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February 20, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2238-P  
P.O. Box 8015  
Baltimore, MD 21244-8015

**Re: CMS-2238-P; Medicaid Program; Prescription Drugs**

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services (CMS) December 22, 2006, proposed rule that would implement provisions of the Deficit Reduction Act of 2005 (DRA) regarding prescription drugs under the Medicaid program. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

ASHP would like to specifically comment on the provision in the proposed rule that requires hospitals to include the 11-digit National Drug Code (NDC) on claims submitted for physician-administered drugs. Fundamentally, ASHP believes that “physician administered drugs” under the DRA is limited to drugs administered to patients in physician offices, not hospital outpatient departments. The DRA references “certain” physician administered drugs as determined by the Secretary. Moreover, the DRA makes no reference to Section 1927 (j) of the Act, which exempts drugs used in certain types of settings from rebate requirements. Therefore, hospital outpatient departments should be exempted from this requirement.

ASHP also believes that this requirement would create an undue financial hardship since the vast majority of affected facilities have no other option but to provide NDC information through a labor intensive process. The requirement is also likely to compromise patient safety because of changes in hospital workflows and the necessity of diverting staff (already in short supply) to the NDC – reporting requirement.

ASHP conducted a survey of pharmacy directors in February 2007 to estimate the impact of this new requirement on hospitals and health systems' current systems and processes. Over 700 surveys were returned and were received from hospitals in every state except Alaska. Respondents were from facilities with an average daily census from less than 50 to greater than 500 and outpatient visits ranged from 12,000 to 180,000 a year. A copy of the results is enclosed.

There are several key areas of concern that ASHP has identified through our own analysis of the survey results. Primary issues include:

- **Negative Impact on Patient Safety.** Current workflow and systems for dispensing and administration of medications were designed to be safe and efficient. Adding a requirement for tracking and reporting NDC numbers would require that systems be redesigned for accurate tracking of billing information, diverting limited staff from accurate dispensing and administration.

*A respondent from Minnesota told us: "This would be a huge requirement. Even if we had a system for tracking the NDC, it would still add time to each order. This added time would also cause further confusion in an already busy pharmacy. Added confusion increases the risk for mistakes. With the constant changes to contracts and supply, managing to the NDC level would be very challenging."*

- **Significant Costs Per Claim.** The proposed rule estimated a cost of 9 cents per claim based on a manual entry taking 15 seconds each. This estimate is inaccurate because it does not take into account the costs associated with making various changes that would be required throughout the institution with respect to the entire medication-use process. There is a range of steps required before filing a claim, including recording and tracking the NDC number from order entry to preparation and administration, as well as finance and patient billing. In our survey, the full estimated cost to comply with this proposal was \$10.80 per claim, taking an average of 24 minutes if this requirement were implemented today.

*A respondent from South Dakota said: "I coordinate services of nearly 20 rural Critical Access Hospital pharmacy departments, many of them with less than one full time staff person and little automation. In my opinion, this would have an enormous impact. Not only would it be almost impossible to be in compliance, it would certainly divert the limited resources we have away from patient care and medication safety, to a tracking exercise. It's likely that the time reduction from patient care and safety activities would tend to increase overall costs."*

- **Unrealistic Tracking Requirements.** Of major concern is a survey finding that 60% of respondent facilities did not have information systems that could store and cross reference alternate NDC numbers for the same generic entity. This means that these institutions could not track or bill an alternate NDC number in the event that a therapeutic equivalent generic entity was administered. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

As one respondent said: *“We recently completed a review of all pharmacy software vendors for cancer care in the outpatient setting and concluded there is no vendor in the marketplace that could provide this tracking.”*

Another respondent indicated that *“the cost to modify computer systems could cost \$1 to \$1.5 million, if the modifications could even be developed and purchased.”*

- **Minimal Bar Coding Capability.** Utilization of bar codes at the point of administration is considered by many to be the only feasible way of implementing the NDC requirement. Existing systems will not offer this as a viable solution for some time since only 6% of the survey respondents indicated they used bar-coding for outpatient medication doses. For bar coding to serve as a solution to providing the unique NDC number, it must be fully implemented throughout all the institution’s information systems, including point of administration.

A respondent from Oklahoma told us: *The health care industry is not currently positioned for this transition. With the future implementation of point-of-care/bedside medication verification scanning technology, hospitals may be better equipped to implement this edict. We are not currently positioned to meet this requirement in our rural health care setting.*

In order to meet the requirements in the proposed rule, institutions would face significant operational and financial hardship that is unrealistic and not justifiable given current workforce and fiscal constraints. Substantial expenditure of human and financial resources would be required.

