

New York
Medicaid Fee-For-Service (FFS)
Federal Fiscal Year (FFY) 2022
Drug Utilization Review (DUR)
Annual Report

Table of Contents

Sect	tion l - Number of Beneficiaries	1
	1. On a monthly average, how many of your State's Medicaid beneficiaries are enrolled in your State's Medicaid Fee-For-Service (FFS) program that have a pharmacy benefit?	
	2. On a monthly average, how many of your State's Medicaid beneficiaries are enrolled in managed care plan(s)?	'1
Sect	tion II - Prospective DUR (ProDUR)	2
	1. Indicate the type of your pharmacy point of service (POS) vendor.	2
	2. Identify your ProDUR table driven criteria source	2
	3. When the pharmacist receives a ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes"?	
	4. Does your State receive periodic reports providing individual pharmacy providers DUR alert override activity in summary and/or in detail?	
	5. Early Refill	3
	6. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does you state's policy allow the pharmacist to override:	
	7. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?	3
	8. Does the State Medicaid program have any policy prohibiting the auto-refill process that occurs at the POS?	4
	9. Does your system have a diagnosis edit that can be utilized when processing a prescription?	4
	10. For drugs not on your Preferred Drug List (PDL), does your Medicaid program have a documented process in place, so that the Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatied drug when medically necessary?	ent
	11. Top Drug Claims Data Reviewed by the DUR Board below	5
	12. Who in your State has responsibility for monitoring compliance with the oral counseling requirement?	7
Sect	tion III - Retrospective DUR (RetroDUR)	8
	1. Indicate the type of vendor that performed your RetroDUR activities during the time period covered by this report.	8
	2. How often does your State perform retrospective practitioner-based education?	8
	3. Summary 1 – RetroDUR Educational Outreach	8
Sect	tion IV - DUR Board Activity	10
	1. Does your State have an approved Medication Therapy Management (MTM) Program?	. 10
	2. Summary 2 – DUR Board Activities	. 10
Sect	tion V - Physician Administered Drugs (PAD)	12
	1. ProDUR?	.12
	2. RetroDUR?	. 12
Sect	tion VI - Generic Policy and Utilization Data	13
	1. Summary 3 – Generic Drug Substitution Policies	. 13

	2. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" fo a brand name drug to be dispensed in lieu of the generic equivalent, does your State have a more restrictive requirement?	
	3. Indicate the generic utilization percentage for all covered outpatient drugs (COD) paid during this reporting period, using the computation instructions in Table 2 – Generic Drug Utilization Data	14
	4. How many innovator drugs are the preferred product instead of their multi-source counterpart based on net pricing?	15
	5. Indicate the percentage dollars paid for generic CODs in relation to all COD claims paid during this reporting period using the computation instructions in Table 2 – Generic Drug Utilization Data	15
	6. Does your State have any policies related to Biosimilars?	15
Sec	tion VII - Program Evaluation / Cost Savings / Cost Avoidance	16
	1. Did your State conduct a DUR program evaluation of the estimated cost savings/cost avoidance?	16
	2. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below	16
	3. The Estimated Percent Impact	16
	4. Does your Medicaid program provide coverage of over-the-counter medications when prescribed by an authorized prescriber?	16
	5. Summary 4 – Cost Savings/Cost Avoidance Methodology	17
Sec	tion VIII - Fraud, Waste and Abuse Detection	19
A	. Lock-In or Patient Review and Restriction Programs	19
	1. Does your State have a documented process in place that identifies potential fraud or abuse of controlled drug by beneficiaries?	
	2. Does your State have a lock-in program for beneficiaries with potential misuse or abuse of controlled substances?	19
	3. Does your State have a documented process in place that identifies possible FWA of controlled drugs by prescribers?	20
	4. Does your State have a documented process in place that identifies potential FWA of controlled drugs by pharmacy providers?	20
	5. Does your State have a documented process in place that identifies and/or prevents potential FWA of non-controlled drugs by beneficiaries, prescribers, and pharmacy providers?	20
В	. Prescription Drug Monitoring Program (PDMP)	20
	1. Does your Medicaid program have the ability to query the State's PDMP database?	20
	2. Have you communicated to prescribers who are covered providers that as of October 1, 2021, they are required to check the PDMP before prescribing controlled substances to beneficiaries who are covered individuals?	
	3. In the State's PDMP system, which of the following beneficiary information is available to prescribers as close to real-time as possible?	
	4. Have any changes to your State's PDMP during this reporting period improved or detracted from the Medicaid program's ability to access PDMP data?	23
_	5. In this reporting period, have there been any data or privacy breaches of the PDMP or PDMP data?	
C	. Opioids	23

	prescription for opioid naïve patients?	.3
	2. Does your State have POS edits in place to limit the quantity dispensed of opioids?2	4
	3. Does your State have measures other than restricted quantities and days' supply in place to either monitor or manage the prescribing of opioids?	
	4. Does your State have POS edits to monitor duplicate therapy of opioid prescriptions?2	4
	5. Does your State have POS edits to monitor early refills of opioid prescriptions dispensed?2	5
	6. Does your State have comprehensive automated retrospective claim reviews to monitor opioid prescriptions exceeding these State limitations?	5
	7. Does your State currently have POS edits in place or automated retrospective claim reviews to monitor opioids and benzodiazepines being used concurrently?	.5
	8. Does your State currently have POS edits in place or automated retrospective claim reviews to monitor opioids and sedatives being used concurrently?	.5
	9. Does your State currently have POS edits in place or automated retrospective claim reviews to monitor opioids and antipsychotics being used concurrently?	.6
	10. Does your State have POS safety edits or perform automated retrospective claims reviews and/or provider education regarding beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis?	.6
	11. Does your State Medicaid program develop and provide prescribers with pain management or opioid prescribing guidelines?	.6
	12. Does your State have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse?	.7
	13. Were there COVID-19 ramifications on edits and reviews on controlled substances during the public health emergency?	.7
D	D. Morphine Milligram Equivalent (MME) Daily Dose2	7
	1. Have you set recommended maximum MME daily dose measures?2	7
	2. Does your State have an edit in your POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded?	.8
	3. Does your State have automated retrospective claim reviews to monitor the MME total daily dose of opioid prescriptions dispensed?	.8
	4. Do you provide information to your prescribers on how to calculate the MME daily dosage or do you provide a calculator developed elsewhere?	.8
E	. Opioid Use Disorder (OUD) Treatment2	9
	1. Does your State have utilization controls to either monitor or manage the prescribing of Medication Assisted Treatment (MAT) drugs for OUD?	9
	2. Does your Medicaid program set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?	9
	3. What are your limitations on the allowable length of this treatment?2	9
	4. Does your State require that the maximum mg per day allowable be reduced after a set period of time?2	9

	5. Does your State have at least one buprenorphine/naloxone combination product available without PA?	30
	6. Does your State currently have edits in place to monitor opioids being used concurrently with any buprenorph drug or any form of MAT?	
	7. Is there at least one formulation of naltrexone for OUD available without PA?	30
	8. Does your State have at least one naloxone opioid overdose product available without PA?	30
	9. Does your State monitor and manage appropriate use of naloxone to persons at risk of overdose?	30
	10. Does your State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or State Medicaid program allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols?	
F	. Outpatient Treatment Programs (OTP)	31
	1. Does your State cover OTPs that provide Behavioral Health (BH) and MAT services?	31
	2. Does your State Medicaid program cover buprenorphine or buprenorphine/naloxone for diagnoses of OUD as part of a comprehensive MAT treatment plan through OTPs?	
	3. Does your State Medicaid program cover naltrexone for diagnoses of OUD as part of a comprehensive MAT treatment plan?	31
	4. Does your State Medicaid program cover Methadone for a substance use disorder?	31
G	6. Psychotropic Medication For Children	31
Δ	Antipsychotics	31
	1. Does your State currently have restrictions in place to limit the quantity of antipsychotic drugs?	31
	2. Does your State have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?	32
S	timulants	33
	3. Does your State currently have restrictions in place to limit the quantity of stimulant drugs?	33
	4. Does your State have a documented program in place to either manage or monitor the appropriate use of stimulant drugs in children?	33
Δ	Antidepressants	34
	5. Does your State have a documented program in place to either manage or monitor the appropriate use of antidepressant drugs in children?	34
N	Aood Stabilizers	35
	6. Does your State have a documented program in place to either manage or monitor the appropriate use of mo stabilizing drugs in children?	
Δ	Antianxiety/Sedatives	36
	7. Does your State have a documented program in place to either manage or monitor the appropriate use of antianxiety/sedative drugs in children?	36
Sec	tion IX - Innovative Practices	39
	1. Does your State participate in any demonstrations or have any waivers to allow importation of certain drugs from Canada or other countries that are versions of FDA-approved drugs for dispensing to Medicaid beneficiarie	
		39

