

# Client Alert

HEALTH INFORMATION TECHNOLOGY PRACTICE GROUP | AUGUST 2010

WIGGIN AND DANA

*Counsellors at Law*

## *ONC Establishes Temporary EHR Certification Program and Publishes Final Rule on EHR Technology Standards: Impact on Meaningful Use Incentive Payments and Stark/Anti-kickback Compliance*

On June 24, 2010, the Office of the National Coordinator for Health Information Technology (ONC) in the United States Department of Health and Human Services (HHS) promulgated a final rule establishing a temporary process for an organization to become an official ONC-Authorized Testing and Certification Body (ONC-ATCB). Approved ONC-ATCBs will be authorized to certify electronic health records (EHRs). EHR certification is already required under certain circumstances and will become increasingly important in the future as a component of the “meaningful use” incentive payment program. Notably, ONC rejected requests by industry leaders to “grandfather” EHRs previously certified by the Certification Commission for Health Information Technology (CCHIT).

Beginning in 2011, certain health care professionals, hospitals, and Medicare Advantage (MA) organizations are eligible for incentive payments under the Health Information Technology for Economic and Clinical Health Act (HITECH) if they show meaningful use of certified EHRs. Moreover, HITECH provides for Medicare payment reductions if eligible professionals, hospitals, and MAs do not become meaningful users of certified EHR technology by 2015. In addition to having responsibility for establishing a process for an organization to become an EHR certification body, ONC is responsible for establishing standards and implementation specifications for EHR technology to support meaningful use. ONC published

a final rule on July 28, 2010 containing an initial set of EHR technology standards. Those interested in obtaining HITECH’s incentive payments and/or avoiding penalties, will need to ensure that their EHR meets the initial standards and is appropriately certified by an ONC-ATCB.

Of significance is the ONC certification rule’s effect on the EHR donation exception to the physician self-referral prohibition law (“Stark law”) and the anti-kickback statute safe harbor for EHR donations. The Stark law prohibits a physician from referring patients to an entity for a designated health service if the physician or a member of his or her immediate family has a financial relationship with the entity, and the anti-kickback statute prohibits direct or indirect remuneration in exchange for referral of items or services paid under Medicare or Medicaid. Both laws permit the donation of EHR software to physicians (and other healthcare practitioners and entities in the case of the anti-kickback statute) under certain circumstances. Among the conditions of the Stark law exception and the anti-kickback statute safe harbor for EHR donation is the prerequisite that the donated EHR be deemed interoperable by “a certifying body recognized by the Secretary . . . within no more than 12 months prior to the date it is provided.” Currently, only CCHIT has been granted status as a “certifying body” by the Secretary. Under the ONC’s newly published rule, however, CCHIT will now lose its status as a “certifying body” and only ONC-ATCBs will be able to deem

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software interoperable for the purposes of the Stark law and anti-kickback statute compliance. CCHIT will have to apply to become an ONC-ATCBs, like any other organization, and has already announced its intent to apply for ONC-ATCB status.

Note that EHR software that has already been deemed interoperable by CCHIT will still be considered interoperable; the loss of CCHIT's status as a certifying body will not effect the status of the EHR that CCHIT has already deemed interoperable. However, anyone planning on making or receiving an EHR software donation and fitting within the Stark law exception and/or anti-kickback statute safe harbor should ensure that any EHR deemed interoperable by CCHIT by June 24, 2010 is provided within 12 months of the date that it was so deemed or should have the EHR deemed interoperable by an ONC-ATCB at least 12 months prior to the donation. Importantly, CCHIT's certification of EHR as interoperable does not render the EHR certified under HITECH for purposes of qualifying for

meaningful use incentive payments. In order to receive incentive payments for meaningful use of EHR, and avoid penalties, certification by an ONC-ATCB is required.

The ONC's final rule establishes the entire process for organizations to be granted status as an ONC-ATCB, from the application procedure, to the principles of proper conduct, to the requirements for testing EHRs, to revocation of ONC-ATCB status. The certification program, however, is temporary and is intended to merely fill the gap until a permanent process is established. The ONC promulgated a temporary process so that EHR certification would be available before the date that health care providers demonstrating meaningful use of certified EHR technology became eligible for incentive payments. The rule sunsets on December 31, 2011, unless the permanent certification is not fully constituted by that date, in which case the temporary process will continue as long as the ONC deems appropriate.

*If you have any questions about EHR certification, Stark or anti-kick-back regulatory requirements for EHR donation, or any other health information technology matter, please do not hesitate to contact:*

MICHELLE WILCOX DEBARGE at 860.297.3702 or [mdebarge@wiggins.com](mailto:mdebarge@wiggins.com)

MARY R. NORRIS at 203.498.4377 or [mnorris@wiggins.com](mailto:mnorris@wiggins.com)

JODY ERDFARB at 203.363.7608 or [jerdfarb@wiggins.com](mailto:jerdfarb@wiggins.com).

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