Safety Net Hospitals for Pharmaceutical Access

February 5, 2007

Melissa Musotto
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development--A
Centers for Medicare and Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Musotto:

Please find attached comments from Safety Net Hospitals for Pharmaceutical Access (SNHPA) in response to the Notice published in the Federal Register on December 8, 2006, pursuant to the Paper Work Reduction Act, inviting public comment on a proposed data submission requirement that would mandate collection of National Drug Code (NDC) information by State Medicaid agencies with respect to covered outpatient drugs that are "physician administered." (71 Federal Register 71178, 71179 (December 8, 2006)) SNHPA, formerly knows as the Public Hospital Pharmacy Coalition (PHPC), is an association of hospitals that qualify as disproportionate share hospitals (DSH) for purposes of Medicare reimbursement, and participate as covered entities under the federal drug discount program established by Section 340B of the Public Health Services Act (the "340B Program").

As the attached comments on the Notice explain, SNHPA and its members believe that the burden associated with the proposed data collection that is the subject of the Notice has been vastly underestimated by CMS, that this burden is significant and excessive, and that the proposed data collection is, at least with respect to hospitals, not only unnecessary but improper.

We appreciate CMS' consideration of SNHPA's attached comments respecting this, in our view, unwise and unjustified data collection proposal.

Sincerely,

William von Oehsen
General Counsel
Safety Net Hospitals for Pharmaceutical Access

Edith Marshall
Special Counsel and Director of Legal Affairs
Safety Net Hospitals for Pharmaceutical Access

Safety Net Hospitals for Pharmaceutical Access
1875 Eye Street NW, 12th Floor Washington, D.C. 20006
Phone: 202-466-6550 Fax: 202-785-1756
www.safetynetrx.org

Safety Net Hospitals for Pharmaceutical Access

COMMENTS OF SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS IN REPONSE TO PAPERWORK REDUCTION ACT NOTICE OF DECEMBER 8, 2006 REGARDING PROPOSED DATA COLLECTION

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is submitting its views in response to the request for comments on proposed data collection, published December 8, 2006 pursuant to the Paperwork Reduction Act. Specifically, we are submitting comments on the proposal to require State Medicaid agencies to collect National Drug Code (NDC) information with respect to outpatient drugs administered to patients incident to a physician's service in physicians' offices, hospital outpatient clinics and departments, and other outpatient settings. On behalf of SNHPA and its hospital members, we strongly oppose the proposed data collection as it would be applied to drugs administered in hospital outpatient settings. The proposed action threatens to impose a burden on hospitals that is not only signification but severe. In addition, as applied to the hospital outpatient setting, the proposed data collection is unnecessary.

Background

The proposed data collection on which the Centers for Medicare and Medicaid Services (CMS) has invited comments is ostensibly undertaken pursuant to the directive of Section 6002 of the Deficit Reduction Act (DRA), which amended Section 1927(a) of the Social Security Act to require State Medicaid agencies to collect NDC information on so called "physician administered" drugs, so that manufacturer rebates can subsequently be collected on those drugs. The Paperwork Reduction Act Notice published December 8 indicates that CMS intends the new data collection requirement to apply to drugs administered in hospital outpatient settings. Proposed regulations to implement Section 6002 of the DRA, published in the Federal Register on December 22, 2006, similarly indicate that hospital outpatient departments and clinics, as well as physicians' offices, will be required to furnish State Medicaid agencies with NDC numbers when billing Medicaid for drugs administered to patients in hospital outpatient settings.

SNHPA represents approximately 400 hospitals that serve a disproportionate share of low income patients in the U.S. In recent months SNHPA, whose membership includes the majority of hospitals qualified (by virtue of the high percentage of indigent patients they serve) to participate in the federal 340B drug discount program, has received a steady stream of e-mails and telephone calls from member hospitals that are deeply concerned about and strongly opposed to the proposed rule on "physician administered" drugs. These comments are being submitted in the hope that the voice of the 340B hospitals, which provide more that 25 percent of the uncompensated hospital care in America, will be heard.

Safety Net Hospitals for Pharmaceutical Access
1875 Eye Street NW, 12th Floor Washington, D.C. 20006
Phone: 202-466-6550 Fax: 202-785-1756
www.safetynetrx.org

CMS has, through these two related regulatory issuances on proposed data collection, indicated that it does not expect the administrative or paperwork burden imposed by the data collection requirement to be significant, or the associated expense to be very great. It has estimated that the cost to providers will be approximately 9 cents per claim, and that an average of 15 seconds of staff time per claim will need to be devoted to accomplish the data submission manually. While acknowledging that the alternative to this manual task would be, in many or most cases, an overhaul of the provider's electronic billing system, and despite offering no estimates of the time or expense that would be involved in this option, CMS has nevertheless taken the position that this new data submission and collection requirement will not have significant impact on providers.

Proposed Data Collection Would be Unreasonably Burdensome for Hospitals

According to our member hospitals, the burden associated with providing NDC numbers in Medicaid billing submissions for drugs administered in hospital outpatient settings would be extraordinary. The 15 second per claim estimate advanced by CMS with respect to manual billing is vastly understated; and, in any event, electronic billing requirements imposed under HIPAA make manual billing procedures an unrealistic solution for anything but, at most, the short term. The expense of adapting hospital billing systems to accommodate the new NDC number requirement would average in the hundreds of thousands of dollars for each hospital, and this is an expense many hospitals – especially small facilities and institutions already struggling to stretch their resources to serve large indigent populations – can ill-afford. Seven years ago, when a similar specter of having to associate NDC numbers with hospital outpatient drugs was raised (and ultimately rejected) in connection with proposed regulations to implement HIPAA, the American Hospital Association's information indicated an average cost of roughly $200,000 to each hospital subjected to the new requirement. That figure would, of course, be substantially higher in current dollars.

