New York
Medicaid Fee-For-Service (FFS)
Federal Fiscal Year (FFY) 2020
Drug Utilization Review (DUR)
Annual Report

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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?	**1,478,000**
2. On a monthly average, how many of your state's Medicaid beneficiaries are enrolled in managed care plan(s)?	**4,781,000**

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**
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.	**First Databank**
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,"	Alerts can be overridden with standard professional codes, Alerts need PA to be overridden
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?	**No**
a. How often does your state receive reports?	**N/A**
Other, please explain.	N/A
b. If you receive reports, does your state follow up with those providers who routinely override with interventions?	**N/A**
Yes, what method does your state follow up?	N/A
Other, please explain.	N/A
No, please explain.	N/A
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%**

Question	Response
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:	
a. Lost/stolen Rx	**No**
b. Vacation	**No**
c. Other, please explain.	**N/A**
7. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?	**Yes**
If "Yes," please explain your edit.	At the time of refill the edit allows for an existing supply of no more than 10 days of medication which is determined by a refill look back of 90 days. For controlled substances the existing supply at the time of refill must be no more than 7 days as determined by a 90 day look back.
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)?	**Yes**
9. 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**
Yes, please.	Automatic PA based on diagnosis codes or systematic review, Trial and failure of first or second line therapies, Pharmacist or

Question	Response
	technician reviews, Direct involvement with Pharmacy and/or Medical Director
Other, please explain.	N/A
No, please explain.	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**
Yes, please.	Real time automated process
Other process, please explain.	N/A
No, please explain.	N/A
10. 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

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	anxiolytic agents	drug-drug interaction	bictegravir/ emtricitabine/ tenofovir	3.10%	ergocalciferol	5.38%
quetiapine	proton pump inhibitor agents	therapeutic duplication	insulin glargine	2.34%	folic acid	2.47%
methylphenidate	analgesics, narcotic agents	early refill: overuse precaution	sitagliptin	2.03%	atorvastatin	1.43%
oxycodone	hypoglycemic agents	drug-disease reported precaution	paliperidone	1.93%	albuterol	1.23%
pantoprazole	anticonvulsant agents	high dose alert	elvitegravir/ cobicistat/ emtricitabine/ tenofovir	1.54%	metformin	1.10%
oxycodone/ acetaminophen	stimulants and related agents		budesonide/ formoterol	1.28%	amlodipine	1.03%
aripiprazole	antidepressant agents		lurasidone	1.25%	gabapentin	0.96%
zolpidem	antiviral agents		apixaban	1.24%	levothyroxine	0.87%
risperidone	attention deficit hyperactivity disorder agents		adalimumab	1.16%	divalproex	0.72%
clonazepam	micellaneous		rufinamide	1.15%	risperidone	0.69%

Question	Response
11. 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?	**Other**
Other, please explain.	The State Education of New York through the Office of Professional Discipline which performs routine periodic onsite inspections has the responsibility for monitoring compliance.

Section III – Retrospective DUR (RetroDUR)

Question	Response
1. 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.	**Health Information Designs**
b. Is the RetroDUR vendor the Medicaid Management 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.	HID maintains a comprehensive list of approved criteria that all claims are run against each month. The criteria include drug/drug interactions, drug/disease contraindication and precautions, overutilization, underutilization, disease state management, and cost savings. Criteria are defined as minor, moderate, or severe according to medical literature. The number of pharmacies and physicians a patient sees is taken into consideration with each drug-related problem. Criterion are added, deleted, or modified per instructions from the Clinical Review Board. Additions and changes are presented to the committee each quarter for approval. All drug classes must be reviewed periodically for the addition of new drugs and new drug-drug interactions, precautions, and contraindications. RetroDUR activity is also performed by Academia on an ad hoc basis. When performed in this manner findings needing attention may be brought to the DUR Board for review and final action where appropriate..
d. Does your state customize your RetroDUR vender criteria?	**Ad hoc based on state-specific needs**
2. How often does your state perform retrospective practitioner-based education?	**Monthly**
Other, please specify.	N/A
a. How often does your state perform retrospective reviews that involve communication of client specific information to healthcare practitioners (through messaging, fax, or mail)?	**Monthly**

Other, please specify.	N/A
b. What is the preferred mode of communication when performing RetroDUR initiatives?	**Mailed letters**
Other, please specify.	N/A
3. Summary 1 – RetroDUR Educational Outreach Summary Summary 1: RetroDUR Educational Outreach is a year-end summary report on retrospective screening and educational interventions. This year-end summary should be limited to the most prominent problems with the largest number of exceptions.	**NEW YORK STATE EDUCATIONAL OUTREACH FFY 2020** **Criteria Description Recipients Interventions Physician Responses** **Concurrent opioids benzo's** **317 653 37** **Concurrent opioids antipsych's** **266 590 36** **Chronic use PPI's 385** **505 28** **Concurrent use opioid gabapentin** **207 413 23** **above 900 mg per day** **Concurrent use gabapentin CNS depressant** **227 336 6** **Cholesterol guidelines in diabetic patients** **187 292 8** **age 40-75** **DPP4 inhibitors risk of arthralgia** **183 229 6** **Antipsychotic use in diabetics** **99 224 17** **Immediate release opioids for pain mgt** **141 217 7** **Duplicate tx of atypical antipsychotics** **119 214 9** **Total top 10 2131** **3673 177** **Total all letters sent** **4607 7643** **382** **This report summarizes the top 10 Retrospective Drug Utilization Review (RDUR) interventions as ranked by the number of intervention letters mailed to prescribers during Federal Fiscal Year (FFY) 2020. Intervention letters are mailed to prescribers to encourage appropriate prescribing and improve drug utilization, which will, in turn,**

	prevent possible adverse drug reactions and improve patient outcomes in the targeted recipient population. **A total of 3,673 prescriber letters were mailed for the top 10 criteria evaluated. Each letter included a response form, soliciting feedback from the prescriber. Responses are voluntary. A response rate of 5% was achieved for the top 10 criteria and a response rate of 5% was achieved for total interventions during FFY 2020. In their responses, 29% of prescribers indicated that some positive action had been or would be taken to address the drug therapy issue identified in the intervention letter.**

