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 events. 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. Effective federal fiscal year 2018, states are required to also report on their Medicaid managed care organization (MCO) DUR processes.

Over the years, technology has changed as has the practice of pharmacy. Therefore, the Centers for Medicare & Medicaid Services (CMS) has revised the reporting instrument (a survey) to address more fully, the current practices and areas of concern within the Medicaid Pharmacy Programs. This Paperwork Reduction Act (PRA) package seeks the authority to survey the states and MCOs using either a CMS-hosted online information technology system called Medicaid Drug Program (MDP), or SurveyGizmo. To generate the required state DUR reports, states submit FFS and MCO responses to the survey using the CMS hosted online MDP system, or SurveyGizmo. Specifically, to account for any unforeseen issues in using MDP, we are seeking approval to use either the MDP system or SurveyGizmo to survey a respondent. 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.

In this 2018 iteration, the annual reporting instrument is being revised to allow states to report responses to the survey directly into the CMS hosted MDP online system, or a SurveyGizmo weblink.

Additionally, for FFY 2018 and beyond, the reporting instrument will include questions for Medicaid MCOs in accordance with the requirement that states are required to report on their MCO DUR processes.

We have also added some new questions to various sections in the FFS portion of the reporting instrument (a survey), and created an additional set of questions focused on MCO DUR activities. This increased the amount of information collected by about 100 percent. The overall annual report preparation burden will change due to the increase in burden of reporting both Medicaid fee-for-service and MCO DUR activity.

Hence, we increased the agency's estimation of the total annual burden hours from the approved 20,808 hours, to 41,004 proposed hour (see section 15 of this Supporting Statement for details).

A. Justification

1. Need and Legal Basis

The authority for requiring States and MCOs 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 and 438.3(s).

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.

The states and MCOs are provided the reporting instrument (a survey) by CMS, and by responding to the survey, the states generate annual reports which are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of states' DUR programs. The survey and the annual recordkeeping and reporting requirements under the pertinent regulations, are completed by pharmacists employed by, or contracted with the various state Medicaid programs and their MCOs. The annual reports submitted by states are 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 annual reports. A comparison/summary of the data from the annual reports is published on Medicaid.gov annually, and serves as a resource for stakeholders, including but not limited to states, manufacturers, researchers, congress, CMS, the Office of Inspector General (OIG), non-governmental payers and clinicians on the topic of DUR in state Medicaid programs.

3. Use of Information Technology

This PRA package seeks the authority to provide states and MCOs with the reporting instrument (a survey) using a CMS-hosted online information technology system called Medicaid Drug Program (MDP). To generate their annual reports, states submit their FFS and MCO responses to the CMS hosted online MDP system. Screenshots of the system have been included in the PowerPoint document titled "DUR - PRA - MDP System DUR Survey Tool 2018." The electronic copy will facilitate long-term storage capabilities, creation of best practice documents, and the comparison/summary report by CMS. The annual reporting instrument is being revised to allow states to report responses to the survey directly into the CMS hosted MDP online system, or a SurveyGizmo weblink. To clarify, the last iteration used a SurveyGizmo weblink as the survey instrument. We do not expect any issues with the transition to the MDP online system. Notwithstanding, to account for any unforeseen issues in transitioning, we are seeking approval to use either the MDP system or SurveyGizmo as the survey instrument. Specifically, a respondent would only need to respond to the survey questions via SurveyGizmo alone if CMS encounters any issues with the MDP online system. The SurveyGizmo weblink for a fee-for-service respondent can be found at https://www.surveygizmo.com/s3/4472282/FFY-2018-Drug-Utilization-Review-Annual-Report-FFS, while that for a managed care respondent can be found at https://www.surveygizmo.com/s3/4472286/FFY-2018-Drug-Utilization-Review-Annual-Report-MCO.

4. Duplication/Similar Information

CMS is the only Department of Health and Human Services (HHS) component collecting Medicaid DUR data. Therefore, there is no existing initiative which duplicates this data collection that could yield findings 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 and MCO reports are required to be submitted annually according to 42 CFR 456.712(b) and 438.3(s)(5) 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 secrets, 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 March 27, 2018 (83 FR 13130). We received one comment in support of the changes. The comment and our response are attached as separate documents.

The 30-day notice published in the Federal Register on July 17, 2018 (83 FR 33225). We did not receive any comments.

