the NJDURB. The MEP is a clinically- based DUR process that does not attempt to influence drug product selection by prescribers. Instead, the MEP utilizes prior authorization as a tool to determine if medications are being prescribed properly and if prescribed medications are clinically appropriate and properly utilized, which also can result in cost savings.

The NJDURB is a nine member board consisting of practicing practitioners and pharmacists representing several major specialties. The Board routinely meets quarterly either virtually or in an open public forum. The Board promotes patient safety through the use of utilization management tools and systems that interface with the FFS claims processing system, conducts prospective screening of drug claims employing DUR standards, recommends DUR protocols for State approval, reviews MCO prior authorization protocols, retrospectively examines claims data to identify patterns of fraud, waste and abuse, and annually reports prescribing patterns and DUR cost savings to the Centers for Medicare and Medicaid Services (CMS).

The Board continues its responsibilities for DHS-administered FFS pharmacy benefit programs. These responsibilities include interventions that involve consultations with the patient and practitioner regarding drug utilization, including possible severe drug-drug interactions, maximum daily dosage having been exceeded, possible therapeutic duplication (the use of more than one drug in a specific drug class), and situations where the recommended duration of use for a drug has been exceeded.

The recommendations of the Board became more relevant with the adoption of the federal managed care rule. The rule led to enhanced collaboration with managed care organizations to address DUR concerns. The rule also led to more consistent utilization management strategies across managed care plans. The rule further emphasized the importance of understanding clinical criteria used by managed care organizations to prior authorize prescription drugs. The Board continues to recommend PDUR edits for MCO implementation to ensure access while minimizing over-expenditures for medically necessary drugs, developing educational strategies designed to influence drug product selection for the management of disease, and recommending utilization protocols for high-cost drugs.

Updated information regarding the Board members, meeting schedule, DURB educational newsletters and annual reports may be found on the Board's official website at: www.nj.gov/humanservices/dmahs/boards/durb/.

FFS Retrospective Drug Utilization Review (RDUR) is conducted on drug claim histories after medications have been dispensed. The process is useful to the State and/or the prescriber to evaluate prescribing patterns and recommend real-time claim interventions. Based on this information, for continuous quality assurance, the Board performs educational outreach activities to encourage clinically-appropriate drug utilization.

IV. Actions/Recommendations

A. Summary of Board Activities in SFY 2020:

Protocol for Hereditary Angioedema (HAE) Products:

The Board recommended the use of seven products (Cinryze[®], Haegarda[®], Takhzyro[®], Firazyr[®], Kalbitor[®], Berinert[®] and Ruconest[®]) for the prophylactic and acute treatment of hereditary angioedema. Prescribers are encouraged to prescribe these products in consultation with an allergist/immunologist or physician that specializes in the treatment of HAE, discontinue other medications known to cause HAE and, provide patients' weight for drugs that has weight-based dosing.

Protocol for Urea Cycle Disorder Products:

The Board recommended the use of three products (Buphenyl[®], Ravicti[®], and Carbaglu[®]) for the treatment of urea cycle disorders. Criteria for approval includes documentation of enzymatic, biochemical, genetic testing, consultation with a physician experienced in treating metabolic disorders and providing documentation of weight for drugs requiring weight-based dosing.

Protocol for Wilson's disease/Cystinuria/Rheumatoid arthritis Products:

The Board recommended the use of two products (Cuprimine[®] and Syprine[®]) for use in the treatment of Wilson's disease, cystinuria, and severe rheumatoid arthritis. One of the recommendations is to use these products when there is intolerance or contraindication to the use of Depen[®], another chelating agent.

Protocol for Zolgensma[®] (onasemnogene abeparvovec-xioi):

The Board recommended **Zolgensma**[®], a product approved by the FDA for the treatment of spinal muscular atrophy (SMA) in patients less than 2 years old. Some of the requirements in the protocol include that the medication is prescribed by a pediatric neurologist or pediatric geneticist with expertise in the treatment of SMA or in consultation with one, the patient's liver is assessed prior to administration of **Zolgensma**[®], and the patient does not have advanced SMA for which efficacy studies have not been done.

Protocol for Hereditary Transthyretin-Mediated Amyloidosis (ATTR) Products:

The Board recommended the use of the products Onpattro[®] and Tegsedi[®] for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis or ATTR. They also recommended Vyndaqel[®] and Vyndamax[®] for the treatment of cardiomyopathy of wild type ATTR. Prescribers are encouraged to prescribe these products in consultation with a neurologist, cardiologist, or a specialist in the treatment of ATTR.

