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THE JOHNS HOPKINS HOSPITAL

February 1, 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:

This letter responds to the Notice published in the Federal Register on December 8, 2006, pursuant to the Paper Work Reduction Act, requesting 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." The Notice appeared at 71 Federal Register pages 71178 to 71179.

The Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center are strongly opposed to application of the new data submission requirement to drugs administered by medical professionals to patients in hospital outpatient clinics or departments because of the enormous additional administrative and paperwork burdens such a requirement will place upon our staff. A more detailed description of these burdens is included in the attached letter, which sets out our more comprehensive comments on proposed regulations published December 22 to implement, among other statutory provisions, Section 6002 of the Deficit Reduction Act of

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departments to the paperwork and administrative burdens associated with the proposed NDC data submission requirement. The purpose of the proposed data submission is to enable State Medicaid agencies to collect rebates on drugs that are "physician administered" within the meaning of Section 1927(a)(7) of the Social Security Act, as amended by Section 6002 of the DRA. However, our understanding has always been that drugs administered in outpatient

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requirements of Section 1927 of the Act. Accordingly, the very burdensome task of submitting NDC numbers on hospital-administered outpatient drugs would not serve the purpose of facilitating rebate collection, as drug manufacturers' statutory rebate payment obligations do not extend to these drugs in the first place. Further, the State of Maryland, through a Memorandum of Understanding which allows Disproportionate Share hospitals to utilize the 340B program, already shares the benefit through a rebate program and would not be able to collect from manufacturers subjecting them to a duplicate discount.

Thank you for your consideration of these views in connection with the recently published Paperwork Reduction Act Notice.

Sincerely,

Shirley B. Geize, R.Ph.
Johns Hopkins Hospital

Nancy Tzeng, Pharm D.
Johns Hopkins Bayview Medical Center