

MEDICAID DRUG UTILIZATION REVIEW ANNUAL REPORT

FEDERAL FISCAL YEAR _____

Section 1927 (g) (3) (D) of the Social Security 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 the 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 this survey instrument or 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 30 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 vender – (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 Other

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. Do you receive and review periodic reports from your ProDUR contractor providing individual pharmacy provider activity in summary and in detail?

Yes No

If answer above is “Yes”, how often is the report received by the agency:

monthly quarterly annually

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

Yes No

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

- Contact pharmacy
- Refer to Program Integrity for Review
- Other (explain)

6. Early Refill:

a) At what percent threshold do you set your system to edit?

Non-controlled drugs: _____%

Controlled drugs: _____%

b) When an early refill message occurs, does the state require prior authorization?

Non-controlled drugs: Yes No

Controlled drugs: Yes No

c) For non-controlled drugs, if the answer to 4 (b) above is “Yes,” who obtains authorization?

 Pharmacist Prescriber Either

d) For controlled drugs, if the answer to 4 (b) above is “Yes,” who obtains authorization?

 Pharmacist Prescriber Either

e) For non-controlled drugs, if the answer to 4 (b) above is “No,” can the pharmacist override at the point of service?

 Yes No

f) For controlled drugs, if the answer to 4 (b) above is “No,” can the pharmacist override at the point of service?

 Yes No

7. When the pharmacist receives an early refill DUR alert message that requires the Pharmacist’s review, does your system allow the pharmacist to override for situations such as:

a) Lost/stolen Rx Yes No

b) Vacation Yes No

c) Other: provide details_____

8. Does your system have an accumulation edit to prevent patients from obtaining additional refills during the calendar year?

 Yes No

If “no” do you plan to implement this edit?

 Yes No

9. Has the state provided DUR criteria data requested on Table 1 – Top 10 Pro DUR Alerts by Problem Type indicating by problem type those criteria with the most significant severity level reviewed by the DUR Board?

Yes No

10. 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

11. 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 Retro DUR activities during the time period covered by this report (company, academic institution, or other organization).

a) Is the Retro DUR vendor also the Medicaid fiscal agent?

Yes No

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

Yes No

If “No”, please explain:

2. Does the DUR Board approve the Retro DUR 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

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

Yes No

If “Yes”, please provide a brief summary of your findings:

If “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

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

Yes No

If “Yes”, please provide a brief summary of your findings.

If “Yes,” is your DUR Board involved with this program?

Yes No

If “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 both Pro DUR and Retro DUR?

- 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) Preauthorization 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.

Grand Estimated Net Savings Amount ÷ Total Dollar Amount × 100 = _____ %

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 pre-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?

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:
-
-

B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

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

Yes No

If “Yes” does your agency have the ability to query the state’s PDMP database?

Yes No

If “Yes”, do you require prescribers (in your provider agreement with the agency) to access the PDMP patient history before prescribing restricted substances?

Yes No

If “Yes,” please explain how the state applies this information to control fraud and abuse.

If “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)

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

If "Yes" do you apply this DEA file to your ProDur POS edits to prevent unauthorized prescribing?

Yes No

If "Yes" please explain how the information is applied

If "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 monitor/manage the prescribing of methadone for pain management? If "yes" check all that apply:

- pharmacist override
- deny claim and require PA
- quantity limits
- intervention letters

D. OPIOIDS

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

Yes No

If “Yes” what are your limitations?

- 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

If “Yes” what are your limitations?

- 30 day supply
 - 90 day supply
 - other, 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

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, 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

1. Does your agency set mg per day limits on the use of buprenorphine?

- Yes No

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

- 8mg
 12 mg
 16 mg
 other, please explain
-
-

2. What are your limitations on the allowable length of 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

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

- 8mg
- 12mg
- other, please explain

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

- 6 months
- 12 months
- no limit
- other, please explain

5. Do you limit the type of dosage form that can be dispensed to only the sublingual film?

- Yes No

F. PSYCHOTROPIC DRUGS/STIMULANTS

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

- Yes No

If “Yes”, do you manage/monitor:

- only children in foster care
- all children
- other, please explain

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

If “No” do you plan on implementing a program in the future?

Yes No

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

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?**

Yes No

X. E-PRESCRIBING

1. Has your state implemented e-prescribing?

Yes No

If “Yes,” please respond to Questions 2 and 3 below. If “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

3. Does your program system (MMIS or pharmacy vendor) have the capability to electronically provide a prescriber, upon inquiry, patient drug history data and pharmacy coverage limitations prior to prescribing?

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 “No,” are you planning to develop this capability?

Yes No

XI. MANAGED CARE ORGANIZATIONS (MCOs)

1. 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.

2. Does the state set requirements for the MCO’s pharmacy benefit?

Yes No

If “Yes” please briefly explain your policy.

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

Yes No

3. Does the state require the MCOs to monitor or report their DUR activities?

Yes No

4. If “no” do you plan to develop a program to monitor or report MCO DUR activities in the future?

Yes No

XII. EXECUTIVE SUMMARY - Attachment 8 – Executive Summary

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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** problem 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 pre- 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 10 PROSPECTIVE DUR CRITERIA REVIEWED BY DUR BOARD

Indicate by problem type those criteria with the most significant severity levels that were reviewed in-depth by DUR Board. For each problem type below in the first column list the drugs/ drug category/ disease combinations for which DUR Board conducted in-depth reviews.

PROBLEM TYPE KEY: INAPPROPRIATE - IA; THERAPEUTIC - TC; DRUG DRUG - D/D; DRUG ALLERGY - D/A; DRUG DISEASE – D/D;

| Table1 | AHFS TC (Level 2) | AHFS TC (Level 4) | AHFS TC (Level 6) | AHFS TC (Level 8) | Drug Name | Disease | Criteria Implemented |
|-------------------------|-------------------|-------------------|-------------------|-------------------|-----------|---------|----------------------|
| IA DOSE1 | | | | | | | |
| IA DOSE2 | | | | | | | |
| IA DOSE3 | | | | | | | |
| TC DUPLICATION1 | | | | | | | |
| TC DUPLICATION2 | | | | | | | |
| TC DUPLICATION3 | | | | | | | |
| D/A INTERACTION1 | | | | | | | |
| D/A INTERACTION2 | | | | | | | |
| D/A INTERACTION3 | | | | | | | |
| IA DURATION1 | | | | | | | |
| IA DURATION2 | | | | | | | |
| IA DURATION3 | | | | | | | |
| D/D INTERACTIONS1 | | | | | | | |
| D/D INTERACTIONS2 | | | | | | | |
| D/D INTERACTIONS3 | | | | | | | |
| D/Dis CONTRAINDICATION1 | | | | | | | |
| D/Dis CONTRAINDICATION2 | | | | | | | |
| D/Dis CONTRAINDICATION3 | | | | | | | |
| OTHER (specify)1 | | | | | | | |
| OTHER (specify)2 | | | | | | | |
| OTHER (specify)3 | | | | | | | |
| OTHER (specify)4 | | | | | | | |
| OTHER (specify)5 | | | | | | | |
| OTHER (specify)6 | | | | | | | |
| OTHER (specify)7 | | | | | | | |
| OTHER (specify)8 | | | | | | | |
| OTHER (specify)9 | | | | | | | |

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> | <i>Total Number of Claims</i> | <i>Total Reimbursement Amount Less Co-Pay</i> | <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.