Supporting Statement – Part A
Information Collection Requirements

Medicaid Drug Use Review Program
Form CMS-R-153, and CMS-R-153a, b and c (OMB #0938-0659)

## A. 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. 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, retrospective drug use review, 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 more fully address the current practices and areas of concern with the Medicaid Pharmacy Programs. It is our intention to provide nonstatistical 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 and Survey & Certification (CMCS), is requesting a 3-year approval of the State data collection requirements, the CMS forms R-153, R-153a, b, and c data collection instruments for the States' annual reporting of their Medicaid Drug Utilization Review Program.

## B. 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 retrospective DUR 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 along with a hard copy for 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 in the electronic format and necessitated that a hard copy be produced to allow for a thorough review of the detailed material.

4. Duplication/Similar Information

The Center for Medicaid and State Operations 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 m is being processed electronically. Therefore, there is no OMB number other than the one current be reviewed.

6. Less Frequent Collection

Retrospective DUR 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

A 60-day Federal Register notice published on October 15, 2010 (75 FR 63484). 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: 8 hours per year per State x 51= 408 hours annually
Cost: $2,500 per report (vendor generated) X 4 reports per year X 51 Medicaid programs = $510,000 per year

42 CFR Section 456.711 – Review Claims data and other record Reports & Interventions

The DUR Board conduct 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 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: 60 hours per quarter x 4 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 30 hours per State, making the total burden for 51 Medicaid programs 1,530 hours.

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

Cost: 30 hours per State X $100 per hour (contractor rate per hour) X 51 Medicaid programs = $153,000 per year.

Annual Burden Summary

| | Hours total (per response) | Cost |
|---|---|---|
| Exception Reports (vendor) | 408 (8) | $510,000 |
| Review of Exception Reports | 6,120 (120) | $918,000 |
| Intervention Activities (contractor) | 12,240 (240) | $1,224,000 |
| Annual Report Preparation | 1,530 (30) | $153,000 |
| Totals | 20,298 (398) | $2,805,000 |

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The cost estimate includes the federal program employee pharmacist reviewing the annual reports, summarizing findings and providing feedback to the States. This estimate includes 50% (Federal share) of States'costs. The hourly rate for Federal review of the States' annual reports is based on a GS -13, step 9 pharmacist's annual salary. The cost for this activity is computed as follows:

$52.76 per hour X 306 hours annually =$16,144.56
Total Federal Cost = $16,144.56 (analysis by federal pharmacist) + $1,402,500 (50% of State cost in FFP) = $1,418,645 per year

15. Changes in Burden

The survey instrument is revised to remove questions pertaining to outdated practices and revised to address advances in the improved clinical practices in the profession and to address innovations going forward in the health care arena, such as e-prescribing. Details of changes made to the original survey are listed below:

Pages 1& 2 - Section III. Prospecitve DUR- amended questions to obtain more detailed information about the source of the DUR criteria and the actual operation decision making process that the State uses in programming system edits. We removed general questions 1, 2, &3 that dealt with the setting up of the electronic monitoring system because all States now have these systems in place.

Page 3 – section IV. Retrospective DUR-reformatted basic questions and removed material that was duplicative or moot.

Page 4 –Section V. DUR Board Activity – changed to Section VI. to Section V. Physician Administered (PA) drugs added. Collection of claims data for PA drugs began with the Deficit Reduction Act of 2005. We are determining if States are properly monitoring this drug category. Renumbered section VI. DUR Board Activity- and maintained the request to provide a description of activities as well as adding asking questions about the whether the State has a Disease Management Program, or a Medication Therapy Management Program and what involvement the Board has in these programs.

Section VI. Program Evaluation/Cost Savings renumbered to Section VIII – (see discussion below)

Added new Section VII. Generic Policy Utilization Data- asked States to indicate if they have added new policies regarding generic substitution and requested that they continue to provide a description of how the compliance with patient counseling requirement is monitored. Developed two new questions to capture information on generic drug utilization percentage and generic drug costs compared to all claims during the reporting period. Provided instructions on how to calculate percentage impact of cost savings to total drug expenditures. (This calculation will provide more accurate data for a future state-to-state comparison).

Section VIII. Program Evaluation /Cost Savings – added new question requesting calculation of a estimated percent impact of cost savings compared to total drug expenditures for the reporting period and provided instructions on how to calculate this figure so that calculation would be uniform across all States. Added Section IX. Fraud, Waste and Abuse Detection (FWA) – added a series of questions (4) addressing what processes the State uses to identify FWA by recipients, prescribers and/or pharmacy providers. Also included question to determine if the State has and is utilizing a Prescription Drug Monitoring Program.

Added Section X. Innovative Practices –asking State to provide brief description of any new, innovative program that they have initiated. The goal being to identify and share Best Practices with all States.

Added Section XI. E-Prescribing –added a series of questions to identify States utilizing or preparing, planning to implement e-prescribing. (E-prescribing is already here and in the future it will be important to more fully monitor various aspects of this program in there of error reduction and cost savings.

16. Publication and Tabulation Dates

CMS does not plan to publish this data.

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.

## C. Collection of Information Employing Statistical Methods

The use of statistical methods does not apply to this form.