Paper Reduction Act
Agency Information Collection Activities: CMS-10215 & CMS-10148
Report Medicaid Pharmacy NDC Codes on Physician & Outpatient Hospital Departments Medicaid Pharmacy Billing Invoices
CMS Responses to Comments Received

A. Creates additional administrative and paperwork burden on staff

Coments Submitted by:

- PRA #1 University of Michigan Hospitals and Health Centers--Michigan
- PRA #2 University of California, Davis-- California
- PRA #3 The Moses H. Cone Memorial Hospital--North Carolina
- PRA #4 Medical Central of Central Georgia Pharmacy Services--Georgia
- PRA # 5 Johns Hopkins Hospital --Maryland
- PRA #6 The Johns Hopkins Hospital & Johns Hopkins Bayview Medical Center Maryland
- PRA#7 Safety Net Hospital for Pharmaceutical Access--Washington DC
- PRA #8 Shands Jacksonville Medical Center—Florida
- PRA #9 Santa Clara Valley Health & Hospital System –California
- PRA #10 Rhode Island Hospital--Brown University
- PRA #11 Providence Hospital --Washington DC
- PRA # 12 Phoenix Children's Hospital --Chief Financial Officer--Arizona
- PRA #13 Phoenix Children's Hospital --President & CEO—Arizona
- PRA#14 Phoenix Children's Hospital --Operations Manager Outpatient Pharmacy Arizona
- PRA #15 North Oaks Health Systems—Louisiana
- PRA #16 MCG) Medical College of Georgia Health System
- PRA #17 Hamilton Medical Center
- PRA #18 Grady Health Systems-—340 B—Georgia
- PRA #19 Gaston Memorial Hospital --North Carolina
- PRA #20 Federation of American Hospitals
- PRA #21 Columbus Regional Medical Center—Georgia--Director of Pharmacy & Clinical Research
- PRA #22 Columbus Regional Medical Center—Georgia
- PRA #23 Charleston Area Medical Center--West Virginia
- PRA #24 Bon Secours Richmond Health System--Virginia
- PRA #25 Women & Infants' Hospital
- PRA #26 Wellstar Douglas Hospital

Comment:
Many commenters stated they oppose the new requirement to collect NDCs on outpatient hospital claims due to the enormous additional administrative and paperwork burden it will place upon staff. Commenters further stated that the proposed rule underestimates the time needed to comply with this requirement. One commenter (PRA #20 Federation of American Hospitals) conducted an observational task analysis of manually tracking NDC numbers at a large hospital.

Response:
This proposed collection is based upon the Deficit Reduction Act of 2005 (DRA) that requires State Medicaid programs to collect NDC codes on provider claims. We recognize that this collection requirement would impose some administrative burden on hospitals outpatient departments. We also acknowledge that hospital outpatient departments would need to change their billing systems to accept

NDCs. We note an estimate by the American Hospital Association of a minimum cost of approximately $230,000 per hospital to make this systems change. Since this estimate is not documented, we also note that if it is an accurate estimate then the cost for all 5,655 Medicaid-certified hospitals would be about $1.3 billion. While we appreciate the burden estimate derived by the Federation of American Hospitals' observational task analysis of manually tracking NDC numbers at a large hospital, we do not believe this limited study should be used as a basis to calculate the administrative and paperwork burden for all hospitals, nationally. Overall, we acknowledge the additional administrative and paperwork burden, but we do not have sufficient data to quantify the burden on all hospitals, nationally.

B. Not necessary to collect NDCs since outpatient drugs administered through hospitals outpatient departments and 340B clinics are excluded from the Medicaid drug rebate

Coments Submitted by:

- PRA #1 University of Michigan Hospitals and Health Centers
- PRA #3 The Moses H. Cone Memorial Hospital--North Carolina
- PRA #4 Medical Central of Central Georgia Pharmacy Services—Georgia
- PRA #5 Johns Hopkins Hospital –Maryland
- PRA #6 The Johns Hopkins Hospital & Johns Hopkins Bayview Medical Center Maryland
- PRA#7 Safety Net Hospital for Pharmaceutical Access--Washington DC
- PRA #8 Shands Jacksonville Medical Center—Florida
- PRA #9 Santa Clara Valley Health & Hospital System –California
- PRA #10 Rhode Island Hospital--Brown University
- PRA #11 Providence Hospital --Washington DC
- PRA # 12 Phoenix Children's Hospital --Chief Financial Officer Arizona
- PRA #13 Phoenix Children's Hospital --President & CEO—Arizona
- PRA#14 Phoenix Children's Hospital --Operations Manager Outpatient Pharmacy Arizona
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- PRA #20 Federation of American Hospitals
- PRA #21 Columbus Regional Medical Center—Georgia
- PRA #23 Charleston Area Medical Center--West Virginia
- PRA #24 Bon Secours Richmond Health System
- PRA #25 Women & Infants' Hospital
- PRA#26 Wellstar Douglas Hospital

Comment:
Many commenters stated they strongly oppose the new requirement to collect NDCs on outpatient hospital claims because hospitals participating in the 340B program are exempt from the rebate

requirements of section 1927 of the Social Security Act as are hospitals that dispense drugs using a formulary system that bill at the hospital's purchasing cost for drugs (section 1927 (j)(2)).