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We urge the agency to reconsider this requirement and exempt hospital outpatient departments, not only because of this significant burden, but also since there is no specific reference to their inclusion in the DRA.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian M. Meyer". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brian M. Meyer  
Director, Government Affairs Division

Enclosure



## **ASHP Survey Results:**

### **Provision of NDC Numbers on Outpatient Medicaid Claims**

February 2007

#### **Key Findings**

- Only 18% of respondents were aware of notification of the new NDC requirement from their state Medicaid program.
- The estimated cost per medication order to include the NDC number on a Medicaid claim was \$10.80 if this requirement were to be implemented today.
- Only 40% of respondent's pharmacy information systems are able to store and cross reference alternate NDC numbers for the same generic entity, functionality considered essential since more than one product is stocked for any generic drug entity.
- Only 16% of respondents that provide outpatient services indicated that their pharmacy information system had the ability to send an NDC number for each drug dispensed and administered to the organization's finance and/or patient accounts system.
- Bar coding of outpatient medication administration is thought to be the only possible way to implement this provision, yet only 6% of respondents utilized bar-coding for their outpatient medication doses.

## **Introduction**

On December 22, 2006, The Centers for Medicare and Medicaid Services (CMS) published a [proposed rule](#) in the Federal Register describing their plans to implement certain provisions in the Deficit Reduction Act of 2005 (DRA). Under the DRA, hospitals will be required to provide NDC information on billing submissions to Medicaid so that states are able to seek manufacturer rebates. Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered in clinic settings. This survey was designed to gauge the feasibility of hospitals and health systems meeting this requirement with current systems and processes.

## **Objective**

The objective of this survey was to determine the impact of the proposed requirement that for all drugs administered to Medicaid outpatients be billed including the 11 digit National Drug Code (NDC). This would include physician offices, outpatient infusion centers, emergency departments, and ambulatory clinics. To determine the impact of this proposed rule the survey posed questions about information technology, workload, operational, and financial implications.

## **Methods**

The survey was sent electronically on February 5, 2007 to 3,200 ASHP members that are primary members of the Section of Pharmacy Practice Managers. This sample included directors of pharmacy, associate directors of pharmacy, and other pharmacy managers from across the United States. The survey was conducted via an e-mail invitation containing a link to an online survey instrument; with a reminder e-mail sent on February 8, 2007 and was closed on February 13, 2007. Of the invitations sent, 718 surveys were completed resulting in a 22% return rate.

## **Detailed Results**

The key findings of this survey included respondent's awareness of any notification from their State Medicaid programs of intentions to implement this DRA rule, the technical ability of pharmacy and hospital information systems, the impact on organization resources and costs, and the anticipated time consumption per outpatient order this NDC reporting requirement would have on health systems.

## **Notification by State Medicaid Programs**

Responses received included pharmacists representing hospitals in all states except Alaska. Of these responses, 48 states had greater than 5 responses each. Ninety-one percent of the respondents provided outpatient services with the range of outpatient volume from 12,000 visits per year to more than 180,000 visits per year (Table 1). These respondents represented a wide range of hospital sizes with an average daily census ranging from less than 50 to greater than 500 (Table 2).

The survey recipients that indicated they provide outpatient services were asked whether their State Medicaid program had announced their intention to implement the requirement that NDC numbers be submitted on outpatient Medicaid claims so that the state might seek rebates from manufacturers. Eighteen percent replied YES, 5 percent replied NO, and 77 percent replied that they were not aware of any announcements.

## **Information Technology**

Those respondents that provide outpatient services were asked to describe their organization's information technology system's ability to operationalize the proposed requirement. The results addressed the pharmacy system as it related to patient care order entry, bar coding of medications and administration processes, documentation, and its interface with hospital patient care systems including the interface with the financial and/or patient accounting information systems.

Six percent of respondents from hospitals with outpatient services utilized bar-coding in their outpatient environments, with only 28 percent of the respondents indicating that they utilized bar-coding in *any* of their organization's medication processes. All of the respondents that utilize bar-coding indicated that they must prepare special packaging for doses within the pharmacy that result in utilizing a bar-code numerical identifier other than the manufacturer's NDC number. Over sixty percent replied that this occurs with over 10% of doses dispensed by their pharmacy, and 22% of the respondents indicated that this occurs with more than 30% of their doses dispensed.

