Delaware
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?	**35,916**
2. On a monthly average, how many of your state's Medicaid beneficiaries are enrolled in managed care plan(s)?	**204,266**

Section II - Prospective DUR (ProDUR)

Question	Response
1. Indicate the type of your pharmacy point of service (POS) vendor.	**Contractor**
a. Vendor Name	**Gainwell Technologies**
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?	**Yes**
a. How often does your state receive reports?	**Monthly**
Other, please explain.	N/A
b. If you receive reports, does your state follow up with those providers who routinely override with interventions?	**Yes**
Yes, what method does your state follow up?	Contact Pharmacy
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:	**83%**
ii) Schedule II controlled drugs:	**90%**
iii) Schedule III through V controlled drugs:	**90%**

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?	Pharmacist or 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?	Pharmacist or 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.	**Overrides by pharmacist are allowed for changes in dosage with a prior authorization, or entry of Submission Clarification code 5 and any required standard professional codes.**
7. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?	**Yes**
If "Yes," please explain your edit.	Delaware posts an edit on claims if the accumulative refills are greater than 4 fills in a 120 lookback day period.
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, Retrospective PA
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)
Lantus	Insulins	Claim failed produr alert	Revlimid 10mg capsule	5.32%	albuterol sulfate inhalation	2.11%
Novolog	Opioid Analgesics	drug covered by Medicare part D	biktarvy 50-200-25 mg tablet	3.89%	fluticasone propionate nasal	1.14%
Oxycodone Tablet	Stimulants - Adrenerics, aromatic catecholamine	member enrolled in managed care	vivitrol 380 mg vial-diluent	2.84%	gabapentin oral 300 mg capsule	0.92%
Humalog	Direct factor XA Inhibitors	members benefits package does not include this medication	novolog 100 unit/ml flexpen	2.50%	buprenorphine hcl/naloxone film	0.87%
oxycodone/ acetaminophen	Antipsychotics - Atypical	member not eligible for HDR DOS	lantus solostar 100 unit/ml	2.19%	omeprazole oral 40 mg capsule	0.84%
Vyvanse	Anticonvulsants		triumeq 600-50-300 mg tablet	1.59%	amlodipine besylate oral 10 m	0.83%
dextroamphetamine /amphetamine	Opioid Withdrawal therapy agents		genvolya tablet	1.59%	cetirizine hcl oral 10 mg tablet	0.75%
buprenorphine/ naloxone	Anti-anxiety benzodiazepines		humira(cf) 40 mg/0.4 ml syringe	1.44%	atorvastatin calcium oral 40	0.71%
Levemir	Antihyperglycemic, DPP-4 Inhibitor		nitrofurantoin 25 mg/5 ml susp	1.42%	aspirin oral 81 mg tablet dr	0.67%
Xarelto	proton pump inhibitor agents		xtandi 40 mg capsule	1.39%	insulin glargine, hum rec anl	0.65%

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 Board of Pharmacy**

Question	Response
state has responsibility for monitoring compliance with the oral counseling requirement?	
Other, please explain.	N/A

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.	**Gainwell Technologies**
b. Is the RetroDUR vendor the Medicaid Management Information System (MMIS) fiscal agent?	**Yes**
c. Is the RetroDUR vendor the developer/supplier of your retrospective DUR criteria?	**Yes**
Please explain "Yes" or "No" response.	Gainwell provides both services for the State of Delaware
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?	**Other**
Other, please specify.	Delaware sends out retroDUR letters that are generated weekly based on DUR criteria that has been established by the DUR Board members. Additionally, we send out blast faxes and the prescriber notifications on an ad hoc basis.
a. How often does your state perform retrospective reviews that involve communication of client specific information to healthcare practitioners (through messaging, fax, or mail)?	**Other**
Other, please specify.	Delaware sends out retroDUR letters that are generated weekly based on DUR criteria that has been established by the DUR Board members. We also send out messaging on an ad hoc based on specific DUR Board request .
b. What is the preferred mode of communication when performing RetroDUR initiatives?	**Mailed letters, Provider phone calls, Newsletters or other non-direct provider communications**
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.	**For FFY 2020, Delaware Medicaid continued to operate under a Medicaid Management Information System (MMIS) and third-party vendor contracts. Delaware used its improved electronic drug utilization review process and a concurrent review functionality that accounts for both pharmacy and medical claim types in the drug utilization review**

