

September 5, 2006

The Honorable Michael O. Leavitt
Secretary, Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Leavitt:

On behalf of the American Society of Health-System Pharmacists (ASHP), I would like to express our concern about recent announcements by state Medicaid programs regarding the inclusion of National Drug Code (NDC) numbers in billing submissions for outpatient drugs." ASHP is the 30,000 member national professional association that represents pharmacists who practice in hospitals and other components of health care systems.

These announcements reflect a larger issue of concern to our members that all Medicaid programs must implement this requirement to be in compliance with the Deficit Reduction Act (DRA) of 2005 (Section 6002). **ASHP requests that the Secretary exempt hospitals from the submission of NDC product numbers in billings for outpatient drugs until deficiencies in the National Drug Code (NDC) Directory are corrected and hospitals are able to develop the information system infrastructure to readily provide such information.**

Based on our interpretation of the DRA, hospitals would have to provide NDC information on a billing submission for drugs administered in clinics. This would create undue hardship since institutions would have to provide this manually. This manual process would entail a serious compromise to patient safety, since it would add steps to an already complex medication ordering, dispensing and administration process.

Specifically, guidance documents from Kansas and Georgia¹ would require pharmacists to interrupt normal workflows with each outpatient order because they would be required to verify the NDC number for the specific product being dispensed. Although the State of Kansas has delayed implementation of its guidance document, if the requirements were required nationwide, they would be immensely burdensome and problematic to hospitals. Order entry for each product is often decentralized from the medication preparation area, especially with injectable medications, which would make it virtually impossible to accurately identify the NDC for the particular product that was used. Further, the recent report by the Office of the Inspector General noted numerous inaccuracies in the NDC database. The OIG noted,² "The Directory is not accurate, with an estimated 34,257 drug products no longer on the market or listed in error, primarily because drug firms failed to report drugs taken off the market." This finding adds to the challenges of implementation.

In discussing this issue with our members, ASHP found that many hospital computer systems will not accommodate the reporting of drug product NDC numbers on bills posted by hospital systems. Hospital systems have integrated inpatient and outpatient pharmacy billing systems, and both rely

on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication. A possible long-term solution might include incorporating the NDC numbers on the medication label with bar-code verification at the point of administration. Our annual national survey of hospitals suggests, however, that fewer than 20% of hospitals have bar-code capacity; the percentage is even lower among smaller institutions.

It is not uncommon for the medication administered to a patient to consist of more than one component, each with a separate NDC number. For example, a pharmacist might prepare an i.v. chemotherapy admixture using two vials of the same medication mixed in a large-volume sterile solution, with each vial coming from a different generic manufacturer, based on what the hospital has in inventory at the time. Each vial, of course, will have a different NDC number. Few if any computer billing systems would be able to accommodate this situation by automatically noting the NDC numbers of the products used in compounding the preparation.

In conclusion, the only current way that the vast majority of hospitals could comply with a requirement that the NDC number of a drug product be submitted with billing would be for this to be handled manually. This is grossly unrealistic given the workflow, staffing and financial constraints of hospitals. Therefore, we appeal to you to exempt hospitals from the submission of NDC product numbers in billings for outpatient drugs. We would be happy to work with the Department, the hospital industry, and other stakeholders to seek a solution to the billing issue that achieves the Department's objectives and is workable at the provider level.

We would be happy to meet with you or others in the Department to further discuss this issue. Please feel free to have your staff contact Brian Meyer, Director of Government Affairs, at (301) 664-8698/bmeyer@ashp.org or Maria Spencer, Director of State Government Affairs, at (301) 664-8687/[mspencer@ashp.org](mailto:m Spencer@ashp.org).

Sincerely,



Henri R. Manasse, Jr., Ph.D., Sc.D.
Executive Vice President and Chief Executive Officer

Cc: Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services

¹The Kansas Medical Assistance Program announcement, dated March 2006, states that starting July 1, 2006, billing for prescription drug products in an office or outpatient setting utilizing J-code or other drug related HCPCS billing code, would require NDC number, quantity of measure, and unit of measure price. However, in a notification, issued on June 30, 2006, the Division of Health Policy and Finance (DHPF) and the fiscal agent indicated that they "have heard providers' concerns regarding the timing and design for the policy and accordingly, **will not be implementing this policy on July 1, 2006 as previously planned.** Implementation will be delayed until other options are explored regarding conversion from HCPCS quantity billed to the NDC quantity."

The Georgia Department of Community Health announcement, dated March 28, 2006, states that starting January 1, 2007, billing for prescription drugs in an office or hospital outpatient setting must utilize NDC numbers instead of HCPCS billing codes or CPT codes.

² "The Food and Drug Administration's National Drug Code Directory," Department of Health and Human Services, Office of the Inspector General Report, OEI-06-05-00060.