JONES WALKER

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CMS, OIG PROPOSE EXTENSION OF EHR EXCEPTION/SAFE HARBOR

Recently, both the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General ("OIG") published proposed rules[1] ("Proposed Rules") that would modify current regulations involving certain donations of electronic health record items and services, which were originally published in 2006.[2] Specifically, on April 10, 2013, CMS and the OIG published in the *Federal Register* complimentary Proposed Rules that would modify the existing Stark exception[3] and the Anti-Kickback safe harbor[4] relating to certain arrangements involving the provision of interoperable electronic health record ("EHR") software or information technology and training services. In the preamble to the Proposed Rules, CMS and the OIG each indicated that, in proposing these rules, they attempted to "ensure as much consistency as possible" between the Proposed Rules, "despite the differences in the respective underlying statutes."

Perhaps most significantly, the Proposed Rules would extend the current Stark exception and Anti-Kickback safe harbor, which are scheduled to sunset on December 31, 2013, until December 31, 2016. In discussing the proposed extensions, CMS and the OIG noted that, while great progress has been made in the adoption of electronic health record technology, use of this technology has not yet been universally adopted, and the continued adoption of such technology remains an important goal of the Department of Health and Human Services. Further, CMS and the OIG indicated that the date of December 31, 2016, was chosen because it corresponds to the last year in which it is possible to receive a Medicare EHR incentive payment, and it is also the last year in which it is possible to initiate participation in the Medicaid EHR incentive program. In addition, CMS and the OIG noted that they are considering establishing a later sunset date, such as December 31, 2021, which corresponds to the end of the EHR Medicaid incentives. The agencies solicited comment on the proposed sunset date of December 31, 2016, as well as whether a later date should be chosen and, if so, what that date should be.

In addition to extending the Stark exception and OIG safe harbor, the Proposed Rules, if adopted, would amend the current regulations to "update the provision under which electronic health records software is deemed interoperable." The exception and safe harbor currently specify that donated software must be interoperable at the time it is provided to the recipient. Further, the regulations state that software is deemed to be interoperable if "a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient."[5] The

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[1] *See*, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exceptions for Certain Electronic Health Records Arrangements," 78 Fed. Reg. 21308 (April 10, 2013); "Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute," 78 Fed. Reg. 21314 (April 10, 2013).

[2] *See*, 71 Fed. Reg. 45140 (Aug. 8, 2006); 71 Fed. Reg. 45110 (Aug. 8, 2006). These rules may hereinafter collectively be referred to as the "2006 Final Rules."

[3] *See,* 42 C.F.R. 411.357(w).

[4] *See*, 42 C.F.R. 1001.952(y).

[5] *See*, 42 C.F.R. 411.357(w)(2);42 C.F.R. 1001.952(y)(2).

Proposed Rules would make two changes to this "deeming" provision. First, the phrase "recognized by the Secretary," would be changed to "authorized by the National Coordinator for Health Information Technology" in order to clarify that to become a certifying body "recognized" by the Secretary, an entity must successfully complete an authorization process established by the Office of the National Coordinator for Health Information Technology ("ONC").

The second proposed modification would remove the requirement that donated software must be certified as being interoperable within 12 months of its donation to the recipient. Rather, software would be eligible if, on the date it is provided to the recipient, it has been certified to any edition of EHR certification criteria that is identified in the then-applicable definition of "Certified EHR Technology" in the regulations.[6] This change is being proposed to be consistent with ONC's regulatory process for adopting certification criteria and standards, which is anticipated to occur on a two-year regulatory interval. In addition, CMS and the OIG noted that they want to ensure that products are certified to the current standard of interoperability when they are donated, and stated that the current provisions do not account for the fact that some certification criteria may not change from one edition to the next. As with the proposed sunset extensions discussed above, CMS and the OIG are seeking comment on these proposed changes, including whether removing the 12-month period would impact donations, and whether the 12-month period should be retained as an additional means of determining eligibility.

