

MEDICAID DRUG UTILIZATION REVIEW ANNUAL REPORT

FEDERAL FISCAL YEAR _____

Section 1927 (g) (3) (D) of the Social Security Act (the Act) requires each State to submit an annual report on the operation of its Medicaid Drug Utilization Review (DUR) program. Such reports are to include: descriptions of the nature and scope of the prospective and retrospective DUR programs; a summary of the interventions used in retrospective DUR and an assessment of the education program; a description of DUR Board activities; and an assessment of the DUR program's impact on quality of care as well as any cost savings generated by the program.

This report covers the period October 1, _____ to September 30, _____ and is **due for submission to CMS Central Office by no later than June 30, _____**. **Answering the attached questions and returning the requested materials as attachments to the report will constitute compliance with the above- mentioned statutory requirement**

If you have any questions regarding the DUR Annual Report, please contact
CMS: DURPolicy@cms.hhs.gov.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid O.M.B. control number. The valid O.M.B. control number for this information collection is 0938-0659. The time required to complete this information collection is estimated to average 32 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

**MEDICAID DRUG UTILIZATION REVIEW ANNUAL REPORT
FEDERAL FISCAL YEAR _____**

I. DEMOGRAPHIC INFORMATION

State Name Abbreviation

Medicaid Agency Information

Identify State person responsible for DUR Annual Report Preparation.

Name: _____

Email Address: _____

Area Code/Phone Number: _____

II. PROSPECTIVE DUR (ProDUR)

Identify by name and indicate the type of your pharmacy POS vendor – (contractor, state-operated other).

1. If not state-operated, is the POS vendor also the MMIS fiscal agent?

Yes No

2. Identify prospective DUR criteria source.

First Data Bank Medi-Span Other

If the answer above is “Other,” please specify.

3. Are new prospective DUR criteria approved by the DUR Board?

Yes No

If answer above is “No,” please explain.

4. 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 “conflict, intervention and outcome” codes?

Yes No

5. How often do you receive and review periodic reports providing individual pharmacy provider activity in summary and in detail?

Monthly Quarterly Annually Never

- a) If the answer above is “Never,” please explain why you do not receive and review the reports.

- b) If you receive reports, do you follow-up with those providers who routinely override with interventions?

Yes No

- c) If the answer to (b) above is “Yes,” by what method do you follow-up?

- Contact Pharmacy
 Refer to Program Integrity for Review
 Other, please explain.

- d) If the answer to (b) above is “No,” please explain why you do not follow-up with providers.

8. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?

Yes No

a) If “Yes,” please explain your edit.

b) If “No,” do you plan to implement this edit?

Yes No

9. Does the state or the state’s Board of Pharmacy have any policy prohibiting the auto-refill process that occurs at the POS?

Yes No

10. Has the state provided the DUR data requested on Table 1 – Top Drug Claims Data Reviewed by the DUR Board?

Yes No

11. Section 1927(g)(A) of the Social Security 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? Check all that apply:

- a) Medicaid agency
 - b) State Board of Pharmacy
 - c) Other, please explain.
-

12. Has the state included Attachment 1 – Pharmacy Oral Counseling Compliance Report a report on state efforts to monitor pharmacy compliance with the oral counseling requirement?

Yes No

III. RETROSPECTIVE DUR (RetroDUR)

1. Identify, by name and type, the vendor that performed your RetroDUR activities during the time period covered by this report (company, academic institution, or other organization).

a) Is the RetroDUR vendor also the Medicaid fiscal agent?

Yes No

b) Is the RetroDUR vendor also the developer/supplier of your retrospective DUR criteria?

Yes No

If “No,” please explain.

2. Does the DUR Board approve the RetroDUR criteria?

Yes No

If “No,” please explain.

3. Has the state included **Attachment 2 – Retrospective DUR Educational Outreach Summary**, a year end summary of the Top 10 problem types for which educational interventions were taken?

Yes No

IV. DUR BOARD ACTIVITY

1. State is including a brief summary of DUR Board activities and meeting minutes during the time period covered by this report as **Attachment 3 - Summary of DUR Board Activities**.

Yes No

2. Does your state have a Disease Management Program?

Yes No

a) If “Yes,” have you performed an analysis of the program’s effectiveness?

Yes No

b) If the answer to (a) above is “Yes,” please provide a brief summary of your findings:

c) If the answer to (number 2) above is “Yes,” is your DUR Board involved with this program?

