New Jersey Drug Utilization Review Board
Annual Report
July 1, 2020 through June 30, 2021

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I. Acknowledgements

The Prospective Drug Utilization Review (PDUR) process for State Fiscal Year (SFY) 2021 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.

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

*Effective February 5, 2021, Gainwell Technologies acquired DXC Technology and is the current fiscal agent for the State of New Jersey.

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 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, 2020 and ending June 30, 2021.

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 2021, 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 $6,713 in SFY 2021.

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 **$8,221,897** 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 $3,363,099 in drug expenditures were cost-avoided by Medicaid and an estimated $4,858,797 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, 2020 through June 30, 2021 was $1,460,640.

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).

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.

DMAHS continues to implement a High-Cost Drug Risk Corridor Program for the non-dual eligible (members without Medicare coverage) and non-MLTSS populations to mitigate unpredictable catastrophic costs for MCO coverage of a predefined list of high-cost drugs. All MCOs participate in this Risk Corridor Program. A risk corridor lump sum payment is made by DMAHS, or an amount of MCO payments are recouped by DMAHS, based on differences between actual incurred costs and predetermined benchmark costs for risk corridor drugs provided by the MCO. NJDURB recommends drug protocols for high-cost corridor drugs to ensure consistency with regards to coverage decisions made by MCOs which are based on medical necessity.

Morphine Milligram Equivalent (MME) protocols approved by the Departments of Health and Department of Human Services encourage prescribers of opioid medications to closely consider the addiction potential of opioid medications and to use MME values as a useful guide when initially prescribing or re-assessing the clinical needs of members receiving pharmacy benefits. MMEs are assigned to opioid medications to represent their relative potency compared to 30mg of morphine. DMAHS, with the support of the NJDURB, established an MME daily dosage value not to exceed 50 MMEs for an opioid naïve patient and an MME daily dosage value not to exceed 90 MMEs, which is in line with CMS/CDC guidelines, 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.

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.

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 assist 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. As is similar for high-risk drugs, 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 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 an eight (8) 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. 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 continues to recommend PDUR standards for both FFS and MCOs to ensure access while minimizing over-expenditures for medically necessary drugs, develop educational strategies designed to influence drug product selection for the management of disease, and recommend utilization protocols for high-risk 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 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 2021:

Addendum to Dupixent® (dupilumab):
The Board recommended changing the eligibility age for Dupixent® from 18 years old to 12 years old per new treatment guidelines. Dupixent® is indicated for the treatment of moderate-to-severe atopic dermatitis.

Addendum to Emflaza® (deflazacort):
The Board recommended changing the eligibility age for Emflaza® from ≥ 5 years old to ≥ 2 years old per new treatment guidelines. They also recommended reducing the trial period with prednisone from 6 months to 3 months allowing more flexibility to prescribers. Emflaza® is indicated for the treatment of Duchenne muscular dystrophy (DMD).

Addendum to protein convertase subtilisin/kexin type 9 (PCSK9) inhibitor products:
The Board recommended expanding the indications for use of these products (Praluent® and Repatha®) to include prophylaxis for myocardial infarction and stroke, and to promote coronary revascularization in adults with established cardiovascular disease per new treatment guidelines.
The drugs in this category are also indicated (a) as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins), for treatment of adults with primary hyperlipidemia, including heterozygous familial hyperlipidemia (HeFH), to reduce LDL-C, and (b) as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

Varubi® (rolapitant):
The Board recommended the use of Varubi® in combination with other antiemetic agents for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.

Vyondys 53® (golodirsen):
The Board recommended the use of Vyondys 53® for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

Protocol for Cryopyrin-associated periodic syndromes (CAPS) products:
The Board recommended the use of Arcalyst® (rilonacept), Ilaris® (canakinumab), and Kineret® (anakinra) for the treatment of Cryopyrin-associated periodic syndromes. This includes familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and neonatal-onset multisystem inflammatory disorder (NOMID), also known as chronic infantile neurologic cutaneous and articular (CINCA) syndrome.

Spravato® (esketamine):
The Board recommended the use of Spravato® in conjunction with an oral antidepressant for the treatment of treatment-resistant depression (TRD).

Addendum to Calcitonin Gene-Related Peptide (CGRP) antagonist products:
The Board recommended two updates to the original protocol approved in April 2019:

a. Addition of a newly approved product in this class, Vyepti®.
b. Modification of the criteria for initiating treatment with this class of products.

Protocol for Vimizim® (elosulfase alfa):
The Board recommended the use of Vimizim® for the treatment of Mucopolysaccharidosis IVA or Morquio A syndrome. The protocol requires that the medication is prescribed by or in consultation with an endocrinologist, geneticist, metabolic disorders specialist, or an expert in the disease state. It also includes a black box warning for possible life-threatening anaphylactic reactions.

Protocol for Naglazyme® (galsulfase):
The Board recommended the use of Naglazyme® for the treatment of Mucopolysaccharidosis VI or Maroteaux-Lamy syndrome. The protocol requires that the medication is prescribed by or in consultation with an endocrinologist, geneticist, metabolic disorders specialist, or an expert in the disease state.

Protocol for Mepsevii® (vestronidase alfa-vjbk):
The Board recommended the use of Mepsevii® for the treatment of Mucopolysaccharidosis VII or Sly syndrome. The protocol requires that the medication is prescribed by or in consultation with an endocrinologist, geneticist, metabolic disorders specialist, or an expert in the disease state. It also includes a black box warning for possible anaphylactic reactions.

Addendum to Opioid Protocol:
To be consistent with the CDC and CMS guidelines, the Board recommended an addendum to the opioid protocol previously approved in October 2018. One of the changes was to reduce the maximum daily morphine milligram equivalent (MME) dose from 120 MME to 90 MME for opioid tolerant patients. The other recommendation was to emphasize the co-prescribing of naloxone, an opioid antagonist, under some circumstances.