Section IV - DUR Board Activity

Question	Response
1. Summary 2 – DUR Board Activities Summary. Summary 2: DUR Board Activities Summary should be a brief descriptive on DUR activities during the fiscal year reported.	**Meetings held; February 23, 2020** **July 23, 2020** **February 23 Meeting** **Drug Utilization Reviews (DUR)** **1. Management of Non Acute Pain Utilization of Opioids and Morphine Milligram Equivalent Parameters** **DOH Recommendation to the DUR Board.** **The purpose of the review was to evaluate the use of opioids for non-acute pain, defined as pain extending past 7 days,in both Medicaid Fee for Service (FFS) and Managed Care (MC) programs and establish maximum daily morphine milligram equivalent (MME) safety edits for the treatment of non-acute pain.** **Prior authorization is required when utilizing greater than or equal to 90 MME per day.** **a Non acute pain is defined as greater than 7 days of opioid therapy.** **b Prior authorization will not be required for members established on greater than 90MME per day.** **The MME parameter will not apply for members with cancer, sickle cell disease, or receiving hospice care.** **2. Management of Eosinophilic Asthma (EA) Utilization of Medication for EA and Place in Asthma Therapy. The presentation was initiated with a review of the biologic agents used in treating this condition (benralizumab, dupilumab, and mepolizumab). The second part of the review was to evaluate the place in therapy of these medications as supported by the Food and Drug Administration (FDA) approved labeling and asthma treatment guidelines.** **DOH Recommendation** **Prior authorization is required when there is** **a. no history of corticosteroid utilization and** **b. no concurrent use of a corticosteroid** **3. Management of Oral Second Generation Antipsychotics (SGAs) Utilization of SGAs and Maximum Daily Dosages (MDD).** **The purpose was to examine the utilization of oral Second Generation Antipsychotics (SGAs)**

Question	Response
	and characterize the utilization in relation to MDDs recommended in the respective product labeling. **DOH Recommendation** **Prior authorization is required when an oral SGA is utilized above the highest MDD according to FDA labeling.** **a. Prior authorization will not be required for members established on a dose greater than the highest MDD.** **Clinical Editing Updates** **1. Utilization Trends for Products Used for the Treatment of Opioid Use Disorder** **The purpose was to assess the impact of currently employed clinical edits on opioid use disorder medications within the New York State Medicaid Program inclusive of both the Fee For Service (FFS) and Managed Care (MC) populations. It was recommended to the DUR Board that the current FFS quantity limits and duration edits established for the products used for OUD in the Medicaid program remain in effect. In addition, a 30 day maximum supply of 60 tablets and 30 tablets be placed on the product buprenorphine/naloxone SL tablets (Zubsolv) 8.6mg/2.1 mg and 11.4mg/2.9 mg respectively.** **2. Utilization Trends for Long Acting Opioids Used for the Management of Pain.** **The purpose of the review was to evaluate long acting opioid (LAO) therapy exceeding the individual LAO quantity limit and to determine the average morphine milligram equivalents (MME) per day calculated for LAO claims. In summary, it was concluded that current NYS Medicaid LAO quantity limits have been effective, 9% of members exceeded the NYS Medicaid LAO quantity limits per claim during this time frame. It was recommended to continue with current LAO quantity limits.** **General Program Updates** **1. Medicaid Retrospective Drug Utilization Review (RetroDUR) Fluoroquinolone Project.** **The update was an assessment of a mailed letter intervention to promote appropriate**

Question	Response
	use of the fluoroquinolone class of antibiotics. The intervention letter was intended to reinforce the FDA message and labeling changes. **The report concluded that the educational letter appears to have had a modest effect (15.1%) on decreasing potentially inappropriate fluoroquinolone prescribing in targeted prescribers. It was acknowledged that the letter may not have been the only influence for any changes in prescribing habits during this time period.** **2. Medicaid Prescriber Education Program Antibiotic Stewardship** **The presentation provided an overview of the NYSMPEP activities including the newest educational module which is Antibiotic Stewardship. The goal of the program is to optimize the quality of care for NYS Medicaid members by providing the most current unbiased evidence based information on best practices in pharmacotherapy. NYSMPEP resources and current available educational modules were identified.** **This newest NYSMPEP educational module focuses on two key messages the promotion of appropriate antibiotic use in a routine practice and the use of delayed prescribing or watchful waiting. The role of proper hand and respiratory hygiene remains an important foundation for infection control. It is expected that the outreach for educational contacts with prescribers will occur during the months of February and March.** **Additional activities performed by the Prescriber Education Program (PEP) were highlighted.** **July 23, 2020 DURB Meeting** **Preferred Drug Program (PDP) Clinical Review** **The following drug categories were reviewed for additions and/or changes to the preferred and non-preferred status on drugs in the following categories listed on the States Preferred Drug list. Financial discussions for each category occurred in Executive Committee however clinical discussions were**

Question	Response
	held in the public meeting. 1. Non Steroidal Anti inflammatory Agents 2. Hepatitis C Agents Direct Acting 3. CNS Stimulants 4. Acne Agents Topical 5. Topical Steroids High Potency 6. Glucagon-Like Peptide (GLP-1) Agonists 7. Sodium Glucose Co Transporter 2 Inhibitors (SGLT2) 8. Sulfasalazine Derivatives 9. Immunosuppressives Oral 10. Phosphate Binders Regulators Based upon presented clinical and financial information the DUR Board recommended changes to the States Preferred Drug program and forwarded those changes to the Commissioner of Health for final determination. Drug Cap Review Spinraza (nusinersen) A background summary of the Drug Cap legislation was presented and followed by a utilization review of Spinraza. Drugs piercing the State Medicaids Drug Cap and having no consensus on a negotiated drug rebate value are by law sent to the States Drug Utilization Review Board (DURB) to determine a calculated target value. The following areas were the subject of the first public presentation prior to any target value being calculated and agreed to by the Board: a. Patients with severe forms of spinal muscular atrophy (SMA) have a life expectancy of less than 2 years. Patients with less severe disease can survive until adulthood. Severe SMA is more common with Type 1 accounting for greater than 50%. b. Two nusinersen phase 3 trials were terminated as results showed favorable outcomes. Post marketing studies showed benefits in adults with spinal muscular atrophy (SMA). c.The incidence of spinal muscular atrophy (SMA) in New York State approximates 20 to 30 cases per 253000 births. New York

Question	Response
	includes SMA testing in newborn screening. d.Between April 2017 and September 2019 there were 336 claims for nusinersen for NY Medicaid members (Fee For Service and Managed Care). e.Total WAC for initial year of nusinersen therapy was presented publicly total WAC for maintenance year therapy was presented publicly. f.Coverage policies (Medicaid programs, commercial insurance) in other states and countries specify criteria andor restrictions for nusinersen coverage. A second public presentation was presented to the Board outlining considerations in calculating a target value. A value assessment of Spinraza was presented and included the following elements in determining a reasonable price for pharmaceuticals. a.Elements of a cost effectiveness threshold. b.Cost effectiveness threshold c.Spinraza improves patient health outcomes compared to best supportive care alone for all subpopulations of SMA. Its greatest impact appears to be when used for pre symptomatic infants. d.In proportion to the clinical benefits, the added cost of Spinraza therapy exceeds commonly used thresholds for cost-effectiveness for all patient subpopulations. e.The modified societal perspective scenario analysis did not notably improve the cost effectiveness of Spinraza. Drug Cap financial review of Spinraza (nusinersen) was performed in Executive Session. Upon their return from Executive Committee the Board agreed to a supplemental rebate target amount and forwarded their recommendation to the Commissioner of Health
2. Does your state have an approved Medication Therapy Management (MTM) Program?	**No**

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?	No
2. RetroDUR?	**No**
If "No," does your state have a plan to include this information in your DUR criteria in the future?	No

