TEXAS HEALTH RESOURCES

611 Ryan Plaza Drive 14th Floor
Arlington, Texas 76011

December 12, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1303-P, Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

RE: Comments concerning proposed rules (File code CMS – 1303-P)

Ladies and gentlemen:

The following comments are submitted on behalf of Texas Health Resources, a Texas non-profit corporation that operates 13 hospitals and related facilities in the Dallas-Fort Worth area.

We are highly supportive of the intent of this regulation. We believe that additional flexibility would reduce unnecessary compliance burdens that this regulation places on regulated entities while accomplishing the intent of the underlying statutes and supporting the national policy in favor of increasing the use of electronic health records. In the remainder of this response, we propose specific ways we think flexibility could be enhanced.

In your request for comments you look particularly for comment on the potential value limit. Costs will vary considerably depending upon the type of physician practice, its geographic location, and the level of technology already in place. Given the challenges of maintaining the security of the networks across which electronic health record information will travel, the interfaces that will be required to provide interoperability, the nature of the information (text or image), and the quantity of information that must be exchanged, it is difficult to establish a methodology for fixing costs. A low, artificially imposed financial barrier may have an adverse impact on physicians whose offices are entirely paper-based. In our environment, we see substantial variations not just between large and small physician groups, but between urban and rural practices. So we do not believe that a single dollar limit can be imposed that would make sense in all settings.

We suggest that if CMS wishes to place a value limit on the dollar value of equipment, software, and training that can be donated by a hospital to a physician, that this limit serve as an alternative to compliance with the otherwise lengthy list of requirements in the regulation, rather than as an additional requirement. Then if hospitals want to donate equipment, software, and training in excess of the limit, they could be permitted to do so if they comply with a list of requirements such as provided in the proposed regulation.

Under the dollar value limit, if a hospital wishes to provide a physician with equipment, software, and training necessary to operate an electronic health record system, the hospital would only be required to maintain records establishing that the value of the hardware and software provided during the given year is less than a particular value. The additional requirement that the hospital make the equipment, software, and training available without reference to number or value of referrals should be sufficient to prevent abuse.

Pre-interoperability electronic health records exception: Section 411.357 (W).
Our comment is aimed at increasing the flexibility available to hospitals to provide hardware and software to physicians in order to facilitate an electronic health record system. We therefore object to the requirement that the donated software have an electronic prescribing component. While we would anticipate providing this, we do not see the necessity for this as serving the purpose of the Stark statute. Instead, we see this as advancing unrelated policy objective, to be enforced through a regulation that is supposed to be facilitating the conversion to the electronic health record, while discouraging payment for referrals. We believe that the restriction in favor of "electronic prescribing" should be removed in favor of a much broader requirement to provide "information relevant to the identification of the presenting patient and for the delivery of care." To the degree that any program promotes the communications of this information, it can improve the outcome for the care recipient, without unnecessarily jeopardizing the statutory objectives.

The post-interoperability electronic health records exception that recognizes that software "could include billing and scheduling software, provided that the core function of the software is electronic health records" should be added to the pre-interoperability phase. It is difficult to understand the logic for making this exception available later but not sooner.

Additionally, we would suggest in response to your inquiry that the electronic prescribing component, if it is provided, should be used to allow transmission of prescription information regarding other items such as supplies and laboratory tests. We do not see a justifiable basis to require these items to be submitted on paper (or on physician-purchased equipment), while other types of information can be submitted via donated electronic means.

We suggest that the prohibition on the provision on other types of technology including hardware connectivity services, billing, and scheduling software be eliminated, because frequently hardware and software is, if well designed, susceptible of multiple uses.