Protocol for Daraprim® (pyrimethamine):
The Board recommended the use of Daraprim® for the treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis. The protocol requires that the medication is prescribed by or in consultation with an infectious disease or HIV specialist.

Protocol for Increlex® (mecasermin):
The Board recommended the use of Increlex® for the treatment of patients diagnosed with growth hormone (GH) gene deletion, with neutralizing antibodies to GH, **or** severe primary insulin-like growth factor-1 deficiency. The protocol requires that the medication is prescribed by or in consultation with an endocrinologist.

Protocol for Exclusion for Victoza® (liraglutide):
The Board recommended the exclusion of doses greater than 1.8mg per day and use for weight loss for this product as recommended by the manufacturer. It will be approved for all FDA listed indications.

Protocol for Korlym® (mifepristone):
The Board recommended the use of Korlym® for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. The protocol requires the prescriber consider first line-recommended treatment of surgical resection when not contraindicated.

Protocol for Juxtapid® (lomitapide):
The Board recommended the use of Juxtapid® as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). One of the protocol criterion is to avoid concomitant use with PCSK-9 inhibitors. The protocol also helps to ensure that Juxtapid® is not used in patients with contraindications such as pregnancy, active liver disease.

Protocol for Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) products:
The Board recommended the use of Kalydeco®, Orkambi®, Symdeko® and Trikafta® because they currently present an important advance in the management of cystic fibrosis (CF). The protocol provides guidelines for confirmation of diagnosis, appropriate prescribing, and monitoring of patients prior to initiation of and during treatment.

B. Assessment of Costs

Drug Utilization

The MEP approved 23,486 claims with service dates on or after July 1, 2020 and prior to June 30, 2021. The top five categories of drugs most often prior authorized include proton-pump inhibitors, gastrointestinal (laxatives), antiretroviral drugs, pain medications, and adrenergics. (see table A below). The top five categories of drugs most often denied included proton-pump inhibitors, antiemetics/antivertigo medications, miscellaneous pain medications (patches), lipotropics, and miotic/intraoptic pressure reduction medications.

Table A
Top 5 Approved Drug Categories

Therapeutic Category (STC)	Claim Count	Estimated Payment Amount
Proton-pump inhibitors (D4J)	1,846	$ 65,304
GI medications (laxatives) [D6S]	1,580	$ 60,747
Biktarvy 50-200-25mg tab (W5X)	1,378	$ 7,673,172
Pain medications (H3A)	1,244	$ 126,923
Triumeq 600-50-300mg tab (W5Z)	1,002	$ 8,031,065

Total denied claims were 1,632. Top 5 denied drug categories are listed in Table B.

Table B: Top 5 Denied Drug Categories **Therapeutic Category (STC)**	**Claim Count**	**Estimated Cost-savings**
Proton-pump inhibitors (D4J)	496	$ 13,524
Antiemetics/antivertigo (H6J)	123	$ 2,838
Topical anti-inflamma, NSAIDs (Q5E)	96	$ 13,234
Lipotropics (M4E)	51	$ 6,782
Miotics/other intrao. pres. reduc (Q6G)	51	$ 6,075

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, 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 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
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 Reports

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

July 2020 - June 2021					
Edit	**ADDP**	**SR. GOLD**	**FFS**	**PAAD**	**GRAND TOTAL**
403 & 404 - Duration Exceeded	$ 927.10	$ 803.25	$ 13,358.50	$ 2,514.50	$ 17,603.35
405 - Possible Therapeutic Class Duplication	$ 25,187.65	$ 688.18	$ 111,640.30	$ 21,775.23	$ 159,291.36
407 - Possible Duplication of HIV Therapy	$ 1,664.97		$ 44,037.35	$ 2,454.94	$ 48,157.26
417 - Generic Substitution Required	$ 27,954.61	$ 3,918.79	$ 136,661.74	$ 28,895.43	$ 197,430.57
449- Inappropriate Narcotic Use			$ 2,182.31		$ 2,182.31
537-NJDURB Daily Drug Quantity Exceeded	$ 5,618.89	$ 40.34	$ 35,092.50	$ 2,003.57	$ 42,755.30
869-Possible Severe Drug-Drug Interaction	$ 154.44	$ 266.64	$ 208.05	$ 161.24	$ 790.37
916- Severe Drug-Drug Interaction	$ 9,581.71	$ 14,101.01	$ 93,077.20	$ 97,932.02	$ 214,691.94
2007- Prior Authorization Required	$ 314,694.24	$ 13,439.19	$ 976,741.74	$ 86,369.11	$ 1,391,244.28
2038- First Fill of HIV or High Dose Narcotic	$ 4,075,330.86	$ 5,735.05	$ 1,060,504.38	$ 31,155.64	$ 5,172,725.93
2046-Prescription Restricted	$ 39.20		$ 1,361.40	$ 261.83	$ 1,662.43
2047- PA required: Prescriber/Drug Restricted	$ 84,749.99		$ 1,436.51		$ 86,186.50
2085-Maximum Allowable Cost (MAC) Override	$ 289.72		$ 7,189.72	$ 88.96	$ 7,568.40
2100-Daily Dose Standard Exceeded			$ 877,955.70		$ 877,955.70
2111- Cough and cold symptoms			$ 1,651.33		$ 1,651.33
Grand Total	**$ 4,546,193.38**	**$ 38,992.45**	**$ 3,363,098.73**	**$ 273,612.47**	**$ 8,221,897.03**

Note: Savings reported here does not include possible 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 unduplicated claims/edits.