The New York State Medicaid Drug Utilization Review Program Annual Report to the Governor and Legislature

Reporting Period: October 2019 through September 2020

I. Introduction

The New York State Medicaid Drug Utilization Review (DUR) Program submits an annual Report to the Governor and Legislature pursuant to the requirements in the State's Social Services Law, Article 5, Title 11-C and Section 1927(g)(3)(D) of the Social Security Act. While most Medicaid Program pharmacy services are provided to members through their managed care plans, this report pertains solely to the Fee-For-Service (FFS) component of the Medicaid pharmacy program. Managed care plans are responsible for managing their individual DUR Programs.

The DUR Program is composed of two separate but complementary components:

- Prospective Drug Utilization Review (ProDUR) Program, and
- Retrospective Drug Utilization Review (RetroDUR) Program

The ProDUR Program is a point-of-service monitoring system that analyzes pharmacy claims during the claims adjudication process. The system can identify drug related problems such as therapeutic duplication, drug-disease contraindications, drug interactions, incorrect dosage or duration of treatment, drug allergy, overutilization, and underutilization. In addition, the system can identify drug therapy related to member demographics including pregnancy, age, and gender. If the system identifies a potential drug related problem, the pharmacy receives an on-line warning message. The pharmacist can then determine the appropriate action prior to dispensing.

The RetroDUR Program is designed to improve prescribing trends by alerting providers through provider education. The Program uses predetermined clinical criteria to generate case reviews of select members using claims data. Medical and pharmacy claims information is evaluated for safety and clinical appropriateness. If inappropriate drug therapy is identified, an intervention letter is sent to prescribers and/or pharmacists detailing the potential drug therapy problem. The drug related problem may include therapeutic duplication, drug-to-disease contraindications, drug-to-drug interactions, incorrect drug dosage or duration of drug treatment, and/or clinical concerns.

Federal legislation that requires a State to implement a DUR Program also requires States to establish DUR Boards. The NYS Medicaid DUR Board establishes medical standards and clinical criteria for the Medicaid pharmacy Program. The DUR Board is comprised of health care professionals appointed by the Commissioner and includes physicians and pharmacists that actively practice in New York.

Responsibilities of the DUR Board include:

- The establishment and implementation of medical standards and criteria for the retrospective and prospective DUR Program.

- The development, selection, application, and assessment of educational interventions for prescribers and pharmacists to improve care.
- The collaboration with managed care organizations to address drug utilization concerns and to implement consistent management strategies across the fee-for-service and managed care pharmacy benefits.
- The review of therapeutic classes subject to the Preferred Drug Program.

The legislative authorities of the DUR Board are provided within the following State statues:

- Medicaid Drug Utilization Review – Social Service Law, Article 5, Title 11-C https://www.nysenate.gov/legislation/laws/SOS/A5T11-C
- Preferred Drug Program - Public Health Law, Article 2A, Title I, Section 272 https://www.nysenate.gov/legislation/laws/PBH/272
- Clinical Drug Review Program – Public Health Law, Article 2A, Title I, Section 274 https://www.nysenate.gov/legislation/laws/PBH/274
- Medicaid Drug Cap – Public Health Law, Article-2A, Title II, Section 280 https://www.nysenate.gov/legislation/laws/PBH/A2-AT2
- Medicaid High-Cost Drug – Social Services Law, Article 5 Title 11, Section 367-A https://www.nysenate.gov/legislation/laws/SOS/367-A

II. DUR Educational Program

In addition to the RetroDUR process, targeted educational letters can also be used for select clinical issues through the actions of the DUR Board. The DUR Board addressed several specific clinical matters by way of targeted educational letters. The chart below lists the number and type(s) of targeted clinical letters that were distributed to providers during the reporting period.

Topic	Provider Type	Number of Letters	Distribution Date
Use of Antipsychotics in Children - SUPPORT Act*	Prescriber	1,076	October 2019
Concurrent Use of Antipsychotics and Opioids - SUPPORT Act*	Prescriber	90	November 2019
Use of Antipsychotics in Children less than 21 years of age and Metabolic Monitoring - SUPPORT Act*	Prescriber	1,076	November 2019
Leukotriene Modifiers for Use in Asthma	Prescriber	94	February 2020

*Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act [5]

III. Drug Utilization Review Interventions

During the reporting period, there were 1.8 million real time/on-line ProDUR claim warning/rejections in which the pharmacy was alerted to potential drug related problems during the claims adjudication process.[1] The RetroDUR process identified approximately 6,000 members who met criteria for intervention letters. There were 3,477[3] claims identified as having potential drug related problems and 3,673 alert letters were mailed to providers[4]. Of note: a single drug related problem may result in multiple provider educational letters.