Starting on Page 59185, 411.357(v)(7)(iv)

There should not be a restriction to "require physicians to certify that the items and services provided are not technically or functionally equivalent to those that the physician already possesses or has already obtained." That definition is onerous and technologically unsound. Older and current personal computers and printers are technically and functionally equivalent, but there are few of us who can tolerate the slower speed machines. There is ample evidence that technically and functionally equivalent equipment cannot always run the same software. This requirement should be eliminated, as we think it creates an unnecessary compliance burden, with no substantial benefit in terms of the objectives of the Stark law.

"Sunset Provision". We do not believe that a sunset provision is appropriate or necessary. We think this is just an additional rule that will increase compliance burdens on regulated entities.

"2. Post -inter-operability electronic health records exception Section 411.357 (X)"

"B Standards with which donated technology must comply"

We agree that "in 411.357(x)(2) that the donated electronic record must be certified...." as we believe the necessity for creating a nationally consistent standard is worth the costs of doing so.

Summary

We thank CMS for this opportunity to provide comments regarding these proposed changes. We hope that CMS appreciates that our healthcare system is committed to creating processes and procedures that help ensure our continued compliance with the Stark law. The changes we are requesting in these comments are designed to create the most workable solution that will apply the intent of the Stark law while also giving hospitals – and ultimately, patients - the ability to fully realize the benefits of an electronic health record system, in an economical manner. We hope that CMS will use its regulatory authority to create a situation that gives hospitals a chance to comply with the statute in a manner that does not discourage movement toward an electronic health record system, or unduly divert hospital resources to another set of compliance requirements.

Fred Carroll
Senior Attorney

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Kenneth E. Raske, President

December
Twelve
2005

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Re: OIG-405-P: Safe Harbor for Certain Electronic Prescribing Arrangements under the Anti-Kickback Statute and CMS-1303-P: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements

Dear Mr. Levinson and Dr. McClellan:

The Greater New York Hospital Association (GNYHA) is pleased to submit the attached comments in response to the Office of Inspector General's (OIG's) proposed safe harbor under the Federal anti-kickback statute published at 70 Fed Reg 59015 on October 11, 2005 ("proposed safe harbor") and the Centers for Medicare & Medicaid Services' (CMS's) proposed exception to the physician self-referral prohibition or "Stark" law published at 70 Fed Reg 59182 on October 11, 2005 ("proposed exception"). We thank you for the opportunity to provide input on behalf of our members, more than 250 not-for-profit hospitals and continuing care facilities, both voluntary and public, in the New York City metropolitan area and throughout New York State, as well as in New Jersey, Connecticut, and Rhode Island.

We believe that the attached comments will enhance the proposed exception and safe harbor and, most importantly, clear the path towards widespread implementation of e-prescribing, EHR, and clinical data exchange technology. As a summary, GNYHA is advocating for the following thematic changes to the current proposals:

- The proposals should be more expansive, allowing contribution of a more comprehensive range of necessary items and services to a larger set of relevant providers. Restricting the covered technology to limited, specified items and services and allowing donation only to a limited group of physicians will not improve patient care, reduce costs appreciably, or spur diffusion of health information technology;

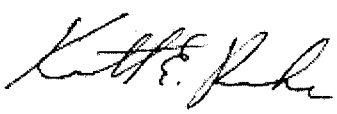
- The proposals should allow for more flexibility, bearing in mind that the ultimate goals of widespread e-prescribing and EHR, and meaningful connectivity can only be achieved by giving providers a wider berth in which to develop functional health care information systems that meet locally articulated needs. The current proposals still leave providers stymied and reluctant to explore the benefits of health care information technology; and

- The proposals should be mindful of the President's stated objective of widespread adoption of interoperable EHRs within 10 years and of HHS's designated underlying goal of interconnecting clinicians through clinical data exchanges. These objectives cannot be achieved under the current proposals, and we are doubtful that any proposed clinical data exchange exception will go far enough, given these proposals.

Please note that GNYHA is providing one set of comments to address both proposals, due to the similarity of the OIG's proposed safe harbor (and discussion of a future safe harbor) and CMS's proposed exception. Our suggestions and concerns are largely identical for each, though we clarify when our comments are directed towards only one of the proposals. We are submitting this letter and the attached comments to each of your offices.

