New Jersey Drug Utilization Review Board
Annual Report
July 1, 2021 through June 30, 2022

Table of Contents

New Jersey Drug Utilization Review Board
Annual Report
July 1, 2021 through June 30, 2022

I. Acknowledgements

The Prospective Drug Utilization Review (PDUR) process for State Fiscal Year (SFY) 2022 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.

Steven Matthew Marcus, M.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 Gainwell Technologies 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, BS Pharm., Pharm.D., Clinical Specialist, Gainwell Technologies

Ruchi Banker, Pharm.D., Clinical Pharmacist, MEP, Gainwell Technologies

Edward J. Vaccaro, R.Ph., Consultant Pharmacist, Gainwell Technologies

II. Executive Summary

In accordance with Public Law 1998, chapter 41, the State of New Jersey Department of Human Services, in consultation with the Department of Health, is 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, 2021, and ending June 30, 2022.

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 met on a quarterly basis in SFY 2022 and 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 $6,876 in SFY 2022.

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 patients, 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 **$6,725,218** 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 $2,447,121 in drug expenditures were cost-avoided by Medicaid and an estimated $4,278,097 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 Gainwell Technologies for the period of July 1, 2021, through June 30, 2022 was $1,489,853.

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). Since April 2020 and continuing in SFY 22, the State has held quarterly virtual public meetings of the New Jersey Drug Utilization Review Board due to COVID 19 restrictions. Routine activities of the Board have been conducted successfully.

The NJDURB is an eight (8) member board consisting of practicing practitioners and pharmacists representing several major specialties. 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) .

Board responsibilities include interventions that involve consultations with the patient and practitioner regarding drug utilization, including possible 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 in which the recommended duration of use for a drug has been exceeded. Adoption of federal legislation also enhances collaboration with managed care organizations to address DUR concerns, resulting in more consistent utilization management strategies across managed care plans and emphasizing the importance of understanding clinical criteria used by managed care organizations to prior authorize prescription drugs. The Board recommends PDUR standards for both FFS and MCOs to ensure proper drug utilization, patient safety and to work to prevent fraud, waste, and abuse. The Board also develops educational strategies designed to influence product selection for the management of disease and recommends utilization protocols for high-risk drugs.

Managed care organizations (MCOs) participating in NJFC are responsible for coverage and reimbursement of 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 members transitioning from FFS to managed care.

During the State's Public Health Emergency (PHE) due to COVID-19, DMAHS made accommodations allowing for the dispensing of a ninety (90) days supply of maintenance medications, other than controlled dangerous substances, and early prescription refills.

To broaden access to SARS-CoV-2 testing under the American Rescue Plan Act of 2021, the Division expanded Medicaid/NJ FamilyCare coverage of at home SARSCoV-2 testing kits. Two (2) Over the Counter (OTC) tests were covered per pharmacy claim, each test kit containing two tests. In addition, up to eight (8) OTC at-home tests per month could be requested by a member at the pharmacy, without a

prescription. Additional OTC at-home tests, if medically necessary, could be provided with a prescription from a prescriber enrolled with Medicaid/NJFC.

To better respond to the needs of individuals requiring Medication-Assisted Treatment (MAT), the Division eliminated prior authorization requirements for MAT medications. Prior authorization was identified by the SUD provider community as a barrier which limited access to MAT medications, discouraging their important use for the treatment of addiction.

The Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions which allowed for the partial filling of Schedule II drugs. Related to this requirement was the reporting of the quantity of medication prescribed. The Centers for Medicare and Medicaid (CMS) Final Rule (CMS-0055-F) also clarified the reporting of the medication quantity necessitating the need for Point-of-Sale (POS) changes. The State expanded the capture of this claim information for all prescription drugs and further enhanced claim editing to prevent the processing of expired prescriptions (i.e. a 30-day limit for controlled drugs and a 365-day limit for non-controlled drugs).

