



Health Law Alert

Legal and political developments
affecting the health care industry

A publication of Nixon Peabody LLP

JUNE 5, 2008

CMS issues favorable advisory opinion for development of customized software for physicians

By *Linn F. Freedman*

In 2006, the Centers for Medicaid and Medicare Services (CMS) and the Office of the Inspector General (OIG) established rules creating exceptions to the Physician's Self-Referral Law (Stark) and a new safe harbor to the Anti-kickback Statute. In essence, the exception and safe harbor allowed physicians to accept donations from hospitals and other qualified donors for establishing electronic prescribing and electronic health-record capabilities (see [Nixon Peabody Health Alert, October 5, 2006](#)).

On May 28, 2008, CMS issued an Advisory Opinion (Advisory Opinion No. CMS-AO-2008-01), relating to the development of customized software given by a hospital system to members of a hospital's staff.

The facts behind the Advisory Opinion are as follows: A nonprofit hospital system proposed to contract with a third-party vendor to install a proprietary health-care software information system that was customized for the hospitals in the system, including a software interface engine that allowed custom access by physician practices on the staffs of the hospitals. The system would have allowed members of the medical staffs of the hospitals to view laboratory reports ordered by a physician and performed by the hospital. The vendor would develop, and the hospitals would pay the costs of the development of, the physician practice interface customized to the existing EHR software of the physician's practice. In addition, the hospital system proposed to purchase licenses to authorize affiliated physicians to use the customized interface during the term of the license agreement with the hospitals. Importantly, CMS noted in the Advisory Opinion that the customized interface would be used *only* to order or communicate the results of tests and procedures performed by the hospitals, and could not be used for any other purpose. In addition, the hospital system certified that the interface would not be applied or altered by the physician to perform any alternate functions, nor would the physician re-sell, transfer, or assign the license.

The CMS Advisory Opinion concluded that the proposed arrangement did not meet the definition of a “compensation arrangement” for purposes of the Stark Law, as defined in Section 1877(h)(1)(A) of the Social Security Act, and was not prohibited. CMS qualified the opinion by stating that the analysis was limited to the use of the interface to communicate results of tests and procedures furnished by the hospital. CMS made no determination as to compliance with the Stark Law if the software interface was used for any other purpose.

Although limited and qualified, the CMS Advisory Opinion offers additional guidance to hospitals and physicians regarding the donation of software and other forms of information technology, provided that certain guidelines and criteria are met.

If you need assistance in determining whether a proposal for the donation of information technology is compliant with the Stark Law or the Anti-kickback Statute, contact your Nixon Peabody LLP attorney or the Nixon Peabody LLP Health Information Technology Team through Linn F. Freedman directly at 401-454-1108 or lfreedman@nixonpeabody.com.