Supporting Statement Part A
Medicaid Drug Use Review (DUR) Program
CMS-R-153, OMB 0938-0659

Background

Section 4401 of the Omnibus Budget Reconciliation Act of 1990 and section 1927(g) of the Social Security Act requires States to provide for a Medicaid Drug Use Review (DUR) program for covered outpatient drugs under fee-for-service. The DUR program is required to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. Each State DUR program must consist of prospective drug use review (ProDUR), retrospective drug use review (RetroDUR), data assessment of drug use against predetermined standards, and ongoing educational outreach activities. In addition, States are required to submit an annual DUR program report that includes a description of the nature and scope of State DUR activities as outlined in the statute and regulations.

Over the years, technology has changed as has the practice of pharmacy. Therefore, CMS has revised the reporting vehicle to address more fully the current practices and areas of concern within the Medicaid Pharmacy Programs. It is our intention to provide non-statistical information, comparisons and trends back to the States based on their reported experiences with DUR. The States may benefit from this information and may fine tune their programs each year based on State reported innovative practices and CMS identified best practices gathered from the DUR annual reports.

A. Justification

1. Need and Legal Basis

The authority for requiring States to collect data for the DUR program is section 1927(g) of the Social Security Act (the Act) and implementing regulations at 42 CFR 456.700.

The information collection requirement is necessary to establish patient profiles in pharmacies, identify problems in prescribing and/or dispensing, determine each program's ability to meet minimum standards required for Federal financial participation, and ensure quality pharmaceutical care for Medicaid patients.

State Medicaid agencies that have prescription drug programs are required to perform prospective and retrospective DUR in order to identify aberrations in prescribing, dispensing and/or patient behavior.

2. Information Users

States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient

profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, e.g., allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The State must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons and trends related to States' experiences with DUR. The States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports.

3. Use of Information Technology

States submit an electronic copy for the review process. The link to the FFY 2015 annual report is: http://www.surveygizmo.com/s3/2517110/FFY-2015-Medicaid-Drug-Utilization-Review-Annual-Report-Copy-December-29-2015 . CMS uses the electronic copy to improve the long-term storage capabilities and to create best practice documents. CMS' past experience found that many of the technical print outs provided by the States were difficult to review. The electronic format allows for a thorough review of the detailed material.

4. Duplication/Similar Information

The CMCS is the only CMS or DHHS component collecting Medicaid DUR data. Therefore, there are no existing data which duplicate this data collection that could be used in place of DUR data.

5. Small Business

These information collection requirements do not affect small businesses. When processing prescriptions, pharmacies have an automated system that utilizes the prospective data edits to complete the proper filling of the prescription. The pharmacy itself does not collect the data. The data is submitted to the state as the claim is being processed electronically.

6. Less Frequent Collection

RetroDUR activity is required by regulation at least quarterly according to 42 CFR 456.709(a) and State reports are required to be submitted annually according to 42 CFR 456.712(b) by June 30th of each calendar year for the previous Federal Fiscal Year, as determined by the Secretary. Less frequent data collection is not applicable.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Federal Register Notice

The 60-day notice published in the Federal Register on January 29, 2016 (81 FR 5014). No comments were received.

Outside Consultation

See section 15 below.

9. Payments/Gift to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

States are required under 42 CFR 431.300(a) to safeguard recipient protected information. Accordingly, each State maintains a State Plan providing safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan per Section 1902(a)(7) of the Social Security Act.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this collection.

12. Burden of Estimate (Hours and Wages)

12.1 Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Pharmacist	29-1051	57.34	57.34	114.68

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 PRA-Related Requirements and Associated Burden Estimates

Claims Data and Other Record Reports Preparation (42 CFR 456.709)

As previously stated above, the pharmacist's profiling and documentation is primarily an automated function due to the implementation of electronic processing system. The pharmacist does not produce exception reports. The details of the prescriptions presented to be filled are what create the data that the State gathers and the State or its vendor produces exception reports and drug claims expenditures reporting from this data.

States are required to collect prescription drug utilization data from claims and assess the data against predetermined standards in order to identify potential problems in prescribing and/or dispensing. Data collection involves sorting prescription drug claims data through the use of exception reports. These reports generate specific information on claims using predetermined criteria for exceptions, such as prior authorization and types of drug therapy problems. States generally have their pharmacy point-of- sales vendor produce the exception reports.