	process for the Fee for Service (FFS) program. Delaware FFS retrospective screening and educational interventions continue to benefit the providers, members, and state by providing a more complete picture of drug utilization issues to improve health outcomes while ensuring continued financial sustainability. **During FFY 2020, the State continued to closely monitor and prioritized outreach to assist in educating providers on safe opioid prescribing. For example, auto-generated letters were sent to 337 providers in FFY 2020 to alert providers of high dose warnings and drug-drug interactions. Of note, , educational outreach to providers began in the Fall 2019 that was in accordance with the DUR requirements of the SUPPORT Act. These letters alerted providers of combinations of opioid-antipsychotic, opioid-muscle relaxant, opioid-benzodiazepine, as well as opioid-sedative combinations. Often these combinations were being provided by multiple prescribers who may have been unaware of the patient's other prescribers and medications. DE's goal is that by increasing awareness of these interactions, the State hopes to increase patient safety, increase coordination of care, and decrease adverse outcomes in this population. Moreover, providers continue to be notified when their patients reached the threshold of greater than 90 MME on opioid pharmacy prescriptions.** **Another method through which Delaware utilizes RetroDUR to improve client health and fiscal responsibility is through targeted provider outreach. Channels used include blast faxes to pharmacies, bulletins to providers, and notifications on our webpage. For example, Delaware sent out a blast fax to pharmacies reminding them of the naloxone protocol for dispensing, and the zero patient cost for this rescue medication.**

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.	**Although faced with the challenges of the COVID-19 public health emergency, Delaware was successful in adapting and transitioning to hold its DUR Board meeting virtually. As in past years, the DUR Board Meeting was held in conjunction with the P&T Committee meeting . By having one cohesive board, Delaware facilitates broad ranging discussions on drug utilization, drug coverage policies and feedback from the community. The annual DUR/P&T Meeting occurred September 24, 2020. Both managed care organizations' pharmacy directors, which represent 85% of the Medicaid population in Delaware, participated in the DUR/P&T committee meeting.** **In Fall 2019, Delaware added the following Drug-Drug interaction alerts to create real time POS warnings and automated retroactive prescriber outreach specifically to address the SUPPORT Act requirement requiring electronic notifications (safety edits) around drug interactions with opioids:** **%u2022 Opioid-Antipsychotic** **%u2022 Opioid-Sedative** **%u2022 Opioid-Muscle Relaxant** **%u2022 Opioid-Benzodiazepine** **It is DE's and the DUR Board's goal that these new alerts coupled with our provider education outreach initiatives will promote safety and proper use and prevent abuse of opioids in our member population. Throughout FFY 2020 various ProDUR alerts were added monthly through FDB DUR updates. For example, below is a sampling of some of the most useful alerts adopted for new drugs released in FFY 2020:** **%u2022 Drug-Geriatric Warnings** **o Maxquin** **o Valtoco** **%u2022 Drug-Pediatric Warnings** **o Fintepla** **o Reblozyl** **%u2022 Drug-Disease Warnings** **o Wakix**

