

## ***DHHS and CMS Issue Final Rules for the Donation of E-Prescribing and Electronic Health Record Technology***

On October 11, 2005, the OIG and CMS each published proposed regulations that would protect certain donations of electronic prescribing (e-Prescribing) and electronic health records (EHR) technology from prosecution under the Federal Anti-kickback statute (70 *Fed. Reg.* 59015; 42 C.F.R. § 1001.952(x)) and violation of the Stark physician self-referral law (70 *Fed. Reg.* 59181; 42 C.F.R. § 411.357(v)-(x)). NACHC submitted comments on the proposed rules to both the OIG and CMS. On August 8, 2006, the OIG and CMS published final regulations.

Although the rules are administered and enforced separately by the individual agencies, in drafting the final regulations, the OIG and CMS engaged in a coordinated effort to make them consistent. Accordingly, the rules are described below by the subject matter of the exception/safe harbor (and not by whether a particular rule applies to the Stark law or to the Anti-kickback law). Instances in which the Anti-kickback safe harbor and the Stark exception differ are noted.

### **E-Prescribing Stark Exception and Anti-Kickback Safe Harbor**

The final regulations allow donations of items and services that are necessary and used solely to receive and transmit electronic prescription information (*i.e.*, non-monetary remuneration in the form of hardware, software, internet connectivity, and training and support services) by:

- A hospital to physicians who are members of its medical staff;
- A group practice to physicians who are members of the group practice; and
- A Medicare Part D Prescription Drug Plan (PDP) sponsor or Medicare Advantage (MA) organization to prescribing physicians.

### **Electronic Health Records Stark Exception and Anti-Kickback Safe Harbor**

The final regulations allow donations of software necessary and used predominantly to create, maintain, transmit, or receive electronic health records (and may include functions related to patient administration such as scheduling functions, billing, and clinical support) by entities that furnish designated health services (DHS) (or, under the Anti-kickback safe harbor, by any individual or entity that provides services paid by a Federal health care program) to any physician (or, under the Anti-kickback safe harbor, to any individual or entity engaged in the delivery of health care).

### **Response to NACHC's Comments**

In its comments on the proposed Anti-kickback safe harbor, NACHC urged the OIG to expand the classes of donors and recipients to include FQHCs so that look-alike entities

that are not protected by the health center safe harbor would be protected by the electronic health records safe harbor. The safe harbor now protects any donor that provides items or services paid by a Federal health care program. In its discussion of the final rule, the OIG specifically included FQHCs in a list of entities that would satisfy this definition.

Similarly, in its comments on the proposed Stark exception, NACHC recommended to CMS that it expand the classes of donors and recipients to include FQHCs in the exception for electronic health records. Protected donors now include all entities that furnish designated health services (DHS). In its discussion of the final rule, CMS states that “FQHCs are protected donors under the final rule.”