Response:
In accordance with section 1927 of the Act, the NDC collection provision of the DRA does not apply to 340B hospitals that receive discounted drugs and bill Medicaid at the actual acquisition cost of the drug. Likewise, hospitals that use a drug formulary system and bill at the hospital's purchasing cost are exempted.

C. Imposes Administrative Burden on Clinicians Instead of Billing Staff

Coments Submitted by:

- PRA #2 University of California, Davis California
- PRA#7 Safety Net Hospital for Pharmaceutical Access--Washington DC
- PRA #9 Santa Clara Valley Health & Hospital System --California
- PRA #20 Federation of American Hospitals

Comment:
Several commenters opposed the new requirement to collect NDCs on outpatient hospital claims because this new administrative burden will initially fall on clinicians, such as physicians and nurses, who should be engaged in administering patient care rather than administrative functions. In addition, when physicians administer urgent care to a patient, they do not know if the patient will be referred to inpatient or outpatient care. The NDC collection requirement would also require hospital staff to record the amount of medication from each package of medication or vial administered to each individual patient in order to bill properly.

Response:
We continue to note that the law requires States to obtain NDCs on claims for physician-administered drugs. Because the public comments did not provide documented estimates of the expected burden, we have no quantitative information to use to revise the estimates.

D. Costly Hospital Systems Changes

Coments Submitted by:

- PRA #6 The Johns Hopkins Hospital & Johns Hopkins Bayview Medical Center Maryland
- PRA#7 Safety Net Hospital for Pharmaceutical Access--Washington DC
- PRA #9 Santa Clara Valley Health & Hospital System –California
- PRA #19 Gaston Memorial Hospital --North Carolina
- PRA #20 Federation of American Hospitals
- PRA #21 Columbus Regional Medical Center--Georgia
- PRA #23 Charleston Area Medical Center--West Virginia

- PRA #25 Women & Infants' Hospital

Comment:

Several commenters stated that the significant and costly systems change, would be needed to accommodate the new collection requirement placed on hospitals, including new interfaces between current billing and information systems to collect multiple entries for the same drug and recognize all correct NDC numbers.

Response:
As previously discussed, hospitals with outpatient departments would need to include NDCs on claims for physician-administered drugs. This would need to be done manually or would require a one-time systems change. Hospital outpatient departments would need to modify their billing systems to capture the NDC on Medicaid claims. We are not able to estimate the cost to make the needed systems changes; however in 2002, the American Hospital Association estimated that these changes would cost hospitals a minimum of $200,000 for each hospital. We have inflated this estimate by the Consumer Price Index to estimate a current cost of $230,000 for a total cost at $1.3 billion for the 5,655 hospitals that operate outpatient departments and participate in Medicaid. Since this estimate is not documented, CMS is not adopting it for purposes of this PRA financial burden analysis; however, we do accept that hospitals will incur some costs.

E. NDC Coding System Suited for Inventory Not Provider Billing

Comment Submitted by:
- PRA #20 Federation of American Hospitals

Comment:
One commenter stated that the NDC coding system is more suited for inventory control and is not appropriate for institutional provider billing.

Response:
As previously discussed, the DRA requires States to collect NDC codes on Medicaid bills for outpatient pharmacy physician-administered drugs.

F. Requests beyond the DRA law and scope of the PRA package

Comment Submitted by:
- PRA #20 Federation of American Hospitals

One commenter urged CMS to direct State Medicaid agencies to limit State collection of NDCs to the top 20 drug list to be published by CMS, provide time-limited add-on payments per hospital claim to support the implementation of barcoding systems, and allow for phased-in implementation.

Response:

CMS is required by law to publish the top 20 multiple source drugs to which the requirement to collect the NDC applies. However, we will not instruct States to only collect the NDCs only for those drugs. States lose millions of dollars in manufacturer rebates because they cannot identify the drugs administered, which is required to bill for rebates. We also cannot require States to pay an add-on fee to hospitals and may only delay implementation if the State requests a time extension.

G. Prompt pay discounts in calculating AMP

Comment Submitted by:

- PRA #21 Columbus Regional Medical Center—Georgia

One commenter asserted that the treatment of prompt pay discounts in calculating the Average Manufacturer Price (AMP) and the revenue loss of nominal pricing would increase hospital outpatient drug prices and, thereby, has a negative impact on the hospital's ability to provide services.

Response:
These comments are outside of the scope of this PRA packet.

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Same Time & Financial Burden As Original Packet—No Change

PRA Packet: No Change to Estimates in Original Proposed Packet

In the public comments that responded to the proposed collections publication for comments, we did not receive documented estimates of the expected time and financial burden imposed by the new requirement to collect NDCs on physician administered drugs. Additionally, we did not receive any quantitative information to use to revise the estimates presented in the proposed collection publication; therefore, we retain the original burden associated with this information request that is .015 hours time burden per physician per claim and 32¢ cost burden 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.

In addition, the DRA 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.

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 of .00027 hours per second
- .015 hours burden per physician per claim
- 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

Please note: We believe that most hospitals outpatient departments would need to modify their billing systems to implement this new collection requirement. Assuming a cost of $230,000 per hospital, as estimated by the American Hospital Association, the total cost would be approximately $1.3 billion for the 5,655 hospitals that participate in Medicaid. Since this estimate is not documented, CMS is not adopting it for purposes of this PRA financial burden analysis; however, we do accept that hospitals will incur some costs.