

Supporting Statement Part A  
Identifying Medicaid Payment for Physician Administered Drugs  
CMS-10215, OMB 0938-1026

*Note: The current title of this collection of information request, “Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs” has been changed as indicated above.*

## **Background**

In accordance with the Deficit Reduction Act of 2005 (DRA), states are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation (FFP) for these drugs. The state’s collection of National Drug Codes (NDC) for certain physician-administered drugs are associated with rulemaking published on July 17, 2007 (72 FR 39142), under CMS-2238-FC (RIN 0938-AO20) pertaining to 42 CFR part 447 (Payments for Services).

Pharmaceutical manufacturer drug rebates are available to state Medicaid programs that provide reimbursement for allowable pharmacy services to Medicaid beneficiaries. Prior to the DRA, many states did not collect Medicaid rebates on certain drugs administered by physicians in their offices, hospital outpatient settings or other entities (e.g., non-profit facilities) when physicians identified the drugs by their Healthcare Common Procedure Coding System (HCPCS) J-codes instead of the drug’s NDC number. Drug NDC numbers are necessary for the states to bill manufacturers for rebates. Consequently, states did not collect rebates for these Medicaid drug expenditures which resulted in loss of Medicaid savings to both the federal and state governments. In the fourteen years since rule-making, states have required their providers submit NDCs on all claims for physician-administered drugs to maximize the reduction on expenditures by enhanced rebates. Although the states are only required to invoice for the top 20 multiple and single source drugs, states have found it prudent to invoice for all drugs.

In this 2021 iteration we are not proposing changes to any of our requirements. As indicated below in section 12, there are no reporting instruments.

We have, however, revised the title of this collection of information request from, “Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs” to “Identifying Medicaid Payment for Physician Administered Drugs.” The change has no impact on the substance of this collection of information request.

As indicated below in section 15, we are also adjusting our total response, total time, and total cost estimates based on FFY 2020 claims data.

## **A. Justification**

### **1. Need and Legal Basis**

Section 6002 of the DRA added provisions under section 1927 to require states to require physicians in their offices and hospital outpatient settings or other entities (e.g., nonprofit facilities) to collect and submit the drug NDC numbers on Medicaid claims to their state.

Section 6002 also added sections 1927(a)(7) and 1903(i)(10)(C) to require that states collect rebates on certain physician-administered drugs in order for FFP to be available for these drugs.

Section 447.520 specifies the NDC numbers for physician administered drugs as follows:

- No FFP is available for physician-administered drugs for which a state has not required the submission of claims using codes that identify the drugs sufficiently for the state to bill a manufacturer for rebates.
- States must require providers to submit claims for physician-administered drugs using NDC numbers in order to secure rebates.

Effective January 1, 2008, 1927(a)(7)(B)(ii) eliminated FFP when states fail to collect NDCs for these drugs.

Prior to the DRA provisions, some states initiated the collection and submission of drug identifier data matching “J” codes and NDC numbers and required NDCs on claims. We believe that without the DRA provisions, other states would have begun to collect and conduct similar matching efforts with “J” codes and/or collect NDCs on claims.

CMS released a letter to State Medicaid Directors on July 11, 2006 (<https://www.medicaid.gov/federal-policy-guidance/downloads/smd071106.pdf>) to explain the requirements for the state collection and submission of the drug NDC numbers on Medicaid claim data.

Currently, all states are implementing and complying with these collection requirements.

## 2. Information Users

Physicians, serving as respondents to states, will submit NDC numbers and utilization information for physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars. States use the NDC number to invoice manufacturers for rebates. Physicians submit required information, as specified by states, on HIPAA compliant claims.

Nothing is submitted to CMS.

## 3. Improved Information Technology

States have the capability to collect information from the physician respondents electronically and via hard copy. It is estimated that 96%<sup>1</sup> of the respondents may use electronic systems for both collection activities and physician claims’ submissions to the states, since all states use electronic claims processing in their Maintenance Management Information System

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<sup>1</sup> <https://healthinformatics.uic.edu/blog/electronic-health-record-use-at-an-all-time-high/>

(MMIS) claims processing and very few hard copy claims are submitted for reimbursement.

#### 4. Duplication of Similar Information

There is no duplication of similar information.

#### 5. Small Businesses

According to the Small Business Administration's size standards, physician practices are small businesses if they have revenues of \$9 million or less in 1 year and hospitals are small businesses if they have yearly revenues of \$31.5 million or less. This collection of information impacts physicians and outpatient units of hospitals that administer specialty and intravenous drugs to Medicaid beneficiaries using HCPCS "J" billing codes instead of NDC numbers. We estimate that there are 20,000 physicians' offices, hospital outpatient settings or other entities (e.g., nonprofit facilities) concentrating in the specialties of oncology, rheumatology and urology, will serve as respondents to the states.