Question	Response
	o Ayvakit %u2022 Drug-Drug Warnings o Zeposia: warning for MAOIs o Nourianz: warning for CYP3A4 Inhinitors o Tabrecta: warning for Clozapine
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?	**Yes**
If "No," does your state have a plan to include this information in your DUR criteria in the future?	N/A
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.	**In federal fiscal year 2020, DMMA policy continued the goal of encouraging generic usage unless there is a price guarantee offered by the labeler, regardless of the federal rebate, to lessen the cost burden on the DMMA Medicaid program. When it was deemed more appropriate to use brand multi-sourced products, the brand name product is listed as preferred on the PDL in bold to draw the prescriber's attention to the fact that the brand name is being preferred over the generic. Leveraging this policy has resulted in an 82.8% generic utilization for paid claims for the year.** **Delaware Medicaid continues to mandate generic dispensing on all drug categories except for members with a seizure diagnosis and drugs deemed to be narrow therapeutic index medications. All other instances of brand name dispensing when generics are available require prior authorization. For members with a seizure diagnosis, the provider includes the diagnosis on the prescription and the pharmacy submits the diagnosis code in the corresponding NCPDP field which will override the need for any paper prior authorization to be submitted. Our state law requires that a doctor must write Brand Medically Necessary on the face of prescriptions for brand name, but Medicaid takes additional steps to ensure the medical necessity of a brand name dispensing. If a patient requests brand and the pharmacy submits a DAW code of two, this code is automatically rejected in our point of sale system.** **Delaware also continues to mandate that a Med Watch form be submitted as part of the prior authorization process for brand name multi%u2010sourced medications. First and foremost, Med Watch forms are detailed descriptions of the generic product that failed and the type of failure that occur. Using this form means that a generic must be tried prior to the request for a brand name product. A**

Question	Response
	minimum of a two%u2010week trial period is required unless an objective adverse event occurs that necessitates the medication being stopped. The Med Watch form must be completely filled out with the National Drug Code (NDC) and lot number. Along with this required information, the physician must document a valid side effect or lack of efficacy that occurred with the member utilizing a generic. The majority of Med Watch forms submitted to Delaware Medicaid do not meet our criterion for prior authorization approval as they lack information, have too short of a trial period, or listed symptoms that cannot be linked to the generic product itself. Delaware has had this policy requiring the Med Watch form to deter brand name dispensing of multi%u2010source drugs for many years and continues to find it to be effective in decreasing unnecessary and costly use of brand name products.
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,"	Require that a MedWatch Form be submitted, Require the medical reason(s) for override to accompany the prescription(s), PA is required, Other
Other, please explain.	A Medwatch form is used to determine the reason why a brand name drug is required

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	10,127	74,590	5,362
Total Reimbursement Amount Less Co-Pay	$3,718,691	$1,304,935	$767,269

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	74,590
Total Number of Claims	90,079
Generic Utilization Percentage	82.81%
4. How many multi-source drugs have the innovator as the preferred drug product based on net pricing?	**1,915**
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	$1,304,935
Total Dollars	$5,790,895
Generic Expenditure Percentage	22.53%

Question	Response
6. Does your state have any policies related to Biosimilars? Please explain.	****Since 2014, Delaware legislation allows for the substitution of FDA approved, interchangeable biosimilar biologic product for prescribed biological reference products with certain safeguards. To substitute a biosimilar product pharmacists must notify the patient and prescriber in writing; record information on the label and dispensing record; and maintain a 3 year record of such substitutions. This bill also provided liability protections for pharmacists who substitute biosimilars.** **In the Medicaid program, biosimilars are covered with the same clinical criteria as the reference product and are addressed within the same policies as the reference product. The MCos have language within all policies to ensure compliance to the FFS Preferred Drug List (PDL) and the placement and preference of biosimilars according to the PDL**

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	Gainwell Technologies
2. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.	

	Data
ProDUR Total Estimated Avoided Costs	$520,932.00
RetroDUR Total Estimated Avoided Costs	$0.00
Other Cost Avoidance	$88,437.00
Grand Total Estimated Avoided Costs	$609,369.00