Yes No

3. Does your state have an approved CMS Medication Therapy Management Program?

Yes No

a) If “Yes,” have you performed an analysis of the program’s effectiveness?

Yes No

b) If the answer to (a) above is “Yes,” please provide a brief summary of your findings.

c) If the answer to (number 3) above is “Yes,” is your DUR Board involved with this program?

Yes No

d) If the answer to (number 3) above is “No,” are you planning to develop and implement a program?

Yes No

V. PHYSICIAN ADMINISTERED DRUGS

The Deficit Reduction Act required collection of 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:

1. ProDUR?

Yes No

If “No,” do you have a plan to include this information in your DUR criteria in the future?

Yes No

2. RetroDUR?

Yes No

If “No,” do you have a plan to include this information in your DUR criteria in the future?

Yes No

VI. GENERIC POLICY AND UTILIZATION DATA

1. State is including a description of policies that may affect generic utilization percentage as **Attachment 4 - Generic Drug Substitution Policies**.

Yes No

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 No

If “Yes,” check all that apply:

- a) Require that a MedWatch Form be submitted
- b) Require medical reason for override accompany prescriptions
- c) Prior authorization is required
- d) Other, please explain.

3. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in **Table 2 - Generic Utilization Data**

Number of Generic Claims _____

Total Number of Claims _____

Generic Utilization Percentage _____

4. Indicate the percentage dollars paid for generic covered outpatient drugs in relation to all covered outpatient drug claims paid during this reporting period using the computation instructions in **Table 2 - Generic Utilization Data**

Generic Dollars: _____

Total Dollars: _____

Generic Expenditure Percentage: _____

VII. PROGRAM EVALUATION / COST SAVINGS/COST AVOIDANCE

1. Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance?

Yes No

2. Who conducted your program evaluation for the cost savings estimate/cost avoidance? (company, academic institution, other institution) (name)

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

ProDUR Total Estimated Avoided Costs	
RetroDUR Total Estimated Avoided Costs	
Other cost avoidance	
Grand Total estimated Avoided Costs	

4. Please provide the estimated percent impact of your state's cost savings/cost avoidance program compared to total drug expenditures for covered outpatient drugs.

Use the following formula:

Divide the estimated Grand Total Estimated Avoided Costs from Question 3 above by the total dollar amount provided in Section VI, Question 4. Then multiply this number by 100.

$$\text{Grand Estimated Net Savings Amount} \div \text{Total Dollar Amount} \times 100 = \underline{\hspace{2cm}} \%$$

5. State has provided the Medicaid Cost Savings/Cost Avoidance Evaluation as **Attachment 5 – Cost Savings/Cost Avoidance Methodology.**

- Yes No

VIII. FRAUD, WASTE, AND ABUSE DETECTION

A. LOCK-IN or PATIENT REVIEW AND RESTRICTIVE PROGRAMS

1. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **beneficiaries**?

- Yes No

If “Yes,” what actions does this process initiate? Check all that apply.

- a) Deny claims and require prior authorization
- b) Refer to Lock In Program
- c) Refer to Program Integrity Unit
- d) Other (e.g. SURS, Office of Inspector General), please explain.

2. Do you have a “lock-in” program for beneficiaries with potential misuse or abuse of controlled substances?

- Yes No

If “Yes,” what criteria does your state use to identify candidates for lock-in? Check all that apply.

- 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

If "Yes," do you restrict the beneficiary to:

- i. a prescriber only Yes No
- ii. a pharmacy only Yes No
- iii. a prescriber and pharmacy Yes No

What is the usual "lock-in" time period?

- 6 months
 - 12 months
 - Other, please explain.
-
-

3. On the average, what percentage of the FFS population is in lock-in status annually?

_____ %

4. Please provide an estimate of the savings attributed to the lock-in program for the fiscal year under review.

\$ _____

5. Do you have a documented process in place that identifies possible fraud or abuse of controlled drugs by **prescribers**?

- Yes No

If "Yes," what actions does this process initiate? Check all that apply.

- a) Deny claims written by this prescriber
 - b) Refer to Program Integrity Unit
 - c) Refer to the appropriate Medical Board
 - d) Other, please explain.
-

-
6. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **pharmacy providers**?

Yes No

If “Yes,” what actions does this process initiate? Check all that apply

- a) Deny claim
b) Refer to Program Integrity Unit
c) Refer to Board of Pharmacy
d) Other, please explain:
-
-

7. Do you have a documented process in place that identifies potential fraud or abuse of non-controlled drugs by **beneficiaries**?

