STARK AND ANTI-KICKBACK PROTECTION FOR E-PRESCRIBING AND ELECTRONIC HEALTH RECORDS

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On October 11, 2005, in two separate rule makings, the Centers for Medicare and Medicaid Services ("CMS") and the Office of Inspector General ("OIG") for the U.S. Department of Health and Human Services ("DHHS") each published proposed rules that provide protection under the Federal Stark law[1] and under the Federal Anti-kickback law[2] for (1) certain arrangements in which a physician receives necessary non-monetary remuneration used solely to receive and transmit electronic drug information ("e-prescribing") and (2) certain arrangements involving the provision of electronic health records software and directly related training services.[3] The e-prescribing portions of the proposed rules were mandated by The Medicare Modernization Act of 2003 ("MMA"), which established a new prescription drug benefit in the Medicare program ("Part D benefit").

As part of the new legislation, Congress mandated the adoption of standards for electronic prescribing,[4] with the objective of improving patient safety, quality of care, and efficiency in the delivery of health care. The new legislation directed the Secretary, in consultation with the Attorney General, to create an exception to the Stark law and a safe harbor to the Anti-Kickback law to protect certain arrangements for the provision of non-monetary remuneration that is necessary and used solely to receive and transmit electronic prescription drug information in accordance with electronic standards published by the Secretary.[5] In addition to the MMA-mandated Stark exception and Anti-kickback safe harbor, and consistent with President Bush's goal of achieving widespread adoption of interoperable

electronic health records, CMS and OIG used their legal authority to create additional protections for certain arrangements involving the provision of electronic health records software and related training services.[6] The deadline for submitting comments on the rules was December 12, 2005. This article will summarize these proposed rules.

Proposed E-Prescribing Exception and Safe Harbor

The MMA-mandated e-prescribing exception and safe harbor describe: (1) the items and services protected; (2) the conditions under which offering these items and services would be protected; and (3) the donors and recipients covered by the exception and safe harbor. According to preamble commentary to the proposed rules, OIG and CMS have attempted to ensure as much consistency as possible between the proposed e-prescribing exception and the corresponding safe harbor, taking into consideration the underlying differences between the Stark law and the Anti-kickback law.[7] The proposed rules provide summary charts that reflect the overall structure and approach of the proposals.[8] However, the summary charts do not contain all of the conditions and information set forth in detail in the preamble commentary and proposed regulations.

Protected Technology – "Necessary" Items and Services

The proposed Stark exception and the corresponding safe harbor for e-prescribing protect only the provision of items and services that are "necessary" and used "solely" to transmit and receive electronic prescription drug information.[9] According to preamble commentary, items and services that are "necessary" to conduct electronic prescription drug transactions might include hardware, software, broadband or wireless internet

connectivity, training, information technology support services, and other items and services used in connection with the transmission or receipt of e-prescribing information. The proposals do not protect items and services that are technically or functionally equivalent to items that the receiving physician (or other recipient) already possesses or services that the physician (or other recipient) has already obtained.[10] For example, the exception/ safe harbor would allow a hospital to provide a physician with a hand-held device, even though the physician may already have a desktop computer that could be used to send the same information. However, the provision of a second hand-held device would not qualify for the exception/safe harbor.[11]

Under both proposals, the physician (or other recipient) must certify in a written agreement between the parties that the items and services are not technically or functionally equivalent to those that the physician (or other recipient) already possesses or has obtained.[12] Additionally, the physician (or other recipient) must update the certification before furnishing any necessary upgrades, items, or services not reflected in the original certification.[13]

CMS and OIG both share concern that the certification process may be ineffective to safeguard against fraud and abuse if it is a mere formality or if recipients simply execute a form provided by the donor entity. In this regard, the proposed rules require that the donor entity must not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the recipient possessed or had obtained items or services that were functionally or technically equivalent to the donated items or services.[14] CMS is soliciting comments on how to address the risk that physicians may intentionally divest themselves of functionally or

technically equivalent technology.[15] OIG is soliciting similar comments.[16]

Protected Technology – "Used Solely" for E-Prescribing

In addition to the "necessary" requirement, the proposed exception and safe harbor require that the protected items and services be used "solely" to transmit or receive electronic prescribing information.[17] As such, free or reduced cost software that bundles valuable general office management, billing, scheduling or other software with electronic prescribing features would not meet the used "solely" requirement.[18]