Once again, GNYHA thanks you for the opportunity to comment on these significant proposals. Please do not hesitate to contact me if I can be of any assistance.

Sincerely,



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CMS-1303-P
OIG-405-P

Greater New York Hospital Association
Comments Regarding Proposed Safe Harbor and Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements

December 12, 2005

Greater New York Hospital Association (GNYHA) welcomes the opportunity to comment on the Department of Health and Human Service's (HHS's) proposed rules regarding certain electronic prescribing (e-prescribing) and electronic health records (EHR) arrangements. Specifically, we are writing in response to the Office of Inspector General's (OIG's) proposed safe harbor under the Federal anti-kickback statute published at 70 Fed Reg 59015 on October 11, 2005 ("proposed safe harbor") and the Centers for Medicare & Medicaid Services' (CMS's) proposed exception to the physician self-referral prohibition or "Stark" law published at 70 Fed Reg 59182 on October 11, 2005 ("proposed exception"). We are providing one set of comments to address both proposals.[1]

GNYHA is a trade association representing more than 250 not-for-profit hospitals and continuing care facilities, both voluntary and public, in the New York City metropolitan area and throughout New York State, as well as in New Jersey, Connecticut, and Rhode Island. GNYHA and its members work with and depend upon many of the over 46,000 patient care physicians in the Greater New York region, roughly 29,000 of whom work in New York City alone. Each of our members and their partner physicians stands to be affected by HHS's proposals.

Over the last five years, GNYHA has been active in assisting members on a variety of health information technology issues. Over the past 18 months, in particular, we have devoted considerable resources to advocating for and coordinating local and regional health information clinical data exchanges (also referred to as community-wide health information systems) on behalf of our members. We are therefore grateful to HHS for exploring issues related to e-prescribing and EHR, and we applaud the initial steps that have been taken in this area. However, we fear that the proposed rules are inadequate to facilitate significant adoption of e-

[1] For ease of understanding, we will refer to the proposed rules collectively as the "proposals" or "proposed rules" when discussing comments that refer to both proposed rules equally. We will clarify our statements appropriately when discussing only one of the two proposals and will identify the specific areas on which we are commenting throughout this document. GNYHA also notes that at times, the proposals seek comments on similar items repeatedly. In such an instance, GNYHA will provide comments at the first prompt and then reference additional applications. Finally, GNYHA has not elected to comment on every issue raised by the HHS in its proposals.

prescribing and EHR, and we applaud the initial steps that have been taken in this area. However, we fear that the proposed rules are inadequate to facilitate significant adoption of e-prescribing and EHR systems. Moreover, we regret that the proposals could be improved in terms of pre-planning for the widespread adoption of community-based clinical data exchanges.

The National Health Information Technology Agenda

GNYHA and its members are committed to achieving the health information technology goals set forth by President Bush and his Administration, namely the widespread adoption of interoperable EHRs within 10 years under the leadership of the Secretary of HHS and the National Coordinator for Health Information Technology, David J. Brailer, MD, PhD.

In their July 21, 2004, strategy plan, "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care, Framework for Strategic Action," Dr. Brailer and then-HHS Secretary Thompson lauded the notion of "a health care industry that is consumer centric and information-rich, in which medical information follows the consumer, and information tools guide medical decisions." They noted that to realize such a new vision, it would be necessary, among other steps, to bring EHRs directly into clinical practice and interconnect physicians through an interoperable infrastructure built on regional collaboratives.

