

Electronic Prescribing and Electronic Health Records Exceptions to The Stark Law

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The electronic prescribing and electronic health records (“EHR”) exceptions to the federal physician self-referral law known as the Stark Law ([42 U.S.C. § 1395nn](#)) were first published in the Federal Register in 2006, yet they remain important considerations for compensation arrangements subject to the harsh provisions of the Stark law. These exceptions may prove helpful for hospitals that want to donate certain health information technology items or services to a referring group practice or individual physician. Health care providers should not delay considering whether they can meet the EHR exception, as it expires on December 31, 2013. The Stark Law generally prohibits a physician, or an immediate family member of a physician, from making referrals for certain designated health services to an entity with which a physician or a physician’s immediate family member has a financial relationship—if the designated health services are to be paid by Medicare. [42 U.S.C. § 1395nn](#). It also prohibits a physician or a physician’s immediate family member from presenting a claim or bill for services from prohibited referrals, or causing such a claim or bill to be presented. [42 U.S.C. § 1395nn](#). The Code of Federal Regulations, Title 42, [Section 411.357](#) (v) and (w) establish exceptions from the Stark Law for electronic prescribing and EHR items and services, respectively. Health care providers should take careful measures to ensure the required conditions are met for each exception. This article analyzes the conditions set forth in 42 C.F.R. [Section 411.357](#) (v) and (w).

Electronic Prescribing Exception The electronic prescribing exception excludes hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information from the Stark Law’s restrictions on compensation arrangements. 42 C.F.R. [Section 411.357](#) (v). Health care providers should consider whether donations meet this exception, because while these items and services may be crucial for a business’ operation they can also be costly. Under this exception, an appropriate entity may donate these items and services to certain physicians. The electronic prescribing exception limits the kinds of entities that may donate the items and services as well as the types of physicians who may receive the donations. The donations may only be provided by a: (i) hospital to a physician who is a member of its medical staff; (ii) group practice to a physician who is a member of the group; or (iii)

prescription drug plan sponsor or Medicare Advantage organization to a prescribing physician. 42 C.F.R. [Section 411.357](#) (v). There are also restrictions on certain actions the donor may take. The donor may not limit or restrict the use or compatibility of the items or services with other electronic prescribing or EHR systems. 42 C.F.R. [Section 411.357](#) (v). Also, for items or services that can be used for any patient without regard to payer status, the donor may not restrict a physician's ability to use the items or services for any patient. 42 C.F.R. [Section 411.357](#) (v); *see also* 42 C.F.R. [Section 411.357](#) (w) (requiring the same for the EHR exception). Additionally, the amount and value of referrals or business generated between the parties may not determine a physician's eligibility to receive items or services—and the amount or nature of the same. 42 C.F.R. [Section 411.357](#) (v); *see also* 42 C.F.R. [Section 411.357](#) (w) (requiring the same for the EHR exception). Last, the donor cannot know or act in reckless disregard or deliberate ignorance of the fact that a physician already has equivalent items or services to those being donated. 42 C.F.R. [Section 411.357](#) (v); *see also* 42 C.F.R. [Section 411.357](#) (w) (requiring the same for the EHR exception). There are additional conditions on the donated items and services. The items and services must be provided as part of, or be used to access, an electronic prescription drug program that meets the Medicare Part D standards at the time items and services are provided. 42 C.F.R. [Section 411.357](#) (v). A physician and his or her practice may not make the receipt of items or services, or the amount thereof, a condition of doing business with the donor. 42 C.F.R. [Section 411.357](#) (v); *see also* 42 C.F.R. [Section 411.357](#) (w) (requiring the same for the EHR exception). Last, the arrangement must be in a written agreement with the terms set forth in the Code of Federal Regulations. 42 C.F.R. [Section 411.357](#) (v); *see also* 42 C.F.R. [Section 411.357](#) (w) (requiring the same for the EHR exception).

EHR Exception The EHR exception exempts software or information technology and training services necessary, and used predominantly, to create, maintain, transmit, or receive electronic health records from the Stark Law's prohibitions on compensation arrangements. 42 C.F.R. [Section 411.357](#) (w). For some health care providers, the Medicare and Medicaid EHR Incentive Program may lead to a new focus on compliance with the EHR Stark Law exception. Those who want to claim the EHR exception should act quickly, as the transaction of items and services must occur, and all conditions of the exception must be met, by December 31, 2013. 42 C.F.R. [Section 411.357](#) (w). As with the electronic prescribing exception, the EHR exception limits who may provide the items and services. Only an entity as defined at [42 C.F.R. §411.351](#) may provide the items and services to a physician. 42 C.F.R. [Section 411.357](#) (w). There are also restrictions on the donor's actions. The donor may not limit or restrict the use or compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems. 42 C.F.R. [Section 411.357](#) (w). Other restrictions for the EHR exception that are shared with the electronic prescribing exception are noted in the section of this article addressing the electronic prescribing exception. The EHR exception has several unique requirements that may create a greater hardship for both the donating entity and receiving physician. 42 C.F.R. [Section 411.357](#) (w). First, the donated software must be interoperable (as defined at [42 C.F.R. §411.351](#)) at the time it is provided to a physician, and it must contain electronic prescribing capability. 42 C.F.R. [Section 411.357](#) (w). Also, before a physician receives the items and services, he or she must pay 15 percent of the donor's cost for the items and services, without any financing by the donor. 42 C.F.R.

[Section 411.357 \(w\)](#). This may be a significant burden to a physician, and it is a major condition absent from the electronic prescribing exception. Additionally, the items and services may not include staffing of physician offices and may not be used primarily to conduct a physician's personal business or business unrelated to a physician's medical practice. 42 C.F.R. [Section 411.357 \(w\)](#). As noted above, transactions of items and services and required conditions must be met by December 31, 2013. Finally, the arrangement may not violate the Anti-Kickback Statute, or any federal or state law or regulation governing billing or claims submission. 42 C.F.R. [Section 411.357 \(w\)](#). This last requirement serves as a reminder to all health care providers that health care regulations are interconnected and complex, and that careful analysis at each step of any health care transaction is crucial.

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