More Regulators Eye Health Info Blocking

Law360, New York (November 23, 2015, 2:35 PM ET) -- The federal government has spent billions to promote adoption and "meaningful use" of health information technology (HIT). There is growing government interest in ensuring that HIT is used to support patient care, but doing so requires electronic exchange of information. Congress, the U.S. Department of Health and Human Services, and states have taken action to identify and prevent "information blocking" — interference with the exchange or use of electronic health information — by health care providers, hospitals, technology developers and service providers. And there likely will be more guidance, statutory and regulatory changes, and enforcement by federal agencies and states in the coming year.

Congress Requests Information and Takes Action

On Dec. 21, 2014, Congress raised concerns about health information blocking, claiming that such activities "frustrate congressional intent" under the Health Information Technology for Economic and Clinical Health (HITECH) Act, "devalue taxpayer investments," and make HIT "less valuable and more burdensome" to hospitals and health care providers. Congress urged the Office of the National Coordinator for Health Information Technology (ONC) at HHS to certify only HIT that does not block health information exchange. Congress also requested ONC publish a detailed report on the scope of health information blocking and a strategy to address it within 90 days.

ONC issued a Congressional Report in April 2015 asserting that health information blocking is a problem today and likely will grow worse. ONC defined "information blocking" as "knowingly and unreasonably interfering with the exchange or use of electronic health information" and made recommendations for agency and congressional action.

In April 2015, Congress enacted a new requirement that prohibits information blocking by eligible persons (including hospitals) under the CMS "meaningful use" program. Specifically, eligible persons must demonstrate that they have "not knowingly or willfully taken action … to limit or restrict the compatibility or interoperability of certified EHR technology (CEHRT)." HHS has not yet interpreted these provisions through regulation to clarify these obligations, but it is expected that such regulations are forthcoming. In the meantime, eligible persons who are complying with meaningful use requirements should begin to assess their practices in light of this statutory requirement.

Congress also has been working on HIT legislation including provisions to ban health information blocking more broadly.

OIG Issues Warning on Information Blocking

On Oct. 6, 2015, the Office of the Inspector General marked "National Health IT Week" 2015 by issuing an alert to warn those who participate in any federal health care program (FHCP) of the consequences information blocking may have on safe harbor protection afforded under the federal anti-kickback statute (AKS). Following on the heels of ONC's report, this OIG alert demonstrates increasing vigilance by HHS about information blocking.

The AKS prohibits entities and individuals from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or reward referrals of business reimbursable under any FHCP. Violation of this statute may result in the imposition of criminal penalties, civil monetary penalties, program exclusion and liability under the False Claims Act.

Software or information technology furnished by a hospital to a referral source, such as a physician practice, may implicate the AKS. To promote the adoption of interoperable technology that benefits patient care, HHS adopted the electronic health record (EHR) safe harbor, which protects certain arrangements involving the provision of interoperable EHR software or information technology and training services. To qualify under the EHR safe harbor, however, one requirement is that individuals and entities refrain from information blocking; the safe harbor requires that the "donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or [EHR] systems." The OIG has stated that such donations "would be suspect under the law as they would appear to be motivated, at least in part, by a purpose of securing business."

The OIG alert provides two examples of information blocking: (1) arrangements in which a donor limits the use, communication or interoperability of donated items or services "by entering into an agreement with a recipient to preclude or inhibit any competitor from interfacing with the donated system"; and (2) arrangements in which a technology vendor agrees with donors to charge high interface fees to non-recipient providers, suppliers or competitors. Such arrangements fail to meet the conditions of the EHR safe harbor and expose the participants to AKS liability.

As hospital systems continue to adopt HIT and make donations of HIT products and services to health care providers, the OIG is increasingly monitoring compliance and assessing its enforcement tools against information blocking. The Federal Trade Commission is also paying close attention to such developments in HIT. Through its blog, the FTC has expressed an interest in ensuring competition in health care markets.

States Follow Suit

In June, Connecticut was the first state to pass a law (C.G.S.A. P.A. 15-146) banning the use of EHRs to block the exchange of health information. The state adopted ONC's definition of the term "information blocking." This law took effect on Oct. 1, 2015, and would apply to technology developers and health care systems. Entities operating in Connecticut that may be within the scope of this law should look at their practices in light of these new limitations.

Stay Tuned

Health information blocking will likely continue to be an area of growing interest, requirements and enforcement. It is gaining attention from agencies that oversee antitrust, fraud and abuse, meaningful use and certification of HIT, and is one of the primary areas of interest in the quest for interoperability. The adoption of HIT, while often beneficial to hospital systems and the promotion of patient care, raises regulatory concerns. Arrangements involving the provision of software or information technology to a referral source should be carefully analyzed for compliance with AKS and other applicable laws. Stay tuned for further developments.

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