

June 29, 2007

Honorable Max Baucus
Chairman
Senate Finance Committee
Dirksen Senate Office Building 219
Washington, D.C. 20510

Honorable Charles Grassley
Ranking Member
Senate Finance Committee
Dirksen Senate Office Building 219
Washington, D.C. 20510

Dear Chairman Baucus and Ranking Member Grassley:

We are writing with regard to Section 6002 of the Deficit Reduction Act of 2005 (DRA)¹, which requires states to collect National Drug Code (NDC) numbers on outpatient drugs that are "physician administered" and billed to Medicaid, so that States can collect manufacturer rebates on those drugs. In its published explanation and discussion of proposed regulations to implement the DRA,² the Centers for Medicare and Medicaid Services (CMS) has indicated its intent to extend the NDC reporting requirement to all outpatient drugs furnished incident to a physician's service, including those administered in hospital outpatient clinics,³ which we believe contravenes legislative intent. We urge the committee to clarify with CMS that DRA Section 6002 was not intended to apply to hospital outpatient settings.

Implementing its proposed rule as CMS apparently intends would create unrealistic requirements and undue burdens for hospitals as well as adverse effects on State Medicaid agency operations and the 340B drug discount program. Based on the legislative history of the DRA, as well as the adverse consequences on patient care and hospital operations that the rule will cause if applied over-broadly, we are convinced that Congress could not have intended the DRA to be implemented as CMS proposes.

Administrative Burdens, Increased Costs and Operational Obstacles

Before proceeding with an explanation of why, from a legal standpoint, Section 6002 of the DRA cannot properly be construed to pertain to hospital outpatient clinic drugs, it may be useful to focus briefly on the enormous practical and financial obstacles presented by the CMS proposal. First, as CMS acknowledged in its Notice of Proposed Rulemaking,⁴ hospitals' computerized billing systems are not presently configured in a way that can accommodate the projected, new NDC reporting requirement. In order to comply with such a requirement, most hospitals -- which now characteristically use so-called "J-codes" (as opposed to NDC numbers) to bill Medicaid for drugs administered in outpatient departments and clinics -- would need to completely re-vamp their electronic billing systems, at great expense and strain on administrative

¹ Pub. L. No. 109-171, 120 Stat. 4 (2006).

² 71 Fed. Reg. 44,174 (December 22, 2006).

³ See 71 Fed. Reg. at 77,188.

⁴ See discussion at 71 Fed. Reg. 77,193 (noting that compliance with the requirement would involve either a manual process or a "systems change").

resources.⁵ While declining to estimate the expense hospitals would incur in this process, CMS has proposed that hospitals might accomplish the proposed NDC reporting manually in advance of the requisite restructuring of their computerized billing, at a cost of about nine cents and 15 seconds of staff-time per claim.⁶ Better informed estimates based on survey data compiled by the American Society of Health-System Pharmacists (ASHP), however, indicate that the true cost and burden associated with a manual NDC reporting process would be \$10.80 and an average of 24 minutes per claim -- that is, a level of expense and additional work that is more than nine thousand percent greater than what CMS has suggested. In addition, tracking and reporting NDC numbers would divert limited staff from accurate and safe dispensing and administration of medication, to the detriment of patient care.

It is not only hospitals that would face administrative and technological obstacles to compliance with the new NDC reporting rule contemplated by CMS. Many State Medicaid agencies lack electronic information systems capable of managing and utilizing NDC information in the processing of hospital claims for outpatient pharmaceutical treatment. We are also informed that the federal Office of Pharmacy Affairs (which administers the federal 340B drug discount program in which many safety-net hospitals participate) does not have current technological capacity to serve its function of compiling and reporting data to States relating to Medicaid claims by 340B participant hospitals, in the context of an NDC-based claiming process. Consequently, both State Medicaid programs and the federal government will incur substantial costs to accommodate CMS' broad construction of the scope of DRA Section 6002. These costs are not only avoidable, but unjustifiable in light of strong indications that the actual intent of the law is much narrower than CMS has proposed.