	2. Summary 5 – Innovative Practices	39
Sec	tion X - Managed Care Organizations (MCOs)	41
	1. How many MCOs are enrolled in your State Medicaid program?	41
	2. Is your pharmacy program included in the capitation rate (carved in)?	41
	3. If covered outpatient drugs are included in an MCO's covered benefit package, has the State updated their MCOs' contracts for compliance with Section 1004 of the SUPPORT for Patients and Communities Act?	41
	4. Does the State set requirements for the MCO's pharmacy benefit?	42
	5. Is the RetroDUR program operated by the State or by the MCOs or does your State use a combination of Stat interventions as well as individual MCO interventions?	
	6. Indicate how the State oversees the FFS and MCO RetroDUR programs? Please explain	42
	7. How does the State ensure MCO compliance with DUR requirements described in Section 1927(g) of the Act of 42 C.F.R. § 456, subpart K?	
	8. Did all of your managed care plans submit their DUR reports?	42
Sec	tion XI - Executive Summary	43
	1. Summary 6 – Executive Summary	43

Section I - Number of Beneficiaries

Question	Response
1. On a monthly average, how many of your State's Medicaid beneficiaries are enrolled in your State's Medicaid Fee-For-Service (FFS) program that have a pharmacy benefit?	1,670,000
2. On a monthly average, how many of your State's Medicaid beneficiaries are enrolled in managed care plan(s)?	5,781,000

Section II - Prospective DUR (ProDUR)

Question	Response
1. Indicate the type of your pharmacy point of service (POS) vendor.	Contractor
a. Vendor Name	General Dynamics Information Technology (GDIT)
b. Who processes the State's National Council for Prescription Drug Programs (NCPDP) transactions?	POS vendor is the fiscal agent (FA)
2. Identify your ProDUR table driven criteria source. This would be initial ratings such as drug to drug interactions, dose limits based on age and pregnancy severity (multiple responses allowed).	First Databank
If "Other," please specify.	N/A
3. When the pharmacist receives a ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes" (reason for service, professional service and resolution)?	Varies by Alert Type
If "Yes" or "Varies by Alert Type," check all that apply.	Alerts can be overridden with standard professional codes, Alerts need prior authorization (PA) to be overridden
If "Other," please explain.	N/A
4. Does your State receive periodic reports providing individual pharmacy providers DUR alert override activity in summary and/or in detail?	Yes
If "No," please explain.	N/A
a. How often does your State receive reports (multiple responses allowed)?	Annually
If "Other," please explain.	N/A
b. If you receive reports, does your State follow up with those providers who routinely override with interventions?	Yes
If "Yes," by what method does your State follow up (multiple responses allowed)?	Other

Question	Response
If "Other," please explain.	Pharmacy provider interventions concerning potential drug related problems are communicated / addressed through the RetroDUR intervention therapeutic criteria exemption program/processes/reviews.
5. Early Refill	
a. At what percent threshold do you set your system to edit?	
i. Non-controlled drugs:	75%
ii. Schedule II controlled drugs:	75%
iii. Schedule III through V controlled drugs:	75%
 b. For non-controlled drugs, when an early refill message occurs, does your State require a PA? 	Yes
If "Yes" or "Dependent on medication or situation," who obtains authorization?	Prescriber
If "No," can the pharmacist override at the POS?	N/A
c. For controlled drugs, when an early refill message occurs, does your State require a PA?	Yes
If "Yes," who obtains authorization?	Prescriber
If "No," can the pharmacist override at the POS?	N/A
6. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does your State's policy allow the pharmacist to override for situations such as (multiple responses allowed):	Other
If "Other," please explain.	Overrides are allowed by pharmacist in an emergency situation as noted in question #10.a. below.
7. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?	Yes
If "Yes," please explain your edit.	For non-controlled substances: no more than a 10 day supply (on hand) using a ninety day look back. For controlled substances: no more than a 7 day supply (onhand) using a ninety day look back.

Question	Response
If "No," does your State plan to implement this edit?	N/A
8. Does the State Medicaid program have any policy prohibiting the auto-refill process that occurs at the POS (i.e., must obtain beneficiary's consent prior to enrolling in the auto-refill program)?	No
9. Does your system have a diagnosis edit that can be utilized when processing a prescription?	Yes
If "Yes," please explain.	The pharmacy system has the capability to validate diagnosis by the way of the patient's medical claim history.
10. For drugs not on your Preferred Drug List (PDL), does your Medicaid program have a documented process (i.e., PA) in place, so that the Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug when medically necessary?	Yes
If "Yes," check all that apply.	Direct involvement with Pharmacy and/or Medical Director, Pharmacist or technician reviews, Automatic PA based on diagnosis codes or systematic review, Trial and failure of first or second line therapies
If "Other," please explain.	N/A
If "No," please explain why not.	N/A
 a. Does your program provide for the dispensing of at least a 72-hour supply of a COD in an emergency situation? 	Yes
If "Yes," check all that apply.	Other process
If "Other process," please explain.	If a prior authorization number has not been obtained by the prescriber and the pharmacist is unable to reach the prescriber, the pharmacist may obtain a prior authorization for up to a 72-hour emergency supply. Once a 72-hour supply prior authorization number is given and a 72-hour supply is dispensed, the prescription is no longer valid for the remaining quantity and refills. The pharmacist is expected to follow-up with the prescriber to determine future needs.
If "No," please explain why not.	N/A

Question	Response
11. Please list the requested data in each category in Table 1 - Top Drug Claims Data Reviewed by the DUR Board below.	

Table 1 – Top Drug Claims Data Reviewed by the DUR Board

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7
Top 10 Prior Authorization (PA) Requests by Drug Name, report at generic ingredient level	Top 10 Prior Authorization (PA) Requests by Drug Class	Top 5 Claim Denial Reasons (i.e., Quantity Limits (QL), Early Refill (ER), PA, Therapeutic Duplications (TD) and Age Edits (AE))	Top 10 Drug Names by Amount Paid, report at generic ingredient level	% of Total Spent for Drugs by Amount Paid (From data in Column 4, determine the % of Total Drug Spend)	Top 10 Drug Names by Claim Count, report at generic ingredient level	Drugs by Claim Count % of Total Claims (From data in Column 6, determine the % of Total Claims)
omeprazole	ataractics- tranquilizers	therapeutic duplication	bictegravir/ emtricitabine/ tenofovir	4.10%	ergocalciferol	5.70%
quetiapine	Anti-Ulcer Preps/Gastrointestinal Preps	drug-drug interaction	paliperidone	2.20%	folic acid	2.50%
oxycodone	Opioid Analgesics	drug- disease reported precaution	sitagliptin	2.20%	atorvastatin	1.50%
pantoprazole	Diabetic Therapy	early refill: overuse precaution	insulin glargine	2.10%	metformin	1.10%
oxycodone/ acetaminophen	anticonvulsants	high dose alert	dulaglutide	1.90%	albuterol	1.00%
zolpidem	Miscellaneous		apixaban	1.70%	amlodipine	1.00%
aripiprazole	Psychostimulants- Antidepressants		empagliflozin	1.50%	gabapentin	0.90%
ketoconazole	Amphetamine Preparations		adalimumab	1.40%	levothyroxine	0.80%
olanzapine	Sedative Non- Barbiturate		cannabidiol (CBD)	1.40%	famotidine	0.80%
ozempic	Antifungals		budesonide/formoterol	1.30%	divalproex	0.70%