Yes No

If “Yes,” please explain your program for fraud, waste, or abuse of non-controlled substances.

B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

1. Does your state have a Prescription Drug Monitoring Program (PDMP)?

Yes No

- a) If the answer above is “Yes,” does your agency have the ability to query the state’s PDMP database?

Yes No

- b) If the answer to (number 1) above is “Yes,” do you require prescribers (in your provider agreement with the agency) to access the PDMP patient history before prescribing restricted

substances?

Yes No

c) If the answer to (number 1) above is “Yes,” please explain how the state applies this information to control fraud and abuse.

d) If the answer to (number 1) above is “Yes,” do you also have access to border states’ PDMP information?

Yes No

2. Are there barriers that hinder the agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb abuse?

Yes No

If “Yes,” please explain the barriers (e.g. lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script)

3. Have you had any changes to your state’s Prescription Drug Monitoring Program during this reporting period that have improved the agency’s ability to access PDMP data?

Yes No

If “Yes,” please explain.

C. PAIN MANAGEMENT CONTROLS

1. Does your state or your agency require that Pain Management providers be certified?

Yes No

2 Does your program obtain the DEA Active Controlled Substance Registrant's File in order to identify prescribers not authorized to prescribe controlled drugs?

Yes No

a) If the answer above is "Yes," do you apply this DEA file to your ProDUR POS edits to prevent unauthorized prescribing?

Yes No

b) If the answer to (a) above is "Yes," please explain how the information is applied

c) If the answer to (a) above is "No," do you plan to obtain the DEA Active Controlled Substance Registrant's file and apply it to your POS edits?

Yes No

3. Do you apply this DEA file to your RetroDUR reviews?

Yes No

If "Yes," please explain how it is applied.

4. Do you have measures in place to either monitor or manage the prescribing of methadone for pain management?

Yes No Other

If "Yes," please check all that apply.

- Pharmacist override
- Deny claim and require PA
- Quantity limits
- Intervention letters
- Morphine equivalent daily dose program
- Step therapy or Clinical criteria

If “No” or “Other,” 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 methadone for pain management.

D. OPIOIDS

1. Do you currently have POS edits in place to limit the quantity of short-acting opioids?

Yes No

a) If “Yes,” what is your maximum daily limit in terms of number of units (i.e. tablets, capsules)?

_____units/day

b) If “Yes,” what is your maximum days supply per prescription limitation?

- 30 day supply
 - 90 day supply
 - Other, please explain.
-
-

2. Do you currently have POS edits in place to limit the quantity of long-acting opioids?

Yes No

a) If “Yes,” what is your maximum daily limit in terms of number of units (i.e. tablets, capsules)?

- 2 units/day
- 3 units/day

b) If “Yes,” what is your maximum days supply per prescription limitation?

- 30 day supply
- 90 day supply

Other, please explain

3. Do you currently have edits in place to monitor opioids and benzodiazepines being used concurrently?

Yes No

If "Yes," please explain.

E. MORPHINE EQUIVALENT DAILY DOSE (MEDD)

1. Have you set recommended maximum morphine equivalent daily dose measures?

Yes No

If "Yes," what is your maximum morphine equivalent daily dose limit in milligrams?

_____mg per day

If "No," please explain the measure or program you utilize.

2. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage?

Yes No

If "Yes," how is the information disseminated?

- Website
- Provider notice
- Educational seminar
- Other, please explain.

3. Do you have an algorithm in your POS system that alerts the pharmacy provider that the morphine equivalent daily dose prescribed has been exceeded?

- Yes No

F. BUPRENORPHINE and BUPRENORPHINE/NALOXONE COMBINATIONS

1. Does your agency set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?

- Yes No

If “Yes,” please specify the total mg/day.

- 12mg
 16 mg
 24 mg
 Other, please explain
-
-

2. What are your limitations on the allowable length of this treatment?

- 6 months
 12 months
 No limit
 Other, please explain.
-
-

3. Do you require that the maximum mg per day allowable be reduced after a set period of time?

- Yes No

a) If “Yes,” what is your reduced (maintenance) dosage?

- 8mg
 - 12mg
 - 16mg
 - Other, please explain.
-
-

b) If “Yes,” what are your limitations on the allowable length of the reduced dosage treatment?