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)

In accordance with section 1927(g) of the Social Security Act (the Act), and regulations at 42 CFR 456.700, 456.709, 456.711, 456.712, and 438.3(s), states and MCOs are required to collect data for their DUR programs. 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. To generate the required annual reports, this PRA package seeks the authority to survey the states and MCOs using either a CMS-hosted online information technology system called Medicaid Drug Program (MDP), or SurveyGizmo. We expect pharmacists employed by, or contracted with the individual states to facilitate the states' responses. The sub-sections below estimate the associated costs of burden of complying with the statutes and regulations for both FFS programs and MCOs. While the content of the FFS survey differs marginally from that of the MCO survey, we estimate that the burden for individual states' combined FFS and MCO reports will be identical.

12.1 Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 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	58.52	58.52	117.04

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 systems. 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: 1,020 hours annually
20 hours per year (or 5 quarterly hours) per State x 51 states
Cost: $119,381 per year
1,020 hours x $117.04/hr (point of service vendor pharmacist).

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 educate the physician or pharmacist on appropriate prescribing or dispensing practices.

Review

Hours: 12,240 hours annually
240 hours (10 members at 24 hours per member) per year per State (or 60 quarterly hours) x 51 Medicaid programs
Cost: $612,000 per year
12,240 hours x $50/hr (DUR Board members).

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: 24,480 hours annually
480 hours per year (or 120 quarterly hours) x 51 states
Cost: $2,865,139 per year
24,480 hours x $117.04 per hour (pharmacist contractor)

Annual Report (42 CFR 456.712 and 438.3)

These sections of the regulation state that the DUR Board and the Medicaid agency are required to report to the Medicaid agency and the Secretary, respectively. We require annual reporting.

Hours: 3,264 hours

It is estimated that the yearly reporting burden is 64 hours per State, making the total burden for 51 Medicaid programs.

Cost: $382,019
3,264 hours x $117.04 per hour (pharmacist contractor rate per hour)

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	5 hr	1,020	117.04	0	119,381
456.711	51	4	204	60 hr (review)	12,240	50.00	0	612,000
		4	204	120 hr (intervention)	24,480	117.04		2,865,139
456.712 & 438.3	51	1	51	64 hr	3,264	117.04		382,019
TOTAL	51	13	663	249 hr	41,004	Varies	0	3,978,539

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 $1,989,269.

15. Changes in Burden

The annual reporting instrument is being revised to allow states to report responses to the survey directly into the CMS hosted MDP online system, or a SurveyGizmo weblink. To clarify, the last iteration used a SurveyGizmo weblink for the survey instrument. We do not expect any issues with the transition to the MDP online system. Notwithstanding, to account for any unforeseen issues with the transition, we are seeking approval to use either the MDP system *or* SurveyGizmo as the survey instrument. Specifically, a respondent would only need to respond to the survey questions via SurveyGizmo *alone* if CMS encounters any issues with the MDP online system. Otherwise, responses would be entered in the MDP online system alone.

Additionally, for FFY 2018 and beyond, the reporting instrument will include questions for

Medicaid MCOs in accordance with the requirement that states are required to report on their MCO DUR processes.

We have also added some new questions to various sections in the FFS portion of the reporting instrument (a survey), and created an additional set of questions focused on MCO DUR activities. This increased the amount of information collected by about 100 percent. The overall annual report preparation burden will change due to the increase in burden of reporting both Medicaid fee-for-service and MCO DUR activity.

Hence, we increased the agency's estimation of the total annual burden hours from the approved 20,808 hours, to 41,004 proposed hours. Specifically, for requirements at 42 CFR 456.709 (claims data and other record reports preparation), we have proposed 1,020 hours, an increase from the approved 816 hours. For requirements at 42 CFR 456.711 (review claims data and record reports and interventions), related to reviews, we have proposed 12,240 hours, an increase from the approved 6,120 hours. For those related to interventions, we have proposed 24,480 hours, an increase from the approved 12,240 hours. For requirements at 42 CFR 456.712 and 42 CFR 438.3 (DUR Board and Medicaid agency reporting requirements), we have proposed a total of 3,264 hours, an increase from the approved 1,632 hours.

16. Publication and Tabulation Dates

CMS plans to post the comparison/summary 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.