Legislative History and Related Statutory Provisions

Section 6002 was drafted soon after and in apparent response to a report by the HHS Office of Inspector General (OIG), which found that States were losing millions of dollars by failing to collect Medicaid rebates on "physician administered drugs."⁷ CMS makes frequent reference to this report in its proposed rule.⁸ However, the OIG report explicitly defined "physician administered drugs" as "drugs that a medical professional administers to a patient *in a physician's office*,"⁹ and did not address drugs administered in hospital outpatient clinics. Logically, the provisions in the DRA based on this report would share the same definition.

Furthermore, the DRA Conference Report expressly indicated that Congress intended to subject NDC reporting only to those drugs for which "there is no specific statutory exclusion" from Medicaid rebates.¹⁰ Drugs administered in physician offices have no such exemption, but drugs

⁵ For example, sixty percent of respondent facilities in a survey conducted by ASHP reported that they do not have information systems that could manage NDC storage and reporting in cases where patients are administered more than one therapeutically-equivalent generic medication. Further, the most feasible way for hospitals to implement the NDC reporting requirement would be through bar code reporting, which currently is not a viable solution because few hospitals have such technology.

⁶ See 71 Fed. Reg. at 77,189.

⁷ See Office of Inspector Gen., Dept. of Health and Human Services., OEI 03-02-00660, *Medicaid Rebates for Physician Administered Drugs* (2004), available at <http://oig.hhs.gov/oei/reports/oei-03-02-00660.pdf>.

⁸ 72 Fed. Reg. at 77,188.

⁹ Office of Inspector Gen., *supra* note 7, at 1 (emphasis added).

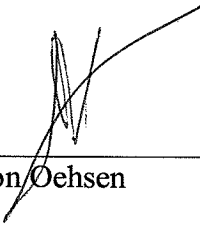
¹⁰ H.R. Rep. No. 109-362, at 262 (2005) (Conf. Rep.).

administered in hospital outpatient clinics (as well as drugs used in a managed care setting) are generally exempt from rebates under Section 1927(j) of the Medicaid Act.¹¹ Thus there is ample basis to conclude that Congress did not intend for drugs administered in such settings to be included in the definition of "physician administered drugs."

We urge the Committee to confirm to CMS that the views and interpretation of the DRA outlined in this letter comport with Congressional intent, and that the proposed CMS rule construes the DRA too broadly. For further information on the matters discussed above, please contact Bill von Oehsen or Edith Marshall with SNHPA, at (202) 552-5850.

Thank you for your time and attention to this very important matter.

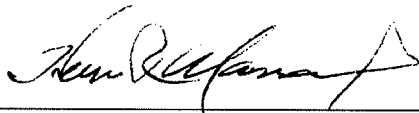
Sincerely,



William von Oehsen
President
Safety Net Hospitals for Pharmaceutical Access



Larry Gage
President
National Association of Public Hospitals
and Health Systems



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

¹¹ Section 1927(j)(1), 42 U.S.C. § 1396r-8(j)(1), exempts drugs dispensed by health maintenance organizations from the rebate provisions of the Medicaid statute. Subsection (j)(2) provides the same exemption to outpatient drugs administered in a hospital that uses a formulary system (as virtually all hospital outpatient clinics do) and bills Medicaid for drugs at no more than the hospital's "purchasing costs" as determined under the applicable Medicaid State Plan. Since the statute specifies that the relevant "purchasing cost" of a drug is one determined under the terms of a Medicaid State Plan (and not negotiations, programs, or market forces external to such a plan), the statutory reference is presumably to the "estimated acquisition cost" or "EAC" established in most Medicaid State Plans as the proper reimbursement level for a drug administered in a hospital on an outpatient basis. Outpatient drugs reimbursed at EAC to hospitals, therefore, would meet the description in subsection (j)(2) and be subject to the rebate exemption; and most hospital outpatient clinic drugs fall within this category.