CMS and OIG are mindful that hardware and connectivity services can be used for the receipt and transmission of a wide range of information services, and that many recipients may prefer to use a single, multi-functional device. Thus, CMS and OIG are both proposing to use their authority to create an additional separate exception/safe harbor to protect the provision by donor entities to recipients of hardware (including necessary operating system software) and connectivity services used for more than one function, so long as a substantial use of the item or service is to receive or transmit electronic prescription information. CMS and OIG are both soliciting comments about the standards that should appear in an additional exception/safe harbor for multi-functional hardware or connectivity services.[19]

Entities Protected

In addition to the limitations placed on the types of electronic prescribing technology that is protected, the types of entities that may provide assistance, and the persons to whom assistance can be provided, are also specifically limited under the proposed rules. The MMA statutory mandate protects the donation of qualifying electronic prescribing technology when the donation is made by: (1) hospitals to members of their medical staffs; (2) group practices to

prescribing health care professionals who are members of such practice; and (3) prescription drug plan ("PDP") sponsors and Medicare Advantage ("MA") organizations to pharmacies, pharmacists, and prescribing health professionals.[20]

The proposed Stark exception mirrors the above statutory language except where the statute refers to persons or entities other than physicians (i.e., pharmacies, pharmacists, and other non-physician prescribing professionals). CMS limited the proposed exception to remuneration provided to physicians because the Stark law's self-referral prohibition is not implicated when remuneration is provided to non-physician prescribing health professionals or to pharmacists and pharmacies not otherwise affiliated with a referring physician.[21]

Under both of the proposed rules, donations of qualifying electronic prescribing technology provided by a hospital to physicians on its medical staff are protected.[22] Neither CMS nor OIG intend to protect remuneration used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital.[23] OIG is soliciting comments on whether the safe harbor should include donations to other individuals or entities, such as other health care prescribing professionals who treat patients at the hospital.[24] Because the Stark Law applies to physician referrals, there was no need for CMS to solicit comments on whether the exception should include donations to other individuals or entities, such as other health care prescribing professionals who treat patients at the hospital.

Under the Stark proposed exception, protection is afforded to donations provided by a group practice to its physician members.[25] CMS is proposing to apply the existing regulatory definitions of "group practice" and "member of a group practice."[26] CMS notes that the inclusion of this provision does not

imply that the donation of these items and services by a group to its members necessarily requires a new exception, as the in-office ancillary services exception or the employment exception may apply in most circumstances. Under the Stark regulations, a "member of a group practice" does not include independent contractor physicians; instead, these physicians are considered "physicians in the group practice."[27] CMS is soliciting comments regarding whether and how a group practice may furnish qualifying e-prescribing technology to a "physician in the group practice."[28]

The proposed safe harbor protects donations provided by a group practice to its members who are "prescribing health care professionals."[29] For consistency with the Stark exception, the OIG proposes to interpret the terms "group practice" and "members" of the group practice consistent with the Stark law and regulatory definitions. Because the Stark law deals only with physician referrals, however, it was necessary for OIG to augment the definition of "member" of a group practice to sufficiently define the full range of "prescribing health care professionals." Thus, for purposes of the safe harbor, "prescribing health care professionals" who are "members" of the group include prescribing professionals who are owners or employees of the group and authorized under State law to prescribe.[30]

The last group of donors and recipients protected under the Stark exception include donations by PDP sponsors or MA organizations to prescribing physicians.[31] CMS notes that, in certain circumstances, the donation may qualify for protection under the existing Stark exception for services provided by an organization to its enrollees.[32] CMS is soliciting comments on whether it should protect donations provided to physicians by other Designated Health Services ("DHS") entities.[33] Similar to the Stark exception, the last group of donors and recipients protected under

the safe harbor proposal include PDP sponsors or MA organizations that donate to prescribing health care professionals, participating pharmacies, and/or participating pharmacists.[34] For purposes of the safe harbor, the terms "pharmacy," "pharmacist," and "prescribing health care professionals" will be interpreted consistent with applicable state licensing and dispensing laws.[35]