Question	Response
12. Section 1927(g)(A) of the Social Security Act (the Act) requires that the pharmacist offer patient counseling at the time of dispensing. Who in your State has responsibility for monitoring compliance with the oral counseling requirement (multiple responses allowed)?	Medicaid Program, State Board of Pharmacy
If "Other," please explain.	N/A

Section III - Retrospective DUR (RetroDUR)

Question	Response
Indicate the type of vendor that performed your RetroDUR activities during the time period covered by this report.	Company
a. Identify, by name, your RetroDUR vendor.	Kepro / Health Information Designs (HID)
b. Is the RetroDUR vendor the MedicaidManagement Information System(MMIS) fiscal agent?	No
c. Is the RetroDUR vendor the developer/supplier of your retrospective DUR criteria?	Yes
Please explain "Yes" or "No" response.	Kepro updates and maintains the RetroDUR clinical criteria. The criteria is updated at least once a month in consideration of new clinical information.
d. Does your State customize your RetroDUR vendor criteria?	Ad hoc based on state-specific needs
How often does your State perform retrospective practitioner-based education?	Monthly
If "Other," please specify.	N/A
a. How often does your State perform retrospective reviews that involve communication of client-specific information to healthcare practitioners (multiple responses allowed)?	Monthly
If "Other," please specify.	N/A
 b. What is the preferred mode of communication when performing RetroDUR initiatives (multiple responses allowed)? 	Mailed letters
If "Other," please specify.	N/A
3. Summary 1 – RetroDUR Educational Outreach RetroDUR Educational Outreach should be a year-end report on retrospective screening and educational interventions. The summary should be limited to the most prominent problems with the largest	Drug to Drug Interaction - Concurrent gabapentinoids & CNS depressants: 608 members selected for intervention; 1,540 intervention letters mailed; 61 responses. Drug to Diagnosis - Antipsychotic use in convulsive disorders: 193 members selected for intervention; 405 intervention letters mailed; 14 responses. Therapeutic Appropriateness -Chronic use of proton pump inhibitors: 250 members selected for intervention; 279 intervention letters mailed; 9

number of exceptions. The results of RetroDUR screening and interventions should be included and detailed below. responses. Drug to Drug Interaction - Concurrent opioids & benzodiazepines SUPPORT Act: 126 members selected for intervention; 262 intervention letters mailed; 13 responses. Therapeutic Duplication - Duplicate therapy of atypical antipsychotics: 166 members selected for intervention; 247 intervention letters mailed; 9 responses. Therapeutic Appropriateness - Asthma & lack of controller medication: 131 members selected for intervention; 240 intervention letters mailed; 0 responses. Drug to Drug Interaction -Concurrent opioids & antipsychotics SUPPORT Act: 105 members selected for intervention; 234 intervention letters mailed; 7 responses. Drug to Drug Interaction -Concurrent duloxetine & other serotonergic drugs: 128 members selected for intervention; 225 intervention letters mailed; 11 responses. Therapeutic Appropriateness - Cholesterol guidelines in diabetic patients age 40-75: 146 members selected for intervention; 207 intervention letters mailed; 10 responses. Drug to Drug Interaction -Concurrent opioids & gabapentin (>900mg/day): 91 members selected for intervention; 181 intervention letters mailed; 6 responses.

Section IV - DUR Board Activity

Question	Response
Does your State have an approved Medication Therapy Management (MTM) Program?	No
Medication Therapy Management (MTM)	There were three DUR Board meetings held during the reporting period. Meeting dates and activities are as follows: November 18, 2021 The DUR Board reviewed the utilization of Central Nervous System (CNS) stimulants use concurrently with other controlled substances, specifically, benzodiazepines and opioids. The DUR Board was provided updates on the following topics: 1. Statewide Formulary for Opioid Dependence Agents and Opioid Antagonists 2. Respiratory Synctical Virus (RSV) Season and palivizumab 3. Direct Acting Antivirals (DAA) for Hepatitis C Virus (HCV) 4. Supplemental Rebate Initiatives May 12, 2022 The DUR Board reviewed information regarding esketamine nasal spray (Spravato) and recommended clinical criteria to ensure appropriate drug utilization. The DUR Board reviewed clinical and financial information, and recommended drugs to be preferred or non-preferred in the following therapeutic classes: 1. Cholesterol Absorption Inhibitors 2. Antimigraine Agents-Other
	 Movement Disorders Agents Acne Agents-Topical Antifungals-Topical Dipeptidyl Peptidase-4 (DPP-4) Inhibitors
	 Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Glucagon-like Peptide-1 (GLP-1) Agonists Growth Hormones Antihyperuricemics

Question	Response
	10. Anticholinergics/COPD Agents
	The DUR Board was presented information regarding asthma guidelines and the use of inhaled corticosteroids / long-acting beta agonist combinations for maintenance and reliever therapy.
	July 14, 2022
	The DUR board was presented information regarding the management of physician/practitioner administered drugs (PADs).
	The DUR Board reviewed clinical and financial information, and recommended drugs to be preferred or non-preferred in the following therapeutic classes: 1. Antipsychotics-Injectable 2. Antipsychotics-Second Generation 3. Other Agents for Attention Deficit Hyperactivity Disorder 4. Immunomodulators-Systemic 5. Glucagon Agents
	The DUR Board reviewed the drugs/drug classes listed below and recommend clinical criteria to ensure appropriate drug utilization: 1. aduncanumab (Aduhlem) 2. Botulinum Toxins onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), rimabotulinumtoxinB (Myobloc), inobotulinumtoxinA (Xeomin) 3. infliximab (Remicade), infliximab-abda (Renflexis), infliximab-axxq (Avsola), infliximab-dyyb (Inflectra) 4. vedolizumab (entyvio)
	Additional DUR Board Meeting information can be found at: https://www.health.ny.gov/health_care/medicaid/program/dur/index.htm

Section V - Physician Administered Drugs (PAD)

The Deficit Reduction Act required collection of national drug code (NDC) numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your MMIS been designed to incorporate this data into your DUR criteria for:

Question	Response
1. ProDUR?	No
If "No," does your State have a plan to include this information in your DUR criteria in the future?	Yes
2. RetroDUR?	No
If "No," does your State have a plan to include this information in your DUR criteria in the future?	Yes

Section VI - Generic Policy and Utilization Data

Question	Response
1. Summary 3 – Generic Drug Substitution Policies Generic Drug Substitution Policies should summarize factors that could affect your generic utilization percentage. In describing these factors, please explain any formulary management or cost containment measures, preferred drug list (PDL) policies, educational initiatives, technology or promotional factors, or other State-specific factors that affects your generic utilization rate.	The Brand Less than Generic Program is a cost containment initiative which promotes the use of certain multi-source brand name drugs when the cost of the brand name drug is less expensive than the generic equivalent. Generic drugs included in this program require prior authorization. Once it is determined that the generic drug is more cost-effective than the brand name equivalent, the prior authorization requirement is removed for the generic drug.
2. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your State have a more restrictive requirement?	Yes
If "Yes," check all that apply.	Prior Authorization (PA) is required
If "Other," please explain.	N/A

Generic Drug Utilization Data

Computation Instructions KEY

Single Source (S) – Drugs having an FDA New Drug Application (NDA), and there are no generic alternatives available on the market.

Non-Innovator Multiple-Source (N) – Drugs that have an FDA Abbreviated New Drug Application (ANDA), and generic alternatives exist on the market

Innovator Multiple-Source (I) – Drugs which have an NDA and no longer have patent exclusivity.