These and similar actions, they argue, could address the problems closely connected to inadequate use of health information technology: high costs, medical errors, variable quality, administrative inefficiencies, and lack of coordination. However, they acknowledge several barriers to the widespread use of EHRs, including clinicians' reluctance to embrace EHR technology due to the expense and necessary disruption in workflow. Accordingly, they note, investment in EHRs must be shared, dividing the financial burden between physicians and others in the healthcare system. GNYHA agrees, particularly in light of the financial hurdles associated with developing health information technology systems: their costs are high, and financing is not readily available, given the nature of the assets involved (hardware/software) and the costs associated with their implementation (more soft costs). We believe that effective partnerships are critical to fund and implement successful information technology systems that will reduce both costs and medical errors, manage care, and improve access.

Accordingly, we at GNYHA are frustrated by the limited approach taken by the OIG and CMS proposals. These proposed rules could be an opportunity to allow physicians to share the financial and operational burden of e-prescribing, EHR, and clinical data exchange technology successfully, yet they instead impose unnecessary limitations on permissible partnerships. We would respectfully submit that the goals so artfully articulated by the Secretary and Dr. Brailer and so meaningfully referenced by the OIG and CMS in the discussion of the proposed regulations are not being well served by the proposals themselves. Moreover, we doubt the need for the stringent regulations proposed; it is not at all clear that, without them, there would be a heightened risk of program or patient abuse.

We are therefore contributing the following comments, which we believe will improve the final rules and, most importantly, clear the path towards widespread implementation of e-prescribing, EHR, and clinical data exchange technology. As a summary, GNYHA is advocating for the following thematic changes to the current proposals:

- The proposals should be more expansive, allowing contribution of a more comprehensive range of necessary items and services to a larger set of relevant providers. Restricting the covered technology to limited, specified items and services and allowing donation only to a limited group of physicians will not improve patient care, reduce costs appreciably, or spur diffusion of health information technology;

- The proposals should allow for more flexibility, bearing in mind that the ultimate goals of widespread e-prescribing and EHR and meaningful connectivity can only be achieved by giving providers a wider berth in which to develop functional health care information systems that meet locally articulated needs. The current proposals still leave providers stymied and reluctant to explore the benefits of health care information technology; and

- The proposals should be mindful of the President's stated objective of widespread adoption of interoperable EHRs within 10 years and of HHS's underlying goal of interconnecting clinicians through clinical data exchanges. These objectives cannot be achieved under the current proposals, and we are doubtful that any proposed clinical data exchange exception will go far enough, given these proposals.

A. ELECTRONIC PRESCRIBING EXCEPTION: §411.357(v), ELECTRONIC PRESCRIBING SAFE HARBOR

1. Protected Nonmonetary Remuneration

a. "Necessary" Non-Monetary Remuneration: Certification Requirement[2]

GNYHA opposes placing responsibility on a donor regarding whether a recipient already has technically or functionally equivalent items and services.

The current proposals seek to deter the donation of items and services to recipients who already possess them with a two-prong process: 1) requiring the recipients to certify that the donated goods are not technically or functionally equivalent to anything the recipients already possess; and 2) forbidding donors to provide such goods and services if they have actual knowledge of, or are acting in reckless disregard or deliberate ignorance of, the fact that the recipient possess such items.

GNYHA believes that donors should not have legal responsibility for any type of tallying of the items and services recipient physicians may or may not already possess. The current proposals will encourage finger pointing, impair hospital-physician relationships, add to the hospital's administrative costs of implementing e-prescribing, and dilute anti-fraud safeguards. Ultimately, they will also reduce hospital implementation of e-prescribing and related technology; facilities will be less likely to make an investment to provide physicians with the covered technology if they fear penalties for doing so. Overall, GNYHA worries that these disincentives are too strong, given the clinical and economic benefits of implementing e-prescribing and related technology. As an aside, we would also note that establishing a check on the physician's certification seems unnecessary, given the high level of trust that we place every day on doctor's pronouncements in terms of medical orders, prescriptions, and other life-or-death situations.