- 6 months
 - 12 months
 - No limit
 - Other, please explain.
-
-

4. Do you have at least one preferred buprenorphine/naloxone combination product available on your PDL?

- Yes No

5. Do you currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug?

- Yes No

If “Yes,” can the POS pharmacist override the edit?

- Yes No

G. ANTIPSYCHOTICS /STIMULANTS

ANTIPSYCHOTICS

1. Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?

- Yes No

If “Yes,” do you either manage or monitor:

- Only children in foster care
 - All children
 - Other, please explain
-
-

If “Yes,” do you have edits in place to monitor:

- Child’s Age
- Dosage
- Polypharmacy

Please briefly explain the specifics of your antipsychotic monitoring program(s).

If you do not have an antipsychotic monitoring program in place, do you plan on implementing a program in the future?

- Yes
- No

If “No,” please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.

STIMULANTS

2. Do you have any documented restrictions or special program in place to monitor, manage, or control the use of stimulants?

- Yes
- No

If “Yes,” is your program limited to:

- Children
- Adults

Both

Please briefly explain your program.

IX. INNOVATIVE PRACTICES

Have you developed any innovative practices during the past year which you have included in **Attachment 6 - Innovative Practices** (e.g. Hepatitis C, Cystic Fibrosis, MEDD, Value Based Purchasing)?

Yes No

X. E-PRESCRIBING

1. Does your MMIS or pharmacy vendor have a portal to electronically provide patient drug history data and pharmacy coverage limitations to a prescriber prior to prescribing upon inquiry?

Yes No

a) If “Yes,” do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?

Yes No

b) If “Yes,” please explain the evaluation methodology in **Attachment 7 – E-Prescribing Activity Summary**.

c) If the answer to (number 1) above is “No,” are you planning to develop this capability?

Yes No

2. Does your system use the NCPDP Origin Code that indicates the prescription source?

Yes No

XI. MANAGED CARE ORGANIZATIONS (MCOs)

1. Does your state have MCOs?

Yes No

If “No,” please skip the rest of this section.

2. Is your pharmacy program included in the capitation rate (carved in)?

Yes No Partial

If “partial,” please specify the drug categories that are carved out.

3. Does the state set requirements for the MCO’s pharmacy benefit (e.g. same PDL, same ProDUR/RetroDUR)?

Yes No

If “Yes,” please check all requirements that apply below:

Formulary Reviews Same PDL Same ProDUR Same RetroDUR

If “Yes,” please briefly explain your policy.

If “No,” do you plan to set standards in the future?

Yes No

4. Does the state require the MCOs to report their DUR activities?

Yes No

If “Yes,” please explain your review process.

If “No,” do you plan to develop a program to have MCOs report their DUR activities in the future?

Yes No

If “No,” please explain.

5. Does all of the Medicaid MCOs in your state have a targeted intervention program (i.e. CMC/Lock In) for the misuse or abuse of controlled substances?

Yes No

If “No,” please explain.

XII. EXECUTIVE SUMMARY - Attachment 8 – Executive Summary

MEDICAID DRUG UTILIZATION REVIEW ANNUAL REPORT

INSTRUCTIONS: Nomenclature Format for Attachments

States: Please use this standardized format for naming attachments.

ATT#-FFY- State Abbrev-Abbreviated Report name (NO SPACES!) Example for Arizona: (each state should insert their 2 letter state code) Attachments:

ATT1-201_-AZ-POCCR (Pharmacy Oral Counseling Compliance Report)

ATT2-201_-AZ-REOS (RetroDUR Educational Outreach Summary)

ATT3-201_-AZ-SDBA (Summary of DUR BD Activities)

ATT4-201_-AZ-GDSP (Generic Drug Substitution Policies)

ATT5-201_-AZ-CSCAM (Cost Savings/Cost Avoidance Methodology)

ATT6-201_-AZ-IPN (Innovative Practices Narrative)

ATT7-201_-AZ-EAS (E-Prescribing Activity Summary)

ATT8-201_-AZ-ES (Executive Summary)

I. EXPLANATION FOR ATTACHMENTS AND TABLES**ATTACHMENT 1 – PHARMACY ORAL COUNSELING COMPLIANCE REPORT**

This attachment reports the monitoring of pharmacy compliance with **all prospective DUR** requirements performed by the State Medicaid Agency, the State Board of Pharmacy, or other entity responsible for monitoring pharmacy activities. If the State Medicaid Agency itself monitors compliance with these requirements, it may provide a survey of a random sample of pharmacies with regard to compliance with the Omnibus Budget Reduction Act (OBRA) of 1990 prospective DUR requirement. This report details state efforts to monitor pharmacy compliance with the oral counseling requirement. This attachment should describe in detail the monitoring efforts that were performed and how effective these efforts were in the fiscal year reported.