Additional Limitations – Interoperability

In order to qualify for the proposed Stark exception and Anti-kickback safe harbor, the items and services donated must be provided as part of, or be used to access, an electronic prescription drug program that complies with the applicable standards under Medicare Part D at the time that the items and services are furnished.[36] Note that on November 1, 2005, CMS published a final rule, which adopts standards for an electronic prescription drug program. These standards are the first set of final uniform standards for an electronic prescription drug program under the MMA.[37] CMS is soliciting comments on whether the exception should permit the technology to be used for the transmission of prescription information for items and services that are not drugs, such as laboratory tests.[38] The OIG is soliciting similar comments.[39]

The term "interoperable" refers to the ability of different information systems, software and applications, and networks to communicate and exchange information in an accurate, secure, effective, useful, and consistent manner.[40] According to preamble commentary in each set of the proposed rules, interoperability can serve as an important safeguard against fraud and abuse, because a requirement that protected technology be fully interoperable would mitigate against the risk that an entity could offer free or reduced price technology to a referring recipient as a way of maintaining or inducing the recipient's referrals. Both CMS and OIG opine that risk would be mitigated if the technology were interoperable, as the

recipient would be free to submit prescriptions to any appropriate pharmacy. In this regard, to the extent that either the hardware or software can be interoperable, the proposed exception and the proposed safe harbor prohibit donors or their agents from taking any actions to disable or limit that interoperability or otherwise impose barriers to compatibility.[41]

Additional Limitations – Value of Protected Technology

CMS and OIG believe that a monetary limit of all items and services provided to a physician (or other recipient) from a single donor is appropriate and reasonable to minimize the potential for fraud and abuse. At this time, neither the e-prescribing proposed exception nor the proposed safe harbor contain a cap, but CMS and OIG are soliciting comments on the amount of a cap, the methodology for a cap, and the retail and non-retail costs of obtaining e-prescribing technology.[42] CMS does caution that the cost of implementing an e-prescribing program will not necessarily correlate to the amount of any cap if one is ultimately established.[43]

According to preamble commentary, OIG is considering various potential caps that would be no higher than any cap that may be ultimately imposed by CMS in the Stark exception for e-prescribing. The OIG is also considering setting an initial cap that would be lowered after a period of time sufficient to promote the initial adoption of technology.[44]

Additional Limitations – Other Conditions

In order to qualify for the e-prescribing exception and the corresponding safe harbor, where possible, recipients must be able to use the technology for all patients without regard to payor status. Accordingly, the donor of technology may not restrict or take any action to limit the recipient's right or ability to use the items or services for any patient, if the items and services are

the type that can be used for any patient regardless of payor status.[45]

The proposed exception and corresponding safe harbor both further provide that neither the recipient nor the recipient's practice (or recipient's group, employees or staff) may make the donation of qualifying items or services a condition of doing business.[46] For example, a physician would be prohibited from requiring a hospital in which he/she was a member of such staff to provide him/her with a hand held device as a condition for the physician to remain on staff with the hospital.

Both proposals also incorporate certain conditions that are consistent with the other regulatory exceptions and safe harbors under the Stark self-referral prohibition and Anti-kickback law. Specifically, the eligibility of a physician (or other recipient, including prescribing health care professionals, pharmacists, or pharmacies) to receive items and services from a donor, and the amount and nature of the items and services received, may not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.[47] Neither provision precludes selection criteria that are based upon the total number of prescriptions written, but would prohibit criteria based upon the volume or value of prescriptions written by the physician (or other recipient) that are dispensed or paid by the donor.[48]

The proposed exception and corresponding safe harbor also require the arrangement to: (1) be in writing; (2) be signed by the parties; (3) identify the items or services being provided and the value of those items or services; (4) cover all of the electronic prescribing items or services to be furnished by the entity; and (5) include a certification by the physician (or other recipient) that the items or services are not technically or functionally equivalent to items or services he or she already possesses or has obtained.[49]

Proposed Electronic Health Records Exceptions and Safe Harbors

In addition to the MMA-mandated e-prescribing exception and safe harbor, both CMS and OIG used their legal authority to propose separate protections for certain electronic health records software and training not covered by the MMA e-prescribing mandate.[50] These rules were proposed by OIG and CMS in recognition that information technology, particularly electronic health records, enhance quality of care and enable more cost-effective care while maintaining the levels of security and privacy consumers expect. CMS and OIG both recognize that full interoperability of electronic health records technology would help reduce some risks of fraud and abuse but that uniform standards and certification requirements for interoperability currently do not exist.

