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 (FFS) and managed care organizations (MCOs). 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 survey that includes a description of the nature and scope of State DUR activities as outlined in the statute and regulations.

This iteration is associated with our December 10, 2024 (89 FR 99340) proposed rule (CMS-4208-P, RIN 0938-AV40) regarding Part D coverage of anti-obesity medications (§ 423.100) and its application to the Medicaid program.

Although the statutory definition of a covered Part D drug at section 1860D-2(e)(2) of the Social Security Act (the Act) excludes certain drugs and uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act it includes, at section 1927(d)(2)(A) of the Act, "agents when used for anorexia, weight loss, or weight gain." In this regard drugs that have been historically used for weight loss have been excluded from the definition of covered Part D drug, regardless of their use for treatment of individuals with obesity and have been an optional drug benefit for Medicaid programs.

Increases in the prevalence of obesity in the United States and changes in the prevailing medical consensus towards recognizing obesity as a disease since the beginning of the Part D program in 2006 have compelled CMS to re-evaluate Part D coverage of anti-obesity medications (AOMs) for Medicare Part D enrollees with obesity where the drug's prescribed use is not for a medically accepted indication (MAI) that is currently covered under Part D.

In this regard the CMS-4208-P rule proposes to reinterpret the statutory exclusion of agents when used for weight loss to allow Part D coverage of AOMs when used to treat obesity by reducing excess body weight or maintaining weight reduction long-term for individuals with obesity who do not have another condition for which the prescribed use is an MAI that is covered under the current Part D policy. The proposed reinterpretation would also apply to the Medicaid program. Thus, AOMs could not be excluded from Medicaid coverage under this interpretation when used for weight loss or chronic weight management for the treatment of obesity.

Under our proposed reinterpretation, AOMs approved for weight loss and chronic weight management that are used for weight loss in individuals who do not have obesity or another

condition that is an MAI for the AOM would remain excluded from the definition of covered Part D drug and would remain optional benefit for Medicaid programs.

There will be a burden for the state Medicaid programs that do not already cover AOMs when used for weight reduction or chronic weight management for Medicaid enrollees with obesity to modify their existing coverage and reimbursement policies and criteria to remove such exclusion of AOMs.

Overall, this iteration would add a one-time burden of 1,560 hours and $66,846. 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 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 surveys 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 surveys. A comparison/summary of the data from the annual surveys 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

States are required to submit their annual FFS, MCO, and Abbreviated MCO responses via the CMR-R-153 reporting instrument (a survey) using a CMS-hosted online information technology system called Medicaid Drug Program (MDP).

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 § 456.709(a) and State and MCO surveys are required to be submitted annually according to §§ 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

Serving as the 60-day notice the NPRM (CMS-4208-P; RIN 0938-AV40) posted for public inspection on November 26, 2024, and published on December 10 (89 FR 99340). Comments are due on/by January 27, 2025.

9. Payments/Gift to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

States are required under § 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 sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Requirements and Associated Burden Estimates

In accordance with section 1927(g) of the Social Security Act (the Act), and regulations at §§ 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. We expect pharmacists employed by or contracted with the individual states to facilitate the states' responses. The sub-sections below estimate the associated 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 will increase by 1 hour.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/2023/may/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialists (All Others)	13-1199	42.85	42.85	85.70
Pharmacist	29-1051	64.81	64.81	129.62

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 other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Burden Estimates

Claims Data and Other Record Reports Preparation (§ 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.

The DUR Medicaid Contact form is included in this package to ensure eligible state Medicaid contacts have access to the annual Medicaid DUR survey to incorporate state collected data into the survey. Contacts include State Medicaid DUR Contacts, State Medicaid Pharmacy Directors,

and State Medicaid Directors. Requested information includes work Email Address, Telephone Number, Fax Number (Area Code), Street Address, City, State and Zip Code.

Time: 1,040 hours annually
20 hours per year (or 5 quarterly hours) per State x 52 states
Cost: $134,805annually
1,040 hours x $129.62/hr (point of service vendor pharmacist wage).

Review Claims Data and Other Record Reports & Interventions (§ 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

Time: 12,480 hours annually
240 hours (10 members at 24 hours per member) per year per State (or 60 quarterly hours) x 52 Medicaid programs
Cost: $648,960 annually
12,480 hours x $50/hr (DUR Board members wage).

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

Time: 24,960 hours annually
480 hours per year (or 120 quarterly hours) x 52 states
Cost: $3,235,315 annually
24,960 hours x $129.62/hr (pharmacist contractor wage)

Annual Report (§§ 456.712 and 438.3)

These sections of the regulation state that the DUR Board and the Medicaid agency are required to report annually to the Medicaid agency and the Secretary, respectively. 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 will increase by 1 hour.

Time: 3,380 hours
It is estimated that the yearly reporting burden for the surveys is 65 hours per State, making the total burden for 52 Medicaid programs.

