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

Reporting Period: October 2020 through September 2021

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.

Social Services (SOS) Chapter 55, Article 5, Title 11-C, Section 369-BB, DUR Board

- 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 Programs

In addition to the RetroDUR program, the Drug Information Response Center (DIRC) provides evidence-based information on pharmacotherapy to prescribers. Pharmacotherapy related questions can be submitted by prescribers and evidence-based responses are prepared by DIRC pharmacists. Below is a summary of topics addressed by the DIRC:

- Risdiplam (Evrysdi) clinical summary
- Respiratory Syncytial Virus (RSV) and palivizumab (Synagis)
- Collagenase (Santyl) ointment and alternative products for the treatment of ulcers
- Buprenorphine micro-induction for patients with substance use disorder (SUD)
- Elapegademase-lvlr (Revcovi) clinical summary
- Human papillomavirus (HPV) vaccine and potential for long-term side effects
- Chantix, Zyban® and nicotine replacement therapy clinical comparison
- Hyaluronic acid clinical summary
- Clozapine Risk Evaluation and Mitigation Strategies (REMS) program update
- Covid-19 vaccines and a third dose in immunocompromised patients
- Covid-19 vaccines safety for adolescents between 12 and 17 years of age
- Covid-19 vaccines and impact on fertility

III. DUR Interventions

During the reporting period, there were 18.9 million on-line/point of service pharmacy claim processed. Approximately 1.9 million ProDUR warnings were issued, in which the pharmacy was alerted to potential drug related problems during the claims adjudication process.[1] The most common ProDUR warnings were associated with therapeutic duplication of therapy, drug pregnancy alert, early refill requests, and drug interactions. Below is a summary of ProDUR interventions:

ProDUR Warning Description	Number of Warnings Issued to Pharmacies	Number of Warnings Overridden at the Pharmacy#	Estimated Number of Alternations in Pharmacy Therapy^
Therapeutic Duplication	2,076,241	1,311,897	764,344
Drug Pregnancy Alert	1,778,033	0	1,778,033
Drug Age Precaution	49,365	0	49,365
Low Dose Alert	134,475	0	134,475
High Dose Alert	283,081	0	283,081
Early Refill	1,637,835	85,709	1,552,126
Drug to Drug Interaction	1,953,560	148,059	1,805,501
Inferred Drug Disease Precaution	995,367	0	995,367

Only severity level one warnings (i.e., therapeutic duplication, early refill and drug to drug interaction) require pharmacy override responses.

^ The number of warnings may include more than one alert per claim or multiple pharmacy overrides within the same claim transmission.

The RetroDUR process identified approximately 6,200 members who met criteria for drug related problem and generating an intervention/educational letter. Over ten-thousand intervention/educational letters were sent to providers (i.e., prescribers and pharmacies).[4] Below is a summary of RetroDUR interventions:

RetroDUR Clinical Criteria Description	Number of members selected for intervention	Number of intervention letters sent to providers*
Concurrent gabapentinoids & CNS depressants	567	1,252
Chronic use of proton pump inhibitors	556	694
Concurrent opioids & gabapentin (>900mg/day)	231	481
Antipsychotic use in convulsive disorders	160	361
Multi-class polypsychopharmacy	162	311
Concurrent opioids & benzodiazepines – SUPPORT Act**	142	307
Duplicate therapy of atypical antipsychotics	159	265
Immediate-release opioids for pain management	170	263
Concurrent opioids & antipsychotics - SUPPORT Act**	116	253
Cholesterol guidelines in diabetic patients age 40-75	157	236
Total all letters	6,214	10,288

*A single drug related problem may result in educational letters being sent to more than one provider.

Social Services (SOS) Chapter 55, Article 5, Title 11-C, Section 369-BB, DUR Board

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

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

Drug Utilization Review (DUR) Board Membership (2021)

- Lisa Anzisi, PharmD, MS, Pharmacist
- Nancy Balkon, PhD, NP, Nurse Practitioner
- Joseph Chiarella, MD, Physician
- Donna Chiefari, PharmD, Drug Utilization Review Expert
- 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
- Brock Lape, Consumer Representative
- Peter Lopatka, FSA, Actuary
- Jadwiga Najib, PharmD, Drug Utilization Review Expert
- Michael Pasquarella, Pharm D, Pharmacist
- Casey Quinn, PhD, Healthcare Economist
- Asa Radix, MD, Physician
- Gloria Rodriquez, MD, Physician
- Tara Thomas, RPh, MBA, Pharmacist
- Deborah Wittman, PharmD, Pharmacist
- Jamie Wooldridge, MD, Physician