1. **Generic Utilization Percentage:** To determine the generic utilization percentage of all covered outpatient drugs paid during this reporting period, use the following formula:

$$N \div (S + N + I) \times 100 = Generic Utilization Percentage$$

2. **Generic Expenditure Percentage of Total Drug Expenditure:** To determine the generic expenditure percentage (rounded to the nearest \$1000) for all covered outpatient drugs for this reporting period use the following formula:

$$\$N \div (\$S + \$N + \$I) \times 100 = Generic Expenditure Percentage$$

CMS has developed an <u>extract file</u> from the Medicaid Drug Rebate Program Drug Product Data File identifying each NDC along with sourcing status of each drug: S, N, or I.

Table 2 – Generic Drug Utilization Data

	Single Source (S) Drugs	Non-Innovator (N) Drugs	Innovator Multi- Source (I) Drugs
Total Number of Claims	555,790.00	8,985,655.00	266,129.00
Total Reimbursement Amount Less Co-Pay	\$507,493,293.00	\$153,714,354.00	\$86,788,107.00

Question	Response
3. Indicate the generic utilization percentage for all covered outpatient drugs (COD) paid during this reporting period, using the computation instructions in Table 2 – Generic Drug Utilization Data.	
Number of Generic Claims	8,985,655
Total Number of Claims	9,807,574
Generic Utilization Percentage	92%

Question	Response
4. How many innovator drugs are the preferred product instead of their multisource counterpart based on net pricing (i.e. brand name drug is preferred over equivalent generic product on the PDL)?	36
5. Indicate the percentage dollars paid for generic CODs in relation to all COD claims paid during this reporting period using the computation instructions in Table 2 – Generic Drug Utilization Data.	
Generic Dollars	\$153,714,354
Total Dollars	\$747,995,754
Generic Expenditure Percentage	21%
6. Does your State have any policies related to Biosimilars? Please explain.	None during this reporting period.

Section VII - Program Evaluation / Cost Savings / Cost Avoidance

Question	Response
 Did your State conduct a DUR program evaluation of the estimated cost savings/cost avoidance? 	Yes
If "Yes," identify, by name and type, the institution that conducted the program evaluation.	
Institution Type	Company
Institution Name	ProDUR: State. RetroDUR: Kepro. Other Cost Avoidance: Magellan Medicaid Administration
Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.	

Cost Avoidance	Cost in Dollars
ProDUR Total Estimated Avoided Costs	\$126,000,000.00
RetroDUR Total Estimated Avoided Costs	\$4,819,908.00
Other Cost Avoidance	\$18,300,000.00
Grand Total Estimated Avoided Costs	\$149,119,908.00

Question	Response
3. The Estimated Percent Impact was generated by dividing the Grand Total Estimated Avoided Costs from Question 2 above by the Total Dollar Amount provided in Section VI, Question 5, then multiplying this value by 100.	19.94%
4. Does your Medicaid program provide coverage of over-the-counter medications when prescribed by an authorized prescriber?	Yes
If "No," please explain why not.	N/A

5. Summary 4 – Cost Savings/Cost Avoidance Methodology

Cost Savings/Cost Avoidance Methodology Summary should include program evaluations/cost savings estimates prepared by the State or contractor. ProDUR: To estimate the impact of ProDUR, the total number of ProDUR claim alerts/conflicts not overridden (i.e. number of alerts/conflicts minus the number of overrides) was multiplied by the average cost per claim (without factoring in any federal or supplemental rebates).

RetroDUR: To determine the impact of RDUR intervention letters on overall drug expenditures, total drug utilization in the targeted intervention population was evaluated six months before and six months after intervention letters were mailed. Kepro then compared drug expenditures and utilization in the targeted intervention population for the pre- and post- intervention timeframes with a comparison group to determine the estimated impact of the RDUR intervention letters.

The comparison group consisted of a random group of recipients who were not chosen for RDUR intervention letters. For a recipient to be included in the analysis for either the intervention or comparison groups, he or she had to have at least one claim for any drug in the pre and post-intervention periods.

For the purpose of this report, recipients were analyzed using 180 days of claims data before and after the RDUR intervention date. In addition, a null period of 14 days was included in the post-analysis period to allow for delivery and circulation of the RDUR intervention letters. Recipients were analyzed based on whether a single or duplicate intervention existed (a duplicate intervention being the occurrence of at least two RDUR intervention letters on the same recipient within FFY 2022). The pharmacy claims costs were compared for the pre- and post-intervention periods. To evaluate the impact of changes over time, such as manufacturer drug price changes or policy changes, the intervention group for each case was compared to a similar comparison group. Anything that happens to one group will also affect the other group and negate any effects.

Other Cost Avoidance: Attributed to the Preferred Drugs Program (i.e. Preferred Drug List and promoting the most cost effective products in a class in consideration of supplemental rebates and market share savings) and the Brand Less than Generic Program (i.e., promoting the utilization of a multisource brand name product when less expensive than the generic [net of all rebates]). Estimates based on State Fiscal Year 2021 - 2022 (April 1, 2021 - March 31, 2022).

Question	Response
	Lock In Program: New York State's Office of the Medicaid Inspector General (OMIG) provides savings estimate amount attributed to the restricted recipient program. OMIG's Lock-In program data encompasses statistics from both Managed Care and Fee-For-Service (FFS). A FFS only savings estimate is difficult to ascertain as beneficiaries often move between Managed Care and FFS (see VIII. Fraud, Waste and Abuse Detection, Lock-in or Patient Review and Restriction Programs section for cost savings estimate which is not included here).

Section VIII - Fraud, Waste and Abuse Detection

A. Lock-In or Patient Review and Restriction Programs

Question	Response
1. Does your State have a documented process in place that identifies potential fraud or abuse of controlled drugs by beneficiaries?	Yes
If "Yes," what actions does this process initiate (multiple responses allowed)?	Deny claims, Refer to Lock-In Program, Refer to Office of Inspector General (OIG), Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation, Require prior authorization (PA)
If "Other," please explain.	N/A
If "No," please explain why not.	N/A
2. Does your State have a lock-in program for beneficiaries with potential misuse or abuse of controlled substances?	Yes
If "Yes," please continue.	Number of controlled as between (CC) Different analysis are
 a. What criteria does your State use to identify candidates for lock-in (multiple responses allowed)? 	Number of controlled substances (CS), Different prescribers of CS, Multiple pharmacies, Days' supply of CS, Exclusivity of short acting opioids, Multiple emergency room (ER) visits
If "Other," please explain.	N/A
b. Does your State have the capability to restrict the beneficiary to:	
i. Prescriber only	Yes
ii. Pharmacy only	Yes
iii. Prescriber and Pharmacy	Yes
c. What is the usual lock-in time period?	As determined by the state on a case-by-case basis
If "Other," please explain.	N/A
d. On average, what percentage of the FFS population is in lock-in status annually?	0.0080%
 e. Please provide an estimate of the savings attributed to the lock-in program for the fiscal year under review. 	\$91,200,000.00

Question	Response
3. Does your State have a documented process in place that identifies possible FWA of controlled drugs by prescribers?	Yes
If "Yes," what actions does this process initiate (multiple responses allowed)?	Refer to the appropriate Medical Board, Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation, Deny claims written by this prescriber
If "Other," please explain.	N/A
If "No," please explain why not.	N/A
4. Does your State have a documented process in place that identifies potential FWA of controlled drugs by pharmacy providers?	Yes
If "Yes," what actions does this process initiate (multiple responses allowed)?	Deny claim, Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation, Refer to Board of Pharmacy
If "Other," please explain.	N/A
If "No," please explain why not.	N/A
5. Does your State have a documented process in place that identifies and/or prevents potential FWA of noncontrolled drugs by beneficiaries, prescribers, and pharmacy providers?	Yes
If "Yes," please explain your program for FWA of non-controlled substances.	ProDUR editing and RetroDUR case reviews (i.e. therapeutic duplication and over utilization).
If "No," please explain why not.	N/A