As an alternative, GNYHA recommends that hospitals incorporate inquiries regarding the technological items and services physicians possess into the surveys physicians must complete to

[2] These comments also apply to the potential certification requirement referenced in the OIG discussion of a proposed pre-interoperability safe harbor (70 Fed Reg 59022) and the CMS proposed pre-interoperability exception (70 Fed Reg 59188).

acquire and maintain staff privileges. Physicians who are found to have submitted false or incomplete responses to these questions could lose staff privileges or otherwise be sanctioned by the hospital. This clarifies the legal burden and lessens the administrative burden associated with certification. GNYHA feels this is a more productive, hands-on, and realistic way to involve hospitals in anti-fraud initiatives than the current proposals.

b. "Used Solely" Requirement

GNYHA supports the immediate creation of an additional safe harbor and exception that allow the donation of hardware and connectivity services that are used for more than one function.

Both the OIG and CMS indicate that they are considering the development of an additional safe harbor and exception to permit the donation of hardware (including necessary operating system software) and connectivity services that are used for multiple functions beyond e-prescribing. GNYHA believes that multi-functional devices and connectivity services are desirable for e-prescribing and additional transactions and thus we support the creation of such an expanded safe harbor and exception. We question, however, the need for delaying the creation of such additional rules and urge their inclusion in the existing proposals before final publication.

"Substantially Advances"

The OIG and CMS have indicated that the additional safe harbor and exception would require that a "substantial use" of the donated hardware and connectivity services be to receive or transmit electronic prescription information. They request comments on methodologies for quantifying or ensuring this substantial use. However, GNYHA questions the value of this approach. Stringently assigning a numerical value to the uses of the multi-function technology will not help promote their use or advance a larger health information technology agenda. We suggest that this requirement be reconfigured to address whether or not the donated technology "substantially advances" the goals of e-prescribing and additional health information technology functions instead.

GNYHA fears that the limitations set forth regarding the additional proposals make it unlikely that physicians will accept or hospitals will make available necessary technology for fear of penalty. The goal of these additional proposals – which we believe to be advancing the legitimate, fair use of e-prescribing and related technology – will not be realized if providers are too gun-shy or fearful of not meeting an arbitrarily imposed quota of "substantial use." GNYHA urges the OIG and CMS to focus on the true issue at hand, which is the need to "substantially advance" the adoption of the relevant technology. We believe that alone should be the litmus test for any multi-function hardware and software and, we would argue, for any of the items or services covered under these proposals. (GNYHA would seek the same modification to the OIG's and CMS's later discussion of and proposal to protect additional software applications provided that they have a "core function" of e-prescribing and EHR. We fear that the OIG and CMS are unnecessarily curtailing progress in these areas. See 70 Fed Reg 59023, 59190.)

GNYHA urges that multi-function technology be able to promote interoperability and data exchange.

Moreover, GNYHA believes that the donated technology – no matter how assessed – will be most efficient when it can support a range of functions beyond e-prescribing. In particular, we believe multi-functional devices and, as possible, single source connectivity should be permissible donations to foster EHR and clinical data exchange transactions, particularly as the

standards and certification requirements for such projects are fully developed. In permitting the donation of such items and services for functions beyond e-prescribing, HHS would be reducing incremental costs to donors and allowing physicians to work off one familiar system for a variety of functions. Such familiarity would breed repeated use and foster adoption. GNYHA respectfully urges HHS to seize this opportunity to broaden the existing proposals.

GNYHA discusses the unnecessary nature of any cap on the value of donated technology.[3] GNYHA does not believe that any cap is appropriate or necessary for the donation of any of the technology discussed in the proposals. Hospitals in general, and the nonprofit hospitals in the greater New York region in particular, are too financially strapped to be giving away useless, expensive technology. A natural cap of sorts will be imposed as hospitals determine how to make the most efficient, meaningful donations to physicians.