ATTACHMENT 2 – RETROSPECTIVE EDUCATIONAL OUTREACH SUMMARY

This is a year-end summary report on RetroDUR screening and educational interventions. The year-end summary reports should be limited to the **TOP 10** problems with the largest number of exceptions. The results of RetroDUR screening and interventions should be included.

ATTACHMENT 3 – SUMMARY OF DUR BOARD ACTIVITIES

This summary should be a brief descriptive report on DUR Board activities during the fiscal year reported. This summary should:

- Indicate the number of DUR Board meetings held.
- List additions/deletions to DUR Board approved criteria.
 - a) For prospective DUR, list problem type/drug combinations added or deleted.
 - b) For retrospective DUR, list therapeutic categories added or deleted.
- Describe Board policies that establish whether and how results of prospective DUR screening are used to adjust retrospective DUR screens. Also, describe policies that establish whether and how results of retrospective DUR screening are used to adjust prospective DUR screens.

- Describe DUR Board involvement in the DUR education program (e.g., newsletters, continuing education, etc.). Also, describe policies adopted to determine mix of patient or provider specific intervention types (e.g., letters, face-to-face visits, increased monitoring).

ATTACHMENT 4 – GENERIC DRUG SUBSTITUTION POLICIES

Please report any factors that could affect your generic utilization percentage and include any relevant documentation.

ATTACHMENT 5 – COST SAVINGS/COST AVOIDANCE METHODOLOGY

Include copy of program evaluations/cost savings estimates prepared by state or contractor noting methodology used.

ATTACHMENT 6 – INNOVATIVE PRACTICES

Please describe in detailed narrative form any innovative practices that you believe have improved the administration of your DUR program, the appropriateness of prescription drug use and/or have helped to control costs (e.g., disease management, academic detailing, automated prior authorizations, continuing education programs).

ATTACHMENT 7 – E-PRESCRIBING ACTIVITY SUMMARY

Please describe all development and implementation plans/accomplishments in the area of e- prescribing. Include any evaluation of the effectiveness of this technology (e.g., number of prescribers e-prescribing, percent e-prescriptions to total prescriptions, relative cost savings).

ATTACHMENT 8 – EXECUTIVE SUMMARY

TABLE 1 – TOP DRUG CLAIMS DATA REVIEWED BY THE DUR BOARD

List the requested data in each category in the chart below.

Column 1- Top 10 Prior Authorization (PA) Requests by Drug Name

Column 2- Top 10 PA Requests by Drug Class

Column 3- Top 5 Claim Denial Reasons other than eligibility (i.e. Quantity Limits, Early Refill, PA, Therapeutic Duplications, Age Edits)

Column 4- Top 10 Drug Names by Amount Paid

Column 5- From Data in column 4, Determine the Percentage of Total Drug Spend

Column 6- Top 10 Drug Names by Claim Count

Column 7- From Data in Column 6, Determine the Percentage of Total Claims

Top 10 PA Requests By Drug Name	Top 10 PA Requests By Drug Class	Top 5 Claim Denial Reasons (i.e. QL, Early Refill, PA, Duplication)	Top 10 Drug Names by Amount Paid	% of Total Spent for Drugs by Amount Paid	Top 10 Drug Names by Claim Count	Drugs By Claim Count % of Total Claims
		XXXXXXXXXXXX				
		XXXXXXXXXXXX				
		XXXXXXXXXXXX				
		XXXXXXXXXXXX				
		XXXXXXXXXXXX				

TABLE 2 – GENERIC UTILIZATION DATA

Please provide the following utilization data for this DUR reporting period for all covered outpatient drugs paid. Exclude Third Party Liability. (COMPLETE TABLE 2)

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 there exists generic alternatives 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 Percentage of Total Drug 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:

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

TABLE 2: GENERIC DRUG UTILIZATION

	Single Source (S) Drugs	Non-Innovator (N) Drugs	Innovator Multi-Source (I) Drugs
<i>Total Number of Claims</i>			
<i>Total Reimbursement Amount Less Co-Pay</i>			

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 (see Key below). This file will be made available from CMS to facilitate consistent reporting across States with this data request.