Thus, both OIG and CMS are proposing an incremental approach for protection in this area. Specifically, they are proposing to promulgate two separate exceptions/safe harbors related to electronic health records software and directly related training services that are necessary and used to receive, transmit, and maintain the electronic health records of the entity's or physician's patients. The first exception/safe harbor would apply to donations made before the Secretary's adoption of product certification criteria, including criteria for the interoperability, functionality, privacy and security of electronic health records technology ("certification criteria"). For purposes of these rulemakings, the exception and safe harbor are referred to as the "pre-interoperability" exception and safe harbor. The second exception and safe harbor would apply to donations made after certification criteria have been adopted and are referred to as the "post-interoperability" exception and safe harbor.[51]

Although CMS proposed specific exceptions in its rulemaking for both "pre-interoperability" and "post-interoperability,"[52] OIG notes that it does not currently have sufficient information to draft appropriate safe harbors. OIG is soliciting comments on the proposed scope and condition for electronic health records safe harbors and provides detailed commentary regarding features it is considering.[53]

Pre-Interoperability Exception and Safe Harbor

Covered Technology

The proposed Stark "pre-interoperability" exception provides protection only to electronic health records software; that is, software used solely for the transmission, receipt, or maintenance of patients' electronic health records.[54] To be protected, the software must have an electronic prescribing component that complies with the electronic prescription drug program standards under Medicare Part D at the time that the items and services are furnished.[55] Additionally, the exception will not protect the provision of other types of technology, including, for example, hardware, connectivity services, and billing or scheduling software. Although the proposed exception will protect necessary training services in connection with the software, the exception will not protect the furnishing of actual staff to physicians or their offices.[56] OIG commentary reflects that the agency is considering similar requirements for its "pre-interoperability safe harbor".[57]

Both CMS and OIG are soliciting comments on whether the electronic health records software should be required to include a computerized provider order entry ("CPOE") component.[58] Additionally, comments are being solicited by CMS and OIG to determine how to address special circumstances, such as rural area providers that may lack sufficient hardware or connectivity services to implement electronic health records systems.[59] Comments are also being solicited to determine how to define "electronic health records" for purposes of the exception and safe harbor.[60]

Under the proposed rulemakings, both OIG and CMS would only protect software and training services that are "necessary," and the term "necessary" will be interpreted consistent with the e-prescribing exception and safe harbor.[61] Further, as with e-prescribing, CMS is proposing a certification requirement to ensure that the provision of items and services are not functionally or technically equivalent to those already possessed by the physician.[62] OIG is considering a similar certification provision.[63]

Standards and Interoperability

Consistent with e-prescribing standards, CMS is proposing that neither donor entities nor their agents take any actions to disable or limit interoperability of any component of the electronic health records software or otherwise impose barriers on compatibility.[64] OIG is considering a similar requirement for its safe harbor. Both CMS and OIG are considering requiring protected software to comply with relevant Public Health Information Network preparedness standards and are soliciting comments on this issue.[65]

Permissible Donors and Recipients

The proposed "pre-interoperability" electronic health records Stark exception would protect the same categories of donors and physicians as the proposed e-prescribing exception discussed above. CMS believes that donors should be limited to hospitals, group practices, PDP sponsors, and MA organizations because they have a direct and primary patient care relationship and will therefore play a vital role in the health care delivery infrastructure. CMS further notes that these donors are also in a better position to promote widespread use of the technology.[66]

OIG commentary reflects that a "pre-interoperability" electronic records safe harbor would similarly protect the same category of donors and recipients as the proposed e-prescribing safe harbor.[67]

Value of Technology

As with the proposed e-prescribing exception and safe harbor, CMS and OIG are both considering limiting the aggregate value of the protected software and training services that a donor could provide to a recipient. The caps would also be directly related to any cap adopted in connection with e-prescribing. Several alternative methodologies are being considered by OIG and CMS in connection with a limiting cap. Specifically, approaches that are being considered include: (1) an aggregate dollar cap; (2) a cap that would be set at a percentage of the value of technology to the recipient (requiring a sharing of costs); or (3) a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the recipient. Comments are being solicited on these approaches.[68]