If caps must be created, however, GNYHA supports one formula for use throughout these comments: any cap to be implemented should be set as a percentage of the value of the donated technology to a certain threshold, with an increasingly lower percentage permitted after that threshold is met. In real terms, GNYHA recommends that a cap be set at 90% of the value of the donated technology until the donor hits a ceiling of some real dollar amount (which may vary based on regional differences in expenses) per recipient. After this ceiling is reached, the cap would be reduced to 80% of the value of the donated technology until a higher ceiling is reached, then 70% until a subsequent ceiling is reached, and so on. The recipient would be required to fund whatever portion of the project is not financed under the cap. The designated ceiling values would be revisited in time, to take into account the fluctuating expense of technology and other changes that may arise. In addition, there would be an exclusion for the cost of any technology that is not used in any way for advancing e-prescribing, EHR, or clinical data exchange functions. If caps must be created, GNYHA would recommend using the same formula throughout the regulations. We feel they better account for the inevitable changes in costs and the price differences hospitals around the country may encounter.

2. Donors and Recipients Protected by the Proposed Safe Harbor/ Designated Health Services (DHS) Entities Protected by the Exception[4]

GNYHA urges the addition of a clinical data exchange as a permissible donor and supports regulatory change to facilitate the development of clinical data exchange projects.
GNYHA strongly supports the addition of a clinical data exchange (or community-wide health information system) to the list of permissible donors under the proposed safe harbor and, to the extent possible, the proposed exception. Based on our research and experience, the successful development of a clinical data exchange may require the formation of a separate entity that coordinates the exchange among the multiple stakeholders. GNYHA urges HHS to permit such an entity – which could be a nonprofit corporation whose members are the stakeholder facilities – to be able to provide the covered items and technology to participating physicians.

This addition is necessary for several reasons. First, individual stakeholders in the projects, including hospitals, are unlikely to develop, purchase, or donate the items necessary to implement and maintain a true community-wide clinical data exchange. When one considers that

[3] These comments also apply to subsequent discussion of any potential caps. See 70 Fed Reg 59020, 59022, 59024, 59186, 59189, 59191.
[4] The comments throughout this section also apply broadly to discussion of protected donors and recipients for the discussion of and proposal for EHR exceptions and safe harbors. See 70 Fed Reg 59023, 59188, 59190.

the success of a data exchange relies on developing a network of providers, there is little appeal for individual providers to develop, purchase, or donate items. Such a unilateral endeavor would be expensive and burdensome.

The flip side of this problem is that individual physicians are equally unlikely to acquire the necessary goods and services independently. Again, this is an expensive proposition, and the currently underdeveloped legal and regulatory guidance in this area makes most physicians reluctant to participate in such a project without financial or in-kind assistance.

Third, it is unlikely that permitting the clinical data exchange entity to provide necessary items and services to participating physicians would induce any form of inappropriate referral or remuneration. To the contrary, in permitting this central entity – which may have competing hospitals as members – to make donations, HHS would be minimizing the likelihood of a closed relationship between a particular hospital and its physicians and reducing the risk of any problematic behavior that could be associated with such a limited relationship.

Finally, GNYHA believes HHS should be facilitating participation by those entities that are qualified and committed to improving patient care. Currently, no individual player in the patient-care industry has the financial means or regulatory safety necessary to single-handedly donate or acquire the goods and services required to create a clinical data exchange. Without government assistance to allow collaborative projects like a clinical data exchange to make the necessary donations, for-profit business entities will step into that void. Indeed, they already are; health insurance payers have begun to "pre-populate" the health care sector by donating technology and training to providers. From a policy perspective, it seems inappropriate to have only a profit-driven venture, be it a payer or private investment fund, set the agenda and requirements of a community-wide clinical data exchange. GNYHA believes that true community stakeholders should be establishing such projects for themselves, but we believe that they will need legal and regulatory assistance from HHS to do so productively. There must be a legal and safe mechanism for the relevant items – and this includes hardware, software, connectivity, training, and support services – to be provided by the central organization.