IV. DUR Board

DUR Board members are appointed by the Commissioner of Heath and consists of twenty-three (23) members as follows:

- One (1) chairperson representing the Department of Health.
- Six (6) licensed and actively practicing physicians.
- Six (6) licensed and actively practicing pharmacists.
- One (1) licensed and actively practicing nurse practitioner or midwife.
- Two (2) drug utilization review experts, at least one of whom is a pharmacologist.
- Three (3) consumers or consumer representatives of organizations with a regional or statewide constituency and who have been involved in activities related to health care consumer advocacy.
- Two (2) health care economists.
- One (1) actuary.
- One (1) member from the New York State Department of Financial Service

Medicaid Drug Utilization Review (DUR) Board Membership (2020)

- Lisa Anzisi, PharmD, MS, Practicing Pharmacist
- Nancy Balkon, PhD, NP, Nurse Practitioner
- Donna Chiefari, PharmD, Drug Utilization Review Expert
- Peter Dean, MD, Physician (resigned 6-4-20)
- Marla Eglowstein, MD, Consumer Representative
- Douglas Fish, MD, Chairperson
- Jill Lavigne, PhD, MD, MPH, Healthcare Economist
- James R. Hopsicker, RPh, MBA, Pharmacist
- Renante Ignacio, MD, Geriatrics
- Jacqueline Jacobi, RPh, Pharmacist
- Peter Lopatka, FSA, Actuary
- Jadwiga Najib, PharmD, Drug Utilization Review Expert
- Michael Pasquarella, Pharm D, Pharmacist
- Casey Quinn, PhD, Healthcare Economist
- Michelle Rainka, PharmD, Pharmacist
- Asa Radix, MD, Physician
- Tara Thomas, RPh, MBA, Practicing Pharmacist
- Deborah Wittman, PharmD, Practicing Pharmacist
- Jamie Wooldridge, MD, Physician

Department of Health DUR Board Support Staff

- Janet Z. Elkind, Deputy Director (retired 5-2021)

- Anthony V. Merola, RPh, MBA
- Robert L. Correia, PharmD
- Jean E. Osterholt (retired 8-2021)
- Robert J. Sheehan, RPh
- Monica M. Toohey, RPh

The DUR Board meets approximately four times per year and may add additional meetings as needed. Due to the COVID-19 pandemic, virtual meetings were held allowing for the DUR Board to conduct business.

V. Summary of DUR Board Activities

The DUR Board held meetings on the following dates during the reporting period:

- February 13, 2020
- July 23, 2020

<u>February 13, 2020 Board Meeting</u>

The DUR Board reviewed the following items and recommended clinical criteria and/or interventions to ensure appropriate drug utilization:

Management of Non-Acute Pain: Utilization of Opioids and Morphine Milligram Equivalent Parameters.

The purpose of the review was to evaluate the use of opioids for non-acute pain, defined as pain extending past 7 days, in both Medicaid Fee-for-Service (FFS) and Managed Care (MC) Programs, and to establish maximum daily morphine milligram equivalent (MME) safety edits for the treatment of non-acute pain. After review and discussion, the Board recommended the following:

- The establishment of a 90-morphine milligram equivalent threshold.
- Prior authorization is required when utilizing more than 90 MME per day.
- The MME parameter will not apply for members with cancer, sickle cell disease, or receiving hospice care.

Management of Eosinophilic Asthma (EA) – Utilization of Medication for EA and Place in Asthma Therapy in the Fee-for-Service and Managed Care Programs.

The purpose was to review biologic agents used in treating EA which include the products benralizumab, dupilumab, and mepolizumab. The DUR Board recommended the following: prior authorization to be required when there is no history of corticosteroid utilization and no concurrent use of a corticosteroid.

