Medicaid Payment for Prescription Drugs - Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs (OMB: 0938-1026)

Supporting Statement

A. Background

We are submitting this information collection to OMB as an "Extension" initiated under OCN: 0938-1026. Pursuant to the Deficit 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 under Volume 72, Number 136, Tuesday, July 17, 2007, Rules and Regulations (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.

B. 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 Code of Federal Regulations 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.
    - As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

    - As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

    - As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

    - A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

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.

Thirty-eight States had requested and received approval for such an extension.

CMS released a letter to State Medicaid Directors on July 11, 2006 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 45% of the respondents may use electronic systems for collection and submissions.

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

   There are no special circumstances.

8. Federal Register Notice/Outside Consultation

   A 60-day Federal Register notice will be published on _____.

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 questions of a sensitive nature associated with these forms.

12. Burden Estimate (Hourly and Cost Burden)

The burden associated with this information collection requirement is the time and effort it would take 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 physicians
- 3,910,000 claims
- 45% electronic
- 195.5 claims per physician annually or 3.76 claims per physician weekly
- 15 seconds equals .00405 hours per claim (based on conversion factor .00027 per PRA instructions)
- .015 hours burden per physician per week
- 3,910,000 x .00405 = 15,836 annual hours

Cost Burden

- .00405 hours burden per claim
- $23.27 hourly wage for physician's staff collecting the NDC numbers on the claims
- .00405 multiplied by $23.27 per hourly wage
- 9.4¢ cost burden per claim based upon .00405 hours and $23.27 per hourly wage
- 35¢ cost burden per physician per week
- $18.20 cost burden per physician per year

Therefore, the total burden associated with section 447.520 (c) is .015 hours burden per physician per week and 35¢ cost per physician 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 the 20 highest dollar volume multiple source drugs lose FFP for these drugs beginning January 2008.

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 or burden changes.

16. Publication and Tabulation Dates

    This collection of information is not intended for publication.

17. Expiration Date for OMB Approval

    This information collection does not lend itself to the display of an expiration date.

18. Certification Statement

    There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

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