An additional proposed modification to the current regulations is that the Proposed Rules would remove from the Stark exception and Anti-Kickback safe harbor the requirement related to electronic prescribing capability. The current exception and safe harbor require that donated software must contain electronic prescribing capability, either through an electronic prescribing component, or through the ability to interface with the recipient's existing electronic prescribing system. In the preamble to the Proposed Rules, CMS and the OIG, while recognizing the critical importance of electronic prescribing, noted that a number of developments have occurred since the 2006 Final Rules were published that have led these entities to conclude that the electronic prescribing component may no longer be necessary. For example, CMS and the OIG noted that, in 2008, Congress enacted legislation addressing electronic prescribing, which authorized an electronic prescribing incentive program for certain types of eligible professionals.[7] In addition, in 2009, the agencies noted that Congress passed the Health Information Technology for Economic and Clinical Health Act, which authorized CMS to establish Medical and Medicaid EHR incentive programs for certain eligible professionals, eligible hospitals, and critical access hospitals.[8] These developments, together with the increased use of electronic prescribing, led CMS and the OIG to state that "there are sufficient alternative policy drivers supporting electronic prescribing capabilities" and that they believe "it is not necessary to retain a requirement related to electronic prescribing capability." In addition, these

[6] The reference to the noted regulations is to 45 C.F.R. Part 170 titled, "Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology."

[7] The preambles state that this legislation was the "Medicare Improvements for Patients and Providers Act of 2008," Pub. L. 110-275.

[8] 42 U.S.C. 1395w-4(o), 1395ww(n), 1395f(l(3) and 1396b(t).

agencies noted that they considered whether removing the electronic prescribing condition in the exception and safe harbor would increase fraud and abuse, and concluded that they do not believe it would.

The Proposed Rules also included additional proposals and considerations with respect to which CMS and the OIG requested comment. For example, the agencies stated that they had received comments suggesting that abusive donations are being made under the exception and safe harbor, and requested comment on whether to limit protected donors to hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations, which they stated are the original protected donors mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. If CMS and the OIG were to so limit protected donors, they requested comment on whether entities with "front-line patient responsibilities," such as safety net providers, should be included as protected donors. In the alternate, CMS and the OIG are considering retaining the current protected donors, but excluding "suppliers of ancillary services associated with a high risk of fraud and abuse." Such suppliers, according to CMS and the OIG, may be more likely to be motivated by a purpose of securing future business rather than by a purpose of better coordinating care for beneficiaries across health care settings, and include laboratory companies, whose donations have been the subject of complaints, durable medical equipment suppliers, and independent home health agencies. CMS and the OIG indicated that they are seeking comment on the alternatives regarding the particular types of providers and suppliers who should and should not be protected donors, and requested that commenters include supporting reasons.

In addition to potentially limiting the scope of permissible donors as a way to prevent donations that are used to "lock in" referrals, CMS and the OIG are also considering new or modified conditions that would both prevent the misuse of the exception and safe harbor, but also encourage the free exchange of data. For example, CMS and the OIG noted that, even though donated software must be interoperable at the time of a donation, policies and practices may affect the true ability of information to be exchanged across organizational and vendor boundaries. Therefore, comment is being sought on whether new or modified conditions should be added to the exception and safe harbor to address the goals of preventing the possibility of lock-in, while also encouraging the free exchange of data.

Finally, CMS and the OIG are seeking comment on whether the regulations should be revised concerning the scope of the term "software information technology and training services necessary and used predominately for EHR purposes." Specifically, comment is sought as to whether this term is sufficiently clear with respect to what technology and services are included or covered thereby. Although CMS and the OIG stated that the current regulatory text, when read in light of the preamble discussion in the 2006 Final Rules, is sufficiently clear concerning the scope of covered technology, they are seeking input regarding this issue.

Comments must be submitted within 60 days from the date the Proposed Rules were published in the *Federal Register* (which, as noted above, was April 10, 2013). Both CMS and the OIG noted that, because of the "close nexus" between the two Proposed Rules, each agency may consider comments submitted in response to the other agency's Proposed Rule when crafting its own final rule.

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Should you need any additional information regarding the Proposed Rules, or the current Stark exception and Anti-Kickback safe harbor regarding EHR donations, or should you need any assistance with EHR matters in general, please contact Lynn M. Barrett, Esq. at lbarrett@joneswalker.com.

— Lynn M. Barrett, Esq.

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