Other Conditions

To ensure that the "pre-interoperability" electronic health records exception and safe harbor do not pose a risk of fraud and abuse, certain other conditions are incorporated in the proposed rules, which are also consistent with the proposed provisions of the e-prescribing exception and safe harbor. Specifically, these include: (1) a restriction on conditioning business on the receipt of technology; (2) a restriction on the provision of items and services related to the volume or value of referrals; (3) a documentation requirement; and (4) a requirement that the donor not restrict or take any action to limit the recipient's right or ability to use the items or services for any patient.[69]

In addition, to further ensure that the arrangements do not pose a risk of fraud and abuse, CMS is proposing that the "pre-interoperability" electronic health records exception contain a requirement that the arrangement not violate the Anti-kickback Statute or any federal or state law or regulations governing billing or claims submission. This is consistent with other regulatory exceptions to the Stark law.[70]

Sunset Provision

CMS is proposing a provision in the "pre-interoperability" electronic health records exception that would sunset the "pre-interoperability" exception applicable to electronic health records software and training once the "post-interoperability" exception becomes effective.[71] OIG is considering a similar sunset provision for the "pre-interoperability" safe harbor.[72]

Post-Interoperability Exception and Safe Harbor

According to preamble commentary, the adoption of uniform interoperability standards for electronic health records, and the adoption of certification standards by the Secretary of DHHS to ensure that products meet such standards, will not vitiate (as parties could still offer or grant free technology in order to capture referrals), but may mitigate the risk of fraud and abuse associated with the provision of electronic health records software and training. Both CMS and OIG opine that it will be important for the protected software to be certified in accordance with product certification criteria adopted by the Secretary and that the electronic prescribing component of such software comply with electronic prescribing standards established by the Secretary under the Part D program. In this regard, once product certification criteria are adopted for interoperable electronic health records technology, both CMS and OIG intend to finalize the "post-interoperability" exception and safe harbor.[73] CMS anticipates that a process to identify product certification criteria, including uniform industry standards for interoperability, functionality, privacy and security, may be completed by next year.[74]

Many of the conditions that were proposed and considered in the proposals for the "pre-interoperability" exception and corresponding safe harbor are also being proposed and considered in the proposals for the "post-interoperability" exception and corresponding safe harbor. As such, the following portion of this article will highlight the differences between the "pre-interoperability" and "post-interoperability" proposals.

Covered Technology

CMS and OIG are both considering expanding the scope of covered software under the "post-interoperability" exception and safe harbor, potentially including other kinds of software, provided that core functions of the donated software are electronic prescribing and electronic health records. The intent is that electronic prescribing and electronic health records will be the core functions of the donated software, but CMS and OIG want to ensure that integrated packages that could have a positive impact on patient care are not excluded from protection.[75]

Permissible Donors

In addition to the categories protected under the e-prescribing and "pre-interoperability" proposed rules, with respect to "post-interoperability" both CMS and OIG are considering whether to expand protection to additional categories of donors and whether different or alternative conditions should apply to any category of donors. CMS and OIG are soliciting comments on these issues.[76]

Selection of Recipients

Because both CMS and OIG recognize that certified, interoperable systems would offer enhanced protection against some types of fraud and abuse, CMS and OIG are proposing to allow donors to use selective criteria for choosing recipients, so long as neither the eligibility of a recipient, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of the referrals or other business generated between the

parties.[77] OIG is considering enumerating several criteria that would be deemed not to be directly related to volume or value of referrals or other business generated between the parties.[78] Likewise, the Stark proposed exception enumerates several acceptable selection criteria, including a determination that is: (1) based on the total number of prescriptions written; (2) based on the size of the recipient's medical practice; (3) based on the total number of hours the recipient practices medicine; (4) based on the recipient's overall use of automated technology in his or her medical practice; (5) based on whether the physician is a member of the hospital's medical staff; or (6) made in any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties.[79]

CMS cautions that outside the context of electronic health records, and except as permitted in the special rules for productivity and profit shares distributed to group practice members (42 C.F.R. §411.352 (i)), direct and indirect correlations between the provision of good or services and the volume or value of referrals or other business between the parties are prohibited. OIG also cautions the public regarding its approach for selection criteria.[80]

Value of Technology

Both CMS and OIG are considering whether a larger cap on the value of donated software would be appropriate for the "post-interoperability" exception and corresponding safe harbor. In this regard, CMS and OIG will be considering issues similar to those discussed above with respect to a limiting cap on the provision of "pre-interoperability" protected technology.

