

February 20, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

***Re: (CMS-2238-P) Medicaid Program: Prescription Drugs, Proposed Rule, (Vo. 71, NO. 246),
December 22, 2006***

Dear Ms. Norwalk:

The American Hospital Association (AHA), on behalf of our approximately 5,000 member hospitals, health care systems and other health care organizations, and our 37,000 individual members, appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule implementing provisions of the *Deficit Reduction Act of 2005* (DRA) that pertain to the Medicaid prescription drug program. Our comments address CMS' interpretation of Section 6002 of the DRA and the new requirement that hospitals report physician-administered drugs using the National Drug Code (NDC). We will focus on two issues:

- the legal premise upon which CMS has based its interpretation of Section 6002, and
- the significant administrative burden these new reporting requirements impose upon hospitals.

We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient clinics and departments.

FFP: CONDITIONS RELATING TO PHYSICIAN-ADMINISTERED DRUGS – SECTION 447.420

Section 6002 of the DRA added a new requirement to the Medicaid statute specifically to enhance the ability of state Medicaid programs to secure rebates from drug manufacturers under the Medicaid drug rebate law. This section ties Medicaid rebate payments for covered outpatient drugs that are physician administered, as determined by the Secretary, to “the collection and submission of such utilization and coding data (such as J-codes and NDC numbers) ... as necessary to identify the manufacturer of the drug.” The data collection requirement extends to



both single and multiple source drugs. However, in the proposed rule, CMS does not define “outpatient drugs that are physician administered” as the statute clearly states that the Secretary must do. Instead, the rule’s preamble indicates that CMS intends to interpret Section 6002 to require submission of the NDC numbers for outpatient drugs furnished as part of a physician’s service to Medicaid beneficiaries in hospital outpatient clinics and departments – not solely in physicians’ offices. CMS’ proposal to apply Section 6002 so broadly is wrong. It is not supported by the statute’s plain language, is inconsistent with congressional intent, and would nullify the *Social Security Act of 1965* exemption of hospital outpatient clinics and departments from Medicaid rebate program obligations.

Section 6002 does not apply to outpatient drugs administered in hospital outpatient clinics and departments.

Section 6002 requires only the collection of utilization and coding data for drugs that are subject to a rebate requirement under Medicaid statute provisions that predate the DRA – a position that CMS acknowledges in the proposed rule. Under Section 6002, state Medicaid programs are expressly directed to provide for the submission and collection of drug utilization and coding data “as necessary to identify [manufacturers of drugs] in order to secure rebates” under the Medicaid rebate law. In other words, the data collection requirement applies only if the state Medicaid agency finds it necessary to obtain a drug’s NDC number in order to identify the responsible manufacturer and enforce a Medicaid rebate payment obligation. On the other hand, for outpatient drugs that are not subject to a rebate payment requirement – like those dispensed in hospital outpatient clinics and departments – the collection of NDC information with respect to that drug plainly is not necessary to securing a rebate, and the law does not require submission or collection of NDC data on the drug.

The statutory language, in fact, does not directly compel states to collect only NDC information on drugs subject to the rebate requirement. While reporting of the NDC numbers is preferred after January 1, 2007, the statute clearly authorizes the Secretary to allow for an alternative coding system. The statute states that the purpose of the data collection is “as necessary to identify” the manufacturer of the drug in order to collect Medicaid manufacturer rebates. The statute mentions J-codes and NDC numbers as examples of the type of “utilization and coding data” that could be collected. To the extent that J-codes can be used to identify a drug for Medicaid rebate purposes, continued use of J-codes to identify drugs is consistent with statutory compliance.

Further, the Secretary is authorized to delay applying the data reporting requirement in order to prevent hardship to any states that require additional time to implement the reporting system. Such hardship is not expressly limited in the statute and may encompass the state’s consideration of difficulties in obtaining data from reporting hospitals and the time needed to reconfigure the systems of reporting hospitals.

Section 6002 was enacted to address a problem with rebate collection on drugs administered in physicians’ offices – not hospital outpatient clinics and departments.

In the proposed rule, CMS seeks to give a much broader application to physician-administered drugs. By including all covered outpatient drugs that “are typically furnished incident to a physician’s service,” the agency expands the scope of Section 6002 well beyond the problem it

was designed to address. Precise congressional impetus for enactment of Section 6002 appears to be the April 2004 report “Medicaid Rebates for Physician-administered Drugs” from the Department of Health and Human Services Office of the Inspector General (OIG). In that report, the OIG projected that the states were losing millions of dollars in Medicaid rebate payments due to their failure to collect rebates on physician-administered drugs. The OIG report expressly defines the physician-administered drugs of concern as “drugs that a medical professional administers to a patient in a physician’s office.”

In the proposed rule, CMS acknowledges the relationship between this OIG report and enactment of Section 6002. The preamble makes numerous references to the “physician-administered drugs” covered by the OIG report, including a statement that current estimates of Medicaid savings from implementing Section 6002 are based on the 2004 OIG report. CMS’ discussion appears to directly equate the physician-administered drugs that were the subject of the OIG report with those that are subject to Section 6002 and its proposed regulation.

Thus, the intent of Congress in enacting Section 6002 will be faithfully executed, and CMS’ projected savings fully realized, if the proposed new NDC submission and collection requirements are construed as applicable only to drugs administered in physician’s offices, and inapplicable to drugs administered in hospital outpatient clinics and departments.

Section 6002 does not affect the existing rebate exemption for drugs administered to patients in hospital outpatient clinics and departments.

