Supporting Statement Part A
Medicaid Drug Use Review (DUR) Program
Form CMS-R-153, and CMS-R-153a and CMS-R-153b (OCN 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 survey 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.

The Centers for Medicare and Medicaid Services (CMS), Center for Medicaid & CHIP Services (CMCS), is requesting a 3-year approval of the State data collection requirements, the CMS forms R-153, R-153a and b, collection instruments for the States' annual reporting of their Medicaid DUR Program.

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, 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 fine tune their programs each year based on State reported best practices that are compiled by CMS from the DUR annual reports.

3. Use of Information Technology

States are to submit an electronic copy for the review process. CMS will use 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. Pharmacies when processing prescriptions 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. Therefore, there is no OMB number other than the one current be reviewed.

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.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on November 29, 2013 (78 FR 71617). No comments were received.

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)

42 CFR Section 456.709 – Claims Data and Other Record Reports Preparation

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 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, e.g., each type of drug therapy is chosen for exception by the degree of problem/severity in the criteria. States generally have their pharmacy point of service vendor produce the exception reports.

Hours: 10 hours per year (or 2.5 quarterly hr) per State x 51= 510 hours annually
Cost: $11,000 per year X 51 Medicaid programs = $561,000 per year

42 CFR Section 456.711 – Review Claims Data and Other Record Reports & Interventions

The DUR Board conducts reviews of the exception reports at their quarterly meetings. As part of the exception reports review, the DUR Board or a specially selected committee determines if intervention is warranted. If intervention is necessary, it may take the 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 hr) X 51 Medicaid programs = 6,120 hours annually
Cost: $150 per hour (DUR Board members) X 120 hours annually per state X
51 Medicaid programs = $918,000 per year

Intervention:
Hours estimate: 240 hours per year (or 60 quarterly hr) x 51 states = 12,240 hr. annually per state
Cost: 12,240 hours per state x $100 per hour = $1,224,000 per year

42 CFR Section 456.712 – Annual Report

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.

Reports are generally prepared by a contractor at a rate of $100 per hour.

Cost: 32 hours per State X $100 per hour (contractor rate per hour) X 51
Medicaid programs = $163,200 per year.

Annual Burden Summary

	Hours (total)	Cost
Exception Reports (vendor)	510	$ 561,000
Review of Exception Reports	6,120	$ 918,000
Intervention Activities (contractor)	12,240	$ 1,224,000
Annual Report Preparation	1,632	$ 163,200
Totals	20,502	$ 2,866,000

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are no systems upgrade costs or any other costs associated with this collection request.

15. Changes in Burden

The survey instrument is being revised to address how states are monitoring clinical practices in the profession and to address innovations going forward in the health care arena. We removed request for data elements that were not considered to be useful any longer such as some demographic information, questions about therapeutic duplication that was addressed elsewhere in the questionnaire, and an attachment that was duplicative of information requested in a table and therefore we no long have a CMS-R-153c. Additionally, we decreased the overall number of problem categories and intervention types that the states had to report to on to CMS by 50 percent.

We added new questions to several sections in the survey. We clarified that the annual report will now be electronically submitted directly to the Central Office (CO) instead of being submitted in hard copy through the Regional Office.

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 would like an exemption from displaying the expiration date as these forms are used on a continuing basis.

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 form.