

October 16, 2007

Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

As organizations representing hospitals, health systems, hospital pharmacies and hospital pharmacists, we are writing to ask your immediate assistance in clarifying the scope of a recently published Centers for Medicare & Medicaid Services (CMS) regulation on the Medicaid Drug Rebate program. We are deeply concerned that CMS plans to expand a requirement imposed on State Medicaid agencies to collect National Drug Code (NDC) numbers for "physician administered" drugs to drugs administered in hospital outpatient settings that are exempt from the requirement. We believe this policy is not consistent with the statute and will result in costly and burdensome reporting requirements for hospitals, which are likely to strain the financial resources of many hospitals and potentially to put patient care at risk. Read as a whole, the underlying statute is clear that drugs administered by a medical professional in most hospital outpatient clinic settings are exempt from the Medicaid Drug Rebate program and from the new NDC reporting and collection requirements. Immediate clarification is necessary before State Medicaid programs fully implement CMS' harmful and erroneous interpretation.

The final regulation published in the *Federal Register* on July 17, 2007 implements the Medicaid and pharmacy provisions of the Deficit Reduction Act of 2005 (DRA). The statutory provision in question is Section 6002 of the DRA (which amends Section 1927 of the Social Security Act) by requiring State Medicaid agencies (as a condition of receipt of Federal Financial participation (FFP) in Medicaid payments) to collect National Drug Code (NDC) numbers on "physician administered" drugs that are billed to Medicaid. The purpose of this rule is to facilitate the collection of manufacturer rebates on those drugs. The regulation largely mirrors the statutory provision it intends to implement, and does not expressly define what is meant by a "physician administered" drug to which the rule applies. Instead, as CMS acknowledges in the preamble discussing the final rule, the scope of the rule's applicability is defined by reference to other, pre-existing provisions of the Medicaid rebate law.

One of the pre-existing provisions of the Medicaid rebate law that must be observed in applying the new physician-administered drug rule is Section 1927(j)(2) of the Social Security Act. As CMS explicitly acknowledges in the regulatory preamble to the new rule, neither the DRA provision requiring the collection of NDCs and rebates for physician administered drugs, nor the portion of the new regulation implementing this provision, apply to a category of hospital outpatient drugs exempted from Medicaid rebates under Section 1927(j)(2). That exemption, as CMS also quite accurately acknowledges in the regulatory preamble, extends to any hospital outpatient clinic drug that is dispensed using a drug formulary system and is billed to Medicaid at no more than the

hospital's "purchasing cost...*as determined under the State plan.*" That the test for falling within the Section 1927(j)(2) rebate exemption hinges on a hospital billing Medicaid at no more than its "purchasing costs for covered outpatient drugs (as determined under the [applicable Medicaid] State plan)" is compelled by the express terms of the statute, which includes this precise language.

Consistent with this analysis, CMS included the following statements in the preamble to the new rule, recognizing the continued applicability of the Section 1927(j)(2) exclusion of covered drugs dispensed by hospital outpatient departments and clinics:

"We agree that the DRA did not change the exclusion of drugs from Medicaid rebates when dispensed in an outpatient hospital setting.... Physician administered drugs will be excluded from the Medicaid Drug Rebate Program requirements only when hospital outpatient departments have dispensed these drugs using drug formulary systems, and have billed Medicaid at acquisition costs, *consistent with section 1927(j)(2) of the Act.*"

"[Section 6002 of the DRA] does not apply to 340B hospitals that receive discounted drugs and bill Medicaid at the acquisition cost of the drugs *as determined under the State plan.*"

"We agree with the commenter that drug manufacturer sales to safety-net hospitals under the 340B program are not subject to Medicaid rebates as long as they are billed to Medicaid at acquisition cost, *as determined under the State plan.*"

In the above passages from the regulatory preamble, referring to the 1927(j)(2) exemption for drugs dispensed in hospital outpatient settings, CMS uses "acquisition cost" interchangeably with "purchasing cost." The only hospital drug purchasing cost or acquisition cost ordinarily determined under the terms of a Medicaid State plan are so-called "estimated acquisition cost" or "EAC" levels, which are specifically established by Medicaid State plans and are referenced in federal regulations as an upper limit on Medicaid billing for pharmaceuticals. [See 42 CFR 447.518, referencing 447.512 and 447.514] *Thus the only reasonable reading of the subsection (j)(2) reference to hospital outpatient drug cost "determined under the state plan" is that it refers to billing Medicaid at or below EAC. Under this reading, most if not all drugs administered to patients in hospital outpatient clinic settings are exempt from rebates and from the new NDC collection requirement.*

CMS, however, now appears to be reading the critically important "as determined under the State plan" language out of the law and to intend to apply the new rule beyond its proper scope, by considering hospital outpatient clinic drugs exempt from rebates only where they are billed to Medicaid at the hospital's *actual* acquisition cost or purchasing cost. But hospitals' actual acquisition costs for drugs do not fall within the express statutory reference to costs "determined under the State plan." Such actual costs are determined, instead, by market forces, private contractual negotiations, and a wide range of other factors entirely external to the provision of any Medicaid State plan. The hospital outpatient drugs qualifying for rebate exemptions under the CMS view, in other words, would simply not be those described in the governing statute as subject to the rebate exemption. This ill-conceived and erroneous construction of the law is apparent in the section of the final rule relating to "Collection of Information Requirements" where CMS states that:

“Many hospital outpatient departments will also need to modify their billing systems to capture the NDC on Medicaid claims (hospitals that receive discounted drugs and bill Medicaid at the *actual acquisition cost* of the drug and hospitals that use [a] drug formulary systems and bill at the hospital’s *purchasing cost* are exempted).”

