

HUMAN SERVICES

HEALTH

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

New Jersey Drug Utilization Review Board

State Fiscal Year 2018 Annual Report

Authorized By: Carole Johnson, Commissioner, Department of Human Services, and
Shereef Elnahal, M.D., M.B.A., Commissioner, Department of Health.

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Submit comments by September 13, 2019, to:

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Take notice that this notice affords the public an opportunity to review and comment on the annual Drug Utilization Review Report, which describes the activities of the New Jersey Drug Utilization Review Board (“NJDURB” or “Board”) for State

Fiscal Year 2018, and its impact on the quality of care provided to beneficiaries participating in the State's pharmaceutical benefit programs.

Take notice that, as required by N.J.S.A. 30:4D-17.18.e, and in fulfillment of requirements established by the Federal Department of Health and Human Services, the following Drug Utilization Review Report is presented for public comment.

The report contains a description of the activities and interventions of the NJDURB for State Fiscal Year 2018 and their impact on the quality of care provided to beneficiaries participating in the State's pharmaceutical benefit programs for the period beginning July 1, 2017 and ending on June 30, 2018. The report also contains an assessment of annual costs and any and all recommendations of the Board.

Full text of the Drug Utilization Review Board Annual Report follows:

**New Jersey Drug Utilization Review Board
Annual Report**

July 1, 2017 through June 30, 2018

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I. Acknowledgements

The Prospective Drug Utilization Review (PDUR) process for State Fiscal Year (SFY) 2018 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. Goen, 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 employees assisted the drug utilization review process:

Martin T. Zanna, M.D., MPH, New Jersey Department of Health, Acting Executive Director NJ Governor's Council for Medical Research and Treatment of Autism.

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

Eugene Azoia, R.Ph. Chief, Pharmaceutical Services, Office of the Medical Director, New Jersey Division of Medical Assistance and Health Services.

Sam Emenike, Pharm.D., Clinical Specialist, Molina Medicaid Solutions.

Dalia Hanna, Pharm.D., Medical Exceptions Process Program Manager, Molina Medicaid Solutions.

Edward J. Vaccaro, R.Ph., Consultant Pharmacist, Molina Medicaid Solutions.

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 by December 1st of each calendar year to provide an annual report, with copies to the United States Department of Health and Human Services, the Governor, the Legislature, the New Jersey Pharmacists Association and the Medical Society of New Jersey. The report includes a description of drug utilization review (DUR) highlights and opportunities identified by the New Jersey Drug Utilization Review Board (NJDURB) for the period beginning July 1, 2017 and ending June 30, 2018.

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 quarterly during State Fiscal Year (SFY) 2018. The Board reviewed and discussed drug utilization data for a number of different drug classes, as well as individual drugs of interest. Several prior authorization/clinical initiatives and outcomes were reviewed. The NJDURB spent \$7,156 in SFY 2018.

As part of the Prospective Drug Utilization Review (PDUR) process (a process that allows interventions by the State prior to a medication being dispensed by a pharmacy), 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 \$8,547,542 in total drug expenditures was 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 \$6,561,399 in drug expenditures was cost-avoided by Medicaid and an estimated \$1,986,143 in expenditures was cost-avoided by pharmacy benefit programs administered by the New Jersey Department of Health. The MEP is tailored to meet the individual authorization 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 to identify possible conflicts and to ultimately encourage appropriate prescribing and/or drug utilization.

The cost of administering the MEP through Molina Medicaid Solutions for the period of July 1, 2017 through June 30, 2018 was \$1,432,080.

III. Background

The NJDURB is responsible for reviewing and recommending drug utilization review protocols for medications provided by NJ FamilyCare (NJFC), 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 program, with the exception of medications dispensed to certain long-term-care clients, State institutional clients, beneficiaries transitioning from FFS to managed care and payments for certain high-cost drugs carved out of the managed care contract. High cost drugs include, but may not be limited to drugs prescribed for the treatment of hemophilia, angioedema, spinal muscular atrophy, Duchenne and Pompe diseases.