Question	Response
3. Estimated Percent Impact	**10.52%**
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.	**Delaware has continued to take a conservative approach in estimating our cost savings due to pro%u2010DUR. While early refill denials could be considered, Delaware has always deemed these savings to be more of cost deferral rather than cost avoidance. Additionally, due to the Covid-19 public health emergency this year, some of the early refill restrictions were lifted to facilitate easier medication access during the uncertainty of the pandemic. However, the refill percentage in Delaware is normally set at 83% for non-controlled drugs and for prior authorization claims we even tighten this percentage more by the date range and quantity for which the drug is approved.** **The two edits that Delaware uses to calculate cost savings/cost avoidance are therapeutic duplication and dose optimization. The list of medications that hit for these two edits are extensive and have produced cost savings on the unnecessary dispensation of additional products or additional units of medication. At**

	point of sale, therapeutic duplication within classes is the best way to proactively prevent duplicate therapy and unnecessary expenditures. **Fee for service comprises about 15% of the Medicaid population. In addition, most newly eligible Medicaid members ultimately transition to an MCO administered benefit. In federal fiscal year 2020, the estimated therapeutic duplication alerts for FFS deferred the dispensing of 4,284 units with an estimated savings of $520,931.** **Delaware has a long%u2010standing history of maximizing dose optimization since its implementation in February 2005. Setting optimal dose edits ensures that the member receives a dose that maximizes compliance and therapeutic appropriateness, and as a result, decreases expenditures for the state by dispensing the minimum units and beneficial healthcare outcomes which drive future cost savings. One current trend that continues to be identified in Delaware by the dose optimization audit, are those healthcare providers who prescribe an FDA approved drug for once daily dosing to be dosed multiple times per day. Research has continued to indicate that there is no benefit from more than once daily dosing. For FFY 2020, the drug classes of proton pump inhibitors, blood pressure medications and antipsychotics were the predominant classes that triggered the edit for %u201cquantity units billed outside the limits%u201d.** **Utilizing dose optimization produces savings and does not sacrifice level of member care; in fact, dose optimization reduces the dosing frequency or number of units taken which often leads to improving patient compliance. Even for products that are indicated with a dosing range such as once to twice daily, Delaware utilized the once daily regimen first and needs to see failure before twice daily dosing would be considered for approval. It is estimated during federal fiscal year 2020, Delaware's dose optimization edits prevented over 67,666 units of medication from being dispensed resulting in an estimated savings of $88,438. Delaware continues to review each drug as it enters the market and add it to the dose optimization list when appropriate.**

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 Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
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?	**Different prescribers of CS, Multiple pharmacies, Number days' supply of CS, Exclusivity of short acting opioids**
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?	**Other**
Other, please explain.	Lock in period does not have an end date but can be reviewed at the member's request
d. On average, what percentage of the FFS population is in Lock-In status annually?	**0.1000%**
e. Please provide an estimate of the savings attributed to the Lock-In program for the fiscal year under review.	**$1.00**
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?	Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation, Refer to the appropriate Medical Board
Other, please explain.	N/A
No, please explain.	N/A

Question	Response
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?	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?	**No**
Yes, please explain your program for FWA of non-controlled substances.	N/A
No, please explain.	Delaware does not have a structured plan in place to identify FWA but currently works closely with the SURs Investigation Team when FWA is suspected or reported. Delaware may develop a more structured program in the future

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.	The Medicaid program does not have access to the Delaware PDMP at this time.
If "Yes," please continue. 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 Border States' PDMP information?	**N/A**
c. Does your state also have PDMP data integrated into your POS edits?	**N/A**

Question	Response
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.	%u2022Delaware's Medicaid provider manual states the following: In accordance with the Delaware Prescription Monitoring Act, all DMAP providers must comply with the Delaware Prescription Monitoring Program (PMP) when generating a prescription for a controlled substance for a DMAP member. Providers are required to review the member's patient utilization report. The query should include Delaware and all of the surrounding states; New Jersey, Pennsylvania and Maryland. For medications that are Drug General Policy Provider Policy Manual Enforcement Agency (DEA) Schedule III-V, the PMP website should be queried at least every six months. For Schedule II medications that are prescribed for chronic conditions, the PMP website should be queried every three months. DMAP requires providers to document in the patient record all controlled substances that have been prescribed and filled inside and outside of the provider's practice. Providers must document all actions taken to collaborate with other clinicians prescribing controlled substances in the patient record in regards to mutual patients.
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?	No