Section VI – Generic Policy and Utilization Data

Question	Response
1. Summary 3 – Generic Drug Substitution Policies Summary 3: 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, PDL policies, educational initiatives, technology or promotional factors, or other state specific factors that affects your generic utilization rate.	**New York State Medicaid administers a DISPENSE BRAND WHEN LESS EXPENSIVE THAT GENERIC (BLTG) program which promotes the use of certain multisource brand name drugs when the cost of the brand name is less expensive to the Medicaid Program than the generic equivalent. Branded drugs on the Preferred Drug List that are determined to be nonpreferred can be reimbursed provided the prescriber obtain a prior authorization. Prescribers also have the ability to request branded products over their generic counterpart by including the statement DISPENSE AS WRITTEN on the prescription.**
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,"	PA is required
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:

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

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

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

CMS has developed an extract file 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	441,924	5,610,005	297,557
Total Reimbursement Amount Less Co-Pay	$385,235,149	$130,355,662	$136,811,392

Question	Response
3. Indicate the generic utilization percentage for all CODs paid during this reporting period, using the computation instructions in Table 2 – Generic Drug Utilization Data.	
Number of Generic Claims	5,610,005
Total Number of Claims	6,349,486
Generic Utilization Percentage	88.35%
4. How many multi-source drugs have the innovator as the preferred drug product based on net pricing?	**31**
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	$130,355,662
Total Dollars	$652,402,203
Generic Expenditure Percentage	19.98%
6. Does your state have any policies related to Biosimilars? Please explain.	**No not at this time**

Section VII – Program Evaluation / Cost Savings / Cost Avoidance

Question	Response
1. Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance? If "Yes," identify, by name and type, the institution that conducted the program evaluation.	**Yes**
Institution Type	Company
Institution Name	Kepra, Health Information and Design
2. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.	

	Data
ProDUR Total Estimated Avoided Costs	$84,500,000.00
RetroDUR Total Estimated Avoided Costs	$3,900,000.00
Other Cost Avoidance	$52,800,000.00
Grand Total Estimated Avoided Costs	$141,200,000.00

Question	Response
3. Estimated Percent Impact	**21.64%**
4. Summary 4 – Cost Savings/Cost Avoidance Methodology Summary 4 Cost Savings/Cost Avoidance Methodology includes program evaluations/cost savings estimates prepared by the state or contractor.	**State Report: During the reporting period for Federal Fiscal Year (FFY) 2020, there were 1.8 million on-line claim rejections where pharmacists encountered dispensing issues that were avoided due to ProDUR safety edits. On-line claim rejections encountered during the review period encompassed early fill, drug-drug interactions, therapeutic duplication, prescriber consult, drug-disease concerns, and high-low dose complications. The over-all cost per prescription as determined by cost (net of rebates) over prescription volume for the survey period was calculated at $46.94 dollars. Calculated savings from the ProDUR Program amounted to approximately $84.5 million dollars in savings (as determined by multiplying the number of on-line claim rejections by the average prescription cost).** **Contractor Report:This report prepared by Health Information Designs (HID) for the New York State Medicaid Program shows the expected estimated cost savings from**

implementing a retrospective drug utilization review (RDUR) and provider education program to effect change on prescribing and utilization.
In an effort to improve clinical outcomes and reduce medication and overall healthcare-related costs, patients found to have a medication-related problem were identified based on the RDUR criteria. Educational intervention letters were mailed to providers during federal fiscal year 2020 (FFY 2020). The drug claims for the selected recipients were evaluated for the six months prior to the intervention and the six months post-intervention to determine the impact of the RDUR intervention letters.
The estimated cost savings are calculated by looking at actual drug claims history for six months before intervention and six months following intervention in both the intervention and random comparison groups. The difference between the two groups is the estimated cost savings. For interventions performed between October 1, 2019 and September 30, 2020, there was an estimated cost savings of $3,873,340.
Table 1 Estimated Cost Savings for FFY 2020 All Interventions

	Intervention Group Change between 6 Month Pre- and Post-Month Pre- and Post	Comparison Group Change between 6 Month Pre- and Post	Estimated Cost Savings
All Interventions	**$3,965,378**	**$92,038**	**$3,873,340**

During FFY 2020, HID reviewed 3,477 recipients with potential drug therapy problems and mailed letters to their providers. The types of drug therapy issues were divided into five general categories: drug-disease interactions, drug-drug-interactions, over-utilization, under-utilization, and therapeutic appropriateness. Recipients reviewed for under-utilization issues are excluded from the cost savings calculation, as a cost increase would be

	expected in response to this type of intervention. For FFY 2020, 3,467 recipients were included in the intervention group. **Analysis Methodology** **Each month, HID evaluates pharmacy and medical claims data against a library of clinical criteria. Once recipients have been identified and RDUR letters have been mailed to their providers, HID tracks drug costs for both the intervention group and a comparison group. Both groups are followed for six months pre- and post-intervention to determine the change in pharmacy claims. The comparison group is used to account for changes within the program including new limitations, changes in drug costs, and overall utilization trends.** **Beneficiary Selection** **A total of 6,000 recipients met the criteria for intervention letters during FFY 2020. Of those recipients, 5,581 were enrolled in fee for service (FFS), and 419 were enrolled in a managed care organization (MCO). The cost savings in this report is calculated for FFS recipients only.** **Estimated Cost Savings Methodology** **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. HID 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 2020). 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.

Estimated Cost Savings Analyses Results

For the intervention and comparison group beneficiaries who had claims for any drug during the pre- and post-intervention periods, HID evaluated total drug expenditures and claims for the six months prior to and six months after the letters were mailed .

Table 3 shows the results for both the intervention and comparison group for the pre- and post-intervention timeframes for recipients with single and multiple interventions during FFY 2020.

Table 3 - Estimated Cost Savings for FFY 2020- Single/Multiple Interventions

	Intervention Group Change between 6 Month Pre- and Post-	Comparison Group Change between 6 Month Pre- and Post-	Estimated Cost Savings
Single Intervention	$3,919,731	$108,737	$3,810,994
Multiple Intervention	$45,648	(-$16,698)	$62,346
Total Estimated Cost Savings			$3,873,340

HID found the intervention group had a decrease of 12.46% in pharmacy claims cost following the RDUR intervention letters,

	whereas the comparison group had a decrease of 4.61%. These changes resulted in an estimated cost savings of $1,117.20 per recipient who received an intervention during FFY 2020. The intervention group utilized for the cost savings calculation included 3,467 recipients. **Results Discussion** **All drug claims and some medical claims or diagnosis data is available for analysis. Any medical or diagnosis data available is processed along with the pharmacy claims data to provide as complete a drug and diagnosis history as possible for each recipient. Medical data that includes the cost associated with hospitalization, doctor visits, and emergency room visits is not analyzed as part of the RDUR intervention program. However, it is suspected that by reducing therapy problems including inappropriate use of drugs and increased risk for drug interactions other medically-associated costs due to adverse drug reactions, drug abuse, and diversion would be reduced in addition to the reduction in drug expenditures.** **Conclusion** **The RDUR program provides an important educational service to providers enrolled in the New York State Medicaid Program. During FFY 2020, 3,477 recipients were identified for RDUR intervention letters. The RDUR intervention program alerted the recipient's provider to the drug therapy issue and provided a complete patient profile including a complete pharmacy and medical claims history. This resulted in an estimated cost savings of $3,873,340 for FFY 2020.** **Additional savings during the survey period:** **Brand Less than Generic Program; $9.6 million** **Preferred Drug Program; $3.3 million** **Lock-In savings; $39.9 million (included MCO data reported by OMIG)**