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 a drug utilization review (DUR) program that satisfy 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 maximum 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 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 develop 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 the Commissioners of Health and 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 influence drug product selections by prescribers. Instead, the MEP utilizes prior authorization as a tool to determine if medications are

being prescribed properly and derives cost savings by ensuring that prescribed medications are clinically appropriate and properly utilized.

The NJDURB is a thirteen (13) member board consisting of practicing practitioners and pharmacists representing several major specialties. The Board meets quarterly in an open public forum. The Board promotes patient safety through 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 to the Centers for Medicare and Medicaid Services (CMS) regarding prescribing patterns and DUR cost savings.

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 role of the Board in managed care will become more relevant with finalization of the managed care rule, including collaborations with managed care to address DUR concerns, implementation of more consistent utilization management strategies across all health benefit plans, advising the Department of Human Services regarding clinical criteria used by MCOs to prior authorize preferred and non-preferred drugs, recommending PDUR edits for MCO implementation to minimize over-expenditures for medically necessary drugs, developing educational strategies designed to influence drug product selection in the management of disease, and recommending 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 for evaluating prescribing patterns and recommending 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 2018:

- **Smoking Cessation Prior Authorization Protocols:**
The Board discussed the outcome of a smoking cessation subcommittee meeting which included the need for updates to Medicaid care plan websites concerning their authorization process, the release of a newsletter to inform providers of these same processes, as well as formulary and prior authorization changes.
- **Protocol for eteplirsen (Exondys 51[®])**
The Board reviewed and approved a protocol for the safe and efficient use of eteplirsen, an FDA-approved medication for the treatment of Duchenne muscular dystrophy (DMD). Dr. Dastgir, a pediatric neurologist at Goryeb Children's Hospital in Morristown was helpful in recommending prescriber specialties to be included in the protocol.
- **Protocol for deflazacort (Emflaza[®])**
The Board reviewed and approved a protocol for the safe and efficient use of deflazacort, an FDA-approved medication also for the treatment of DMD in patients ≥ 5 years of age.
- **Protocol for nusinersen (Spinraza[®])**
The Board reviewed and approved a protocol for nusinersen (Spinraza[®]). The Board suggested that a further review may be needed if there is a substantial increase in utilization.
- **Pediatric Protocol for sofosbuvir (Sovaldi[®])**
The Board reviewed and approved a protocol for sofosbuvir for the treatment of children and adolescents with hepatitis C infection. The Board recommended the removal of stage 2 fibrosis (METAVIR 2) that is required for adults as part of this protocol. They also recommended that use of the protocol be limited to patients between 12 and 17 years of age.
- **Pediatric Protocol for sofosbuvir/ledipasvir (Harvoni[®])**
The Board recommended a protocol for sofosbuvir/ledipasvir (Harvoni[®]) for children and adolescents infected with hepatitis C virus. The Board made a similar recommendation for this protocol as noted for sofosbuvir above.
- **Review of Opioid Utilization by Dentists**
The Board reviewed a report from Molina Medicaid Solution which identified twenty-two (22) Medicaid fee-for-service recipients who received more than a 30-day supply of opioid medication prescribed by dentists in CY2015. They recommended forwarding the report to the Medicaid Fraud Division (MFD), a department under the NJ attorney general's office for investigation. They investigated and sent a report of their findings to the Board. No further action was necessary.