Question	Response
No, please explain.	Since the Medicaid program does not have access to the PDMP, nothing can be verified and the state has not asked for such documentation.
3. Does the State require pharmacists to check the PDMP prior to dispensing?	**No**
No, please explain.	Delaware Medicaid Pharmacy providers are required to review the Prescription Monitoring Program (PMP) patient utilization report with the receipt of every Schedule III-V prescription. Schedule II prescriptions should be reviewed each time, unless the member is receiving these medications for a chronic illness. Medications prescribed for chronic illnesses should be monitored at least every three months. Pharmacy providers must document that the PMP was reviewed and adhere to in-house documented protocols when the PMP indicates potential controlled substance abuse or a clinical issue.
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?	**PDMP drug history, The number and type of controlled substances prescribed to and dispensed to the beneficiary during at least the most recent 12-month period., The name, location, and contact information, or other identifying number, such as a national provider identifier, for previous beneficiary fills**
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 current barrier is that there is no direct access by Medicaid agency; any request must go through the PDMP agency
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**

Question	Response
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**
Please explain answer above.	The initial fill of any long acting opioid requires a prior authorization. The first fill of a short acting opioid cannot exceed 7 day supply. In addition, DMMA limits the quantity allowed based on day's supply, MME per day as well as global number of units per year. For example, oxycodone 15, 20, and 30MG have monthly, quarterly and yearly limits in place
a. Is there more than one quantity limit for various opioids? Additionally, please explain ramifications when addressing COVID-19 if applicable?	**No**
Yes, please explain.	N/A
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 some opioids**
Please explain above response.	a
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.	The total dose of opioid cannot exceed 90mg MME per 24 hours. The total quantity of short acting opioids may not exceed 120 per 30 days with a total of 720 units per year.
No, please explain.	N/A

Question	Response
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
Other, please explain.	Total dose of opioid cannot exceed 90mg MME per 24 hours
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, Requirement that patient has a pain management contract or Patient-Provider agreement, Requirement that prescriber has an opioid treatment plan for patients, Require documentation of urine drug screening results, Require diagnosis, Require PDMP checks
Other, please specify.	N/A
Please provide details on these opioid prescribing controls in place.	Prior Authorization criteria contains the following requirements: verification that the prescriber verified the PDMP, verification of first line drug therapies used for treatment based on diagnosis provided, pain assessment and pain contract, and urine drug screen
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.	Duplicate claims are identified by comparing the current drug claim to drugs in claim history having the same generic sequence number or the same therapeutic class with overlapping day supply date ranges. Claim is flagged for Pharmacy verification, and a prior authorization is required to override duplicate therapy or the use of submission clarification

Question	Response
	code of 5 to override in the case of a therapeutic change by prescriber.
6. Does your state have POS edits and automated retrospective claim reviews to monitor early refills of opioid prescriptions dispensed?	**Yes, POS edits**
If any response is "Yes," please explain scope and nature of reviews and edits in place.	Early refills for opioid claims are denied if less than 90% of the day supply has been used
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?	**No**
Yes, please explain in detail scope and nature of these retrospective reviews.	N/A
No, please explain.	Claims that are denied and subsequently overridden are flagged for review. This review may be used for a potential prescriber score card report generation project, and ongoing provider education. Since the FFS population is often comprised of dual eligible individuals with Medicaid as secondary payor, this poses a challenge in creating a automated comprehensive retrospective claims review. Individual provider outreach is done to educate providers when patient's dose exceeds state limits.
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).	**Prior authorization for all opiates can only be approved if the member is not receiving a concurrent benzodiazepine. In addition, providers are notified retroactively via a provider letter when the drug-drug interaction alert flags for one of their patients for opioid-benzodiazepine combinations.
No, please explain.	N/A

