

November 30, 2007

The Honorable John Dingell
Chairman
Energy and Commerce Committee
2328 Rayburn House Office Building
Washington, DC 20510

The Honorable Joe Barton
Ranking Member
Energy and Commerce Committee
2109 Rayburn House Office Building
Washington, DC 20510

Dear Chairman Dingell and Ranking Member Barton:

On behalf of the American Society of Health-System Pharmacists (ASHP) and Safety Net Hospitals for Pharmaceutical Access (SNHPA), we are writing to ask for your help with regard to a new requirement imposed by CMS on hospital outpatient pharmacy departments. The Deficit Reduction Act (DRA) of 2005 requires states to collect national drug code (NDC) numbers in order to secure Medicaid rebates on physician-administered drugs. As a result, CMS has interpreted this to mean that the agency can require hospital outpatient pharmacy departments to report unique 11-digit NDC numbers to state Medicaid agencies. The new rule, which impacts federal financial participation, goes into effect January 1, 2008. ASHP and SNHPA are concerned over the accuracy of CMS's interpretation of the law and the ability of hospital outpatient pharmacies to comply with this new requirement. We would greatly appreciate the opportunity to meet with committee staff in person to discuss the issue in more detail and, ideally, to develop a strategy for relief on the issue.

ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals and other components of health care systems. ASHP members are involved in many phases of the medication-use process, promoting public health by fostering safe and effective use of medicines in hospitals and health systems. SNHPA is an association of over 400 public and private non-profit hospitals that constitute an important part of the nation's health care "safety net" for indigent, uninsured, and underinsured individuals. SNHPA members are participants in the federal 340B drug discount program, which enables them to provide indigent and other especially vulnerable populations with prescription drugs at reduced costs, and whose capacity to do so in infusion centers, emergency rooms, oncology clinics, and other hospital outpatient settings will be threatened by implementation of the new CMS policy.

The DRA included a requirement that state Medicaid agencies collect NDC numbers in order to secure Medicaid rebates on "physician-administered drugs". As part of its final rule to implement the DRA, CMS went further to require state Medicaid programs to collect NDC numbers for drugs administered in hospital outpatient settings. Beginning January 1, 2008, the unique 11-digit numbers will be required to be submitted for both single-source drugs and 20 multiple-source drugs identified by the Secretary of Health and Human Services. ASHP and SNHPA do not agree with CMS that hospital outpatient

departments should be subject to the NDC requirement, and we submitted comments to CMS arguing that hospital outpatient pharmacies are exempt from these requirements under the Medicaid statute. The law governing Medicaid drug rebates currently exempts drugs administered by hospital clinics. ASHP and SNHPA believe CMS incorrectly interpreted the law as it relates to physician-administered drugs.

Also in our comment letters, we outlined survey results from the ASHP membership that indicated that 60% of respondent facilities did not have information systems that could store and cross reference alternate unique NDC numbers for the same generic entity. This means that these institutions could not track or bill an alternate NDC number in the event that a therapeutic equivalent generic entity was administered. This is because hospitals 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 unique NDC number) of the same medication.

ASHP and SNHPA, along with the National Association of Public Hospitals and Health Systems, the National Association for Children's Hospitals, the American Hospital Association, the National Rural Health Association and the Federation of American Hospitals, sent a letter to Secretary of Health and Human Services Michael Leavitt explaining our concerns over CMS's interpretation and asked for his assistance in clarifying the law. Neither CMS nor Secretary Leavitt has provided legal justification for interpreting the law in this manner.

In order to meet these new requirements, hospitals will face significant operational and financial hardship that is unrealistic and not justifiable given current workforce and fiscal constraints. Substantial expenditure of human and financial resources will be required. CMS has thus far refused to grant an exception, therefore, we are asking Congress for help. We are seeking clarification that hospital outpatient departments are exempt from the NDC reporting requirement. If you have any questions or would like to review our comments to CMS and/or Secretary Leavitt, please feel free to have your staff contact Joseph Hill, ASHP Director of Federal Legislative Affairs at 301-664-8710 or by e-mail at jhill@ashp.org, or Jonni McCrann, SNHPA Director of Government Relations, at 202-552-5852 or by e-mail at jonni.mccrann@safetynetrx.org.

Sincerely,

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



William von Oehsen
President
Safety Net Hospitals for Pharmaceutical Access