B. Prescription Drug Monitoring Program (PDMP)

Question	Response
1. Does your Medicaid program have the ability to query the State's PDMP database?	No
If "No," please explain.	N/A
If "Yes," please continue. a. How does your State access the PDMP database (multiple responses allowed)?	N/A

Question	Response
If "Receive PDMP data" please indicate how often (multiple responses allowed).	N/A
If "Other," please explain.	N/A
If "Direct access to the database," please specify (multiple responses allowed).	N/A
 a. Please explain how the State applies this information to control FWA of controlled substances. 	N/A
b. Does your State also have access to contiguous States' PDMP information?	N/A
c. Does your State also have PDMP data integrated into your point of sale (POS) edits?	N/A
2. Have you communicated to prescribers who are covered providers that as of October 1, 2021, they are required to check the PDMP before prescribing controlled substances to beneficiaries who are covered individuals?	Not applicable
If "Not applicable," or "No," please explain.	Practitioners are required to check the PDMP database prior to prescribing any controlled substance listed on schedule II, III or IV. Communication to prescribers is done by the New York State Department of Health Bureau of Narcotic Enforcement. https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/
If "Yes," please check all that apply.	N/A
If "Other," please explain.	N/A
If "Yes," please continue.	N/A
a. Has the State specified protocols for prescribers checking the PDMP?	
If "Yes," please explain.	N/A

Question	Response
b. Do providers have protocols for responses to information from the PDMP that is contradictory to information that the practitioner expects to receive, based on information from the client (example: when a provider prescribing pain management medication finds medications for opioid use disorder (OUD) during a PDMP check, when client denies opioid use disorder)?	N/A
c. If a provider is not able to conduct PDMP check, does your State require the prescriber to document a good faith effort, including the reasons why the provider was not able to conduct the check?	N/A
If "No," please explain why not.	N/A
If "Yes," does your State require the provider to submit, upon request, documentation to the State?	N/A
If "No," please explain.	N/A
3. In the State's PDMP system, which of the following beneficiary information is available to prescribers as close to real-time as possible (multiple responses allowed)?	The number and type of controlled substances prescribed to and dispensed to the beneficiary during at least the most recent 12-month period
If "Other," please explain.	N/A
a. Are there barriers that hinder the Medicaid agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb FWA?	Yes
If "Yes," please explain the barriers (i.e., lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script).	Data sharing or access to information for Medicaid members only.

Question	Response
4. Have any changes to your State's PDMP during this reporting period improved or detracted from the Medicaid program's ability to access PDMP data?	No
If "Yes," please explain.	N/A
5. In this reporting period, have there been any data or privacy breaches of the PDMP or PDMP data?	No
If "Yes," please summarize the breach, the number of individuals impacted, a description of the steps the State has taken to address each such breach, and if law enforcement or the affected individuals were notified of the breach.	N/A

C. Opioids

Question	Response
1. Does your State currently have a POS edit in place to limit the days' supply dispensed of an initial opioid prescription for opioid naïve patients?	Yes, for some opioids
If "No," please explain why not.	N/A
If the answer to question 1 is "Yes, for all opioids" or "Yes, for some opioids," please continue. If the answer to question 1 is "No," please skip to 1b. a. What is the maximum number of days allowed for an initial opioid prescription for an opioid naïve patient?	7
 b. Does your State have POS edits in place to limit days' supply of subsequent opioid prescriptions? If "yes," please indicate your days' supply limit. 	30-day supply
If "Other", please specify.	N/A
If "No," please explain.	N/A

Question	Response
2. Does your State have POS edits in place to limit the quantity dispensed of opioids?	Yes
If "No," please explain why not.	N/A
If "Yes," please continue.	Other
a. Does your State have POS edits in place to limit the quantity dispensed of short-acting (SA) opioids?	
If "Yes," please specify limit as # of units.	N/A
If "No," or "Other," please explain.	Initial prescription for opioid-naive patients limited to a 7-day supply. Prior Authorization (PA) required for initiation of opioid therapy for patients on established opioid dependence therapy. PA required for use if greater than or equal to 90 MME of opioid per day for management of non acute pain (greater than 7 days). PA is required for opioid-naive patients for prescription requests if greater than or equal to 50 MME per day.
b. Does your State currently have POS edits in place to limit the quantity dispensed of long-acting (LA) opioids?	Other
If "Yes," please specify limit as # of units.	N/A
If "No," or "Other," please explain.	Yes. Quantity limits are based on FDA maximum daily doses in the product labeling extended to a thirty day supply.
3. Does your State have measures other than restricted quantities and days' supply in place to either monitor or manage the prescribing of opioids?	Yes
If "Yes," check all that apply.	Require PDMP checks, Intervention letters, MME daily dose program, Require diagnosis, Step therapy or clinical criteria
If "Other," please specify.	N/A
If "No," please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of opioids.	N/A
4. Does your State have POS edits to monitor duplicate therapy of opioid prescriptions? This excludes regimens that include a single extended-release product and a breakthrough short acting agent?	N/A
If "No," please explain why not.	IV/A

Question	Response
5. Does your State have POS edits to monitor early refills of opioid prescriptions dispensed?	Yes, both POS edits and automated retrospective claims review process
If "No," please explain why not.	N/A
6. Does your State have comprehensive automated retrospective claim reviews to monitor opioid prescriptions exceeding these State limitations (early refills, duplicate fills, quantity limits and days' supply)?	Yes
If "Yes," please explain in detail scope, nature, and frequency of these retrospective reviews.	The RetroDUR program maintains criteria to identify the incidence of therapeutic duplications. If inappropriate drug therapy is identified, an intervention letter is sent to prescribers and/or pharmacists detailing the potential drug therapy problem. In addition to the RetroDUR process, targeted educational letters can also be used for select clinical issues through the actions of the DUR Board.
If "No," please explain why not.	N/A
7. Does your State currently have POS edits in place or automated retrospective claim reviews to monitor opioids and benzodiazepines being used concurrently?	Yes, both POS edits and automated retrospective claim reviews
If "Yes," please explain above response and detail the scope and nature of these reviews and edits. Additionally, please explain any potential titration processes utilized for those patients chronically on benzodiazepines and how the State justifies pain medications, i.e., Oxycodone/APAP, for breakthrough pain without jeopardizing patient care (i.e., quantity limits/practitioner education titration programs).	POS: Prior authorization required. RetroDUR: The Retro DUR program maintains criteria to identify coadministration of opioids and benzodiazepines. If inappropriate drug therapy is identified, an intervention letter is sent to prescribers and/or pharmacists detailing the potential drug therapy problem. In addition to the RetroDUR process, targeted educational letters can also be used for select clinical issues through the actions of the DUR Board.
If "No," please explain why not.	N/A
8. Does your State currently have POS edits in place or automated retrospective claim reviews to monitor opioids and sedatives being used concurrently?	Yes, both POS edits and automated retrospective claim reviews
If "No," please explain why not.	N/A

Question	Response
9. Does your State currently have POS edits in place or automated retrospective claim reviews to monitor opioids and antipsychotics being used concurrently?	Yes, both POS edits and automated retrospective claim reviews
If "No," please explain why not.	N/A
10. Does your State have POS safety edits or perform automated retrospective claims reviews and/or provider education regarding beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis?	Yes
If "No," please explain why not.	N/A
If "Yes," check all that apply.	POS edits, Automated retrospective claims review, Provider education
If "Automated retrospective claim reviews" and/or "Yes, provider education," please indicate how often.	Ad hoc
If "Other," please specify.	N/A
If "No," does your State plan on implementing POS edits, automated retrospective claim reviews and/or provider education regarding beneficiaries with a diagnosis history of OUD or opioid poisoning in the future?	N/A
If "Yes," when does your State plan on implementing?	N/A
If "No," please explain why not.	N/A
11. Does your State Medicaid program develop and provide prescribers with pain management or opioid prescribing guidelines?	Yes
If "Yes," please check all that apply.	Your state Medicaid program refers prescribers to the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain.
If applicable, please identify the "other" guidelines.	N/A
If "No," please explain why no guidelines are offered.	N/A

