Charleston Area Medical Center

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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 Charleston Area Medical Center, which is the tertiary care safety net hospital for Southern and Central West Virginia, 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. We currently do not track the NDC administered to outpatients at CAMC. These drugs are stocked in Automated Unit Based Cabinets (AUBC), which allow nurses and physicians to remove a specific drug for a specific patient at the time of treatment. However, because many drugs are available from a variety of manufacturers and the software within the AUBC tracks this dispensing based upon a generic nomenclature versus an NDC, the effective, efficient capture of this information is impossible. In addition, the current billing system is not configured in a manner that would allow for the reporting of the requested information without significant expensive modification. This is an added burden and expense with no value to the hospital.

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