Department of Health DUR Board Support Staff

- Amir Bassiri, Chief of Staff to the Medicaid Director
- Kimberly Laurenzo, PharmD
- Anthony V. Merola, RPh, MBA
- Robert L. Correia, PharmD
- Jacqueline Nahlik
- Jean Osterholt

Social Services (SOS) Chapter 55, Article 5, Title 11-C, Section 369-BB, DUR Board

- Robert J. Sheehan, RPh
- Monica M. Toohey, RPh

V. Summary of DUR Board Activities

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

- November 5, 2020
- February 11, 2021
- May 13, 2021
- June 15, 2021

November 5, 2020

Meeting Agenda for November 5, 2020

The DUR Board reviewed clinical and financial information for six therapeutic class subject to the Preferred Drug Program and recommended preferred or non-preferred status.[6]

The DUR Board reviewed opioids used for the treatment of acute pain as well as and long-acting injectable antipsychotics and recommended clinical criteria and/or intervention to ensure appropriate drug utilization.

Meeting Summary for November 5, 2020

February 11, 2021

Meeting Agenda for February 11, 2021

The DUR Board reviewed three drugs and three drug classes subject to the Clinical Drug Review Program and recommended changes to the clinical criteria or other drug utilization review interventions to ensure appropriate utilization.[6]

The DUR Board was provided updates on the Medicaid Drug Cap Initiative and the Pharmacy benefit transition out of the managed care benefit and into the fee-for-service program.

Meeting Summary for February 11, 2021

May 13, 2021

Meeting Agenda for May 13, 2021

The DUR Board reviewed clinical and financial information for six therapeutic class subject to the Preferred Drug Program and recommended preferred or non-preferred status.

Meeting Summary for May 13, 2021

June 15, 2021

Meeting Agenda for July 15, 2021

The DUR Board reviewed clinical and financial information for eight therapeutic class subject to the Preferred Drug Program and recommended preferred or non-preferred status. [6]

Meeting Summary for July 15, 2021

New RetroDUR criteria (e.g., drug interactions, diagnosis alerts, contraindications, therapeutic appropriateness, overutilization, underutilization, adherence, etc.) for the list of drugs below was vetted through DUR Board:

Month	Drugs
October 2020	alpelisib, upadacitinib, binimetinib, cobimetinib, selumetinib, capmatinib, enasidenib, everolimus, fedratinib, gilteritinib, midostaurin, regorafenib, sorafenib, idelalisib, duvelisib,
November 2020	istradefylline, diroximel, diroximel/dimethyl fumarate, apalutamide, darolutamide, entrectinib, ivosidenib, vorinostat, trifluridine/tipiracil, selinexor, tazemetostat, venetoclax, topotecan, celecoxib oral solution, forfivo XL
December 2020	cenobamate, ibrutinib, enasidenib, panobinostat, capecitabine, abiraterone, abiraterone micronized, bicalutamide, enzalutamide, flutamide, nilutamide, fluticasone/umeclidinium/vilanterol
January 2021	duloxetine, pexidartinib, fostemsavir, pralsetinib, rucaparib, temozolomide, gabapentin IR, gabapentin/pregabalin
February 2021	osilodrostat, budesonide/glycopyrrolate/formoterol, procarbazine, mitotane, olaparib, talazoparib, ixazomib, bexarotene, hydroxyurea, decitabine/cedazuridine
March 2021	amifampridine, acalabrutinib, afatinib, alectinib, avapritinib, axitinib, bosutinib, brigatinib, cabozantinib, ceritinib, crizotinib, dasatinib, rosuvastatin sprinkle
April 2021	brigatinib, opicapone, guselkumab
May 2021	viloxazine, seckinumab, erlotinib, gefitinib, ibrutinib, imatinib, lapatinib, lenvatinib, lorlatinib, neratinib, nilotinib, erdafitinib
June 2021	vibegron, pralsetinib, monetelukast, budesonide inhalation powder, ciclesonide, fluticasone HFA, fluticasone diskus, mometasone inhalation, budesonide/formoteol, mometasone inhalantion aerosol, fluticasone/salmeterol
July 2021	rosuvastatin/ezetimibe, capmatinib, ivosidenib
August 2021	ozanimod, ponesimod
September 2021	vorinostat, serdexmethylphenidate/dexmethylphenidate, elexacaftor/tezacaftor/ivacaftor, exenatide/exenatide ER, fesoterodine

VI. Assessment of ProDUR and RetroDUR Cost Avoidance/Savings

ProDUR cost avoidance/savings was calculated by estimating the number of claims not overridden at the pharmacy or altered by the prescriber (using the estimated number of alternations in pharmacy therapy as a baseline[1]) and multiplying by the average cost per prescription. The estimated ProDUR cost avoidance for the reporting period was estimated at

$138 million (1.9 million claims x $72.78 cost per claim). This cost avoidance estimate does not take into consideration subsequent paid claims related to changes in pharmacotherapy resulting from ProDUR alerts and is prior to drug rebate offsets. [1,2] Note: the number of on-line claim warnings issued to pharmacies may include multiple alerts per claim and multiple overrides of the same claim.