#### 6. Consequence if Collection is not Conducted or Conducted Less Frequently

Providers submit claims to the Medicaid programs on a regular basis so they can receive payment timely. The majority of states have a timely filing period of one-year. States must utilize the NDC information on these claims to create the invoices submitted to the drug manufacturers. If states do not fully collect this information from their physician respondents, states cannot claim FFP for such Medicaid expenditures.

#### 7. Special Circumstances

We estimate that physician claims are submitted to states on a weekly basis, since it is standard practice in provider's offices to "bundle" claims and submit them weekly to the states for reimbursement.

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

- 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

The 60-day notice published in the Federal Register on May 4, 2021 (86 FR 23729). While comments were due July 6, 2021, none were received.

The 30-day notice published in the Federal Register on July 9, 2021 (86 FR 36281). Comments must be received by the OMB desk officer by August 9, 2021.

#### 9. Payment/Gift to Respondent

There are no payments of gifts associated with this collection.

#### 10. Confidentiality

There are no confidentiality issues as NDCs have no associated confidentiality when being submitted by physicians to the states for payment.

#### 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. Burden Estimates

##### *Wages*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates ([https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Billing and Posting Clerks	43-3021	20.01	20.01	40.02

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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

### *Requirements and Associated Burden Estimates*

The burden associated with this information collection requirement is the time and effort it would take a Billing/Posting Clerk or other entity to include the NDC numbers on billing claims submitted to the states. Originally, when first introduced in Section 6002 of the DRA, PAD utilization by providers was limited; however, since that time, with enhanced medical standards of practice, rule-making and introduction of high cost drugs (specialty drugs), PAD services have increased. As PAD claims increased, so did providers offering these services in private practices and hospital outpatient programs to compensate for increased utilization of PAD services. In this 2021 iteration, we estimate that this requirement will provide a burden of 0.00415 hrs/claim resulting in \$0.16/claim.

We believe the burden associated with this requirement is:

- 84,589,433 million claims per year<sup>2</sup>
- 15 sec. per claim or 0.00415 hrs.
- 351,046 annual hours = 84,589,433 claims x 0.00415 hrs./claim
- \$14,048,861 (total) = 351,046 hours x \$40.02/hour
- \$0.17/claim = \$14,048,861 / 84,589,433 claims

Drug rebates are collectible on all physician-administered drugs so there is a financial incentive for states to spend the time and effort to implement this collection of information requirement. In addition, states not collecting this information on physician-administered drugs lose FFP for these drugs.

Nothing is submitted directly to CMS.

### *Information Collection Instruments/Instruction/Guidance Documents*

State Medicaid Director Letter (06-016) dated July 11, 2006.  
(<https://www.medicaid.gov/federal-policy-guidance/downloads/smd071106.pdf>)

#### 13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

#### 14. Cost to the Federal Government

There are no costs to the Federal Government.

#### 15. Program or Burden Changes

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<sup>2</sup> PAD claim count has been estimated through the Medicaid State Drug Utilization Data for FFY 2020  
<https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html>

In this 2021 iteration we are not proposing changes to any of our requirements. As indicated below, we propose to adjust our burden estimates to reflect current responses and hourly wages. There are no reporting instruments associated with this collection.

We have, however, revised the title of this collection of information request from, “Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs” to “Identifying Medicaid Payment for Physician Administered Drugs.” The change has no impact on the substance of this collection of information request.

### *Burden Adjustments*

We are also adjusting our total response, total time, and total cost estimates based on FFY 2020 claim count data. The total number of responses has increased by 80,679,433 (from 3,910,000 active claims to 84,589,433 proposed claims) resulting in an increase in our total time estimate (plus 334,819 hours = 351,046 proposed hr - 16,227 active hr) and an increase in our total cost estimate (plus \$13,462,742 = \$14,048,861 proposed - \$586,119 active). The increased cost also takes into account BLS’ current wages (plus \$3.90/hr = \$40.02/hr proposed - \$36.12/hr active)

While this iteration’s burden is based almost entirely on FFY 2020 claims data, our active burden had been carried over in each subsequent iteration since it was last approved by OMB on January 30, 2011.

### *Active Burden*

- 3,910,000 claims
- 15 seconds per claim or 0.00415 hours
- 16,227 annual hours = 3,910,000 claims x 0.00415 hr/claim
- \$586,119.24 (total) = 16,227 hours x \$36.12/hour

### *Proposed Burden*

See section 12 of this Supporting Statement.

### 16. Publication and Tabulation Dates

This collection of information is not intended for publication.

### 17. Expiration Date

CMS will display the expiration date.

### 18. Certification Statement

There are no exceptions to the certification statement.

## **B. Collection of Information Employing Statistical Methods**

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