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?	Deny claims, Require PA, Refer to Lock-In Program, Refer to Office of Inspector General (OIG)
Other, please explain.	N/A
2. Does your state have a Lock-In program for beneficiaries with potential misuse or abuse of controlled substances? If "Yes," please continue.	**Yes**
a. What criteria does your state use to identify candidates for Lock-In?	**Number of controlled substances (CS), Different prescribers of CS, Multiple pharmacies, Number days' supply of CS, Exclusivity of short acting opioids, Multiple ER visits**
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?	**Lock-in time period is based on number of offences**
Other, please explain.	N/A
d. On average, what percentage of the FFS population is in Lock-In status annually?	**0.0500%**
e. Please provide an estimate of the savings attributed to the Lock-In program for the fiscal year under review.	**$39,900,000.00**
3. Does your state have a documented process in place that identifies possible FWA of controlled drugs by prescribers?	**Yes**
Yes, what actions does this process initiate?	Deny claims written by this prescriber, Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation, Refer to the appropriate Medical Board, Other
Other, please explain.	Academic retro-dur case reviewers refer potential prescriber fraud cases to the DUR program. They are then forwarded to the

Question	Response
	Medicaid Office of the Inspector General (OMIG) for further review and/or possible investigation.
No, please explain.	N/A
4. Does your state have a documented process in place that identifies potential FWA of controlled drugs by pharmacy providers?	**Yes**
Yes, what actions does this process initiate?	Deny claim, Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation, Refer to Board of Pharmacy
Other, please explain.	N/A
No, please explain.	N/A
5. Does your state have a documented process in place that identifies and/or prevents potential FWA of non-controlled drugs by beneficiaries?	**Yes**
Yes, please explain your program for FWA of non-controlled substances.	Academic retro-dur case reviewers refer potential prescriber fraud cases to the DUR program. They are then forwarded to the Medicaid Office of the Inspector General (OMIG) for further review and/or possible investigation.
No, please explain.	N/A

B. Prescription Drug Monitoring Program (PDMP)

Note: Section 5042 of the SUPPORT for Patients and Communities Act requires states to report metrics in reference to their state's PDMP. CMS has included questions to reference these metrics to help your state establish processes to be in compliance with provisions outlined in Section 5042 and CMS reporting, beginning in FFY 2023.

Question	Response
1. Does your Medicaid program have the ability to query the state's PDMP database?	**No**
Yes, receive PDMP data.	N/A
Other, please explain.	N/A
Yes, have direct access to the database.	N/A
No, please explain.	No direct sharing of the PDPM program and Medicaid at this time
If "Yes," please continue. a. Please explain how the state applies this information to control FWA of controlled substances.	**N/A**

Question	Response
b. Does your state also have access to Border States' PDMP information?	**N/A**
c. Does your state also have PDMP data integrated into your POS edits?	**N/A**
2. Does your state or your professional board require prescribers to access the PDMP patient history before prescribing controlled substances?	**Yes**
No, please explain.	N/A
If "Yes," please continue. a. Are there protocols involved in checking the PDMP?	Yes
Yes, please explain.	Practitioners (except veterinarians) are required to check the PDMP registry prior to prescribing or dispensing a controlled substance in schedules II, III, IV for a patient. Pharmacists also have access to the same information found on the PDMP but are not required to check the site. Pharmacists and dispensing practitioners are required to submit controlled substance dispensing data to the Bureau of Narcotic Enforcement. Data will be submitted to the Bureau on a "real time" basis as defined by the Commissioner within the regulations. Dispensers are required to report refills and partial refills to the Department of Health.
b. Are providers required to have protocols for responses to information from the PDMP that is contradictory to the direction that the practitioner expects from the client?	**Yes**
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?	**Yes**
No, please explain.	N/A
If "Yes," does your state require the provider to submit, upon request, documentation to the State?	Yes
No, please explain.	N/A

Question	Response
3. Does the State require pharmacists to check the PDMP prior to dispensing?	**No**
No, please explain.	Pharmacists will have the ability to access the same information as prescribers on the PDMP should they have an individual Health Commerce Account but are not required to check prior to dispensing.
If "Yes," are there protocols involved in checking the PDMP?	N/A
Yes, please explain.	N/A
4. In the State's PDMP system, which of the following pieces of information with respect to a beneficiary is available to prescribers as close to real-time as possible?	**The number and type of controlled substances prescribed to and dispensed to the beneficiary during at least the most recent 12-month period.**
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**
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).	The Medicaid Agency cannot access the PDMP at this time.
5. Have you had any changes to your state's PDMP during this reporting period that have improved the Medicaid program's ability to access PDMP data?	**No**
Yes, please explain.	N/A
6. 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 quantity dispensed of an initial opioid prescription? If the answer to question 1 is "Yes, for all opioids" or "Yes, for some opioids," please continue.	**Yes, for all opioids**

Question	Response
Please explain answer above.	A quantity limit of a 7-day supply is a POS edit for initial opioid prescriptions for acute pain in recipients who are opioid naive. Exceptions are for recipients with a diagnosis of cancer or sickle cell disease.
a. Is there more than one quantity limit for various opioids? Additionally, please explain ramifications when addressing COVID-19 if applicable?	**Yes**
Yes, please explain.	Quantity limits are placed on various opioids based upon the maximum dosing guidelines established by the FDA extended over a 30 day period.
b. What is the maximum number of days allowed for an initial opioid prescription for an opioid naïve patient?	**7**
c. Does this days' supply limit apply to all opioid prescriptions?	**Yes, for all opioids**
Please explain above response.	The 7 day limit applies to naive recipients being treated for acute pain.
2. For subsequent prescriptions, does your state have POS edits in place to limit the quantity dispensed of short-acting (SA) opioids?	**Yes**
Yes, what is your maximum days' supply per prescription limitation?	Other
Other, please explain.	Quantity limits are based upon FDA maximum daily doses extended for a maximum of a 30-day period. Patients are limited to a total of 4 opioid prescriptions every 30 days. PA is required for use of opioids equal to or greater than 90 MME per day for management of nonacute pain defined as pain greater than 7 days. (exception for patients diagnosed with cancer or Sickle Cell disease). PA required for continuation of opioid therapy beyond an initial 7 day supply in patients established on gabapentin or pregabalin. PA is required for patients prescribed an opioid while on established opioid dependence therapy.
No, please explain.	N/A
3. Does your state currently have POS edits in place to limit the quantity dispensed of long-acting (LA) opioids?	**Yes**
Yes, what is your maximum days' supply per prescription limitation?	Other

