

SHANDS Jacksonville

February 2, 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.

Shands Jacksonville Medical Center is 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 2005 (DRA).

In addition, it is unnecessary to subject hospitals and their outpatient clinics and 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 settings in hospitals, like ours which uses a formulary system for outpatient drugs and bills Medicaid as prescribed under the applicable Medicaid state plan, are exempt from the rebate 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.