Conclusion

Attorneys advising hospitals, health plans, physicians, pharmacies, pharmacists, and other prescribing professionals should carefully scrutinize OIG's and CMS's proposed rules and related preamble commentary. The areas of e-prescribing and electronic health records are ever evolving— both from a technological and from a legal perspective. Attorneys, health care providers and health plans should stay tuned for further developments affecting these areas, including future uniform standards and certification for electronic health records technology. Given the status of the proposals, it is anticipated that the two rules will be consistent to the extent practicable, given the differences in the underlying nature of the Anti-kickback Statute and Stark law. Attorneys, health care providers and health plans should also note CMS' final rule published November 1, 2005, which adopts the first set of final uniform standards for an electronic prescription drug program under the MMA.[81]

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Endnotes

1   42 U.S.C. Section 1395nn.

2   42 U.S.C. Section 1320a7b(b).

3   70 Fed. Reg. 59182 - 59198 and 70 Fed. Reg. 59015 - 59027

4   Section 1860D-4(e)(4)(A) of the Social Security Act.

5   Section 1860D-4(e)(6) of the Social Security Act.

6   70 Fed. Reg. at 59187-59191, and 70 Fed. Reg. at 59021-59024.

7   70 Fed. Reg. at 59183.

8   CMS summary chart at 70 Fed. Reg. at 59184 and OIG summary chart at 70 Fed. Reg. at 59017.

9   Section 1860D-4(e)(6). See also proposed 42 CFR Section 411.357(v) and proposed 42 CFR Section 1001.952(x). 70 Fed. Reg. at 59197 and 59026 respectively.

10   70 Fed. Reg. at 59184-59185 and 70 Fed Reg. at 59018.

11   70 Fed. Reg. at 59185 and 70 Fed. Reg. at 59018-59019.

12   Proposed 42 CFR Section 411.357(v)(7)(iv) and proposed 42 CFR Section 1001.952(x)(7)(iv), 70 Fed. Reg. at 59197 and 59026 respectively.

13   70 Fed. Reg. at 58185 and 70 Fed. Reg. at 59018.

14   Proposed 42 CFR Section 411.357(v)(8) and proposed 42 CFR Section 1001.952(x)(8), 70 Fed. Reg. at 59197 and 59026 respectively.

15   70 Fed. Reg. at 59185.

16   70 Fed. Reg. at 59018.

17   Proposed 42 CFR Section 411.357(v) and proposed 42 CFR Section 1001.952(x), 70 Fed. Reg. at 59197 and 59026 respectively.

18   70 Fed. Reg. at 59185 and 70 Fed. Reg. at 59018.

19   70 Fed. Reg. at 59185 and 70 Fed. Reg. at 59018-59019.

20   Section 1860D-4(e)(6)(A), (B), and (C) of the Social Security Act.

21   70 Fed. Reg. at 59185.

22 Proposed 42 CFR Section 411.357(v)(1)(i) and proposed 42 CFR Section 1001.952(x)(1)(i), 70 Fed. Reg. at 59197 and 59026 respectively.

23 70 Fed. Reg. at 59185 and 70 Fed. Reg. at 59019.

24 70 Fed. Reg. at 59019.

25 Proposed 42 CFR Section 411.357(v)(1)(ii), 70 Fed. Reg. at 59197.

26 Id.

27 42 CFR Section 411.351.

28 70 Fed. Reg. at 59186.

29 Proposed 42 CFR Section 1001.952(x)(1)(ii), 70 Fed. Reg. at 59026.

30 70 Fed. Reg. at 59019.

31 Proposed 42 CFR Section 411.357(v)(1)(iii), 70 Fed. Reg. at 59197.

32 42 CFR Section 411.355(c).