Cost: $438,116
3,380 hours x $129.62/hr (pharmacist contractor wage)

>Proposed (CMS-4208-P, RIN 0938-AV40) ICRs Regarding Part D Coverage of Anti-Obesity Medications (§ 423.100) and Application to the Medicaid Program

Although the statutory definition of a covered Part D drug at section 1860D-2(e)(2) of the Social Security Act (the Act) excludes certain drugs and uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act it includes, at section 1927(d)(2)(A) of the Act, "agents when used for anorexia, weight loss, or weight gain." In this regard drugs that have been historically used for weight loss have been excluded from the definition of covered Part D drug, regardless of their use for treatment of individuals with obesity and have been an optional drug benefit for Medicaid programs.

The CMS-4208-P rule proposes to reinterpret the statutory exclusion of agents when used for weight loss to allow Part D coverage of AOMs when used to treat obesity by reducing excess body weight or maintaining weight reduction long-term for individuals with obesity who do not have another condition for which the prescribed use is an MAI that is covered under the current Part D policy. The proposed reinterpretation would also apply to the Medicaid program.

There will be a burden for the state Medicaid programs that do not already cover AOMs when used for weight reduction or chronic weight management for Medicaid enrollees with obesity to modify their existing coverage and reimbursement policies and criteria to remove such exclusion of AOMs.

This burden may include the time and cost for administrative processes and requirements, including changes to utilization management criteria, claims processing to allow coverage of these products for this indication, review of stakeholder input, change to provider and beneficiary documents to reflect this change in policy, and state internal operational implementation procedures.

We believe that it will take a business operations specialist 40 hours at $85.70/hr to modify the state's policies and criteria. In aggregate, we estimate a burden of:

Time: 1,560 hours (one-time)
39 states × 40 hr
Cost: $133,692 (one-time)
1,560 hr x $85.70/hr

Once the modifications are developed, there should be no additional burden.

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 Time (hr)	Labor Rate ($/hr)	Total Capital/ Maintenance Costs ($)	Total Annual Co ($)
456.709	52	4	208	5 hr	1,040	129.62	0	134,804
456.711	52	4	208	60 hr (review)	12,480	50.00	0	624,000
		4	208	120 hr (intervention)	24,960	129.62	0	3,235,315
456.712 & 438.3	52	1	52	65 hr	3,380	129.62	0	438,116
PROPOSED* 423.100	39	1	39	40 hr	1,560	85.70	0	133,692
TOTAL	**52**	**varies**	**715**	**varies**	**43,420**	**Varies**	**0**	**4,565,927**

*One-time burden.

The federal government pays 50% of the states' costs, which is $282,964 ($4,565,927 x 0.5).

Information Collection Instruments and Instruction/Guidance Documents

States are required to submit their annual survey responses via the CMS-R-153 reporting instrument using a CMS-hosted online information technology system called Medicaid Drug Program (MDP). The DUR State Agency Contact form ensures system access to eligible state representatives. To generate their annual reports, states submit their responses to the FFS, MCO (or MCO Abbreviated) Surveys to the CMS hosted online MDP system.

- FFS Annual Surveys (No change)
- MCO Annual Surveys (No change)
- Abbreviated MCO Surveys (No change)
- State DUR Agency Contact Form (No change)

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The federal government pays 50% of the states' costs, which is $2,282,964 ($4,565,927 x 0.5).

15. Changes in Burden

The following changes are associated with our December 10, 2024 (89 FR 99340) proposed rule (CMS-4208-P, RIN 0938-AV40) regarding Part D coverage of anti-obesity medications (§ 423.100) and its application to the Medicaid program.

Although the statutory definition of a covered Part D drug at section 1860D-2(e)(2) of the Social Security Act (the Act) excludes certain drugs and uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act it includes, at section 1927(d)(2)(A) of the Act, "agents when used for anorexia, weight loss, or weight gain." In this regard drugs that have been historically used for weight loss have been excluded from the definition of covered Part D drug, regardless of their use for treatment of individuals with obesity and have been an optional drug benefit for Medicaid programs.

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There will be a burden for the state Medicaid programs that do not already cover AOMs when used for weight reduction or chronic weight management for Medicaid enrollees with obesity to modify their existing coverage and reimbursement policies and criteria to remove such exclusion of AOMs.

This burden may include the time and cost for administrative processes and requirements, including changes to utilization management criteria, claims processing to allow coverage of these products for this indication, review of stakeholder input, change to provider and beneficiary documents to reflect this change in policy, and state internal operational implementation procedures.

We believe that it will take a business operations specialist 40 hours at $85.70/hr to modify the state's policies and criteria. In aggregate, we estimate a one-time burden of 1,560 hours (39 states × 40 hr) at a cost of $133,692 (1,560 hr x $85.70/hr). Once the modifications are developed, there should be no additional burden.

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
423.100	39	39	40	1,560	85.70	133,692	N/A

The federal government pays 50% of the states' costs, which is $66,846 ($133,692 x 0.5).

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:

The revised expiration date will be displayed.

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.