

**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 CMS 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
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FEDERAL FISCAL YEAR _____

I. STATE NAME ABBREVIATION

II. MEDICAID AGENCY INFORMATION

1. Identify State person responsible for DUR Annual Report Preparation.

Name: _____

Street Address: _____

City/State/Zip Code: _____

Area Code/Phone Number: _____

2. Identify pharmacy POS vendor - (contractor, state-operated, other).

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

___ Yes ___ No

III. PROSPECTIVE DUR

1. Identify prospective DUR criteria source.

___ First Data Bank ___ Other (specify): _____

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

___ Yes ___ No

If answer above is "No," please explain:

3. When the pharmacist receives prospective DUR messages that deny the claim, does your system:

a) ___ Require preauthorization

- b) Allow the pharmacist to override with the correct “conflict,” “intervention,” and “outcome” codes?
- c) a) and/or b) above - depending on the situation. Please explain:

4. Early Refill:

- a) At what percent threshold do you set your system to edit?
 - i) Non-controlled drugs: %
 - ii) Controlled drugs: %
- b) When an early refill message occurs, does the state require prior authorization?
 - i) Non-controlled drugs: Yes No
 - ii) 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

5. Therapeutic Duplication:

- a) When there is therapeutic duplication, does the State require prior authorization for:

i) Non-controlled drugs: ___ Yes ___ No ___ Sometimes

If answer above is “Sometimes,” please explain:

ii) Controlled drugs: ___ Yes ___ No ___ Sometimes

If answer above is “Sometimes,” please explain:

b) If the answer to 5 (a) above is “Yes,” who obtains authorization?

i) Non-controlled drugs:

 ___ Pharmacist ___ Prescriber ___ Either

ii) Controlled drugs:

 ___ Pharmacist ___ Prescriber ___ Either

c) If the answer to 5 (a) above is “No,” can the pharmacist override at the point of service?

i) Non-controlled drugs: ___ Yes ___ No

ii) Controlled drugs: ___ Yes ___ No

Additional Comment:

6. State has provided DUR criteria data requested on Table 1 - Pro DUR Criteria Reviewed by DUR Board¹, indicating by problem type those criteria with the most significant severity level reviewed in-depth by the DUR Board in this reporting period.

 ___ Yes ___ No

7. State has included Attachment 1 – Prospective DUR Review Summary².

 ___ Yes ___ No

8. State has included Attachment 2 – Prospective DUR Pharmacy Compliance Report³, a report on State efforts to monitor pharmacy compliance with the oral counseling requirement.

¹ Please see Instruction for Table 1 on page 13

² Please see Explanation for Attachment 1 on page 10

³ Please see Explanation for Attachment 2 on page 10

___ Yes ___ No

IV. RETROSPECTIVE DUR

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

- a) Is the retrospective DUR vendor also the Medicaid fiscal agent?

___ Yes ___ No

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

___ Yes ___ No

If “No,” please explain:

2. Does the DUR Board approve the retrospective DUR criteria supplied by the criteria source?

___ Yes ___ No

3. State has provided the DUR Board approved criteria requested on Table 2 - Retrospective DUR Approved Criteria⁴.

___ Yes ___ No

4. State has included Attachment 3 - Retrospective DUR Screening and Intervention Summary Report⁵.

___ 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

⁴ Please see Instruction for Table 2 on page 13

⁵ Please see Explanation for Attachment 3 on page 11

programs. Has your MMIS been designed to incorporate this data into your DUR criteria for both prospective DUR and retrospective DUR?

Yes No

If “No,” when do you plan to include this information in your DUR criteria? mm/dd/yyyy

VI. DUR BOARD ACTIVITY

1. State has included a summary report of DUR Board activities and meeting minutes during the time period covered by this report as Attachment 4 - Summary of DUR Board Activities⁶.

Yes No

2. Does your state have a Disease Management Program?

Yes No

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

Yes No

3. Does your state have a Medication Therapy Management Program?

Yes No

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

Yes No

VII. GENERIC POLICY AND UTILIZATION DATA

1. State has included a description of **new** policies used to encourage the use of therapeutically equivalent generic drugs as Attachment 5 - Generic Drug Substitution Policies⁷.

Yes No

2. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in Table 3 - Generic Utilization Data⁸.