The New Jersey Drug Utilization Review Board (NJDURB) completed a review of Stromectol® (ivermectin) drug utilization. The intent was to evaluate the frequency with which ivermectin was being prescribed as an off-label treatment for the SARS-CoV-2 infection. The Board's review demonstrated a dramatic increase in the off-label use of ivermectin. Although the FDA approved ivermectin for the treatment of some parasitic worms, head lice and skin conditions, the Centers for Disease Control and Prevention (CDC), the FDA and other professional organizations including, but not limited to, the American Medical Association (AMA) and the American Society of Health-System Pharmacists (ASHP), have expressed serious concerns regarding adverse clinical reactions to the unapproved use of this medication for the treatment of the SARS-CoV-2 infection. The NJDURB recommended an exclusion protocol for ivermectin which was communicated to pharmacies in the NJDURB Newsletter Volume 32, No. 11.

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/.

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), MCOs are required to establish and maintain drug utilization review programs that are consistent with the FFS DUR program satisfying minimum requirements for PDUR and Retrospective Drug Utilization Review (RDUR), as described in Section 1927(g) of the Social Security Act, amended by the Omnibus Budget Reconciliation Act (OBRA) of 1990. To support MCO DUR programs, DMAHS provides its expertise for developing drug protocols and assists MCOs in analyzing drug utilization.

DUR standards encourage proper drug utilization by ensuring maximum compliance, minimizing potential fraud, waste, and abuse, and taking into consideration both the quality and cost of a pharmacy benefit. Managed care PDUR standards, those applied prior to payments, and RDUR standards, those applied post payment, are consistent with standards recommended by the NJDURB and approved by both the Commissioner of Health and the Commissioner of Human Services. These standards include therapeutic

duplication, drug-drug interactions, maximum daily dosage, and therapy duration. The Board works with the MCOs to develop measures to ensure consistency among DUR protocols used to prior authorize prescription drugs.

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 clinicallybased DUR process that does not attempt to influence 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 FFS 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 2022:

Addendum to Direct Acting Antivirals (DAAs) for HCV protocol:
The Board recommended updating this protocol to remove restrictions on prescribers thereby increasing access to treatment.

Addendum to Dupixent® (dupilumab) protocol:
The Board recommended updating this protocol to change the eligibility age from 12 to 6 years of age per new guidelines. The requirement to provide "dates of trial" for step therapy drugs was also removed.

Addendum to Vyondys® (golodirsen) protocol:
The Board recommended updating this protocol to include a new drug in this class, Viltepso® (Viltolarsen).

Addendum to Epidiolex® (cannabidiol) protocol:
The Board recommended updating this protocol to include a new indication for "Tuberous Sclerosis Complex" or TSC. The eligibility age was also changed from 2 to 1 year of age.

Addendum to Cablivi® (caplacizumab) protocol:
The Board recommended updating this protocol to include a new indication for "Thrombotic Microangiopathy" or TMA.

Protocol for Cabenuva® (cabotegravir/rilpivirine) injectable:
The Board recommended the use of Cabenuva, a long-acting injection which was recently approved for the treatment of HIV-1 infection. One-month lead-in therapy with oral medications will be required.

Protocol for biologic response modifier products used in plaque psoriasis:
The Board recommended 12 products for the treatment of moderate to severe plaque psoriasis. There is a requirement for a trial of conventional therapies unless contraindicated or not tolerated.

Protocol for Lumizyme® (alglucosidase alfa):
The Board recommended the use of Lumizyme as an enzyme replacement therapy for the treatment of Pompe disease. The protocol requires confirmation of infantile-onset and late-onset disease among other requirements.

Protocol for Myalept® (metreleptin):
The Board recommended the use of Myalept as an adjunct to diet as replacement therapy for patients with congenital or acquired generalized lipodystrophy. The protocol lists exclusions where Myalept is ineffective (partial lipodystrophy) and others where is not recommended per product guidelines.