Question	Response
12. Does your State have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse (i.e., presence of an abuse deterrent opioid with preferred status on your preferred drug list)?	Yes
If "Yes," please explain.	Abuse Deterrent agents listed as preferred on preferred drug list.
If "No," please explain.	N/A
13. Were there COVID-19 ramifications on edits and reviews on controlled substances during the public health emergency?	No
If "Yes," please explain.	N/A

D. Morphine Milligram Equivalent (MME) Daily Dose

Question	Response
1. Have you set recommended maximum MME daily dose measures?	Yes
If "Yes," please continue.	
 a. What is your maximum morphine equivalent daily dose limit in milligrams? 	90 MME mg per day
If "Less than 50 MME," please specify the amount in mg per day.	N/A mg per day
If "Greater than 200 MME," please specify the amount in mg per day.	N/A mg per day
If "Other," please specify the amount in mg per day.	N/A mg per day
b. Please explain nature and scope of dose limit (i.e., Who does the edit apply to?, Does the limit apply to all opioids?, Are you in the process of tapering patients to achieve this limit?).	Prior authorization required in opioid-naive patients for prescription requests equal to or greater than 50 MME per day. Prior authorization required for the management of non acute pain (greater than 7 days) if the dose is equal to or greater than 90 MME of opioid per day. Exceptions for diagnosis of cancer or sickle cell disease, or hospice program.
If "No," please explain why not.	N/A

Question	Response
2. Does your State have an edit in your POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded?	Yes
If "Yes," does your State require PA if the MME limit is exceeded.	Yes
If "No," please explain why not.	N/A
3. Does your State have automated retrospective claim reviews to monitor the MME total daily dose of opioid prescriptions dispensed?	No
If "No," please explain why not.	The RetroDUR criteria identifies doses > 100 mg morphine equivalents per day and includes information indicating that higher doses of opioids may increase risk for opioid-related adverse effects and overdose, members may benefit from a change of opioid regimen or substitution with non-opioid analgesics, discontinuation or opioid tapering may decrease risks and guidelines recommend tapering when risks outweigh benefits.
4. Do you provide information to your prescribers on how to calculate the MME daily dosage or do you provide a calculator developed elsewhere? If "Yes," please continue.	No
a. Please name the developer of the calculator.	N/A
If "Other," please specify.	N/A
b. How is the information disseminated (multiple responses allowed)?	N/A
If "Other," please explain.	N/A

E. Opioid Use Disorder (OUD) Treatment

Question	Response
1. Does your State have utilization controls (i.e., preferred drug list (PDL), prior authorization (PA), quantity limit (QL)) to either monitor or manage the prescribing of Medication Assisted Treatment (MAT) drugs for OUD?	Yes
If "Yes," please explain.	Quantity Limits for all products based units per day extended to a thirty days supply. For buprenorphine sublingual (SL): six tablets dispensed as a two-day supply; not to exceed 24 mg per day. Prior authorization required for initiation of opioid therapy for members on established opioid dependence therapy. Prior Authorization required for initiation of a central nervous system stimulant for members established on opioid dependence therapy.
If "No," please explain.	N/A-See Explanation Above
2. Does your Medicaid program set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?	Yes
If "Yes," please specify the total mg/day.	24 mg
If "Other," please explain.	N/A
3. What are your limitations on the allowable length of this treatment?	No limit
If "Other," please explain.	N/A
4. Does your State require that the maximum mg per day allowable be reduced after a set period of time? If "Yes," please continue.	No
a. What is your reduced (maintenance) dosage?	N/A
If "Other," please explain.	N/A
b. What are your limitations on the allowable length of the reduced dosage treatment?	N/A
If "Other," please explain.	N/A

Question	Response
5. Does your State have at least one buprenorphine/naloxone combination product available without PA?	Yes
6. Does your State currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug or any form of MAT?	Yes
If "No," please explain why not.	N/A
If "Yes," can the POS pharmacist override the edit?	No
7. Is there at least one formulation of naltrexone for OUD available without PA?	Yes
8. Does your State have at least one naloxone opioid overdose product available without PA?	Yes
9. Does your State monitor and manage appropriate use of naloxone to persons at risk of overdose?	Yes
If "No," please explain why not.	N/A
10. Does your State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or State Medicaid program allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols?	Yes, State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or state Medicaid program under protocol

F. Outpatient Treatment Programs (OTP)

Question	Response
Does your State cover OTPs that provide Behavioral Health (BH) and MAT services?	Yes
If "No," please explain why not.	N/A
If "Yes," is a referral needed for OUD treatment through OTPs?	No
Please explain.	Members have open access to outpatient services / outpatient treatment programs. State law prohibits prior approval for these services across public and commercial insurance programs that are regulated by New York State.
2. Does your State Medicaid program cover buprenorphine or buprenorphine/naloxone for diagnoses of OUD as part of a comprehensive MAT treatment plan through OTPs?	Yes
If "No," please explain.	N/A
3. Does your State Medicaid program cover naltrexone for diagnoses of OUD as part of a comprehensive MAT treatment plan?	Yes
If "No," please explain.	N/A
4. Does your State Medicaid program cover Methadone for a substance use disorder (i.e., OTPs, Methadone Clinics)?	Yes
If "No," please explain why not.	N/A

G. Psychotropic Medication For Children

Antipsychotics

Question	Response
1. Does your State currently have restrictions in place to limit the quantity of antipsychotic drugs?	Yes
Please explain restrictions or N/A.	Frequency and quantity limits in place for the following products: asenapine, lumateperone, paliperidone, paliperidone, quetiapine, and quetiapine ER.

Question	Response
2. Does your State have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children? If "Yes," please continue.	Yes
a. Does your State either manage or monitor:	All children
If "Other," please explain.	N/A
b. Does your State have edits in place to monitor (multiple responses allowed):	Child's age, Dosage, Indication, Polypharmacy
Specify child's age limit in years.	5
If "Other," please explain.	N/A
c. Please briefly explain the specifics of your documented antipsychotic monitoring program(s).	Prior authorization is required when an oral SGA is utilized above the highest MDD according to FDA labeling. Prior authorization is required for patients less than 21 years of age when there is concurrent use of 2 or more different oral antipsychotics for greater than 90 days. Prior authorization is required for patients 21 years of age or older when 3 or more different oral second-generation antipsychotics are used for more than 180 days. Confirm diagnosis of FDA-approved or compendia-supported indication PA is required for initial prescription for beneficiaries younger than the drug-specific minimum age. Require confirmation of diagnosis that supports the concurrent use of a Second-Generation Antipsychotic and a CNS Stimulant for patients <18 years of age. For all Second-Generation Antipsychotics used in the treatment of Major Depressive Disorder in the absence of other psychiatric comorbidities, trial with at least two different antidepressant agents is required. For Example PA is required for initial prescription for beneficiaries younger than the drug-specific minimum age as indicated below: aripiprazole (Abilify) 6 years aripiprazole (Abilify MyCite) 18 years asenapine (Saphris) 10 years Asenapine (Secuado) 18 years brexpiprazole (Rexulti) 13 years cariprazine (Vraylar) 18 years clozapine (Clozaril, Versacloz) 12 years iloperidone (Fanapt) 18 years lumateperone (Caplyta) 18 years lurasidone HCl (Latuda) 10 years olanzapine (Zyprexa) 10 years paliperidone ER (Invega) 12 years pimavanserin (Nuplazid) 18 years quetiapine fum. (Seroquel, Seroquel XR) 10 years risperidone (Risperdal) 5 years ziprasidone HCl (Geodon) 10 years.