33 70 Fed. Reg. at 59186.

34 Proposed 42 CFR Section 1001.952(x)(1)(iii), 70 Fed. Reg. at 59026.

35 70 Fed. Reg. at 59019.

36 Proposed 42 CFR Section 411.357(v)(2) and proposed 42 CFR Section 1001.952(x)(2), 70 Fed. Reg. at 59197 and 59026 respectively.

37 70 Fed. Reg. 67568 – 67595.

38 70 Fed. Reg. at 59186.

39 70 Fed. Reg. at 59020.

40 70 Fed. Reg. at 59186 and 44 USC Section 3601(6).

41 Proposed 42 CFR Section 411.357(v)(3) and proposed 42 CFR Section 1001.952(x)(3), 70 Fed. Reg. at 59197 and 59026 respectively.

42 70 Fed. Reg. at 59186 and 70 Fed. Reg. at 59020.

43 70 Fed. Reg. at 59186.

44 70 Fed. Reg. at 59020.

45 Proposed 42 CFR Section 411.357(v)(4) and proposed 42 CFR Section 1001.952(x)(4).

46 Proposed 42 CFR Section 411.357(v)(5) and proposed 42 CFR Section 1001.952(x)(5).

47 Proposed 42 CFR Section 411.357(v)(6) and proposed 42 CFR Section 1001.952(x)(6).

48 70 Fed. Reg. at 59187 and 70 Fed. Reg. at 59021.

49 Proposed 42 CFR Section 411.357(v)(7) and proposed 42 CFR Section 1001.952(x)(7).

50 Proposed 42 CFR Sections 411.457(w) and (x), and 70 Fed. Reg. at 59021-59024.

51 70 Fed. Reg. at 59187 and 70 Fed. Reg. at 59021.

52 Proposed 42 CFR Section 411.357(w) and (x).

53 70 Fed. Reg. at 59021-59024.

54 Proposed 42 CFR Section 411.357(w).

55 Proposed 42 CFR Section 411.357(w)(9).

56 Proposed 42 CFR Section 411.357(w)(8).

57 70 Fed. Reg. at 59022.

58 70 Fed. Reg. at 59188 and 70 Fed. Reg. at 59022.

59 70 Fed. Reg. at 59188 and 70 Fed. Reg. at 59022.

60 70 Fed. Reg. at 59188 and 70 Fed. Reg. at 59022.

61 70 Fed. Reg. at 59188 and 70 Fed. Reg. at 59022.

62 Proposed 42 CFR Section 411.357(w)(5)(iv).

63 70 Fed. Reg. at 59022.

64 Proposed 42 CFR Section 411.357(w)(2).

65 70 Fed. Reg. at 59188 and 70 Fed. Reg. at 59022.

66 Proposed 42 CFR Section 411.357(w)(1)(i), (ii), and (iii), and 70 Fed. Reg. at 59189.

67 70 Fed. Reg. at 59023.

68 70 Fed. Reg. at 59189 and 70 Fed. Reg. at 59022.

69 Proposed 42 CFR Section 411.357(w)(3), (4), (5) and (7) and 70 Fed. Reg. at 59023.

70 Proposed 42 CFR Section 411.357(w)(10).

71 Proposed 42 CFR Section 411.357(w)(11).

72 70 Fed. Reg. at 59023.

73 70 Fed. Reg. at 59189-59190 and 70 Fed. Reg. at 59023.

74 70 Fed. Reg. at 59190.

75 70 Fed. Reg. at 59190 and 70 Fed. Reg. at 59023.

76 70 Fed. Reg. at 59190 and 70 Fed. Reg. at 59023.

77 70 Fed. Reg. at 59190 and 70 Fed. Reg. at 59023-59024.

78 70 Fed. Reg. at 59024.

79 Proposed 42 CFR Section 411.357 (x) (4) (i)-(vi).

80 70 Fed. Reg. at 59190 and 70 Fed. Reg. at 59024.

81 70 Fed. Reg. 67568 - 67595.

For additional information on e-prescribing, see "e-Prescribing: CMS and OIG Proposed Rules, Technology and Drafting Documents," December 2005, available in the ABA's webstore at www.abanet.org/abastore.