CMS’ intention to apply its new rule in this overbroad and unlawful manner was also reflected in recent public presentations by CMS representatives at a conference in Washington, DC sponsored by a coalition of “safety net” provider organizations called the 340B Coalition.

The result of this error in legal construction improperly applies NDC collection and rebate requirements to a large category of hospital clinic drugs that should be exempted from those requirements under the law. Such mistaken application of the law is of particularly grave concern because hospitals’ patient accounting systems are not capable of associating NDC numbers with billing data. As a consequence, hospitals will incur enormous costs to associate the NDC with the Healthcare Common Procedure Coding System (HCPCS) codes ordinarily used for electronic billing and reimbursement for outpatient clinic drugs. In essence hospitals will need to report two numbers for each drug on the billing system – the NDC and the HCPCS. The final rule also fails to include instructions on how to handle compound drugs and differences in dosage (HCPCS unit vs. NDC actual unit plus wastage (remaining drug that is unusable)). In any case, just the requirement to report the NDC numbers along with the routine Medicaid billing for drugs (namely the HCPCS) requires costly new billing routines, most of which still involve considerable manual effort. Presently there are no known computerized billing systems that can seamlessly integrate this reporting for both numbers. The final rule does not mention reimbursing hospitals for the added cost of staff and for developing new computerized billing systems that integrate the NDC into the patient accounting systems and ultimately in the billing transaction standard.

In the near-term, the reporting requirements will force hospitals to increase staff in order to manually accomplish NDC collection and reporting functions. Increases in staffing could be put to better use for the purposes of patient care; and, especially for struggling, “safety net” hospitals whose limited resources are already stretched thin, will represent a severe, additional burden inevitably detracting from patient care. Although CMS, in its recent *Federal Register* publication, discounted previous cost estimates, it offered no real tangible study of the magnitude and impact of this burden to hospitals and instead issued a ridiculously low estimate of the time it would take.¹ In neglecting to provide real evidence of the cost to comply, it badly underestimates the cost and difficulty that will be imposed on hospitals. Our preliminary analysis indicates that the financial and administrative burden is tremendous and will likely exceed the amount of the rebates.

These objections have been communicated to CMS through numerous comments submitted by hospitals in response to the Notice of Proposed Rulemaking, and more recently to the final CMS rule.

¹ In its final rule, CMS estimated that the time required to comply with the NDC requirement would be 15 seconds per claim, and the cost per claim under 9 cents. ASHP conducted a survey of pharmacy directors in February 2007 to estimate the impact of the new requirement on hospitals and health systems’ current systems and processes. In ASHP’s survey, the full estimated cost to comply with the proposal was \$10.80 per claim, taking an average of 24 minutes. The survey is attached to this letter as Appendix A.

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A sample of these hospital comments is attached to this letter as Appendix B for your interest. Thus far, however, CMS has failed adequately to respond to the very serious concerns and points of law raised by the hospital community.

We therefore ask for assistance at the highest levels of your Department to assure that CMS:

- (1) Does *not* proceed with implementation of the new physician administered drug rule on what appears to be its current course;
- (2) Neither applies that rule, nor instructs States to apply that rule, to hospital outpatient clinic settings that are exempt from Medicaid rebate and associated NDC collection requirements under section 1927(j)(2); and
- (3) Construes "purchasing costs" referenced in the 1927(j)(2) exemption applicable to Medicaid rebates and the physician administered drug rule to mean "estimated acquisition costs" as determined under the Medicaid State plan.

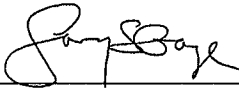
Thank you for your attention to this very important matter.



William von Oehsen
President
Safety Net Hospitals for Pharmaceutical
Access



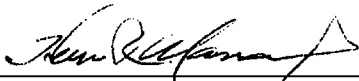
Rick Pollack
Executive Vice President
American Hospital Association



Larry Gage
President
National Association of Public Hospitals and
Health Systems



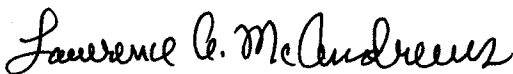
George N. Miller Jr.
President
National Rural Health Association



Henri R. Manasse, Jr.
Executive Vice President and Chief
Executive Officer
American Society of Health-System
Pharmacists



Charles N. Kahn III
President
Federation of American Hospitals



Lawrence A. McAndrews
President and CEO
National Association for Children's Hospitals



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 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.