Hours: 16 hours per year (or 4 quarterly hours) per State x 51 states= **816 hours** annually
Cost: 816 hours x $114.68/hr (point of service vendor pharmacist) = **$93,578.88** per year.

Review Claims Data and Other Record Reports & Interventions (42 CFR 456.711)

The DUR Board conducts reviews of the exception reports at their quarterly meetings. As part of the review process, the DUR Board or a specially selected committee determines if intervention is warranted. If intervention is necessary, a pharmacist contractor executes the interventions by form of telephone contact, correspondence, or face-to- face interviews. Interventions are conducted to attempt to educate the physician or pharmacist on appropriate

prescribing or dispensing practices.

Review

Hours: 120 hours per year per State (or 30 quarterly hours) x 51 Medicaid programs = **6,120 hours** annually (10 members at 12 hours per member).
Cost: 6,120 hours x $50/hr (DUR Board members) = **$306,000.00** per year.

DUR board members typically receive a nominal honorarium as represented above. Being a member of the DUR board is looked favorably upon by their employers and the medical community, as they provide their medical expertise for public service.

Intervention

Hours: 240 hours per year (or 60 quarterly hours) x 51 states = **12,240 hours** annually
Cost: 12,240 hours x $114.68 per hour (pharmacist contractor) = **$1,403,683.20** per year

Annual Report (42 CFR 456.712)

This section of the regulation states that the DUR Board and the Medicaid agency are required to report to the Medicaid agency and the Secretary, respectively. We require one report per State annually.

Hours: It is estimated that the yearly reporting burden is 32 hours per State, making the total burden for 51 Medicaid programs **1,632 hours**.
Cost: 1,632 hours x $114.68 per hour (pharmacist contractor rate per hour) = **$187,157.76**.

12.3 Burden Summary

Annual Recordkeeping and Reporting Requirements

Regulation Under Title 42 of the CFR	**Respondents**	**Responses (per respondent)**	**Total Responses**	**Time per Response**	**Total Annual Burden (hr)**	**Labor Rate ($/hr)**	**Total Capital/ Maintenance Costs ($)**	**Total Cost ($)**
456.709	51	4	204	4 hr	816	114.68	0	93,579
456.711	51	4	204	30 hr	6,120	50.00	0	306,000
		4	204	60 hr	12,240	114.68		1,403,683
456.712	51	1	51	32 hr	1,632	114.68		187,158
TOTAL	**51**	**13**	**663**	**126 hr**	**20,808**	**varies**	**0**	**1,990,420**

When processing prescriptions, pharmacies have an automated system that utilizes the prospective data edits to complete the proper filling of the prescription. The pharmacy itself does not collect the data. The data is submitted to the state as the claim is being processed electronically.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The federal government pays 50% of the states' costs, which is $995,210.

15. Changes in Burden

The annual reporting instrument is being revised to address how states are monitoring clinical practices in the profession. As a result of our consultation with a committee comprised of state Medicaid drug utilization review program managers, we discovered the prospective problem type information collected in the table was not considered to be useful to their DUR programs. Moreover, in an earlier part of the prospective DUR section of the report, we inquire about the state's review of the prospective problem type information contained in their exception reports and their follow-up with providers who routinely override the ProDUR alert messages, capturing essential information on which CMS would provide a response.

With input from the state representatives, we revised table 1 with the top claims data reviewed by the DUR board. The new table collects information on prospective edits, such as the top 10 medications and drug classes for which prior authorization is required, top 5 claim denial reasons (such as early refill, therapeutic duplication), and the top 10 drug expenditures by claim count and the amount paid.

The estimated impact of replacing table 1 decreased the amount of information the states had to report to CMS by 20 percent. We have also added new questions to several sections in the report, which increased the amount of information collected by 20 percent. The overall annual report preparation burden did not change due to the decrease in burden of the revised table 1 and the increase in burden due to new questions.

However, as a result of our consultation with the committee, we recognize state utilization of additional exception reports and claim expenditure reports generated by its point-of-sales vendor. Hence, we increased the agency's estimation of the annual burden hours for the vendor to create exception reports by 60 percent (in aggregate, 510 currently approved hours vs 816 proposed hours).

16. Publication and Tabulation Dates

CMS plans to post the reports on Medicaid.gov within six months from the submission due date.

17. Expiration Date:

CMS is willing to display the expiration date for OMB approval.

18. Certification Statement:

This submission does not contain exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

The use of statistical methods does not apply to this collection of information.