

Dedicated to the Health
of the Whole Community

January 30, 2007



rec'd 2/15/07

Melissa Musotto
Office of Strategic

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.

Santa Clara Valley Health and Hospital System 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. Currently, our electronic billing system does not have this capability and there is no updated software that will allow for us to track this new data. This means that we will have to come up with a manual system. The healthcare professional (i.e. nurse or doctor) will need to write out a charge slip with the patient's name and billing number and the name, strength and NDC's of all drugs administered during the visit. Plus, a staff will need to gather and manually input it into a spreadsheet that can be used by patient billing for cross reference. With about 80 clinics and 14,000 patient visits per day, this will be an extremely labor intensive process for Santa Clara. As a 340B covered entity, we will also need to look up and disclose our purchasing price to our billing department so that they can charge Medicaid acquisition cost for these physician administered drugs to comply with double discounting prevention regulation. This will further exacerbate our work load. This new process will require training and follow up to ensure accuracy and compliance. This administrative burden will require us to reallocate our manpower and take time away from patient care and limit the number of patients that can be seen in a day; thus, further limiting access to patient care.

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