GNYHA appreciates the steps CMS has already taken in promulgating a Stark exception that addresses community-wide health information systems. However, we request that any proposed safe harbor not follow the template of the existing exception, which providers and commentators around the country have found to be unfortunately inadequate. Instead, GNYHA would recommend that, at the least, clinical data exchanges be added to the list of permissible donors for e-prescribing, EHR, and ultimately clinical data exchange items and technology. We believe this is the first necessary step towards fostering a true culture of information exchange in the nation's healthcare arena. We would also take this opportunity to respectfully request that CMS re-think the existing community-wide health information system exception to address its shortcomings.

GNYHA urges that the proposed safe harbor and exception be expanded to cover all medical staff physicians.

GNYHA opposes the OIG's and CMS's proposals to limit donations only to physicians who routinely furnish services at the hospital. If a hospital has extended privileges to a physician, the hospital should be permitted to donate necessary items and services to that physician as appropriate. In an era of hospitalists, it is not practical to exclude doctors who are not

routinely at the hospital from receiving necessary clinical information. This restriction would curtail the necessary flow of patient data significantly.

GNYHA supports expanding the list of approved recipients under the proposed safe harbor to include non-physician prescribing health care professionals.
GNYHA advocates expanding the list of recipients under the proposed safe harbor to include all health care professionals who can write and order prescriptions other than just physicians who treat patients in hospitals. Assuming such professionals abide by all necessary supervision requirements (established both by law and by hospital policy), we believe it would be efficient and sensible to include them in the safe harbor. As a general rule, GNYHA believes that if a professional is permitted to issue prescriptions, he or she should have access to e-prescribing technology within necessary supervision parameters. This will allow patients to receive all prescriptions more quickly, will promote use of the covered technology throughout a hospital staff, and will reduce any unnecessary two-step processes (prescribing professional to physician, physician to employ technology) that could foster delay, error, or cost. We note that such an expansion is desirable across the boards: if a non-physician professional has the ability to take any of the steps recorded in an EHR or transmitted through a clinical data exchange, he or she should have access to the necessary technology and training to do so.

3. Additional Conditions/Limitations on the Provision of Qualifying Electronic Prescribing Technology

a. Promoting Compatibility and Interoperability[5]

GNYHA supports expanding the proposals to cover donation of technology facilitating the transmission of prescription information regarding non-drug items and services.
Just as GNYHA supports expanding the safe harbor list of acceptable recipients for e-prescribing items and technology to include non-physician prescribing personnel, we believe both proposals should be expanded to cover donation of technology facilitating the transmission of prescription information regarding non-drug items and services such as diagnostic tests. The distinction between pharmaceuticals and non-drug items and services seems unnecessary: it would take little additional technology or training to facilitate the transaction relating to non-drug items and services; patients may require prescriptions for both pharmaceutical and non-drug items and services at the same time; the same professionals would be issuing both types of transactions; and the development of two different e-prescribing protocols at two different points of time would be inefficient to hospitals, physicians, and patients. Most importantly, the provision of additional patient information (including lab results, blood samples, etc.) and the ability to order necessary diagnostic tests immediately would increase patient safety and quality of care.

GNYHA supports the proposed definition of "interoperability" and encourages the use of standards and certification requirements to promote interoperability.
GNYHA supports the proposed definition of interoperability. In terms of ensuring the maximum level of interoperability, we believe that adoption of evolving standards and certification requirements is the most straightforward means of doing so. Such standards are the best tools available and, we expect, will have already contemplated the appropriate issues. GNYHA supports their use.

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[5] These comments also apply to similar issues raised in the discussion of possible EHR safe harbors and proposed EHR exceptions. See 70 Fed Reg 59022, 59023, 59188, 59190.

B. PROPOSED ELECTRONIC HEALTH RRECORDS SAFE HARBOR/ EXCEPTION FOR CERTAIN ARRANGEMENTS INVOLVING ELECTRONIC HEALTH RECORDS ITEMS AND SERVICES: §411.357(w) AND §411.357(x)

Note: GNYHA acknowledges that the OIG has not proposed regulatory safe harbor language regarding EHR. We strongly urge the OIG to do so swiftly. We are addressing our comments to the OIG's proposed scope and condition in this area, as well as to the proposed CMS exceptions.