Question	Response
Other, please explain.	Quantity limits are based upon FDA maximum daily doses extended for a maximum of 30 days. In addition there is a POS limitation of no more than 4 opioid prescriptions obtained within a 30 day period. Exceptions to this are prescriptions for the treatment of Sickle Cell disease and cancer. PA is required for patient initiating opioid therapy while on established opioid dependency therapy. Patients are limited to a total of 4 opioid prescriptions every 30 days (except in patients with a diagnosis of cancer or Sickle Cell disease). PA required for use if the amount of opioid per day for the management of nonacute pain (pain greater that 7 days) is greater than or equal to 90MME. PA required for initiation of long acting opioid therapy in opioid naive patients. PA required for any additional long acting opioid prescription for patients currently on long acting opioid therapy.
No, please explain.	N/A
4. 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,":	Deny claim and require PA, Intervention letters, MME daily dose program, Step therapy or Clinical criteria, Require diagnosis, Require PDMP checks
Other, please specify.	N/A
Please provide details on these opioid prescribing controls in place.	Claims may be subject to PA requirements subject to peer to peer review with the State's Medicaid Management Administrator. PA's can be required on select opioids as directed by the States DUR Board (ie required diagnosis). DUR Board may require educational letters addressing prescribing habits and retro-dur reviewers may subject non-compliant prescribers to intervention letters. DUR Board has determined the following for opioid prescribing; a 90 MME maximum daily dose requirement, diagnosis requirement, step therapy and clinical criteria for select opioids. State legislation also requires physicians to check the State's PDMP patient listing prior to writing prescriptions for opioids.

Question	Response
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
5. 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?	**Yes**
Please explain above response.	POS edits determine therapeutic duplicates of opioids (and other agents) for pharmacist review at time of order entry. PA is required in situations where patients are receiving more than 4 opioids within a 30 day period, for recipients receiving any opioid while on opioid dependence therapy, for additional long acting opioids prescribed for patients currently on long acting opioid therapy.
6. Does your state have POS edits and automated retrospective claim reviews to monitor early refills of opioid prescriptions dispensed?	**Yes, both POS edits and automated retrospective claim reviews**
If any response is "Yes," please explain scope and nature of reviews and edits in place.	Early refills of opioid prescriptions are denied at POS if the remaining amount is greater than a 7 day supply of an opioid medication which has been obtained over a period of 90 days. Where necessary the DUR Board will require retrodur utilization review reports be performed by academia at the University of the State of New York at Buffalo and presented to the Board for the need for specific action. In addition, pharmacists review individual requests for early fill services of opioid prescriptions reviewing the request, background for the need, and supply amounts where necessary with the prescribing practitioner.
If "No," please explain.	N/A
7. Does your state have a comprehensive automated retrospective claims review process to monitor opioid prescriptions exceeding these state limitations?	**Yes**
Yes, please explain in detail scope and nature of these retrospective reviews.	Opioid claims are reviewed retrospectively by pharmacy academia from the State University of New York at Buffalo. Ad Hoc reviews by the DUR Board using drug utilization presentations by pharmacy academia from the State

Question	Response
	University of New York at Buffalo are used by the Board in identifying the effectiveness of State limitations. Depending on the outcome, targeted educational letters, stricter point of service edits, additional , quantity limits and day's supply durations would be determined by the DUR Board.
No, please explain.	N/A
8. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and benzodiazepines being used concurrently?	**Yes, both POS edits and automated retrospective claim reviews**
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).	NY Medicaid put into place a POS edit requiring prior authorization for claims submitted with concurrent use of opioids and benzodiazepines. Claims of concurrent use of these agents are retrospectively reviewed by pharmacy academia at the State University of New York at Buffalo as ad hoc presentations to the DUR Board. The DUR Board, after reviewing the utilization data from the reports, will determine the course of action.
No, please explain.	N/A
9. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and sedatives being used concurrently?	**Yes, Automated retrospective claim reviews**
Please explain above and detail scope and nature of reviews and edits.	A POS drug to drug interaction warning will alert pharmacists of concurrent use of sedatives and opioids on a patient. These claims are retrospectively reviewed by pharmacy academia at the State University of New York at Buffalo as ad hoc presentations to the DUR Board. The DUR Board, after reviewing the utilization data from the reports, will determine the course of action.
No, please explain.	N/A
10. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and antipsychotics being used concurrently?	**Yes, both POS edits and automated retrospective claim reviews**
Please explain in detail scope and nature of reviews and edits.	A POS drug to drug interaction warning will alert pharmacists of concurrent use of antipsychotic agents and opioids on a patient. These claims are retrospectively reviewed by

Question	Response
	pharmacy academia at the State University of New York at Buffalo as ad hoc presentations to the DUR Board. The DUR Board, after reviewing the utilization data from the reports, will determine the course of action. During this period the Board recommended that prior authorization be required when an oral second generation antipsychotic is utilized above the highest MDD according to FDA labeling.
No, please explain.	N/A
11. Does your state have POS safety edits or perform automated retrospective claim reviews and/or provider education in regard to beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis?	**Yes, both POS edits and automated retrospective claim reviews and/or provider education**
If "Yes, Automated retrospective claims reviews and/or "provider education," please indicate how often.	Ad hoc
Other, please specify.	N/A
Please explain nature and scope of edits, reviews and/or provider education reviews performed.	POS PA's are required for the initiation of opioid therapy on patients receiving established opioid dependence therapy. These claims are retrospectively reviewed monthly by pharmacy academia at the State University of New York at Buffalo. Ad Hoc presentations are provided to the DUR Board which identify clinical issues associated with dual therapy. The DUR Board, after reviewing the utilization data from the reports, will determine the course of action.
If "No," does your state plan on implementing automated retrospective claim reviews and/or provider education in regard to beneficiaries with a diagnosis history of OUD or opioid poisoning in the future?	N/A
Yes, when does your state plan on implementing?	N/A
No, please explain.	N/A
12. Does your state Medicaid program develop and provide prescribers with pain management or opioid prescribing guidelines?	**Yes**
If "Yes," please.	Your state Medicaid program refers prescribers to the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain., Other guidelines.
Other guidelines, please identify.	New York State offers licensed prescribers an Opioid Prescribing Training Program available

Question	Response
	at no charge to prescribers and is accredited for continuing education. The program covers 8 topics required per legislation. New York Medicaid, through its Medicaid Physician Education program (PEP) offers prescriber visits by pharmacy educators on the use of agents for the treatment of chronic non-cancer pain using on-site education programs. Modules are accredited by the Accreditation Council for Continuing Education.
If "No," please explain why no guidelines are offered.	N/A
13. 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**
Yes, please explain.	New York has abuse deterrent agents available on the preferred section of the State's Preferred Drug List. Opioid antagonists (Narcan Nasal Spray, naloxone, and naltrexone). and injectable opioid dependence agents (Vivitrol and Sublocade) are preferred. Oral trans-mucosal opioid dependent agents (buprenorphine and Suboxone) are preferred but require a PA for initiation of opioid therapy for patients on established opioid dependence therapy.