It is clear that the present proposal has not fully taken into account the financial and administrative burden that hospitals would face if forced to change their current systems and begin using NDC numbers in their billing practices. Currently, hospitals use NDC numbers for two purposes: drug purchasing and inventory maintenance. NDC numbers are rarely, if ever, utilized in hospital accounting or billing systems. In order to incorporate NDC data into billing submissions, nearly all practice management systems would need to be adapted to accommodate expanded fields and larger databases to display and store thousands of NDC numbers.

Because NDC numbers contain packaging information, resulting in many NDC descriptions for the same drug, a partial dosage is very difficult to report. For example, if an injectable medication was administered from a vile that was packaged with nine other vials, it would be very difficult to accurately record dosage information. Hospital staff would have to calculate how much of the vial, from the box of ten vials, was used in that instance. A patient receiving a cocktail of multiple medicines would present an exponentially compounded reporting difficulty. Furthermore, because hospitals frequently purchase the same medication in a variety of packaging options, based on the

hospital's needs and the relative cost of the packages, hospital staff would have to monitor each package of medication to know which patient received medication from which type of package in order to bill that patient properly. The burden of tracking these matters in a treatment setting would, we fear, risk serious and detrimental distraction of staff and diversion of resources from patient care. The magnitude of the additional administrative burden and expense associated with NDC data collection is of especially great concern to the safety net hospitals that SNHPA represents, moreover, because the limited resources of these hospitals are already strained by the demands of caring for a patient population that includes a high proportion of uninsured or underinsured individuals unable to pay for their own care.

Proposed Extension of Data Collection to Hospitals Is Unnecessary and Improper

Importantly, contrary to what appear to be CMS' current conclusions, the administrative and financial burdens, described above, are not required under the law and are neither necessary nor appropriate to impose on hospitals. Properly read, the DRA does not mandate submission of NDC numbers in billing Medicaid for drugs administered incident to physicians' services in hospital outpatient settings. Numerous factors that support this conclusion appear to have been overlooked by CMS in promulgating both its proposed Paperwork Reduction Act Notice and its new proposed rule.

First, on its face, the statutory provisions added to the law by Section 6002 of the DRA, and on which the new data collection requirement is ostensibly based, require States to collect drug utilization and coding data "such as NDC number *or J-Codes* for drugs that are physician administered." Accordingly, collection of J-Codes with respect to drugs administered in hospital outpatient clinics would comply with the letter of law. Since virtually all hospital billing systems are now configured to bill for outpatient clinic drugs with the HCPCS codes known as "J-Codes," compliance with the new law plainly does not necessitate the burdensome changes that, as we have explained above, would be involved in submission and collection of NDC numbers.

Second, we believe CMS misconstrues the "physician administered" drug provision to pertain to hospital outpatient clinic drugs at all. The purpose of the NDC submission and collection requirement, as expressed by Congress in the words of the statute itself, is to better enable States to collect manufacturer rebates on drugs pursuant to Section 1927 of the Social Security Act.[1] However, drugs administered on an outpatient basis in most hospital clinic settings have long been exempt from application of the Medicaid rebate laws pursuant to a provision of the law in Section 1927(j)(2) of the Medicaid Act. Thus, since as a general rule manufacturer rebate obligations do not apply to hospital outpatient clinic drugs, Congress could not have intended to require NDC number information to be collected by States in order to pursue rebates on those drugs. Nothing in the DRA or the amendments it made to the Social Security Act casts any doubt on the continued force and effectiveness of the exemptions from rebate requirements established by Section 1927(j) of the Social Security Act. Indeed, in the

[1] Section 1927 of the Social Security Act is codified at 42 U.S.C. §1396r-8.

Conference Report accompanying the DRA, the conferees expressly noted that the "physician administered" drug provision does not apply to categories of drugs that are exempt from rebates as a matter of statute.[2]

The "physician administered" drugs properly subject to a new NDC submission and collection requirement under the newly amended Medicaid rebate statute, therefore, cannot reasonably be read to include the hospital outpatient clinic drugs exempted from rebates by a pre-existing provision of the same statute. This conclusion is consistent, moreover, with the fact that the DRA physician administered drug provision was developed to address deficiencies in State Medicaid rebate collection, pointed out in an Office of Inspector General (OIG) Report issued in April of 2004 on the specific topic of "physician administered" drugs. That OIG Report, which has apparently formed the basis of the current government estimates of cost associated with the data collection requirement, specifically limited its definition of "physician administered" drugs to medications administered to patients by medical professionals in physicians' offices.[3] The same term is properly given the same meaning in Section 6002 of the DRA.

Conclusion

In summary, the Paperwork Reduction Act Notice of December 8, 2006 fails to accurately quantify or characterize the administrative and financial burdens on hospitals that would be associated with the proposed data collection. Furthermore, there is no necessity for the data collection in the hospital outpatient clinic context, and in fact application of the data collection requirement in this setting would be improper and contrary to the intent of currently effective statutory law.

We urge CMS carefully to consider the points discussed above, and to revise the scope of applicability of the proposed data collection, so that its impact will not extend to hospital outpatient clinic treatment settings.

William von Oehsen
General Counsel

Edith S. Marshall
Special Counsel and Director of
Legal Affairs

[2] See H.R. Rep. No. 109-362 at 262 (2005).
[3] See Report of Office of Inspector General, Department of Health and Human Services, OEI 03-02-00660, Medicaid Rebates for Physician Administered Drugs (2004), at page 9.