Zenovia ✓

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

why necessary action? why not response?

TO	DATE
Myers/Zenovia/"BZ"	6-9-08

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 000641	[ ] Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR _____ cc: Ms. Forkner Cleared 6/20/08, letter attached.	[X] Prepare reply for appropriate signature DATE DUE 6/18/08 [ ] FOIA DATE DUE _____ [ ] Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1. Brenda Vaughn	6/19/08		
2.			
3.			
4.			

RECEIVED
Dept. of Health & Human Services
JUN 10 2008
Bureau of Health Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

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Myers	6-9-08

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4.			

June 4, 2008

Emma Forkner, Director
Department of Health and Human Services
P.O. Box 8206
Columbia, SC 29202

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

Dear Ms. Forkner:

The South Carolina Society of Health-System Pharmacists (SCSHP), as an affiliate of the American Society of Health-System Pharmacists (ASHP), would like to request that you support further delaying the requirement that hospital pharmacies report the National Drug Code (NDC) on all outpatient claims for physician-administered drugs.

SCSHP believes that, at this time, this requirement would have a significantly negative effect on the safety of medication dispensing and administration. The shortage of pharmacists and qualified, trained technicians has already placed a huge burden on hospital pharmacies. The NDC reporting requirement would increase this burden by requiring pharmacies to change their workflows and duties and spend more time on reporting or bookkeeping duties. SCSHP is particularly concerned this would divert pharmacists' and pharmacy technicians' focus away from providing patient education, ensuring the accuracy of medication order entry, and working on safety initiative.

There are still very few hospitals in the state that have the ability to comply with the NDC reporting requirement. In fact, according to a national survey done by ASHP, only 40% of our nation's hospitals have information systems that could store and cross reference alternate NDC numbers for the same generic entity. These hospitals would have to implement a labor-intensive manual solution which, of course, takes time away from other duties. This survey clearly shows that our hospitals are not ready to meet the NDC reporting requirement. This survey is attached for your reference.

Please consider further delay of the NDC reporting requirement. Our hospitals are not equipped for it and our patients' safety may be jeopardized if hospital pharmacies have to change their workflows to accommodate manual systems to meet this reporting requirement.

Sincerely,

SOUTH CAROLINA SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Fredrick H. Bender

Fredrick H. Bender, PharmD, President
Director, Pharmacy Services
Greenville Hospital System University Medical Center
fbender@ghs.org

ASHP Survey Results:

Provision of NDC Numbers on Outpatient Medicaid Claims

February 2007
Corrected February 23, 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 mediation 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

Reponses 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 hospitals 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 manufacturers 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 it's results, please contact Brian Meyer, Director, Government Affairs, American Society of Health-System Pharmacists at 301-664-8698 or bmeyer@ashp.org.

Table 1

What is the estimated number of outpatient visits (hospital clinic, emergency room services, and outpatient infusion centers) per month at your organization?

Visits	*Number of Responses*	*Percentage*
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

Please indicate the average daily census at your organization.

Average Daily Census	*Number of Responses*	*Percentage*
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

For each of the resources/costs below, please indicate the impact that you foresee at your organization:					
	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 *tomorrow*, your organization is required to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients (hospital clinic, emergency department services, and outpatient infusion centers).

Approximately how much time per order would this take for each item below:

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					

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Log # 641

State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Forkner
Director

June 23, 2008

Fredrick H. Bender, PharmD
President, South Carolina Society of Health System Pharmacists
Post Office Box 1763
Columbia, South Carolina 29202

Dear Mr. Bender:

Thank you for your letter of June 4, 2008, asking that the South Carolina Department of Health and Human Services support your request to further delay the National Drug Code (NDC) requirement for physician-administered drugs in the hospital outpatient setting.

As you may know, as of June 1, 2008, providers were required to begin submitting the NDC on outpatient UB-04 claims to Medicaid. The Centers for Medicare and Medicaid (CMS) granted a 6-month extension to South Carolina to allow additional time to get our claims processing system ready to receive and report the NDC. Providers were notified by Medicaid Bulletin dated April 24, 2008, that we would begin editing claims for the presence of a valid NDC effective June 1.

If you have additional questions about the South Carolina process for reporting the NDC, please contact Ms. Zenovia Vaughn, Director, Division of Hospital Services, at (803) 898-2665.

Sincerely,

BZ Giese

Melanie "BZ" Giese, RN
Bureau Director
Bureau of Health Services

MG/vb

Bureau of Health Services
P.O. Box 8206 • Columbia, South Carolina 29202-8206
(803) 898-2868 • Fax (803) 255-8353