Supporting Statement for Collection of Physician Administered Drug National Drug Code Numbers on State Medicaid Claims and Supporting Regulations at 42 CFR 447.520

A. Background

We are submitting this information collection to OMB as a "New Collection." This collection is associated with CMS-2238-FC: Medicaid Program; Prescription Drugs which was published on July 17, 2007.

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.

Section 1927 (a) (7) (C) of the Act requires that, beginning January 1, 2007, States must provide for physicians to submit to them utilization data with NDC numbers for the top 20 high dollar volume multiple-source physician-administered drugs.

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 have 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.

Section 1927 (a) (7) (D) allows for States to apply for a one-time extension to implement or modify its reporting systems to comply with this requirement.

CMS released a letter to State Medicaid Directors on July 11, 2006 and will also address these requirements in forthcoming regulations.

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.

4. Duplication of Similar Information

Not all States are collecting this information from the physicians and other entities. This is a "New Collection."

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

Section 1927 (a) (7) (D) of the Act allows States to seek "hardship waivers" defined as time extensions to requiring collection of the NDC numbers. It would take time and effort to apply for an extension.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register was published on 12/8/2006.

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
- $21.14 hourly wage for physician's staff collecting the NDC numbers on the claims
- .00405 multiplied by $21.14 per hourly wage
- 8.6¢ cost burden per claim based upon .00405 hours and $21.14 per hourly wage
- 32¢ cost burden per physician per week
- $16.64 cost burden per physician per year

The rule allows States requiring additional time to comply with the information collection requirements to apply for an extension. The burden associated with this requirement is the time and effort it would take for each State to apply for a one-time extension. We estimate that it would take 5 hours for each State to apply for the extension. However, we believe that less than 10 States would apply for the extension. Therefore, we believe this requirement to be exempt as specified at 5 CFR 1320.3.

Therefore, the total burden associated with section 447.520 (c) is .015 hours burden per physician per week and 32¢ 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 would 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

This is a new collection.

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.