Management of Oral Second-Generation Antipsychotics (SGAs): Utilization of SGAs and Maximum Daily Dosages (MDD)

The purpose was to review the utilization of oral SGAs and compare dosages being utilized to MDDs recommended in the product-specific FDA labeling. Data was inclusive of

the Fee-For-Service (FFS) and Managed Care (MC) Programs. The DUR Board recommended the following: prior authorization to be required when an oral SGA is utilized above the product's highest MDD according to FDA labeling. Prior authorization will not be required for members established on a dose greater than the highest MDD.

The DUR Board was provided with a review of the effectiveness of current clinical edits implemented as a result of their recommendations to ensure safe and appropriate medication therapy within the Medicaid Program for the following topics:

Utilization Trends for Products Used for the Treatment of Opioid Use Disorder

Conclusion: The current FFS quantity limits and duration edits established for the Opioid Use Disorder (OUD) products were effective and should remain in effect.

Utilization Trends for Long-Acting Opioids Used for the Management of Non-acute Pain

Conclusion: The current long action (LAO) quantity limits were effective. Regarding the treatment of non-acute pain with LAOs, data identified that only three percent of opioid naïve members taking opioids for non-acute pain had an average morphine milligram equivalents (MME) equal to or greater than 90 MME and approximately 9% of non-opioid naïve members utilized equal to or greater than 90 MME. The low percentages indicate excessive quantity prescribing is minimal and clinical edits should remain in effect.

The DUR Board was provided with general Program updates for the following initiatives/Programs:

Retrospective Drug Utilization Review (RetroDUR) – Fluoroquinolone Project

The purpose of this initiative was to promote appropriate use of the fluoroquinolone class of antibiotics. The update concluded that the educational intervention letters appeared to have had a modest effect on decreasing potentially inappropriate fluoroquinolone prescribing by prescribers.

Prescriber Education Program – Antibiotic Stewardship

The purpose of this update was to review Medicaid Prescriber Education Program (NYSMPEP) activities, including the newest educational module - Antibiotic Stewardship which focuses on two key messages: the promotion of appropriate antibiotic use in routine practice, and the use of "delayed prescribing" or "watchful waiting".

<u>July 23, 2020 Board Meeting</u>

The DUR Board reviewed new clinical and/or financial information and made recommendations for preferred or non-preferred status for the following therapeutic classes subject to the FFS Preferred Drug Program (PDP):

Hepatitis C agents, (direct acting), Central Nervous System Stimulants, Topical Acne Agents, High Potency Topical Steroids, Glucagon-Like Peptide Agonists, Sodium Glucose

Co-Transport 2 Inhibitor Agents, Sulfasalazine Derivatives, Oral Immunosuppressive Agents, and Phosphate Binder/Regulators.

The recommendations of the DUR Board were forwarded to the Commissioner of Health for approval.

The DUR Board performed a review of Spinraza (nusinersen) which was identified as contributing to pharmacy expenditures exceeding the Medicaid Drug Cap. A DUR Board recommendation for supplemental rebate target amount was forwarded to the Commissioner of Health for approval.

VI. Assessment of ProDUR and RetroDUR Cost Avoidance/Savings

ProDUR cost avoidance is calculated by multiplying the total number of ProDUR claim rejections (1.8 million) by the average cost per prescription (net of the federal rebate), which in 2020 was calculated to be $46.94.[1,2] The estimated ProDUR cost avoidance for the reporting period was $84.5 million. This cost avoidance estimate does not take into consideration subsequent paid claims related to changes in pharmacotherapy resulting from ProDUR alerts.

RetroDUR estimated savings are determined by evaluating total drug expenditures and claims for the six months prior to and six months after alert letters are mailed. Based on this methodology, the alert letter (intervention) group had a 12.4% decrease in pharmacy claim costs compared with the 4.6% decrease in the comparison (no intervention) group.[3] The RetroDUR cost avoidance was estimated at $3.9 million prior to rebate offsets. [3]

The total DUR Program (ProDUR and RetroDUR) cost avoidance/savings is estimated at $88.4 million. Total FFS pharmacy expenditures net of all rebates for the reporting period was $298 million.[2] The estimated DUR cost avoidance/savings therefore represents approximately twenty-nine percent (29.7%) of the total net pharmacy spend.