Nothing in Section 6002 casts doubt on the continuing existence of the Medicaid statute’s pre-existing exemption from drug rebate requirements for outpatient drugs established by Section 1927(j) of the *Social Security Act*. Section 6002’s language is entirely silent as to any legislative intent to repeal or amend this pre-existing exemption, which expressly identifies outpatient drugs dispensed through hospital outpatient clinics and departments as not subject to the Medicaid drug rebate requirements.

The DRA Conference Report explicitly states that hospital outpatient clinic and managed care drugs described in Section 1927(j) are exempt from rebate requirements, and that the Section 6002 data collection requirements are intended to pertain only to physician-administered drugs for which there is no statutory exemption from rebate requirements (See H.R. Rept. No. 109-362 accompanying S.1932, December 19, 2005) Although the conference report does not directly cite Section 1927(j) *per se*, it expressly acknowledges the existence of exemptions from rebate requirements for outpatient prescription drugs using terms that unmistakably mirror the descriptions of managed care drugs in Section 1927(j)(1) and hospital drugs in Section 1927(j)(2).

Notwithstanding this clear legislative intent, CMS’ proposed rule to implement Section 6002 makes no mention of the statutory exemptions from rebate requirements for either hospital outpatient clinic drugs or outpatient drugs dispensed by managed care organizations. The fact that neither exemption is addressed in the proposed rule is, at best, confusing, but clearly evidence that CMS overlooked the entire matter of these statutorily exempt physician-

administered drugs in construing how Section 6002 should be properly applied, as opposed to having simply construed Section 1927(j)(2) to have severely limited application to hospital outpatient clinic drugs.

It is clear that the physician-administered drug provision enacted by Section 6002 can only be read to impose a data collection requirement with respect to drugs that are not within the Section 1927(j) (2) exemption. Because the subsection (j) remains unchanged in the Medicaid rebate law, CMS cannot ignore the statutory exemption. The agency must continue to give subsection (j) the same meaning it had prior to the enactment of the DRA as the agency applies Section 6002. In doing so, CMS is compelled to draw meaning from Section 1927(j) (2) in a concrete way by referring to drugs dispensed or administered in an actual hospital setting.

Section 1927(j)(2) specifically exempts from the rebate requirements outpatient drugs that are administered in a “hospital ... that dispenses covered outpatient drugs using formulary systems, and bills [the Medicaid state plan in the relevant state] no more than the hospital’s purchasing costs for covered outpatient drugs (as determined under the State plan).” This section cannot plausibly be construed as a reference to hospitals participating in the 340B federal drug discount program because the 340B program did not exist at the time Section 1927(j) was enacted.

On the other hand, drugs administered by medical professionals to patients on an outpatient basis in hospital clinics and departments generally have not been subject to Medicaid rebate collections, and fall squarely within the (j)(2) exemption, as properly construed. Drugs administered in the hospital outpatient clinic setting are dispensed almost always within a formulary system – thus meeting the first statutory criterion for inclusion in the (j)(2) exemption. Covered outpatient drugs administered in hospital clinic settings also are billed to Medicaid in a manner that meets the description of the second (j)(2) criterion, namely that the hospital “bills the [Medicaid state plan] no more than the hospital’s purchasing costs for covered outpatient drugs (as determined under the state plan).” Most, if not all, drugs administered to Medicaid-eligible patients in hospital outpatient clinics and departments fall within the (j)(2) exemption from rebates, and accordingly must be excluded from the physician-administered drugs to which Section 6002 applies.

ADMINISTRATIVE BURDEN FOR HOSPITALS

Many state Medicaid programs have moved forward with implementing this new NDC reporting requirement. Hospitals in these states have been instructed to bill outpatient drugs using the drug manufacturer’s 11-digit NDC number. The AHA is concerned because these instructions fail to recognize the significant difficulty, burden and cost imposed upon the hospital community in order to meet these new billing requirements. Most, if not all, hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer’s NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS), in particular, the HCPCS J-codes to report a particular drug or biologic rendered to a patient. The J-code is not exclusive to a particular drug manufacturer but rather used to describe the general ingredient and dosage of a drug. Patient accounting systems can easily report HCPCS codes, but not the NDC.

To be able to report the NDC, hospitals must make major revisions to their charge description master (CDM), including significant increases to the CDM in order to include multiple manufacturers of a particular type or category of drug. Additionally, any manufacturer changes in the packaging, dosage and/or ingredients would require adding another NDC to the CDM and thereby increase the frequency of updating the CDM.

It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must “provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered.” The DRA further states that the “reporting would include J-codes and NDCs.” As such, the AHA believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take roughly 500 to 1,500 work hours to design, build and test a short-term work around. Even with these changes, there are no assurances that the NDC indicated on the claim reflects the manufacturer of the drug that was given to the patient. Many hospital pharmacy acquisition systems have limited record keeping ability and can assign only a primary NDC for a particular drug. The primary NDC reflects the manufacturer of a particular type of drug. When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital’s need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. This is a common occurrence. Consequently, the hospital pharmacy’s record keeping systems will need the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

During the past several years many hospitals have introduced new automated drug dispensing systems in an effort to reduce medication errors. Many of these systems also would require costly modifications. For example, these drug dispensing systems have bins for each specific drug based on ingredient and dosage – not on manufacturer NDC. There also is a human cost since hospitals that are interested in acquiring such systems to reduce medication errors would have to postpone their acquisition until the vendors make all of the system modifications.

We are willing to work with you to ensure the appropriate implementation of Section 6002 of the DRA. If you have questions about our comments, please contact me or Molly Collins Offner, senior associate director for policy, at (202) 626-2326 or mcollins@aha.org.

Sincerely,

Rick Pollack
Executive Vice President