New York Medicaid FFS DUR FFY 2022 Individual State Annual Report

Question	Response
If "No," does your State plan on implementing an antipsychotic monitoring program in the future.	N/A
If "Yes," please specify when you plan on implementing a program to monitor the appropriate use of antipsychotic drugs in children.	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.	N/A

Stimulants

Question	Response
3. Does your State currently have restrictions in place to limit the quantity of stimulant drugs?	Yes
4. Does your State have a documented program in place to either manage or monitor the appropriate use of stimulant drugs in children? If "Yes," please continue.	Yes
a. Does your State either manage or monitor:	All children
If "Other," please explain.	N/A
b. Does your State have edits in place to monitor (multiple responses allowed):	Child's age, Dosage, Indication, Polypharmacy
Specify child's age limit in years.	3
If "Other," please explain.	N/A

Question	Response
c. Please briefly explain the specifics of your documented stimulant monitoring program(s).	Confirm diagnosis of FDA-approved, compendia-supported, and Medicaid covered indication for beneficiaries less than 18 years of age. Prior authorization is required for initial prescriptions for stimulant therapy for beneficiaries less than 3 years of age. Require confirmation of diagnoses that support concurrent use of CNS Stimulant and Second Generation Antipsychotic agent. For Example, short-acting CNS stimulants: not to exceed 3 dosage units daily with maximum of 90 days per strength (for titration) and long-acting CNS stimulants: not to exceed 1 dosage unit daily with maximum of 90 days. Concerta 36mg and Cotempla XR-ODT 25.9 mg; not to exceed 2 units daily. Azstarys; not to exceed 1 dosage unit per day. Pitolisant (Wakix): not to exceed 2 dosage units daily of the 17.8 mg tablets or 3 dosage units daily of the 4.45 mg tablets.
If "No," does your State plan on implementing a stimulant monitoring program in the future?	N/A
If "Yes," please specify when you plan on implementing a program to monitor the appropriate use of stimulant drugs in children.	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of stimulant drugs in children.	N/A

Antidepressants

Question	Response
5. Does your State have a documented program in place to either manage or monitor the appropriate use of antidepressant drugs in children? If "Yes," please continue.	Yes
a. Does your State either manage or monitor:	Other
If "Other," please explain.	The RetroDUR criteria is not specific to children as it monitors for appropriate use over all ages. See additional information in "c." below.

Question	Response
b. Does your State have edits in place to monitor (multiple responses allowed):	Child's age, Dosage, Indication, Polypharmacy
Specify child's age limit in years.	0
If "Other," please explain.	N/A
c. Please briefly explain the specifics of your documented antidepressant monitoring program(s).	The RetroDUR process monitors for appropriate use of antidepressants. The criteria addresses drug-drug, drugdisease interactions, under over utilization, and therapeutic duplication. Some criteria include references to children including that antidepressant-containing medications may increase the risk of suicidal thinking and behaviors (suicidality) in children, adolescents, and young adults. Patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior especially during the initial months of drug therapy, or at times of dose changes.
If "No," does your State plan on implementing an antidepressant monitoring program in the future?	N/A
If "Yes," please specify when you plan on implementing a program to monitor the appropriate use of antidepressant drugs in children.	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of antidepressant drugs in children.	N/A

Mood Stabilizers

Question	Response
6. Does your State have a documented program in place to either manage or monitor the appropriate use of mood stabilizing drugs in children? If "Yes," please continue.	Yes
a. Does your State either manage or monitor:	Other
If "Other," please explain.	The RetroDUR criteria is not specific to children as it monitors for appropriate use over all ages. See additional information in "c." below.

Question	Response
b. Does your State have edits in place to monitor (multiple responses allowed):	Child's age, Dosage, Indication, Polypharmacy
Specify child's age limit in years.	0
If "Other," please explain.	N/A
c. Please briefly explain the specifics of your documented mood stabilizer monitoring program(s).	The RetroDUR process monitors for appropriate use of antidepressant drugs. The RetroDUR criteria is not specific to children as it monitors for appropriate use over all ages. The criteria addresses drug-drug, drug-disease interactions, under utilization, over utilization, and therapeutic duplication.
If "No," does your State plan on implementing a mood stabilizer monitoring program in the future?	N/A
If "Yes," please specify when you plan on implementing a program to monitor the appropriate use of mood stabilizing drugs in children.	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of mood stabilizing drugs in children.	N/A

Antianxiety/Sedatives

Question	Response
7. Does your State have a documented program in place to either manage or monitor the appropriate use of antianxiety/sedative drugs in children? If "Yes," please continue.	Yes
a. Does your State either manage or monitor:	Other
If "Other," please explain.	The RetroDUR criteria is not specific to children as it monitors for appropriate use over all ages. See additional information in "c." below.
b. Does your State have edits in place to monitor (multiple responses allowed):	Child's age, Dosage, Indication
Specify child's age limit in years.	0
If "Other," please explain.	N/A

Question Response

c. Please briefly explain the specifics of your documented antianxiety/sedative monitoring program(s).

The RetroDUR process monitors for appropriate use of antianxiety/sedatives. The RetroDUR criteria is not specific to children as it monitors for appropriate use over all ages. The criteria addresses drug-drug, drug-disease interactions, under utilization, over utilization, and therapeutic duplication.

Benzodiazepines:

For Example, Benzodiazepines used in Generalized Anxiety Disorder (GAD) or Social Anxiety Disorder (SAD) require trial with a Selective Serotonin Reuptake Inhibitor (SSRI) or a Serotonin Norepinephrine Reuptake Inhibitor (SNRI) prior to initial benzodiazepine prescription. Panic Disorder requires concurrent therapy with an antidepressant (SSRI, SNRI, or Tricyclic antidepressant [TCA]). Skeletal muscle spasms, require trial with a skeletal muscle relaxant prior to a benzodiazepine

DURATION LIMIT:

For Insomnia: 30 consecutive days For Panic Disorder: 30 consecutive days

Require confirmation of FDA approved or compendia

supported use

PA required for initiation of benzodiazepine therapy in patients currently on opioid or oral buprenorphine therapy PA required for any additional oral benzodiazepine prescription in patients currently on benzodiazepine therapy

PA required when greater than a 14-day supply of a benzodiazepine is prescribed for someone on a CNS stimulant

Sedative Hypnotics/Sleep Agents

For Example, Zolpidem products: Confirm dosage is consistent with FDA labeling for initial prescriptions. Benzodiazepine Agents (estazolam, Halcion, Restoril, temazepam, triazolam): confirm diagnosis of FDA-approved or compendia-supported indication; PA required for initiation of benzodiazepine therapy in patients currently on opioid or oral buprenorphine therapy; PA required for any additional benzodiazepine prescription in patients currently on benzodiazepine therapy; PA required when greater than a 14-day supply of a benzodiazepine is prescribed for someone on a CNS stimulant.

Frequency and duration limits for the following products:

New York Medicaid FFS DUR FFY 2022 Individual State Annual Report

Question	Response
	-For non-zaleplon and non-benzodiazepine containing products: 30 dosage units per fill/1 dosage unit per day/30 days -For zaleplon-containing products: 60 dosage units per fill/2 dosage units per day/30 days -Duration limit equivalent to the maximum recommended duration: 180 days for immediate-release zolpidem (Ambien, Edluar) products
If "No," does your State plan on implementing an antianxiety/sedative monitoring program in the future?	N/A
If "Yes," please specify when you plan on implementing a program to monitor the appropriate use of antianxiety/sedative drugs in children.	N/A
If "No," please explain why you will not be implementing a program to monitor the appropriate use of antianxiety/sedative drugs in children.	N/A