VII. Program Enhancements

The Medicaid Program underwent additional changes and updates as the Program continues to adapt to the ever-changing needs of the State's Program beneficiaries. Changes to the Program included the following:

- System edits to validate the ingredient cost of 340B drug claims ensuring the reimbursement does not exceed the Federally determined 340B ceiling price.
- Enhanced Program logic for "Dispense as Written" submitted claims to enforce Program rules for both the "Brand Less than Generic Program" and the "Mandatory Generic Program".
- Changes to the State's formulary were made and removed drugs that are covered by Medicare B and/or D for dual eligible members.
- System changes were implemented to alleviate order entry errors regarding co-pay and co-insurance claims submitted by providers potentially resulting in delayed provider reimbursements.

- The High-Cost Drug initiative was established which gave the Department the authority to seek supplemental rebates on drugs meeting certain criteria as defined in legislation.
- Changes to contraceptive coverage were made to allow for the dispensing of up to a 12-month supply per prescription, which was an increase from the previous 6-month supply allowance per prescription.

VIII. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act[6]

The SUPPORT Act was passed and became law in October 2018 and provisions of Section 1004 became effective in October 2019. The SUPPORT Act was designed to supplement the requirements of the Social Security Act (section 1927[g]) to promote the proper use of prescription opioids by updating standard requirements of the Medicaid Drug Utilization Review Program. The Act is intended to boost the oversight and the prescribing of opioids within a State's Medicaid Program which address the following:

- Requirements for filling opioid prescriptions.
- Prescription monitoring for opioids and other drugs when prescribed at the same
- time as benzodiazepines.
- Antipsychotic prescription monitoring for children.
- Fraud and abuse detection.

The Act included requirements that State Medicaid Programs consider electronic notifications, described as "safety edits", at the point of pharmacy services that notify healthcare professionals such as pharmacists to dispensing improprieties. Safety edits, at the time of service, allow pharmacists to intervene if potential concerns with a patient's medication are identified before dispensing can occur. All Medicaid Programs were required by CMS to comply with the provisions of Section 1004 commencing October 1, 2019.

The following clinical criteria is in place to promote proper prescribing of antipsychotics and opioids:

- Limit of 4 opioid prescriptions within a 30-day period with exemption for cancer and sickle cell disease.
- A controlled substance early fill edit denies a controlled substance if more than a 7-day supply of the medication remained from the cumulative amount dispensed over the previous 90 days.
- Drug quantity limits based upon FDA maximum dosing guidelines for morphine and its congeners.
- 7-day supply limit on an initial prescription for an opioid naïve patient without the diagnosis of sickle cell disease or cancer.
- 90-day supply limit on short acting opioids in patients without the diagnosis of sickle cell disease or cancer.
- Prior authorization is required in the following cases:
    - Initiation of opioid therapy in patients established on opioid dependence therapy.
    - Initiation of opioid therapy in patients currently on benzodiazepine therapy.
    - Initiation of long-acting opioid therapy in opioid naïve patients except for those with sickle cell disease or cancer.

- For opioid naïve patients, prescriptions for greater than or equal to 90 morphine equivalents (MME) per day.
- Continuation of opioid therapy beyond an initial 7-day supply in patients established on gabapentin or pregabalin.
- For any additional long-acting opioid prescription for patients currently on long-acting opioid therapy.
- For patients less than 21 years of age, concurrent use of two or more different oral antipsychotics for greater than 90 days.
- For patients 21 years of age or older, when three or more different oral second-generation antipsychotics are used for more than 180 days.
- For an initial prescription for member younger than the drug specific minimum age as provide in the product labeling.
- For confirmation of diagnosis that supports the concurrent use of a second-generation antipsychotic and a CNS stimulant for patients less than 18 year of age.

Subsequent to implementation of the SUPPORT Act guidelines, the following clinical criteria was implemented:

- Prior authorization is required for opioid-naïve patients exceeding a morphine milligram equivalent (MME) of 90mg per day.
- Prior authorization is required for patients less than 21 years of age when there is concurrent use of two or more different oral antipsychotics for greater than 90 days.

IX. Pharmacy Program – COVID-19 Pandemic

In March 2020, the Governor of New York issued Executive Order 202 continuing the temporary suspension and modification of laws relating to the disaster health emergency resulting from the COVID-19 pandemic in New York. The order, in part, was an attempt to eliminate obstacles affecting provisional supplies and medical treatment to ensure that the New York healthcare system had adequate capacity to provide care for all who needed it. The Medicaid Pharmacy Program responded in the following ways to temporarily establish flexibilities in order to ensure access to medications during the state of emergency:

Medication 90 Day Supplies: Medicaid covers a 90-day supply for most prescription and over the counter (OTC) maintenance medications, in accordance with State and federal laws. Where practicable, practitioners and pharmacists were encouraged to utilize 90-day supplies of long-term maintenance medications for individuals in quarantine, sheltered in place, or those that were identified by the CDC as being at a higher risk for developing serious illness from COVID-19. In the event of supply chain interruptions, medications for these populations were to be prioritized. To ensure adequate supply for high-demand products, practitioners and pharmacists were encouraged to prioritize 90-day supplies for the populations mentioned above.

