

Supporting Statement Part A
Medicaid Payment for Prescription Drugs - Physicians and
Hospital Outpatient Departments Collecting and Submitting Drug
Identifying Information to State Medicaid Programs
CMS-10215, OMB 0938-1026

Background

In accordance with the Deficit Reduction Act of 2005, 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 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, under RIN 0938-AO20.

Pharmaceutical manufacturer drug rebates are available to state Medicaid programs that provide reimbursement for allowable pharmacy services to Medicaid beneficiaries. Prior to the Deficit Reduction Act (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 National Drug Code (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.

A. Justification

1. Need and Legal Basis

Section 6002 of the DRA of 2005 added provisions under section 1927 to require states to require physicians in their offices and hospital outpatient settings or other entities (e.g., non profit facilities) to collect and submit the drug NDC numbers on Medicaid claims to their state.

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

Requirements under Federal regulations presently codified at 42 CFR 447.520 specify the collection of 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, Section 1927(a)(7)(B)(ii) of the Act eliminates Federal Financial Participation (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 requiring 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 “J” code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars.

3. Improved Information Technology

States have the capability to collect information from the physician respondents electronically and via hard copy. It is estimated that 95% of the respondents may use electronic systems for both collection activities and physician claims’ submissions to the states.

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., non profit 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 Frequent

If states do not fully collect this information from their physician respondents, states will be denied FFP for such Medicaid expenditures, effective January 1, 2008. We are estimating that claims will be submitted to states on a weekly basis.

7. Special Circumstances

We estimate that physician claims are submitted to states on a weekly basis.

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 Federal Register notice published on December 27, 2014 (78 FR 78967). No comments were received.

9. Payment/Gift To Respondent

There are no payments of gifts associated with this collection.

10. Confidentiality

We make no pledges of confidentiality.

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 Estimate (Hourly and Cost Burden)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 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)
Billing and Posting Clerks	43-3021	\$17.45	\$17.45	\$34.90

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.

Burden Estimates

The burden associated with this information collection requirement is the time and effort it would take a Billing and Posting Clerk in a physician's office or other entity to include the NDC numbers on billing claims submitted to the states. We estimate this requirement will affect an excess of 20,000 physicians, who will each submit 3.76 claims per physician each week or 195.5 claims per physician each year on an average.

We believe the burden associated with this requirement is:

Hourly Burden

- 20,000 physician' offices
- 3,910,000 claims
- 95% electronic
- 195.5 claims per physician's office annually or 3.76 claims per physician's office weekly
- 15 seconds equals .00415 hours per claim (based on conversion factor .00027 per PRA instructions)
- .015 hours burden per physician per week
- $3,910,000 \times .00415 = 16,227$ annual hours

Cost Burden

- .00415 hours burden per claim
- \$34.90 hourly wage for physician's staff collecting the NDC numbers on the claims
- .00415 multiplied by \$34.90 per hourly wage
- 14.5¢ cost burden per claim based upon .00415 hours and \$34.90 per hourly wage $\times 3,910,000$ claims = \$566,950 annually

Therefore, the total burden associated with section 447.520(c) is .015 hours burden per physician's office per week and 55¢ cost per physician's office per week. 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.

Information Collection Instruments/Instruction/Guidance Documents

None.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to the Federal Government

There is no cost burden to the Federal Government.

15. Program or Burden Changes

There are no program changes or burden adjustments.

16. Publication and Tabulation Dates

This collection of information is not intended for publication.

17. Expiration Date

CMS will display the expiration date. OMB Control Number 0938-1026
(Expires: TBD).

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.