RetroDUR estimated cost avoidance/savings was determined by evaluating total drug expenditures and claims for the six months prior to and six months after the intervention/alert letters are mailed. Based on this methodology, the intervention group (i.e., providers sent an intervention/alert letter) had a 15.4% decrease in pharmacy claim costs compared with the 5.3% decrease in the comparison intervention group (i.e., no intervention/alert letter sent). The RetroDUR cost avoidance/savings was estimated at $5.8 million prior to drug rebate offsets. [3]

The total DUR Program (ProDUR and RetroDUR) cost avoidance/savings is estimated at $143.8 million. Total FFS pharmacy expenditures (prior to drug rebate offsets) for the reporting period was $706.6 million.[2] The estimated DUR cost avoidance/savings therefore represents approximately twenty percent (20.3%) of the total pharmacy spend (prior to drug rebate offsets).

VII. FFS Pharmacy Program Enhancements

The Medicaid Program underwent additional changes and updates to the Program as follows:

- Changed the prescription duration and refill period. Prescriptions may be filled for up to one year from the date issued. This is a change from the existing FFS policy, where prescriptions were valid for six months and must have been filled within 60 days of the date issued.

- Implemented a Statewide formulary for opioid dependence agents and opioid antagonists whereas, the coverage parameters are consistent across the Medicaid FFS and Managed Care programs. Preferred products no longer required prior authorization when prescribed consistent with Food and Drug Administration (FDA) package labeling, and standard clinical criteria was used as the basis of approval for non-preferred drugs.

- Instituted a website dedicated to the anticipated transition of the pharmacy benefit (scheduled for April 2023), whereas Medicaid members enrolled in mainstream managed care plans will receive their prescription drugs through the Medicaid FFS pharmacy program. Medicaid Pharmacy Program (NYRx)

- Instituted a website dedicated to Physician Administered Drug Policy. This website provides information on clinical criteria and program policy for Physician Administered Drugs. New York State Medicaid Fee-for-Service Practitioner Administered Drug Policies and Billing Guidance

- Instituted a website dedicated to Medicaid members to provide information on their Pharmacy Benefit. It includes search tools for the Medicaid pharmacy formulary and network pharmacy providers. New York State Medicaid Members

VIII. FFS Pharmacy Program and COVID-19

As announced in Executive Order 210, the New York State Declared Disaster Emergency ended, effective June 25, 2021. The Pharmacy Program returned to pre-emergency policies effective July 9, 2021, as outlined below.

- Allowance of a ninety-day supply of prescription and over the counter (OTC) maintenance medications was revised. Coverage of a ninety-day supply for most prescription and over the counter (OTC) maintenance medications remains in place, in accordance with State and federal laws.

- Confirmation of delivery via phone call, text or email, in lieu of signature, was discontinued.

- Previous guidance allowing the use of the early refill override was discontinued.

IX. Future Enhancements

Transition of the Pharmacy Benefit for Medicaid Mainstream Managed Care members to NYRx, the Medicaid Pharmacy Program.

Establishing Parity and Uniform Clinical Standards across both Medical and Pharmacy Benefits in FFS program.

Updating and modernizing the Medicaid Prescriber Education Program Website inclusive of an outpatient antibiotic stewardship program addressing antibiotic resistance.

X. 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.

XI. References/Sources

[1] DOH EmedNY, Mobius Report (CR50028-R0119) for 10/01/2020 to 09/30/2021

[2] SUNY, CMS Annual Report FFY2021 2022_05_02 Report for 10/01/2020 to 9/30/2021

[3] Kepro, NY RDUR Estimated Cost Savings Report (ATT4-2021-NY-SCSAM)

[4] Kepro, Retrospective Educational Outreach Summary Report (SUM1-2021-NY-REOS)

[5] SUPPORT for Patients and Communities Act

[6] Preferred Drug and Clinical Drug Review Programs

Social Services (SOS) Chapter 55, Article 5, Title 11-C, Section 369-BB, DUR Board