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**
Less than 50 MME, please specify.	N/A mg per day
Greater than 200 MME, please specify.	N/A mg per day

Question	Response
b. Please explain nature and scope of dose limit (i.e. who does this edit apply to? Does the limit apply to all opioids? Are you in the process of tapering patients to achieve this limit?).	**Prior authorization is required for management of non-acute pain when utilizing greater than or equal to 90 MME per day. (Non-acute pain is defined as greater than 7 days of opioid therapy). Prior authorization will not be required for members already established on greater than or equal to 90 MME per day. The MME parameter will not apply for members with cancer, sickle cell disease, or receiving hospice care. POS claim denial will occur on patients treated with opioid use of greater than or equal to 90 MME.**
If "No," please explain the measure or program you utilize.	N/A
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
3. Does your state have automated retrospective claim reviews to monitor the MME total daily dose of opioid prescriptions dispensed?	**Yes**
Please explain.	Retrospective claims are reviewed monthly by pharmacy academia at the State University at Buffalo. When appropriate, utilization reviews are prepared as a means of identifying clinical issues surrounding MME total daily dose of opioids and are presented to the DUR Board. After their review the Board will recommend any action needed to address outlying concerns.
4. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage or do you provide a calculator developed elsewhere? If "Yes," please continue.	**Yes**
a. Please name the developer of the calculator:	**Other**
Other, please specify.	New York State Opioid Training program addresses opioid prescribing.
b. How is the information disseminated?	**Educational seminar**
Other, please explain.	N/A

E. Opioid Use Disorder (OUD) Treatment

Question	Response
1. Does your state have utilization controls (i.e. PDL, PA, QL) to either monitor or manage the prescribing of Medication Assisted Treatment (MAT) drugs for OUD?	**Yes**
Yes, please explain.	**PA required for initiation of opioid therapy for patients on established opioid dependent therapy. Quantity limits on select opioid dependent agents.**
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
Other, please explain.	N/A
3. What are your limitations on the allowable length of this treatment?	**No limit**
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**
Other, please explain.	N/A
b. What are your limitations on the allowable length of the reduced dosage treatment?	**N/A**
Other, please explain.	N/A
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**
Other, please explain.	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?	**No**
8. Does your state have at least one naloxone opioid overdose product available without PA?	**Yes**

Question	Response
9. Does your state retrospectively monitor and manage appropriate use of naloxone to persons at risk of overdose?	**Yes**
No, please explain.	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
1. Does your state cover OTPs that provide Behavioral Health (BH) and MAT services?	**Yes**
No, please explain.	N/A
If "Yes", is a referral needed for OUD treatment through OTPs?	No
Please explain.	On the Medicaid managed care side, individuals have the ability to self-refer to outpatient services and OTPs are considered essential community providers so they have the ability to rapidly access treatment. State law prohibits prior authorization for these services across insurance products (public/private) that are regulated by NYS.
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**
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**
No, please explain.	N/A
4. Does your state Medicaid program cover Methadone for a substance use disorder (i.e. OTPs, Methadone Clinics)?	**Yes**

G. Antipsychotics / Stimulants

Antipsychotics

Question	Response
1. Does your state currently have restrictions in place to limit the quantity of antipsychotics?	**Yes**
Please explain restrictions or N/A.	Maximum daily limits have been placed on the following antipsychotics. paliperidone ER, quetiapine, quetiapine ER based upon tablet strength, lumateperone.
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**
Other, please explain.	N/A
b. Does your state have edits in place to monitor:	**Child's age, Dosage, Indication, Polypharmacy**
Other please explain.	N/A
c. Please briefly explain the specifics of your documented antipsychotic monitoring program(s).	**PA for cases where an oral SGA is used above the highest MDD per FDA labeling. PA where patients under 21 years are prescribed 2 or more different antipsychotics for greater than 90 days or when 3 or more oral SGA's are used for more than 180 days. Confirm diagnosis of FDA approved or compendia supported indications. PA required for initial prescription for beneficiaries younger that the drug specific minimum age. Require confirmation of diagnosis that supports the concurrent use of a SGA and CNS stimulant for beneficiaries under the age of 18 years.**
If "No," does your state plan on implementing a program in the future.	N/A
Yes, please specify when you plan on implementing a program to monitor the appropriate use of antipsychotic drugs in children.	N/A
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 stimulants?	**Yes**

Question	Response
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**
Other, please explain.	N/A
b. Does your state have edits in place to monitor:	**Child's age, Dosage, Indication, Polypharmacy**
Other, please explain.	N/A
c. Please briefly explain the specifics of your documented stimulant monitoring program(s).	**Confirm diagnosis of FDA approved , compendia supported indications for beneficiaries less than 18 years. PA required for initial prescription for beneficiaries under the age of 3 years. Require confirmation of diagnosis that supports concurrent use of CMS stimulant and SGA agents. For patients older than 18 years confirm diagnosis of FDA approved, compendia supported indications. Dose optimization for CNS listed drugs and strengths. Quantity limits based upon FDA labeling**
If "No," does your state plan on implementing a program in the future?	N/A
Yes, please specify when you plan on implementing a program to monitor the appropriate use of stimulant drugs in children.	N/A
No, please explain why you will not be implementing a program to monitor the appropriate use of stimulant 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**
Yes, please explain.	N/A
2. Summary 5 – Innovative Practices Summary 5: Innovative Practices should discuss development of innovative practices during the past year (i.e. Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MME, and Value Based Purchasing).	**2020 Jan thru Sept** **1 Claim edits in place to assure appropriate Medicare D billing of OTC insulin and legend drugs with OTC alternatives.** **2 System edits affecting coordination of benefit claims implemented to ensure simultaneously submitted copay or coinsurance values secondary to Medicaid are not permitted.** **3 Establishment of billing guidance for COVID19 testing and specimen collection for pharmacy providers.** **4 Public notification of DURB Preferred Drug program recommendations affecting the following categories NSAIDs CNS stimulants high potency steroids GLP1 agonists sulfasalazine derivatives oral immunosuppressive agents phosphate binder regulators.** **5 Removal of PA criteria except for identified retreatment and instances in a members claim history where absence of an approved FDA or compendia supported diagnosis is noted for nonpreferred Hepatitis C agents.** **6 System changes were implemented to allow provider bypass for agents requiring PA prescribed for domiciled residents in specific facilities when Medicaid eligibility is obtained within 90 days from the prescription date of service or fill date for claims not included in the rate.** **7 Medicaid pharmacy provider COVID19 guidance in the form of relaxed editing for formulary adherence for payment of lab testing and specimen collection and for vaccine administration in the pharmacy. Guidance in accord with State and Federal laws addressed 90 day supplies where indicated and medication delivery authorizations as well as prescription**