- **Utilization Review of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors**
 The Board reviewed a CY2017 paid claims report for proprotein convertase subtilisin/kexin type 9 or PCSK9 inhibitors. No further action was recommended based on report findings.
- **Updated Protocol for Direct Acting Antivirals (DAAs) Used in Hepatitis C Treatment**
 The Board reviewed an updated protocol for DAAs used in the treatment of chronic hepatitis C infection. This protocol was originally approved in June 2016. The update included a new requirement to test patients for hepatitis B prior to, during, and post treatment. Two new products, sofosbuvir/velpatasvir/voxilaprevir (Vosevi[®]) and glecaprevir/pibrentasvir (Mavyret[®]) were also added to the list of DAAs.
- **Protocol for cerliponase alfa (Brineura[®])**
 The Board reviewed a proposed protocol for cerliponase alfa (Brineura[®]), approved by the FDA for the treatment of patients with late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease. Dr. Marissa P. DiGiovine, a pediatric neurologist at Children’s Hospital of Philadelphia was helpful in the review and recommendations for this protocol.
- **Morphine Milligram Equivalent (MME) Letter**
 The Board reviewed and approved a proposed letter to prescribers alerting them when their patients are prescribed 120 morphine milligram equivalents of opioid or greater.
- **Protocol for Opioid-Induced Constipation Products**
 The Board reviewed and approved a protocol for the safe and efficient use of opioid-induced constipation products which include lubiprostone (Amitiza[®]), naloxegol (Movantik[®]), methylnaltrexone (Relistor[®]), naldemedine (Symproic[®]) and linaclotide (Linzess[®]).
- **Fee-for-service/MCO Prior Authorization Report**
 As part of its monitoring responsibilities, the Board reviews and comments on prior authorization reports that compare prior authorization approval rates among managed care plans and the FFS program. The objectives are to minimize barriers to accessing care and to minimize administrative burdens for prescribers.
- **Top Drugs Report/Physician-Administered Drugs**
 The Board regularly reviews the top drugs paid for by MCO plans and fee-for-service (FFS) to determine trends and appropriate utilization.
- **MCO/FFS Protocols Compared:**
 The Board reviews FFS and managed care plan drug utilization review protocols with the goal of understanding reasons for inconsistencies and to achieve a consensus. Changes were recommended to improve efficiencies related to managed care prior authorization policies and procedures. Protocols reviewed by the Board are indicated below.

- Pulmonary arterial hypertension drugs;
- Opioid induced constipation products;
- Smoking cessation products; and
- Addiction treatment products

Board recommendations are subject to approvals received from the Commissioners of Health and Human Services.

B. Assessment of Costs

Drug Utilization

The MEP approved 31,609 claims with service dates on or after July 1, 2017 and prior to July 1, 2018. The top five categories of drugs most often prior authorized include proton-pump inhibitors, opioid dependency treatment agents, pain medications, antiretroviral drugs, anti-angina/anti-ischemic agents. (see table A below). The top five categories of drugs most often denied included proton-pump inhibitors, antiemetics/antivertigo medications, pain medications, inhaled beta adrenergic agents and opioid dependency agents. Total denied claims in this category were 5,694. (see table B below). Other reasons (not stated below) for denying prior authorization requests were: 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

Top 5 Approved Drug Categories from Total of 31,609

| Therapeutic Category (STC) | Claim Count | Estimated Payment Amount |
|---|--------------------|---------------------------------|
| Proton-pump inhibitors (D4J) | 3,346 | \$ 244,087 |
| Opioid dependency agents (H3W)* | 2,447 | \$ 720,368 |
| Pain medications (H3A) | 1,923 | \$ 318,383 |
| Antiretroviral agents (W5Z) | 1,349 | \$11,265,776 |
| Anti-anginal/anti-ischemic agents (A2C) | 1,191 | \$ 1,202,205 |

*Note: Opioid dependency agents were denied due to potential drug-drug conflicts.

Table B

Top 5 Denied Drug Categories from Total of 5,694

| Therapeutic Category (STC) | Claim Count | Estimated Cost-savings |
|--------------------------------------|--------------------|-------------------------------|
| Proton-pump inhibitors (D4J) | 1,290 | \$ 40,496 |
| Antiemetics/antivertigo (H6J) | 294 | \$ 18,079 |
| Pain medications (H3A) | 248 | \$ 33,809 |
| Inhaled Beta Adrenergic Agents (B6W) | 182 | \$ 5,938 |
| Opioid dependency agents (H3W) | 142 | \$ 33,643 |

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 age, maximum age, standards based on relationships between a claim's reported metric quantity and its days supply and the ability to immediately deny or override claim denials with prior authorization or allow a 30-day supply of a drug to be dispensed to allow for interventions with the prescriber to take place. The PDUR program prevents drug-related problems and inappropriate drug utilization protecting the patient while 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. Many of these same standards continue to apply to the remaining NJFC FFS population. The role of the NJDURB will continue to ensure that medications provided FFS or by managed care are prescribed to meet the medical necessity needs of our beneficiaries and are utilized appropriately.