Question	Response
9. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and sedatives being used concurrently?	**Yes, both POS edits and automated retrospective claim reviews**
Please explain above and detail scope and nature of reviews and edits.	POS alert and retrospective provider notification letters are activated for high and medium severity Drug-Drug interactions between opioid and sedative combinations. High and medium severity combinations were chosen to avoid alert fatigue
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.	POS alert and retrospective provider notification letters are activated for high and medium severity Drug-Drug interactions between opioid and antipsychotic combinations. High and medium severity combinations were chosen to avoid alert fatigue
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?	**No**
If "Yes, Automated retrospective claims reviews and/or "provider education," please indicate how often.	N/A
Other, please specify.	N/A
Please explain nature and scope of edits, reviews and/or provider education reviews performed.	N/A
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?	Yes
Yes, when does your state plan on implementing?	Continuing collaboration between Department of Public Health (DPH) and Substance Abuse and Mental Health (DSAMH) is ongoing to develop ways of data sharing to assist in identifying patients with a history of Opioid Use Disorder (OUD) with the eventual goal of providing an outreach and intervention

Question	Response
	alert mechanism for referral to specialized care
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, please identify.	N/A
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.	Abuse deterrent medications do not require prior authorization if member is prescribed one unit per day. A select list of abuse deterrent medications are preferred in Delaware.

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?).	**Delaware follows the most recent CDC recommendations. When the dose is above the current recommended dose, physicians receive retroactive written notification in order to reduce patient risk by encouraging re%u2010evaluation of the necessity of the higher dose. The 90 MME limit is also part of the clinical criteria for approval of PA. The 90 MME limit has been in place since July 1, 2018, however Delaware would further re%u2010evaluate this limit if new recommendations for lower doses are released.**
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.	Providers are notified retroactively in cases where the high dose alert is set on a claim
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.	**No**
a. Please name the developer of the calculator:	**N/A**
Other, please specify.	N/A
b. How is the information disseminated?	**N/A**
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.	**Delaware maintains open access for OUD treatments in accordance with the SUPPORT ACT**
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?	Yes
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**

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.	n/a
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**

Question	Response
Please explain restrictions or N/A.	Prior authorization is required for all antipsychotics for patients under six (6) years of age and for any product being prescribed outside of FDA approved age ranges. We also edit for therapeutic duplication.
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, Polypharmacy**
Other please explain.	N/A
c. Please briefly explain the specifics of your documented antipsychotic monitoring program(s).	**Delaware monitors all children but in addition, we do targeted intervention in the foster care population. Ages on the atypical antipsychotic agents are set to the FDA approved indications. Synergy is also achieved in Delaware by the Department of Family Services working with Medicaid on foster children to reduce unnecessary therapies. Doses are edited based on FDA approved doses.**
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**
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

Question	Response
b. Does your state have edits in place to monitor:	**Child's age, Dosage**
Other, please explain.	N/A
c. Please briefly explain the specifics of your documented stimulant monitoring program(s).	**Ages on stimulant agents are set to the FDA approved indications. Doses are edited based on FDA approved doses and Pro%u2010DUR edits are in place to monitor for therapeutic duplication within the stimulant class of medications. Synergy is also achieved in Delaware by the Department of Family Services working with Medicaid on foster children to reduce unnecessary therapies**
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).	**Much of Delaware's innovative practices centered around COVID-19 responses. Delaware responded quickly to any needed changes to policies and coverage related to COVID-10:** **%u2022 Temporarily added PA requirement for Hydroxychloroquine and Chloroquine to avoid shortage for patients with chronic conditions, such as Lupus.** **%u2022 Waived Pharmacy copays to ensure access for our all of our members who might have been affected by the financial downturn related to COVID-19** **%u2022 Expanded the PDL for rescue inhalers to remove any barriers patients could face in getting their much-needed breathing treatments** **%u2022 Removed the POS edit for early refills on non-controlled substances to allow members to consolidate their trips to the pharmacy and make sure necessary chronic medications were on hand when needed** **%u2022 Strategized on how to adapt system changes and reimbursement policy for the anticipated COVID-19 vaccines that were eventually released mid December 2020:** **o *Built a framework for future in advance of vaccine release that ensured consistent reimbursement with CMS on COVID-19 vaccinations** **o Worked quickly to ensure providers were able to submit claims for COVID-19 vaccinations** **%u2022 DE enacted mandatory e-prescribing law with limited exceptions for providers. Delaware Medicaid provided information to our enrolled providers.**