Question	Response
	transfers allowing more convenient medication access and changes in formulary listing due to drug supply availability in addition to changes in select prior authorization requirements and permissible pharmacy provider overrides in select early fill situations. **8 Dose Optimization Program updates.** **9 Brand Less than Generic change updates. There were two for the period.** **10 Reimbursement for FFS providers enrolled in National Diabetes Prevention Program.** **2019 Oct thru Dec** **1 Allowance for family planning contraception prescriptions to be filled 12 times in one year provided the prescription is for a one month supply.** **2 DUR Board educational letter to prescribers highlighting the SUPPORT ACT requirements addressing the concurrent use of antipsychotic and opioid medications and the importance of mental health treatment and the coordination of care.** **3 DUR Board educational letter to prescribers found in a retrodur review to be prescribing multiple antipsychotics to children under 21 years of age. Prior authorization will be required for children under 21 years of age prescribed two or more different antipsychotics for greater than 90 days.** **4 DUR Board educational letter to prescribers addressing the need to monitor metabolic requirements in children less than 21 years of age prescribed antipsychotic as addressed in the SUPPORT ACT.** **5 DUR Board educational letter the subject of a retroDUR review on the treatment of asthma to prescribers of Leukotriene Modifiers and Their Use in the Treatment of Asthma.** **6 DUR Board educational letter to prescribers highlighting the establishment of a PA requirement in opioid naive recipients receiving greater than 90 morphine milligram per day.** **7 Brand Less than Generic Program change updates one for the period.**

Section X – Managed Care Organizations (MCOs)

Question	Response
1. How many MCOs are enrolled in your state Medicaid program? If "Zero" or "None", please skip the rest of this section.	**18**
2. Is your pharmacy program included in the capitation rate (carved in)?	**Yes**
Please specify the drug categories that are carved out.	N/A
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?	**No, contracts are not updated**
Yes, contracts are updated to address each provision. Please specify effective date:	N/A
No, contracts are not updated, please explain.	The March 1, 2019 model contract was sent into CMS. CMS sent a returned guidance response with language documenting the need for an attestation or changes to the contract since it was learned that the State was unable to update their MMCO contracts during the SPA review process due to work on amendments required to address the COVID crisis. In response to the CMS request to provide an attestation regarding compliance with requirements of the SUPPORT ACT New York sent the following attestation: Under the requirements of Section 35.1 of the existing MMCO model contract MMCO's are required to follow all applicable legal and regulatory requirements which would include the requirements of the SUPPORT ACT, information to contracted MMCOs were disseminated regarding requirements of the SUPPORT ACT. In the fall of 2019, all MMCO's were surveyed by the Department to confirm compliance with the SUPPOR ACT. MMCO's are regularly survey for compliance with the model contract. The State will all requirements of Section 1004 as described in section 1927(g) of the Act and 42CFR part 456, subpart K to the next Model Contract amendment which will be drafted once CMS has approved the 3-1-19 Model Contract which has been with CMS since April 2019.

Question	Response
a. Is the state complying with Federal law and monitoring MCO compliance on the 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**
Yes, state is complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions. Please explain monitoring activities.	Under the requirements of Section 35.1 of the existing MMCO model contract MMCO's are required to follow all applicable legal and regulatory requirements which would include the requirements of the SUPPORT ACT, information to contracted MMCOs were disseminated regarding requirements of the SUPPORT ACT. In the fall of 2019 all MMCO's were surveyed by the Department to confirm compliance with the SUPPOR ACT. MMCO's are regularly survey for compliance with the model contract. The State will include all requirements of Section 1004 as described in section 1927(g) of the Act and 42CFR part 456, subpart K to the next Model Contract amendment which will be drafted once CMS has approved the 3-1-19 Model Contract.
No, please explain.	N/A
4. Does the state set requirements for the MCO's pharmacy benefit (i.e. same PDL, same ProDUR/RetroDUR)?	**Yes**
a. If "Yes," please explain.	**Formulary Reviews**
b. Please briefly explain your policy.	**MCOs mimic the therapeutic categories on the FFS formulary but are not required to make available the exact same drugs that are covered by the Medicaid program. Rules and regulations of each MCO plan regarding elements for PA requirements appeals etc. remain with each individual plan.**
If "No," does your state plan to set standards in the future?	N/A
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.	**In accordance with NYS Social Services Law 369bb the DUR board is responsible for collaborating with MCOs to address drug utilization concerns and implementing consistent management strategies across the FFS and managed care pharmacy benefits.**

Question	Response
	This is done through an ongoing evaluation of retrospective pharmacy claims data (FFS and MCO) for which the data is included as DUR Board meeting agenda items as needed. MCO data (specific to their member population) are provided to each MCO upon DUR Board evaluation. The DUR Board's recommendations and associated RetroDUR programmatic improvements are communicated to the MCO to necessitate any drug related interventions as needed.
7. How does the state ensure MCO compliance with DUR requirements described in Section 1927(g) of the Act and 42 CFR part 456, subpart K?	**The NYS Medicaid Managed Care Model contract requires MCOs provide coverage of outpatient drugs as defined in Section 1927(k)(2) of the Social Security Act, in alignment with standards for such coverage imposed by Section 1927 of the Social Security Act. Additionally, in accordance with 42 CFR 438.3(s)(4), MCOs are required to operate a drug utilization review program that complies with the requirements described in Section 1927(g) of the Social Security Act and 42 CFR 456, Subpart K. The NYS Medicaid Pharmacy Program monitors the MCOs using encounter data to ensure compliance of the above provisions. https://www.health.ny.gov/health_care/managed_care/docs/medicaid_managed_care_fhp_hiv-snp_model_contract.pdf**
8. Did all of your managed care plans submit their DUR reports?	**Yes**
No, please explain.	N/A

Section XI – Executive Summary

Question	Response
Summary 6: Executive Summary Summary 6: Executive Summary should provide a brief overview of your program. It should describe 2020 highlights of the program, FFS initiatives, improvements, program oversight of managed care partners when applicable, and statewide (FFS and MCO) initiatives.	**Prospective and Retrospective Review Programs** **Management of the ProDUR program is a function of the Department of Health's (DOH) Medicaid pharmacy support staff with the assistance from Medicaid Administration vendors (Magellan Medicaid Administration, State University of New York at Buffalo, HID/KEPRO and the DURB). ProDUR edits allow for online claim rejections and can instill savings within the Medicaid program while at the same time promoting safe medication use for program beneficiaries. During the reporting period for Federal Fiscal Year (FFY) 2020, there were 1.8 million on-line claim rejections where pharmacists encountered dispensing issues that were avoided due to ProDUR safety edits. On-line claim rejections encountered during the review period encompassed early fill, drug-drug interactions, therapeutic duplication, prescriber consult, drug-disease concerns, and high-low dose complications. The over-all cost per prescription as determined by cost (net of rebates)over prescription volume was $46.94 dollars. Calculated savings from the ProDUR Program amounted to approximately $84.5 million dollars in savings as determined by multiplying the number of on-line claim rejections by the average cost per prescription. The RetroDUR Program is designed to improve prescribing trends. Claims are screened using DURB adopted criteria and reviews are carried out using the combined efforts of clinical pharmacists from the State University of New York at Buffalo and the State's RetroDUR vendor, Kepro Health Information Design (HID). During FFY 2020 the computer-based clinical criteria identified approximately 3,477 claims for recipients meeting criteria for intervention letters. The types of drug therapy issues were divided into five general categories:drug-disease interactions (12%), drug-drug-interactions (40%), over-utilization (3%), under-utilization (2%) and therapeutic appropriateness (43%). During the review**