Addendum for Duchenne Muscular Dystrophy (DMD) drugs protocol:
The Board recommended updating this protocol to add a recently FDA-approved product, Amondys 45 (casimersen), and to change the name from "Vyondys 53 protocol" to "Duchenne muscular dystrophy products"

Protocol for Aduhelm® (aducanumab):
The Board recommended the use of Aduhelm, a product which was recently approved by the FDA for the treatment of early-stage Alzheimer's disease.

Protocol for Bronchitol® (mannitol):
The Board recommended the use of Bronchitol as add-on treatment for cystic fibrosis.

Protocol for Imcivree® (setmelanotide):
The Board recommended the use of Imcivree for the treatment of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. The protocol requires confirmation of this type of obesity prior to treatment.

Exclusion Protocol for Stromectol® (ivermectin):
The Board recommended that only the quantity of ivermectin required for the treatment of FDA-approved diseases will be authorized. The Board also recommended a "dear prescriber letter" to ensure that prescribers are aware of these limits and the reason for recommending this limit.

Addendum to protein convertase subtilisin/kexin type 9 (PCSK9) inhibitors protocol:
The Board recommended updating this protocol to accommodate recently FDA-approved indications for both products, Praluent, and Repatha.

Addendum to Spravato® (esketamine) protocol:
The Board recommended updating this protocol to add a recently FDA-approved indication for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Protocol for Gamifant® (emapalumab-lzsg):
The Board recommended the use of Gamifant for the treatment of primary hemophagocytic lymphohistiocytosis or HLH.

Protocol for Nitisinone products (Nityr® and Orfadin®):
The Board recommended Nityr and Orfadin for the treatment of tyrosinemia type 1.

Protocol for Lucemyra® (lofexidine):
The Board recommended the use of Lucemyra in medicallysupervised opioid withdrawal therapy.

Protocol for Paxlovid® (nirmatrelvir):
The Board recommended the use of Paxlovid for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients aged >12 years and weight > 40 kg under the FDA's emergency use authorization (EUA) guidelines.

Protocol for molnupiravir:
The Board recommended the use of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults under the FDA's EUA guidelines.

Protocol for Hetlioz® (tasimelteon):
The Board recommended the use of Heltioz for the treatment of non-24-hour sleep-wake disorder or nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

Protocol for cysteamine products (Cystagon® and Procysbi®):
The Board recommended the use of Cystagon and Procysbi for the treatment of nephropathic cystinosis.

Protocol for Revcovi® (elapegademase-lvlr):
The Board recommended the use of Revcovi for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

Protocol for Luxturna® (voretigene neparvovec-rzyl):
The Board recommended the use of Luxturna for the treatment of retinal dystrophy.

Dear Prescriber Letter on ivermectin:
The Board recommended a letter to educate the prescribers on the status of ivermectin as it relates to the prophylaxis and treatment of COVID-19 infection.

Managed Care Organization (MCO) Partners:
The NJDURB continues to work with the State's MCO partners to ensure that prior authorizations are streamlined for efficient and timely delivery of medications to New Jersey patient population.

B. Assessment of Costs

Drug Utilization

The MEP approved 18,024 claims with service dates on or after July 1, 2021, and prior to July 1, 2022. The top five categories of drugs most often prior authorized and approved are listed in table A below. Total denied claims were 2,459. The top five categories of drugs most often denied are listed in table B below.

Table A
Top 5 Approved Drug Categories are listed below

Therapeutic Category (STC)	Claim Count	Estimated Payment Amount
Laxatives and Cathartics (D6S)	1,483	$ 87,206
ARV-Nucleoside, Nucleotide RTI, Integrase Inhibitors (W5X)	1,232	$ 7,061,260
Proton-Pump Inhibitors (D4J)	1,188	$ 44,726
Opioid Analgesics (H3A)	954	$ 81,485
Opioid Withdrawal Therapy Agents, Opioid-Type (H3W)	830	$ 183,665

Table B
Top 5 denied drug categories are listed below.