Protocol for Elaprase® (idursulfase):

The Board recommended the use of Elaprase[®] for the treatment of Hunter syndrome. This product has been shown to improve walking capacity in patients 5 years and older. Prescribers are encouraged to prescribe this product in consultation with a specialist in inherited metabolic disorders and to provide weight information when needed.

Protocol for Gaucher disease Products:

The Board recommended the use of three products (Cerezyme[®], Elelyso[®] and Vipriv[®]) as enzyme replacement therapy for the treatment of Gaucher disease. They also recommended two other products, Cerdelga[®] and Zavesca[®] for use as substrate replacement therapy for the same disease. Due to the unique nature of this disease, prescribers are encouraged to write for these products in consultation with a hematologist, neurologist or geneticist.

Protocol for Cablivi[®] (caplacizumab-yhdp):

The Board recommended Cablivi[®], a product approved by the FDA for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura or aTTP. It is recommended to be prescribed by or in consultation with a hematologist.

Protocol for Fabry Disease Products:

The Board recommended the use of the products Fabrazyme[®] and Galafold[®] for the treatment of patients with Fabry disease, a rare genetic disorder.

Protocol for Lambert-Eaton Myasthenic Syndrome Products:

The Board recommended the use of Firdapse[®] and Ruzurgi[®] for the treatment of patients with Lambert-Eaton Myasthenic Syndrome (LEMS), a rare autoimmune disorder of the neuromuscular junction.

Protocol for Strensiq® (asfotase):

The Board recommended the use of Strensiq for the treatment of hypophosphatasia (HPP), a rare inherited disorder characterized by the abnormal development of bones and teeth.

Update on Nicotine Replacement Therapy:

The Board reviewed reports on the utilization of nicotine replacement therapy (NRT) products for SFY 2017, 2018 and 2019.

- Overall utilization showed steady increases. Claims grew by 28% in 2018 and by 27% in 2019, when compared to previous years. Payments also increased, by 6% and 123% respectively, driven mostly by the increased cost of products like varenicline or Chantix[®].
- There was a slight decrease in the utilization of bupropion/Zyban[®]

The board recommendations are subject to approvals by both the Commissioner of Health and the Commissioner of Human Services.

B. Assessment of Costs

Drug Utilization

The MEP approved 31,102 claims with service dates on or after July 1, 2019 and prior to June 30, 2020. The top five drug classes most often prior authorized include proton-pump inhibitors, pain medications, gastrointestinal (laxatives), antiretroviral drugs, and adrenergics. (see table A below) The top five drug classes most often denied include proton-pump inhibitors, antiemetics/antivertigo medications, pain

medications, miscellaneous pain medications (patches), and allergy medications. Total denied claims in this category were 4,807 (see table B below). Other reasons for denying prior authorization requests include multiple prescribers, dosage and duration of therapy above established DUR standards, clinical criteria not met, inappropriate diagnosis, and other drugs causing drug-drug conflicts.

Table A

		Estimated Payment
Therapeutic Category (STC)	Claim Count	Amount
Proton-pump inhibitors (D4J)	2,564	\$ 130,277
Pain medications (H3A)	1,749	\$ 169,774
GI medications (laxatives) (D6S)	1,666	\$ 42,648
Antiretrovirals (W5X)	1,621	\$ 6,327,567
Adrenergics (J5B)	1,409	\$ 154,238

Top 5 Approved Drug Categories from Total of 31,102

Table B

Top 5 Denied Drug Categories from Total of 4,807

Therapeutic Category (STC)	Claim Count	Estimated Cost-savings					
Proton-pump inhibitors (D4J)	884	\$ 25,318					
Antiemetics/antivertigo (H6J)	255	\$ 4,351					
Pain medications (H3A)	151	\$ 18,111					
Miscellaneous pain meds (Q5E)	135	\$ 5,264					
Allergy medications (Z2Q)	132	\$ 901					

The PDUR program offers the State resources needed to efficiently monitor drug utilization. The program incorporates different sets of standards, including standards for uniquely identifying a drug or groups of drugs minimum allowable age, maximum allowable age, or approved dosing based on metric quantity and days supply, and allows for the immediate denial of inappropriate claims, which can be overridden, if necessary, with a prior authorization or a one-time 30-day supply of drug to be dispensed, allowing for interventions with the prescriber to take place. The PDUR program aims to prevent drug-related problems and inappropriate drug utilization while protecting the patient, preventing fraud, waste and abuse.

C. Recommendations

With over 95% of NJFC beneficiaries now enrolled in managed care, the Division will continue to work closely with its managed care partners to develop DUR standards that accommodate the needs of those members enrolled in managed care. DUR standards recommended by the DURB and approved by both the Department of Health and Department of Human Services continue to apply to the remaining NJFC FFS

populations. The role of the NJDURB will continue to ensure that medications provided by the State pharmacy benefit programs or by managed care organizations are prescribed to meet the medical necessity needs of all NJFC members and are utilized appropriately.

