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HRO Alert

HRO HEALTHCARE LAW ALERT

DEVELOPMENTS IN ELECTRONIC PRESCRIBING AND ELECTRONIC HEALTH RECORDS

On October 5, 2005, Secretary Mike Leavitt of the U.S. Department of Health & Human Services ("HHS") announced two sets of proposed regulations relating to the use of electronic prescribing and electronic health records. The proposed regulations, issued by the Centers for Medicare & Medicaid Services ("CMS") and by the Office of Inspector General ("OIG"), have been published in the Federal Register today. These proposals reflect a coordinated effort by CMS and OIG to create certain exceptions that would allow for sharing of technology for e-prescribing and certain electronic health records, which arrangements otherwise might violate physician self-referral and anti-kickback laws administered by CMS and OIG.

Each of the two agencies proposed its regulations pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") and noted that the proposals were "consistent with the President's goal of achieving widespread adoption of interoperable electronic health records for the purpose of improving the quality and efficiency of health care, while maintaining the level of security and privacy that consumers expect." The current proposed regulations follow on the proposed regulations issued by CMS on February 4, 2005,¹ which suggested standards for an electronic prescription drug program under Title I of the MMA.

REGULATIONS PROPOSED BY CMS

The proposed CMS regulations are titled "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements." If adopted, these proposed regulations would add new exceptions under 42 C.F.R. § 411.357 to prohibitions set forth in Section 1877 of the Social Security Act (sometimes called the "physician self-referral law" or the "Stark Law"). The physician self-referral law prohibits physicians from making referrals for certain Medicare patients to entities in which the physician, or a family member, may have a financial interest and also includes related restrictions on compensation provided to physicians for referrals. Subject to certain conditions set forth in the proposed regulations, the new exceptions would expressly allow hospitals, group practices, Prescription Drug Plan Sponsors, and Medicare Advantage organizations to provide to physicians the following without violation of the physician self-referral law: (1) hardware, software, information technology, and training services necessary and used solely to receive and transmit electronic prescription information; (2) *uncertified* software and directly-related training services necessary and used solely to receive, transmit, and maintain electronic health records, provided that no actions are taken to limit the compatibility with other electronic health information systems; and (3) software and directly-related training services that become *certified* under criteria to be established by HHS.

October 11, 2005

¹ 70 F.R. 6256 (Feb. 4, 2005).

REGULATIONS PROPOSED BY OIG

The proposed OIG regulations are titled “Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements under the Anti-Kickback Statute.” If adopted, these proposed regulations would add new safe harbors under 42 C.F.R. § 1001.952 to the anti-kickback provisions set forth in Section 1128B of the Social Security Act (the Federal “Anti-Kickback Statute”). The Anti-Kickback Statute provisions include criminal penalties for direct or indirect remuneration in exchange for referral of business under federal health care programs. Subject to certain conditions set forth in the proposed regulations, the new safe harbors would expressly allow hospitals, group practices, Prescription Drug Plan Sponsors, and Medicare Advantage organizations to provide to physicians the following without violation of the Anti-Kickback Statute: hardware, software, information technology, and training services necessary and used solely to receive and transmit electronic prescription information. The proposed regulations indicate that the OIG is also contemplating including a comparable safe harbor for electronic health records software, if such software includes an electronic prescribing component. The OIG identified several areas where it is soliciting comment with respect to any safe harbor for electronic health records software, including scope and conditions, use with respect to non-drug information such as supplies or laboratory tests, value caps, and the definition of “electronic health records.” Additionally, OIG requests comments on the possibility of a safe harbor for community-wide health information systems, comparable to the existing Stark safe harbor for such community-wide systems.²

CONCLUSION

HHS has described the newly-proposed regulations related to electronic prescribing and electronic health records as a “major step forward in transforming American healthcare.”³ Individuals and organizations in the healthcare industry would be well served by reviewing the newly-proposed regulations to become familiar with the sharing of technology that would be permitted thereunder. While the principal emphasis of the proposed regulations is electronic prescribing, it is particularly noteworthy that the regulations proposed by CMS and OIG contemplate an exception with respect to software for electronic health records. This electronic health records exception, as proposed, further indicates that HHS is developing a standard for interoperable electronic health record systems under which the software can be certified in the future. Individuals or organizations with input regarding the proposed regulations or the open questions posed by CMS and OIG should consider providing comment in response to the proposed regulations. The comment period for both sets of proposed regulations will expire December 12, 2005.

For further information regarding the topics described herein, please contact Stephen P. Nash, Laurel A. Durham, or Elizabeth A. Meier by telephone at (303) 861-7000 or by email at the addresses listed on the first page.

This article is a periodic publication of Holme Roberts & Owen LLP and should not be construed as legal advice or legal opinion on any specific facts or circumstances. Nor is it intended to address specific disclosure or compliance issues that may arise in particular circumstances or to provide an exhaustive discussion of the topics discussed herein. The contents are intended for general informational purposes only, and you are urged to consult counsel concerning your own situation and any specific legal questions you may have.

² 42 CFR § 411.357 (u).

³ U.S. Department of Health & Human Services, News Release, dated Oct. 5, 2005, available at hhs.gov/news/press/2005pres/20051005.html.

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