Section IX - Innovative Practices

Question	Response
1. Does your State participate in any demonstrations or have any waivers to allow importation of certain drugs from Canada or other countries that are versions of FDA-approved drugs for dispensing to Medicaid beneficiaries?	No
If "Yes," please explain.	N/A
2. Summary 5 – Innovative Practices Innovative Practices Summary should discuss development of innovative practices during the past year (i.e., Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MME, and Value Based Purchasing). Please describe in detailed narrative below any innovative practices that you believe have improved the administration of your DUR program, the appropriateness of prescription drug use and/or have helped to control costs (i.e., disease management, academic detailing, automated PA, continuing education programs).	As part of an administrative budget initiative, uniform clinical standards for coverage of Physician/Practitioner-Administered Drugs (PADs) are being developed to modernize the process for the review of drugs covered under the medical benefit. Clinical criteria for PADs may be established through actions of the DUR board and subsequent approval by the Commissioner of Health. https://www.health.ny.gov/health_care/medicaid/progra m/dur/meetings/2022/07/attachment.pdf Beginning April 1, 2023, all Medicaid members enrolled in Mainstream Managed Care will receive their prescription drugs through NYRx, the Medicaid Pharmacy Program. NYRx allows New York State to pay pharmacies directly for the drugs and supplies of Medicaid members. Prior to April 1, 2023, Mainstream Medicaid members accessed their pharmacy benefits through a health plan, rather than Medicaid Fee-For Service (NYRx). This includes anyone in Managed Care (MC) plans, Health and Recovery Plans (HARPs) and HIV Special Needs Plans (HIV-SNPs). In this case, the state reimburses the health plan rather than the pharmacy. Moving all Medicaid members under the NYRx Program allows for a single, uniform list of covered drugs and standardized, consistent rules and regulations. Thus, New York State is able to offer an improved, simplified process for Medicaid members to get the medicines and supplies they need. Medicaid members have comprehensive drug coverage and equitable access to an extensive network of over 5,000 pharmacy providers. High Cost Drug initiative which allows the negotiation for supplemental rebates across the fee-for-service and managed care populations on newly launched drugs meeting certain criteria: 1) a brand name drug or biologic

Question	Response
	that has a launch wholesale acquisition cost of thirty thousand dollars or more per year or course of treatment, or 2) a biosimilar drug that has a launch wholesale acquisition cost that is not at least fifteen percent lower than the referenced brand biologic at the time the biosimilar is launched, or 3) a generic drug that has a wholesale acquisition cost of one hundred dollars or more for a thirty day supply or recommended dosage approved for labeling by the federal Food and Drug Administration, or 4) a brand name drug or biologic that has a wholesale acquisition cost increase of three thousand dollars or more in any twelve-month period, or course of treatment if less than twelve months. CMS has authorized the State of New York to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled 'Outcome-Based Supplemental Rebate Agreement' submitted to CMS and authorized for use beginning April 1, 2022. Effective April 1, 2022, for New York State (NYS) Medicaid is reimbursing providers for pediatric vaccine counseling visits as part of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program when provided to Medicaid members ages 18 years of age or younger. Vaccine counseling visits align with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP).

Section X - Managed Care Organizations (MCOs)

Question	Response
 How many MCOs are enrolled in your State Medicaid program? If "Zero" or "None", please skip the rest of this section. 	15
2. Is your pharmacy program included in the capitation rate (carved in)?	Yes
If "Partial, "please check what categories of medications are carved out and handled by your FFS program (multiple responses allowed):	N/A
If "Other," please specify the drug categories.	N/A
3. Contract updates between State and MCOs addressing DUR provisions in Section 1004 Support for Patients and Communities Act are required based on 1902(00). If covered outpatient drugs are included in an MCO's covered benefit package, has the State updated their MCOs' contracts for compliance with Section 1004 of the SUPPORT for Patients and Communities Act?	No, contracts are not updated
If "Yes," please specify effective date.	N/A
If "No, contracts are not updated," please explain why not.	Medicaid Managed Organizations (MCOs) are required to comply with all applicable state and federal laws and regulations under the provisions of Section 35.1 of the contract, which would include compliance with the SUPPORT Act. We have surveyed our contracted MCOs and have verified that all are in compliance with the SUPPORT Act. Specific SUPPORT ACT contract language will be amended to the contract in a forthcoming amendment.
 a. Is the State complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions? 	Yes, state is complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions

Question	Response
If "Yes," State is complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions. Please explain monitoring activities.	The State staff monitor activities (i.e. ProDUR editing and/or RetroDUR interventions) and verify /confirm compliance with SUPPORT Act provisions.
If "No," please explain why not.	N/A
4. Does the State set requirements for the MCO's pharmacy benefit (i.e., same preferred drug list, same ProDUR/RetroDUR)?	Yes
a. If "Yes," check all that apply.	Formulary Reviews, No State PDL
b. Please briefly explain your policy.	MCOs establish their own formularies and prior authorization processes. MCO formularies must include all categories of medications on the FFS list of reimbursable drugs. MCO formulary reviews, by the State staff, occur at least twice a year.
If "No," does your State plan to set standards in the future?	N/A
If "No," please explain.	N/A
5. Is the RetroDUR program operated by the State or by the MCOs or does your State use a combination of State interventions as well as individual MCO interventions?	State uses a combination of state interventions as well as individual MCO interventions
6. Indicate how the State oversees the FFS and MCO RetroDUR programs? Please explain oversight process.	State staff continually evaluate of retrospective pharmacy claims data (FFS and MCO) by State staff. MCO data is included in retrospective review of pharmacy and medical claims information. MCO data / information, specific to each MCO's member population, is provided to the MCO upon DUR Board review inclusive of any DUR Board clinical criteria recommendations.
7. How does the State ensure MCO compliance with DUR requirements described in Section 1927(g) of the Act and 42 C.F.R. § 456, subpart K?	State staff monitor MCO drug utilization data, policies and coverage parameters. The MCOs submitted formulary coverage and prior authorization information on a quarterly basis. MCO drug utilization is compared to feefor-service data to identify areas for which each drug utilization could be improved across the MCO and FFS programs / benefits.
8. Did all of your managed care plans submit their DUR reports?	Yes
If "No," please explain why not.	N/A

Section XI - Executive Summary

Question Response

Summary 6 – Executive Summary
 Executive Summary should provide a brief overview of your program. It should describe FFY 2021 highlights of the program, FFS initiatives, improvements, program oversight of managed care partners when applicable, and statewide

(FFS and MCO) initiatives.

Beginning April 1, 2023, all Medicaid members enrolled in Mainstream Managed Care will receive their prescription drugs through NYRx, the Medicaid Pharmacy Program. NYRx allows New York State to pay pharmacies directly for the drugs and supplies of Medicaid members. Prior to April 1, 2023, Mainstream Medicaid members accessed their pharmacy benefits through a health plan, rather than Medicaid Fee-For Service (NYRx). This includes anyone in Managed Care (MC) plans, Health and Recovery Plans (HARPs) and HIV Special Needs Plans (HIV-SNPs). In this case, the state reimburses the health plan rather than the pharmacy. Moving all Medicaid members under the NYRx Program allows for a single, uniform list of covered drugs and standardized, consistent rules and regulations. Thus, New York State is able to offer an improved, simplified process for Medicaid members to get the medicines and supplies they need. Medicaid members have comprehensive drug coverage and equitable access to an extensive network of over 5,000 pharmacy providers.

The DUR Program is composed of three main components, Prospective Drug Utilization Review (ProDUR) Program, Retrospective Drug Utilization Review (RetroDUR) Program and the DUR Board.

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.

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.

The NYS Medicaid DUR Board is comprised of health care professionals and financial experts appointed by the Commissioner and their responsibilities include: The establishment and implementation of medical standards

Question	Response
	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-forservice and managed care pharmacy benefits.
	The review of therapeutic classes subject to the Preferred Drug Program. The DUR Program continues to help to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical consequences.
	The DUR Program continues to focus innovate practices including the development of a physician/practitioner administered drug (PAD) management program and the transition of the pharmacy benefit for managed care members into the fee-for-service program.
	The DUR Program continues to protect and improve the health and improve the health of New York State Medicaid members. The Department will continue to enhance the ProDUR and RetroDUR Programs and work cooperatively with the DUR Board to develop and implement medication
	management processes that improve patient outcomes and reduce unnecessary medication costs.