

December 12, 2005

Dr. Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Re: File Code CMS-1303-P; Medicare Program; Physicians' Referrals to Health Care Entities With Which They May Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Proposed Rule

Dear Dr. McClellan:

The National Association of Community Health Care Centers, Inc. ("NACHC"), on behalf of more than 1,000 Federally Qualified Health Centers ("FQHCs"), submits these comments on the proposed regulation by the Centers for Medicare & Medicaid Services ("CMS") to provide an exception to the Stark physician self-referral ("Stark") law for certain electronic prescribing ("e-Prescribing") and electronic health records ("EHR") arrangements. We appreciate the opportunity to comment on the proposed rule.

Electronic Prescribing Exception: § 411.357(v)

Protected Entities

CMS requested comment on whether it should use its own authority under section 1877(b)(4) of the Social Security Act ("the Act") to protect qualifying e-Prescribing technology provided to physicians by other DHS entities. The proposed rule protects donations made by a group practice to its physician members.

We agree with CMS that the provision of e-Prescribing technology by a group to its members does not necessarily require a new exception because other exceptions would apply to protect those arrangements (e.g., in-office ancillary services exception, employment exception, personal services exception, and non-monetary compensation exception).

To the extent that CMS concludes, however, that a new exception is required to protect donations made by a group practice to its physician members, we believe that, in certain circumstances, the existing regulatory definition of "group practice" may not encompass FQHCs.

We therefore urge CMS to expand the covered entities within the proposed exception so that it protects donations made by an FQHC (as defined at 42 C.F.R. § 405.2401(b)) to physicians who provide services to patients of the FQHC.

Definition of “Necessary”

CMS requested comment on its interpretation that the term “necessary” excludes items or services that are technically or functionally equivalent to items that the receiving physician already possesses or services that the physician has already obtained. We believe that interpretation is unduly restrictive, inconsistent with the purpose of the exception, and will not achieve its intent.

In our view, the purpose of the term “necessary” in section 1860D-4(e)(6) of the Medicare Modernization Act (“MMA”) was simply to ensure that the donated items and services are related to the transmission and receipt of electronic prescription information. Congress did not want e-Prescribing to be used as a “marketing platform or other mechanism to unduly influence the clinical decisions of physicians.” H.R. Conf. Rep. No. 108-391, at 456 (2003).

CMS has interpreted “necessary”, however, in a way that gives higher priority to the policy concerns of the Stark law than to the e-Prescribing exception explicitly directed by Congress under the MMA. Because of uncertainty in making the required technical comparisons, the proposed physician certification scheme proposed by CMS is likely to chill those donations altogether. This defeats the purpose of the e-Prescribing exception which is that it be rapidly adopted as a vehicle to reduce medical errors and to improve efficiencies in the health care system.

Although CMS recognizes that the donors of items and services will not necessarily know which items and services that the physician already possesses or has obtained, it also true that the physician recipient will not necessarily have the technical expertise to determine whether the items and services are technically or functionally equivalent to items or services that he or she already possesses or has already obtained. Because the physician will need to rely on the technical expertise of others, the certification scheme will become a mere formality.

We therefore urge CMS to broaden the definition of “necessary” to mean donated items and services that relate to the transmission and receipt of electronic prescription information.

Exceptions for Certain Arrangements involving Electronic Health Records Items and Services: § 411.357(w) and 411.357(x)

Covered Technology

In both exceptions, CMS proposes to protect only EHR software that is separate from and independent of related hardware, connectivity services, billing or scheduling software, or software that might be used by a physician to conduct personal business or business unrelated to the physician’s medical practice. We believe that definition is too limited in scope and will not be practical for many rural health care providers (such as FQHCs).

The interoperable health information infrastructure that CMS seeks to promote under these exceptions requires more than software. It also requires hardware and connectivity, such as T1 lines and broadband connectivity, transmission interfaces, and secure connections. As CMS acknowledges, rural providers are more likely to lack sufficient hardware or connectivity

services to implement effective EHR systems.

In addition, CMS requires that the covered technology be “used solely” for the transmission, receipt, or maintenance of patients’ EHRs. This would exclude technology that includes billing, computerized order entry (CPOE), or scheduling functions as well as decision-support tools such as a medical reference library and clinical practice protocols. Currently, some EHR systems on the market include these functions and tools and there will be a loss of potential efficiencies if the Stark exceptions force these functions to be carved out.

We therefore urge CMS to revise the definition of covered technology to include hardware, software, and connectivity services related to EHRs and not to require that the technology be used solely for the transmission, receipt, or maintenance of patients’ EHRs.

Permissible Donors

In these two exceptions for EHR arrangements, CMS proposes to protect the same categories of donors and physicians as the proposed exception for e-Prescribing items and services. For the reasons described above in our comments on proposed § 411.357(v), we believe these exceptions should be broadened to protect donations from FQHCs to physicians who provide services to patients of the FQHC.

Definition of “Necessary”

In these two exceptions for EHR arrangements, CMS proposes to apply the same definition of “necessary” in these exceptions as it uses in the exception for e-Prescribing items and services. For the reasons described above in our comments on proposed § 411.357(v), we urge CMS to revise the definition of “necessary” to mean donated items and services that relate to EHR technology.

Conclusion

Congress and the President have determined that the electronic transmission of both drug prescriptions and health records of all patients will enhance the quality of their health care. In furtherance of this goal, we submit the above recommendations to the proposed rule for e-Prescribing and EHRs.

Again, thank you for the opportunity to submit these comments. Please do not hesitate to contact us at (202) 296-0158 if you have any questions.

Sincerely,

Roger Schwartz
Legislative Counsel and Director of State Affairs
National Association of Community Health Centers