Table 1

What is the estimated number of outpatient visits (hospital clinic, emergency room services, and outpatient infusion centers) per month at your organization?		
<i>Visits</i>	<i>Number of Responses</i>	<i>Percentage</i>
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.		
<i>Average Daily Census</i>	<i>Number of Responses</i>	<i>Percentage</i>
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 <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).					
Approximately how much time per <u>order</u> 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					

August 13, 2007

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs, Division of Regulations
Development
Attn: Melissa Musotto, [CMS-2238-FC]
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Office of Information and Regulatory Affairs, Office of Management and Budget
Attn: Katherine Astrich, CMS Desk Officer, CMS-2238-FC
Room 10235
New Executive Office Building
Washington, DC 20503

RE: Rule implementing the provisions of the Deficit Reduction Act of 2005
pertaining to prescription drugs under the Medicaid program.

To Whom It May Concern:

I am responding on behalf of [REDACTED] Hospital to the request for comments on the CMS final rule issued July 17, 2007, implementing the Deficit Reduction Act of 2005 (DRA), specifically on the provision regarding "physician administered" drugs. [REDACTED] Hospital, located in [REDACTED], is licensed for 1,050 beds and is part of a major academic medical center campus. As a part of a nonprofit 403(b) institution, [REDACTED] Hospital supports the medical center's missions for medical education, biomedical research, patient care and community service. The hospital qualifies as a Medicare disproportionate share (DSH) hospital and is enrolled as a covered entity under the federal 340B drug discount program.

We appreciate the efforts by CMS to solicit input on these important regulatory changes, although we are distressed by what appears to be the intent of CMS, as stated in the preamble to the new rule, to proceed with an overly broad application to outpatient clinics and departments. We wish to comment specifically on Section 447.520 of the rule, which would compel States to require that providers utilize National Drug Code (NDC) numbers to submit claims for Medicaid reimbursement of costs of all single source outpatient drugs, and 20 designated multiple source outpatient drugs, that are physician administered.

In discussing Section 447.520, CMS has stated that the impact on hospitals will be "small" or "insignificant." We disagree and believe that CMS has overlooked the magnitude of the administrative burden and expense. From our point of view, the final regulation would impose burdensome billing requirements for drugs administered in hospital outpatient clinics, resulting in significant lost revenue. We ask that you consider the following major issues.

1. In today's pharmaceutical supply chain, NDCs change frequently due to company mergers, company purchases, supply issues requiring a change to another package size, price fluctuations, and other factors. Therefore, the supply pipeline within an institution is not always filled with a single NDC for a single drug. It would be very difficult to build an electronic or automated system for billing purposes that would always accurately identify the NDC for the drug used on any given day for any given patient. Even if such a system were built, additional staffing would be required to regularly update the system in order to maintain accurate data. Both system development and ongoing maintenance would be costly, taking additional resources away from our institutional missions.
2. The only point at which some NDCs could be accurately captured would be at the point of drug administration to the patient. This means the data collection would fall not to administrative personnel as CMS has stated, but to our clinical staff of doctors and nurses, requiring them to take valuable, and often unavailable, time away from patient diagnosis and treatment. With the large number of drugs administered per day in [REDACTED] Hospital and Clinics, such a volume of data collection is an unreasonable expectation of already-busy frontline healthcare providers. In order for us to utilize administrative staff for recording the NDCs, the clinical staff would have to save and pass along the actual used drug containers, such as vials and pre-filled syringes. Handling these used medical supplies would pose an unworkable health risk to both our clinical and administrative staff.
3. Although the CMS rules would require the NDC collection only on single-source drugs and 20 multiple-source drugs, given the ever-changing market place, the only reasonable way to ensure accuracy of the collected information would be to collect the NDC on *all* drugs. To do otherwise would require all clinical staff to maintain a thorough knowledge of which drugs are sole source, which are not, which drugs are on the list of 20 and which are not, as well as to know the patient payer status at the time of encounter. With over 60,000 drug encounters at [REDACTED] Hospital and Clinics per year, this poses an immense administrative burden, and it would be an unreasonable expectation for already-busy staff whose primary responsibility is high-quality patient care.
4. The payer (Medicaid) status of a patient is not always known to the clinical staff at the time of the patient visit. An intrinsic part of our institutional mission is to provide care for all who need our services, regardless of their ability to pay. Therefore we could not limit the NDC collection to Medicaid patients only; instead, we would have to collect the NDC on all drugs administered to all outpatients, regardless of the patient's payer status.

5. It is our belief that covered entities under the PHS/340B program such as Disproportionate Share Hospitals were not intended by Congress to fall under this provision of the DRA. To include these settings in this ruling will undermine the intent and benefit of the PHS/340B program and may cause some entities to cease participation in the program, much to the detriment of their indigent and most vulnerable patients.

Thank you for considering the potential problems that we have addressed in this letter. We urge you to reconsider the current intention, as described in the rule's preamble, to apply the NDC reporting requirement to hospital outpatient clinic settings.

Sincerely,

[REDACTED]
Pharmacy Program Manager
[REDACTED] Hospital