Sixty percent of the respondents that provide outpatient services stated that their pharmacy information system could not store and cross reference alternate NDC numbers for the same generic entity. This means that these institutions could not track or bill an alternate NDC number in the event a therapeutic equivalent generic entity was utilized. Seventy-three percent of the respondents replied that their information systems are not able to identify the unique NDC number of a product utilized in preparing an IV admixture, which is noted to be due to the fact that current systems are designed to ensure accuracy of a specific generic drug charge code versus multiple NDC numbers that could be represented by the charge code.

In addition, only 16% of respondents that provide outpatient services indicated that their pharmacy information system had the ability to send an NDC number for each drug

dispensed and administered to the organization's finance and/or patient accounts system.

### **Operational Impact on Resources**

To determine what the operational impact would be on organizations, including both staff resources and time to make process changes, respondents were asked to indicate what this would be for their organizations. Seventy-eight percent of respondents indicated that it is a significant impact on the pharmacy department and staff time required to implement any manual short term solutions. Seventy percent of respondents indicated that the staff hours required making soft-ware changes for long term solutions would also be significant. And sixty-eight percent of respondents felt that any process changes to develop long term solutions would have a significant impact on their organization (Table 3).

### **Time Per Outpatient Order to Implement DRA Provisions**

Respondents that indicated that they provided outpatient services were asked to consider the amount of time it would take per outpatient order to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients, assuming such a requirement were to go into effect "tomorrow" for their organization. For the process of recording and tracking the NDC number from order entry to preparation to administration more than 48 percent indicated that it would be greater than 10 minutes per order and 36 percent indicated it would take between 5 to 10 minutes. For the process of providing the patient specific NDC number information for utilization in the finance and/or patient billing accounting more than 47 percent indicated that it would be greater than 10 minutes per order and 34 percent indicated that it would take between 5 to 10 minutes (Table 4).

Utilizing an average pharmacy personnel hourly rate of \$27.00 (less benefits), this would translate into an estimated average cost to meet the proposed requirements of the DRA of \$10.80 per outpatient drug order (average reported time of 24 minutes per order); with the current technology and processes in place in the United States as of February 2007.

### **Conclusion**

In order to meet the requirement to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients it would result in significant operational and financial hardship for the United States' health systems. Additionally, the current information technology infrastructure would need to be substantially altered to accommodate this requirement.

## Contact information

For more information on this survey and its results, please contact Brian Meyer, Director, Government Affairs, American Society of Health-System Pharmacists at 301-664-8698 or [bmeyer@ashp.org](mailto:bmeyer@ashp.org).

**Table 1**

<b>What is the estimated number of outpatient visits (hospital clinic, emergency room services, and outpatient infusion centers) per month at your organization?</b>		
<b>Visits</b>	<b>Number of Responses</b>	<b>Percentage</b>
Less than 1,000 visits	95	15%
Between 1,000 to 5,000 visits	219	34%
Between 5,000 to 15,000 visits	139	22%
More than 15,000 visits	140	22%
Don't know	47	7%
Total responses: 640		

**Table 2**

<b>Please indicate the average daily census at your organization.</b>		
<b>Average Daily Census</b>	<b>Number of Responses</b>	<b>Percentage</b>
Not applicable	9	1%
Less than 50	109	17%
50-99	87	14%
100-199	139	22%
200-299	98	15%
300-399	78	12%
400-499	30	5%
500 or more	84	13%
Total responses: 634		

**Table 3**

<b>For each of the resources/costs below, please indicate the impact that you foresee at your organization:</b>					
	None	Insignificant	Moderate	Significant	Don't know
Pharmacy and other staff time for manual short-term solutions	1%	3%	14%	78%	4%
Staff time for software changes for long-term implementation	2%	2%	18%	70%	9%
Process changes for long-term implementation	1%	2%	21%	68%	8%
Total Responses: 637					

**Table 4**

Assume that starting <i>tomorrow</i> , your organization is required to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid <u>outpatients</u> (hospital clinic, emergency department services, and outpatient infusion centers).					
<b>Approximately how much time per <u>order</u> would this take for each item below:</b>					
Item	Less than 5 minutes	5 to 10 minutes	10 to 20 minutes	20 to 30 minutes	More than 30 minutes
Recording and tracking NDC from order entry, preparation, to administration	16%	36%	26%	11%	11%
Provision of NDC information to finance/patient accounts	19%	34%	23%	8%	16%
Total Responses: 637					