⁶ Please see Explanation for Attachment 4 on page 11

⁷ Please see Explanation for Attachment 5 on page 12

Number of Generic Claims: _____

Total Number of Claims: _____

Generic Utilization Percentage: _____

3. 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 3 - Generic Utilization Data⁹.

Generic Dollars: _____

Total Dollars: _____

Generic Expenditure Percentage: _____

VIII. PROGRAM EVALUATION / COST SAVINGS

1. Did your state conduct a DUR program evaluation/cost savings estimate?

_____ Yes _____ No

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

3. State has provided the Medicaid program evaluation/cost savings estimate as Attachment 6 - Cost Savings Estimate¹⁰.

_____ Yes _____ No

4. Please provide the total net cost savings estimate. \$_____

5. Please provide the estimated percent impact of your state’s cost savings program compared to total drug expenditures for covered outpatient drugs. Divide the estimated net savings amount provided in Section VIII, Question 4 above by the total dollar amount provided in Section VII, Question 3. Then multiply this number by 100.

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

IX. FRAUD, WASTE, AND ABUSE DETECTION

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

⁸ Please see Instruction for Table 3 on page 13
⁹ Please see Instruction for Table 3 on page 13
¹⁰ Please see Explanation for Attachment 6 on page 12

Yes No

If “Yes,” what action(s) does this process initiate? Check all that apply.

- a. Deny claim and require pre-authorization
- b. Refer recipient to lock-in program
- c. Refer to Medicaid Fraud Control Unit (MFCU) or Program Integrity
- d. Other - please explain:

2. Do you have a 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 MFCU or Program Integrity
- c. Refer to the appropriate Medical Board
- d. Other - please explain

3. Do you have a 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 MFCU or Program Integrity
- c. Refer to Board of Pharmacy
- d. Other - please explain:

4. Does your state have a Prescription Drug Monitoring Program (PDMP)? See Attachment 7 - Prescription Drug Monitoring Program¹¹ for a description of this program.

¹¹ Please see Explanation for Attachment 7 on page 12

___ Yes ___ No

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

If “No,” does your State plan to establish a PDMP?

___ Yes ___ No

X. INNOVATIVE PRACTICES

Have you developed any innovative practices during the past year which you have included in Attachment 8 - Innovative Practices¹²?

___ Yes ___ No

XI. 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 9 - E-Prescribing Activity Summary¹³.

¹² Please see Explanation for Attachment 8 on page 12

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

___ Yes

___ No

¹³ Please see Explanation for Attachment 9 on page 12

MEDICAID DRUG UTILIZATION REVIEW ANNUAL REPORT

ATTACHMENT AND TABLE SUPPLEMENT

I. EXPLANATION FOR ATTACHMENTS

ATTACHMENT 1 – PRODUR REVIEW SUMMARY

This attachment is a year-end summary report on prospective DUR screenings. It should be limited to the **Top 20** type/drug combinations which generate the largest number of messages. For each problem type/drug combination included, a denominator must be reported. The denominator is the total number of prescription claims adjudicated (during a given time period) for the drug compared to the number of messages generated for the problem type/drug (incorrect dosage/drug) during the same time period. Denominators permit comparison in percentage terms of the relative frequency of different problem type/drug combinations. For problem type/drug combinations involving more than one drug (e.g., drug/drug interactions), the denominator is the number of prescription claims for the drug submitted for adjudication.

Include for the **Top 20 problem type/drug alerts** with a severity of Level I:

- The number of messages generated by the system and a denominator. The number of messages must relate to problem type/drug combinations (incorrect dosage/drug). Report levels of messages by problem type only, incorrect dosage or drug only are not acceptable.
- The number of messages overridden (i.e., adjudication process carried through to completion even though a message was generated).
- The number of reversals/cancellations/denials (i.e., adjudication not carried through to completion) and data on types of interventions by pharmacists and the outcomes of such interventions using applicable NCPDP standards (e.g., Standard Format Version 5.1)
- The number of refill too soon messages, duplicate prescription messages transmitted, and, where applicable, claims denials.