The State will continue to work with its managed care partners to optimize the quality of encounter claims.

V. Acronyms

ADDP	AIDS Drug Distribution Program
DMAHS	Division of Medical Assistance and Health Services
DUR	Drug Utilization Review
DURB	Drug Utilization Review Board
FFS	Fee For Service
HIV	Human Immunodeficiency Virus
МСО	Managed Care Organizations
MEP	Medical Exception Process
NJDURB	New Jersey Drug Utilization Review Board
OTC	Over-the-Counter
OTC PA	Over-the-Counter Prior Authorization
РА	Prior Authorization
PA PAAD	Prior Authorization Pharmaceutical Assistance to the Aged and Disabled
PA PAAD PDUR	Prior Authorization Pharmaceutical Assistance to the Aged and Disabled Prospective Drug Utilization Review
PA PAAD PDUR POS	Prior Authorization Pharmaceutical Assistance to the Aged and Disabled Prospective Drug Utilization Review Point-of-Sale
PA PAAD PDUR POS PPI	Prior Authorization Pharmaceutical Assistance to the Aged and Disabled Prospective Drug Utilization Review Point-of-Sale Proton Pump Inhibitor

VI. Appendices

Appendix A

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

§ 30:4D-17.6. 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 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.

"Criterion" 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.

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 recommendation to the board in regard thereto.

The Board shall consist of 15 members, including the Commissioners of Human Services and Health or their designees, who shall serve as nonvoting ex officio members, and 13 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.

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, 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.

- 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 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 identities 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 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.
- 1. 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, 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 requirements of P.L.1968, c. 410 (C.52:14B-1 et seq.).

HISTORY: L. 1998, c. 41, § 4.

Appendix B

DXC Technology Cost Avoidance Reports

Claims represented in this report were not resubmitted for future payment and are considered an avoidance of inappropriate expenditures

Edit	ADDP		SR. GOLD		FFS		PAAD		GRAND TOTAL	
403 & 404 - Duration Exceeded	\$	2,357.51	\$	589.22	\$	8,527.00	\$	1,076.43	\$	12,550.16
405 - Possible Therapeutic Class Duplication	\$	8,506.37	\$	693.31	\$	106,084.77	\$	2,925.90	\$	118,210.35
407 - Possible Duplication of HIV Therapy	\$	1,254.55	Ŧ		\$	83,208.24	\$	1,319.63	\$	85,782.42
417 - Generic Substitution Required	\$	6,378.22	\$	6,502.45	\$	432,564.56	\$	56,256.07	\$	501,701.30
449- Inappropriate Narcotic Use		· · ·			\$	11,177.10			\$	11,177.10
537-NJDURB Daily Drug Quantity Exceeded	\$	2,952.79	\$	75.16	\$	70,730.64	\$	2,676.63	\$	76,435.22
869-Possible Severe Drug-Drug Interaction	\$	141.33	\$	565.37	\$	570.97	\$	147.89	\$	1,425.56
916- Severe Drug-Drug Interaction	\$	5,719.02	\$	10,680.62	\$	104,917.58	\$	114,311.63	\$	235,628.85
2007- Prior Authorization Required	\$	175,607.47	\$	11,689.64	\$	1,780,172.25	\$	89,273.15	\$	2,056,742.51
2038- First Fill of HIV or High Dose Narcotic	\$	1,461,445.65	\$	6,414.32	\$	2,061,413.94	\$	28,444.13	\$	3,557,718.04
2046-Prescription Restricted	\$	1,380.06			\$	784.80	\$	304.73	\$	2,469.59
2047- PA required: Prescriber/Drug Restricted	\$	12,596.05			\$	2,438.82			\$	15,034.87
2085-Maximum Allowable Cost (MAC) Override	\$	548.46	\$	33.38	\$	10,288.52	\$	166.46	\$	11,036.82
2100-Daily Dose Standard Exceeded					\$	1,017,694.43			\$	1,017,694.43
2111- Cough and cold symptoms					\$	5,244.07			\$	5,244.07
Grand Total	\$	1,678,887.48	\$	37,243.47	\$	5,695,817.69	\$	296,902.65	\$	7,708,851.29

July 2019 - June 2020

Note: Savings reported here does not include manufacturer rebates

- Cost savings identified in this report reflects costs for DUR claims denied by a DUR edit for which no future paid claims were identified during the 60-day period following the date of denial
- This report is unduplicated by claim and edit