Table B: Top 5 Denied Drug Categories **Therapeutic Category (STC)**	**Claim Count**	**Estimated Cost-savings**
Proton-Pump Inhibitors (D4J)	561	$ 9,185
Antiemetic/Antivertigo Agents (H6J)	106	$ 2,448
Topical Anti-Inflammatory, NSAIDs (Q5E)	98	$ 2,435
Lipotropics (M4E)	93	$ 11,514
Antiretroviral-Integrase Inhibitor and NNRTI Comb. (W0I)	62	$ 344,576

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. These denials 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 and 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 NJDURB and approved by the Commissioner of Department of Health and the Commissioner of the Department of Human Services continue to apply to the remaining NJFC FFS populations. The role of the NJDURB is to continue to ensure that medications provided by the State pharmacy benefit programs or managed care organizations are prescribed to meet the medical 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
MEP	Medical Exception Process
NJDURB	New Jersey Drug Utilization Review Board
OTC	Over-the-Counter
PA	Prior Authorization
PAAD	Pharmaceutical Assistance to the Aged and Disabled
PDUR	Prospective Drug Utilization Review
POS	Point-of-Sale
PPI	Proton Pump Inhibitor
RDUR	Retrospective Drug Utilization Review
SFY	State Fiscal Year
STC	Specific Therapeutic drug Class

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 (PDUR)" 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 (RDUR)" 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 17 members, including the Commissioner of Human Services and the Commissioner of Health 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 both the Commissioner of Health and the Commissioner of Human 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 RDUR and PDUR 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 the Commissioner of Human 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 RDUR and PDUR. RDUR 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. PDUR 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.

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, 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, 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

Gainwell Technologies Cost Avoidance Report

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

JULY 2021 - JUNE 2022					
EDIT	**ADDP**	**SR. GOLD**	**FFS**	**PAAD**	**GRAND TOTAL**
403 & 404 - Duration Exceeded	$ 514	$ 218	$ 7,953	$ 2,546	$ 11,231
405 - Possible Therapeutic Class Duplication	$ 161,814	$ 859	$ 45,854	$ 6,540	$ 215,068
407 - Possible Duplication of HIV Therapy	$ 275		$ 28,825	$ 3,977	$ 33,077
417 - Generic Substitution Required	$ 48,650	$ 564	$ 89,883	$ 27,026	$ 166,123
449- Inappropriate Narcotic Use			$ 1,189		$ 1,189
537-NJDURB Daily Drug Quantity Exceeded	$ 1,309	$ 89	$ 26,525	$ 3,512	$ 31,436
869-Possible Severe Drug-Drug Interaction	$ 86	$ 218	$ 857	$ 1,647	$ 2,808
916- Severe Drug-Drug Interaction	$ 33,062	$ 4,789	$ 46,223	$ 93,744	$ 177,819
2007- Prior Authorization Required	$ 419,012	$ 10,614	$ 556,965	$ 88,520	$ 1,075,111
2038- First Fill of HIV or High Dose Narcotic	$ 3,251,013	$ 2,176	$ 885,198	$ 36,928	$ 4,175,315
2046-Prescription Restricted			$ 534	$ 422	$ 955
2047- PA required: Prescriber/Drug Restricted	$ 76,748		$ 2,721	$ 15	$ 79,484
2085-Maximum Allowable Cost (MAC) Override	$ 698		$ 5,553	$ 511	$ 6,762
2100-Daily Dose Standard Exceeded			$ 746,472		$ 746,472
2111- Cough and cold symptoms			$ 2,370		$ 2,370
GRAND TOTAL	**$ 3,993,181**	**$ 19,527**	**$ 2,447,121**	**$ 265,390**	**$ 6,725,218**

Notes:

- Savings reported here do not include any manufacturer rebates
- 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.