ATTACHMENT 2 – PROSPECTIVE DUR PHARMACY 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 3 – RETROSPECTIVE DUR SCREENING AND INTERVENTION SUMMARY REPORT

This is a year-end summary report on retrospective DUR screening and interventions. Separate reports on the results of retrospective DUR screening and interventions are acceptable at the option of the State. The report(s) should:

- Report the level of criteria exceptions by drug class (or drugs within the class) and problem type. (An exception is an instance where a prescription submitted for adjudication does not meet the DUR Board-approved criteria for one or more problem types within a drug class.)

NOTE: a) Reporting levels of criteria exceptions by only drug class (drug) or problem type is not acceptable.

b) Year-end summary reports should be limited to the **Top 20** problem types with the largest number of exceptions.

- Include a denominator for each drug class/problem type for which criteria exceptions are reported. A denominator is the number of prescription claims adjudicated for a drug class (or individual drugs in the class) during a given time period compared to the number of criteria exceptions for the drug class (or individual drugs in the class) during that time period.
- Report, for each drug class (or drugs within the class) and problem type included in this summary report, the number of interventions (letters, face-to-face visits, etc.) undertaken during the reporting period.
- For states which engage in physician or pharmacy profile analysis (i.e., review prescribing or dispensing of multiple prescriptions for multiple patients involving a particular problem type or diagnosis) or engage in patient profiling, include the number of each type of profile (physician, pharmacy, patient) reviewed and identify the subject(s) (diagnosis, problem type, etc.) involved.

ATTACHMENT 4 – 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 5 – GENERIC DRUG SUBSTITUTION POLICIES

Describe any policies used to encourage the use of generic drugs such as State maximum/minimum allowable cost (pricing, higher dispensing fee for generic and/or lower co-pay for generics). Include relevant documentation.

ATTACHMENT 6 – COST SAVINGS ESTIMATES

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

ATTACHMENT 7 – PRESCRIPTION DRUG MONITORING PROGRAM

In FY 2002, Congress appropriated funding to the U.S. Department of Justice to support Prescription Drug Monitoring Programs (PDMPs). These programs prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collections system exists. States that have implemented PDMPs have the capability to collect and analyze data on filled and paid prescriptions more efficiently than those without such programs, where the collection of prescription information can require a time-consuming manual review of pharmacy files. If used properly, PDMPs are an effective way to identify and prevent diversion of the drugs by health care providers, pharmacies, and patients.

ATTACHMENT 8 – 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 9 – 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).

II. INSTRUCTION FOR TABLES**TABLE 1 – 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 Boards. (COMPLETE ATTACHED TABLE 1)

TABLE 2 – RETROSPECTIVE DUR BOARD APPROVED CRITERIA

On the vertical axis, list the therapeutic categories reviewed by the DUR Board and on the horizontal axis list the problem types that may be associated with a therapeutic category. If the retrospective DUR program has approved criteria for drugs in a given therapeutic category, check boxes for the relevant problem types for which criteria have been established. You may add additional problem types as appropriate. (COMPLETE ATTACHED TABLE 2)

TABLE 3 – 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 ATTACHED TABLE 3)

Computation Instructions:

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 1

PROSPECTIVE DUR CRITERIA

FOR EACH PROBLEM TYPE BELOW

LIST (DRUGS/ DRUG CATEGORY/ DISEASE COMBINATIONS) FOR WHICH DUR BOARD CONDUCTED IN-DEPTH REVIEWS.

PLEASE INDICATE WITH AN ASTERISK (*) THOSE FOR WHICH CRITERIA WERE IMPLEMENTED.

<p><u>INAPPROPRIATE DOSE</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>	<p><u>THERAPEUTIC DUPLICATION</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>	<p><u>DRUG ALLERGY INTERACTION</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>
<p><u>INAPPROPRIATE DURATION</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>	<p><u>DRUG/ DRUG INTERACTIONS</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>	<p><u>DRUG DISEASE CONTRAINDICATION</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>
<p><u>OTHER (specify)</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>	<p><u>OTHER (specify)</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>	<p><u>OTHER (specify)</u></p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>

TABLE 3

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.

KEY:

Single-Source (S) - Drugs that have an FDA New Drug Application (NDA) approval for which there are no generic alternatives available on the market.

Non-Innovator Multiple-Source (N) - Drugs that have an FDA Abbreviated New Drug Application (ANDA) approval and for which there exists generic alternatives on the market.

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