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February 2, 2007

Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development--A  
Attention: Melissa Musotto  
Centers for Medicare and Medicaid Services  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Comment on December 8, 2006 Federal Register Publication of Documents  
CMS-10215 and CMS-10148

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 University of California Davis Health System opposes the imposition of the new data submission requirement to drugs administered by medical professionals to patients in hospital outpatient clinics or departments for the following reasons:

1. This new administrative burden would fall initially on clinicians (as opposed to billing personnel) while they are otherwise engaged in patient care. There is often no way to record the exact source of drugs administered, except by the person administering them. This is because a common drug provided at one clinic may come in several different generic versions, and be packaged in several different size containers. It just won't work to impose this kind of additional painstakingly detailed 9 or 11 digit data entry duty on a physician or nurse while they are in the process of administering the drugs. This isn't something that can be easily reduced to a check-off form, because 600 milligrams of a particular drug might be filled with various generics kept in stock (lowest cost at the time of purchase), and it might be filled one time from a 500 mg vial, plus a 100 mg vial, and another time from a 1000 mg vial, each with different NDC numbers. In addition, preparation of drugs for infusion will require fine-tuning the amounts to bodyweight or other indicators. If the clinicians cannot just check it off, it's not reasonable or practical to impose this kind of meticulous recordkeeping burden on them. It won't work, and if tried it will cause more providers to simply refuse to deal with Medicaid patients.