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	period 3,673 alert letters were mailed to prescribers for the top 10 criteria evaluated (7,642 letters for all instances). Approximately 5% of the prescribers voluntarily replied to the program intervention letters with 29% responding that positive steps were taken to address the drug therapy issues identified in the alert letter. HID found that the intervention group had a decrease of 12.46% in pharmacy claims cost following the RetroDUR intervention letters, whereas, the comparison group had a decrease of 4.61%. The total RetroDUR cost avoidance, calculated by the RetroDUR vendor was estimated at $3,873,000 ($3.9)million dollars. The RetroDUR program also tracks potentially fraudulent controlled substance claims forwarding them to the Office of the Inspector General (OMIG) for final review and action. For the period of this survey 66 findings were found and sent to OMIG for review and possible action. **DUR Educational Program. In addition to the monthly RetroDUR intervention letters under the directions of the State's retrodur vendor, targeted educational letters may also be sent to providers for select clinical issues by the DURB. For FFY 2020, DURB educational letters sent out addressed the following:Use of Antipsychotic Medication in Children related to the Substance Use-Disorder Prevention that promotes Opioid Recovery and Therapy (SUPPORT) for Patients and Communities Act, Antipsychotic Use in Children as related to the Support ACT, Concurrent Use of Opioids and Antipsychotics as related to the SUPPORT ACT, Leukotriene Modifiers and Their Use in the Treatment of Asthma. A retrodur program update was presented to the DURB demonstrating the effectiveness of a previous educational letter sent to prescribers outlining the newly discovered adverse events attributed to fluoroquinolones.** **PDP and Brand Less Than Generic (BLTG)Programs, New York Medicaid belongs to a multi-state Medicaid pharmaceutical purchasing pool administered by the vendor,**

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	Magellan Medicaid Administration Inc (MMAI). Based upon clinical drug updates and/or financial information provided by the MMAI, the DURB manages the PDP. For State Fiscal Year (SFY) 2020 (April 1, 2019 to March 31, 2020) program savings amounting to $3,261,769 ($3.3) million dollars. An additional cost containment program is the BLTG Program. Managed by the State's Medicaid Administrator along with Department of Health staff, the BLTG program estimated savings was $9,640,501 ($9.6) million dollars for SFY 2020. $39.9 million in cost avoidance (includes MCO data reported by OMIG) was obtained from the Lock-In Program during the initial 5 month period October 2019 to February 2020. The pandemic saw lifting of restrictions after February 2020. **DUR Board Activities: There were 2 meetings held during FFY 2020:February 23 and July 23.** **February 23 Meeting** **Drug Utilization Reviews (DUR)** **1. Management of Non-Acute Pain, Utilization of Opioids and Morphine Milligram Equivalent Parameters: Board recommended prior authorization is required when utilizing greater than or equal to 90 MME per day. 2. Management of Eosinophilic Asthma (EA):The Board recommended prior authorization is required when there is a)no history of corticosteroid utilization and b) no concurrent use of a corticosteroid. 3. Management of Oral Second-Generation Antipsychotics (SGAs):Utilization of SGAs and Maximum Daily Dosages (MDD):The Board Recommended prior authorization is required when an oral SGA is utilized above the highest MDD according to FDA labeling. Prior authorization will not be required for members established on a dose greater than the highest MDD.** **Clinical Editing Updates 1. Utilization Trends for Products Used for the Treatment of Opioid Use Disorder. The DUR Board agreed that the current quantity limits and duration edits established for most of the products used for OUD in the Medicaid program**

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	remain in effect. Quantity limits were adjusted for the product having recently introduced package size changes 2. Utilization Trends for Long-Acting Opioids Used for the Management of Pain:The Board recommended to continue with current LAO quantity limits. **General Program Updates 1. Medicaid Retrospective Drug Utilization Review (RetroDUR): Fluoroquinolone Project. The update was an assessment of a mailed letter intervention to promote appropriate use of the fluoroquinolone class and concluded that the letter appeared to have had a modest effect (15.1%) on decreasing potentially inappropriate fluoroquinolone prescribing. 2. Medicaid Prescriber Education Program:Antibiotic Stewardship. The presentation provided an overview to the Board of the New York State Medicaid Prescriber Education Program activities, including the newest educational module, Antibiotic Stewardship. The goal of the NYSMPEP program is to optimize the quality of care for NYS Medicaid members by providing the most current, unbiased, evidence-based information on best practices in pharmacotherapy.** **July 23, 2020 DURB Meeting** **1. PDP Clinical Review. 10 therapeutic drug categories were reviewed for additions and/or changes to the preferred and non-preferred status of the drug categories being presented. The DUR Board recommended changes to those therapeutic categories based upon clinical and financial information.** **2. Drug Cap Review, Spinraza (nusinersen) Drugs piercing the State Medicaid's Drug Cap and having no consensus on a negotiated drug rebate value are, by State law, sent to the State's DURB to determine a calculated target rebate value. The Board agreed to a supplemental rebate target amount for Spinraza as required by law. Innovative changes addressing the COVID Pandemic, Medicaid pharmacy provider COVID19 guidance relaxed editing of formulary adherence for payment of lab testing and**

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	specimen collection and for vaccine administration in the pharmacy. Provider guidance issued in accord with State and Federal laws addressed 90 day supplies where indicated and medication delivery authorizations as well as prescription transfers allowing more convenient medication access and changes in formulary listing due to drug supply availability in addition to changes in select prior authorization requirements and permissible pharmacy provider overrides in select early fill situations. **Declared Executive Orders, effective for the extent of the pandemic, modified the laws of New York designating licensed pharmacists as qualified healthcare representatives for the purpose of directing a limited service laboratory for patient COVID 19 testing. In addition, pharmacists were approved for COVID 19 vaccine administration after receiving proper training.** **Managed Care Oversight** **As of 10-24-2019 New York was awaiting approval of the 3-1-19 model Managed Care Contract. Once approved work on specific language to an amendment addressing specific requirements of the SUPPORT ACT will begin. Contract language follows the SUPPORT ACT as evidenced by section 35.1 of the current 3-1-10 model contract. A compliance attestation was sent to CMS addressing current contract compliance with the following addition; New York State will include all requirements of Section 1004 of the SUPPORT for Patients and Communities Act to the next model contract amendment which will commence once approval of the 3-1-2019 model contract has been receive from CMS. Medicaid Managed Care plans meet quarterly with the Medicaid Formulary and Operation Systems Implementation Unit to discuss statewide initiatives and major program changes. Discussion of returning the pharmacy program back to Medicaid from the Managed Care plans is being pursued. Routine meetings are held to discuss each plans adherence to NY Medicaid's formulary**

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	requirements for beneficiaries. Medicaid Managed Care formularies are reviewed for agents that are not considered Covered Outpatient Drugs. In addition, new pipeline drugs are introduced for discussion.