Medication Delivery: Pharmacies that chose to provide delivery to individuals quarantined or sheltered in place were to confirm receipt of medications by the member using a phone call, text or email in accordance with state and federal laws, in lieu of getting a signature. Such

confirmation had to be documented and retrievable upon audit If a member could not be reached via phone, text or email, confirmation of delivery had to be documented within the pharmacy's processing system.

Prescription Transfers: Members with a prescription filled from a pharmacy that was inaccessible or if traveling to a pharmacy was not feasible, were encouraged to obtain a new prescription/fiscal order from the prescriber, or a refill of the prescription could be transferred to another Medicaid participating pharmacy (where allowed by law).

Prescription Early Fills: Early refills for members in need of medications (controlled substances and non-controlled substances) due to quarantine or outbreak were allowed, per the provider's discretion, and in accordance with State and federal laws. During the Declared Disaster Emergency in the State of New York, pharmacies were allowed to override early fill edits for denials at the point of sale. In addition to using override codes, pharmacists were required to document early fill overrides within the pharmacy's processing system using the statement, "Declared Disaster Emergency in the State of New York".

COVID-19 Testing and Specimen Collection billed by Pharmacies: Per the Governor's Executive Orders #202.24 and #202.82, during the declared disaster emergency, Section 6801 of the NYS Education Law and Subdivision (6) of Section 571 of the NYS Public Health Law were temporarily modified to authorize licensed pharmacists to participate as adjunct support personnel in response to the pandemic. NYS Medicaid FFS covered COVID-19 specimen collection or CLIA waived COVID-19 testing at pharmacies in accordance with the Executive Orders. To comply, the Medicaid Bureau of Program Implementation and Administration set up new procedures for billing to occur. Pharmacists were allowed to perform and bill Medicaid FFS for COVID-19 tests subject to completion of appropriate training developed by the Department of Health. Pharmacists were designated as qualified healthcare professionals for the purpose of directing limited-service laboratories, pursuant to Section 579(3) of the Public Health Law, and to test patients suspected of a COVID-19 infection or its antibodies provided that such test was FDA-approved and waived for use in a limited-service laboratory. Medicaid FFS covered COVID-19 specimen collection or CLIA waived COVID-19, influenza, and RSV testing at pharmacies in accordance with the Executive Orders.

X. Future Enhancements

Future enhancements being considered are as follows:

Movement of the Pharmacy benefit for Medicaid Managed Care members to the Medicaid Fee-for-Service Program. This has since been delayed and scheduled to be implemented in 2023.

Establish a statewide formulary (FFS and Managed Care) for opioid dependence agents and opioid antagonists. On October 1, 2021 this initiative was implemented.

XI. Conclusion

The DUR Program has proven to be an asset in the efforts of New York Medicaid to protect and improve the health of Medicaid members. The Department of Health will continue to work cooperatively with the DUR Board to develop and implement medication management processes that improve patient outcomes and reduce unnecessary medication costs.

XII. References/Sources

[1] Computer Sciences Corporation – Mobius Report (CR50028-R0119) Annual Federal Report on ProDUR 10/01/2019 to 09/30/2020.

Note: the number of on-line claim rejections (1,844,218) may include multiple edits per claim or multiple submissions of the same claim. The Department calculates the estimated ProDUR cost savings by multiplying the number of rejected claims by the average cost per prescription.

[2] DOH, Office of Health Insurance Programs, Division of Finance and Rate Setting, 11/2019 to 10/2020.

[3] Health Information Design/Kepro, Summary 1, NY RetroDUR Estimated Cost Savings Report.

[4] Health Information Design/Kepro, Summary 4, Retrospective Educational Outreach Summary Report.

[5] Text - H.R.6 - 115th Congress (2017-2018): SUPPORT for Patients and Communities Act | Congress.gov | Library of Congress