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.	**2**
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?	**Yes, contracts are updated to address each provision**
Yes, contracts are updated to address each provision. Please specify effective date:	1/1/2019
No, contracts are not updated, please explain.	N/A
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.	Delaware has managed care operations oversight in place in Delaware including monthly operational meetings with the MCOs to discuss operational issues, annual External Quality Review processes, and corrective action plan remediation activities. The SUPPORT Act compliance is being incorporated into those operations. To increase oversight operations, Delaware added a contract compliance officer position in October of 2019. This position participates in the MCO oversight activities and also attends monthly leadership meetings to discuss issues that are larger in scope with MCO leaders.
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.	**Same PDL**
b. Please briefly explain your policy.	**Delaware has a unified PDL between FFS and the MCOs to ensure consistency for our providers and members. Although MCOs may adopt different clinical review requirements,**

Question	Response
	any such deviation from FFS standards are approved by the state
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.	**Prospective and retrospective DUR alerts and edits are put into place for MCO and FFS only with approval from the state. Educational programs, such as blast faxes, provider newsletters, and other provider outreach modalities all require approval by the state.**
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?	**Delaware ensures MCO compliance with DUR requirements of the act by requiring that MCOs employ a prospective and retrospective DUR program, provide education to enlisted providers, and comply with DUR board requirements.**
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.	**Federal Fiscal Year 2020 brought the novel challenge of responding the COVID-19 public health emergency but also the opportunity to show resiliency and demonstrate flexibility. For example:** **%u2022 Added PA requirement for Hydroxychloroquine and Chloroquine to avoid shortage for patients with chronic conditions, such as Lupus.** **%u2022 Waived Pharmacy copays to ensure access for our all of our members who might have been affected by the financial downturn related to COVID-19** **%u2022 Expanded the PDL for rescue inhalers to remove any barriers patients could face in getting their much-needed breathing treatments** **%u2022 Removed the POS edit for early refills on non-controlled substances to allow members to consolidate their trips to the pharmacy** **%u2022 Strategized on how to adapt system changes and reimbursement policy for the anticipated COVID-19 vaccines that were eventually released mid December 2020:** **o Ensured consistent reimbursement with CMS on COVID-19 vaccinations** **o Worked quickly to ensure providers were able to submit claims for COVID-19 vaccinations** **%u2022 In all of these endeavors, Delaware FFS and MCOs remained aligned to avoid provider confusion and ensure consistency for our members.** **Although the COVID-19 public health emergency occupied a significant focus for Delaware, we can reflect back on other wins for Federal Fiscal Year 2020. In line with the SUPPORT ACT we accomplished the following:** **%u2022 Added real time and retroactive provider notifications for patients on concurrent use of opioids with the following** **o Antipsychotics** **o Sedatives**

Question	Response
	o Benzodiazepines **o Muscle relaxants** **%u2022 Reminded providers through blast fax that naloxone rescue medications are available in Delaware under a state standing order and at no charge to the patient.** **In addition, Delaware continues to utilize MMIS to automatically generating Retro%u2010DUR alerts to prescribers utilizing Pharmacy and medical information within the system. Provider specific letters with a compilation of clients is generated for portal retrieval, copies of the letters generated are data stored in document repository available for retrieval for faxing upon provider request. This system has served as a cost saving for the state through elimination of returned mail due to wrong addresses when an office relocation has occurred. It also guarantees the providers have access and receive these alerts.** **Delaware has continued to run all drug encounters through established edit/audit rules to track the MCO's management of the drug benefit aligned with Delaware State policies. MMIS generates a monthly report that tracks submitted encounter acceptance rate of our two MCOs. This report is utilized to analyze both MCO efficiency and compliance with all existing state policies and to identify potential modification** **In Federal Fiscal Year 2020 Delaware FFS served approximately 15% of the Delaware Medicaid population. This population continues to be a transient group where the majority will transition into one of our two Managed Care Organizations. To provide consistency for our members and providers, Delaware uses a unified PDL which optimizes cost savings across the entire program.**