Discussions continue between Division staff and managed care to standardize the way information is shared and to better understand the informational needs of managed care organizations. The Division will continue to enhance the quality of encounter claims received from managed care to better evaluate the utilization of healthcare services.

V. Acronyms

| | |
|--------|--|
| ADDP | AIDS Drug Distribution Program |
| DMAHS | Division of Medical Assistance and Health Services |
| DUR | Drug Utilization Review |
| DURB | Drug Utilization Review Board |
| 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 |

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 17 members, including the Commissioners of Human Services and 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 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.
- 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

Molina Medicaid Solutions Cost Avoidance Reports

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

July 2017 – June 2018

| Edit | ADDP | SG | FFS | PAAD | Grand Total |
|--------------------|------------------------|---------------------|------------------------|----------------------|------------------------|
| 0403 | \$ 4,810.13 | \$ 1,355.21 | \$ 23,950.60 | \$ 5,207.54 | \$ 35,323.48 |
| 0404 | \$ 7,923.56 | \$ 172.04 | \$ 117,861.15 | \$ 8,865.39 | \$ 134,822.14 |
| 0405 | \$ 8,674.74 | \$ 2,057.84 | \$ 84,052.56 | \$ 6,816.47 | \$ 101,601.61 |
| 0407 | \$ 3,253.70 | | \$ 71,964.73 | \$ 2,158.15 | \$ 77,376.58 |
| 0417 | \$ 6,562.62 | \$ 2,907.46 | \$ 277,735.67 | \$ 23,304.30 | \$ 310,510.05 |
| 0449 | \$ - | \$ - | \$ 3,452.69 | \$ - | \$ 3,452.69 |
| 0537 | \$ 3,119.73 | \$ 1,555.93 | \$ 106,304.39 | \$ 2,769.04 | \$ 113,749.09 |
| 0869 | \$ 148.76 | \$ 846.29 | \$ 925.28 | \$ 2,673.63 | \$ 4,593.96 |
| 0916 | \$ 16,071.86 | \$ 23,783.87 | \$ 82,163.81 | \$ 257,285.10 | \$ 379,304.64 |
| 2007 | \$ 326,452.97 | \$ 36,146.15 | \$ 3,377,788.03 | \$ 165,707.85 | \$ 3,906,095.00 |
| 2038 | \$ 1,038,100.97 | \$ 2,241.00 | \$ 1,826,928.19 | \$ 11,039.73 | \$ 2,878,309.89 |
| 2046 | \$ 2,988.20 | \$ 87.84 | \$ 9,203.33 | \$ 2,932.50 | \$ 15,211.87 |
| 2047 | \$ 7,857.70 | | \$ 3,708.16 | | \$ 11,565.86 |
| 2085 | \$ 264.49 | | \$ 18,600.48 | | \$ 18,864.97 |
| 2100 | | | \$ 551,506.94 | | \$ 551,506.94 |
| 2111 | | | \$ 5,253.42 | | \$ 5,253.42 |
| Grand Total | \$ 1,426,229.43 | \$ 71,153.63 | \$ 6,561,399.43 | \$ 488,759.70 | \$ 8,547,542.19 |

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 been unduplicated by claim and edit.

Description of Edits

0403 Duration Exceeded
0404 Duration Exceeded
0405 Possible Therapeutic Class Duplication
0407 Possible duplication of HIV therapy
0417 Generic Substitution Required
0447 Daily Dose Exceeds Recommended Limits
0449 Inappropriate Narcotic Use
0537 NJDURB Daily Drug Quantity Exceeded
0577 PA Required for WFNJ/GA Drug Coverage
0869 Possible Severe Drug-Drug Interaction
0916 Severe Drug-Drug Interaction
2007 Prior Authorization Required
2021 Medicare Part D Wraparound Drug Requires PA
2038 First Fill of HIV or High Dose Narcotic
2046 Prescription restricted
2047 PA required: Prescriber/Drug Restricted
2085 Maximum Allowable Cost (MAC) Override
2100 Daily Dose Standard Exceeded
2111 Cough and cold symptoms