1. Proposed Pre-Interoperability Safe Harbor/ Pre-Interoperability Exception

a. Covered Technology[6]

GNYHA proposes to include hardware, connectivity, and related items and services as covered technology.

The current EHR proposal limits permissible donation to software and directly-related or necessary training services, leaving donors unable to provide recipients with any hardware, connectivity, or other related items or services, including maintenance. GNYHA disagrees with this approach and encourages the OIG and CMS to include hardware, connectivity, and related items and services to the proposals relating to EHR.

GNYHA images that the OIG and CMS have restricted the EHR proposals to software and training because they are assuming that the necessary hardware, connectivity, and related items and services would have already been donated as necessary to implement e-prescribing systems. By this logic, it would make sense to keep those items off the table to avoid unnecessary redundancies that could facilitate fraud.

Practically speaking, however, providers will not be able to effectively employ the covered e-prescribing hardware, connectivity, training, or associated services for EHR purposes and will be required to acquire additional or enhanced hardware and related services when they are ready to convert to EHR. The reality for our members – and, we expect, a range of nonprofit hospitals throughout the northeast and nation – is that they cannot afford to donate the necessary e-prescribing and EHR goods and services at the same point in time. Not only would it be prohibitively expensive to do so, but also hospitals may be disinclined to take on such large operational projects at once.

For these and other reasons, the majority of hospitals will be required to wait a significant amount of time before they institute EHR if they are required to deploy e-prescribing first. (This is the sequence contemplated in the proposals, though it is not the sequence GNYHA would recommend, as discussed below.) It is thus likely that existing e-prescribing hardware will become obsolete or, at the least, incompatible with evolving EHR needs during the gap in time between feasible implementation of e-prescribing and feasible implementation of EHR. This means that additional donations of both hardware and software, as well as training and maintenance, will be necessary to implement EHR widely, particularly because participating physicians are unlikely to finance the new systems voluntarily.

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[6] These comments also apply to the issue of covered technology in the discussion of a possible post-interoperability EHR safe harbor and the proposed post-interoperability EHR exception. See 70 Fed Reg 59023, 59190.

GNYHA also notes that adding additional items to be covered by the proposals seems unlikely to foster fraud or abuse. Currently, software and training are more expensive and valuable to the would-be recipients than hardware or connectivity. These latter items are not special plums that would be likely to sway referrals.

GNYHA urges removal of e-prescribing requirement in EHR proposals.
We also take this opportunity to urge the OIG and CMS to remove the required nexus between e-prescribing and EHR for the donation of EHR technology. Though we understand the limitations imposed by the requirements of the MMA, we believe that patients would ultimately benefit if hospitals were permitted to first adopt EHR technology and then add in an e-prescription function as necessary and financially possible. In terms of patient safety and quality of care, it makes more sense for hospital staff to have access to all aspects of a patient's record – including, perhaps, those generated outside of the hospital itself – before issuing a prescription online. If EHRs were available to a prescribing physician, he or she could be informed on any drug interaction concerns, allergies, prior medical history, and the like, and the physician would be better able to prescribe any appropriate medication. By requiring the implementation of e-prescribing before or concurrent with the implementation of EHR, GNYHA fears that HHS may be working in the wrong order and missing a critical opportunity to promote patient safety.

GNYHA opposes the requirement that electronic health records software include a computerized provider order entry ("CPOE") component.
Though CPOE technology is potentially valuable, GNYHA cannot support its inclusion as a requirement of covered EHR software. There are two primary problems with such a proposed requirement. First, CPOE and e-prescribing functionalities can be quite similar, such that GNYHA fears that requiring CPOE technology is akin to demanding implementation of redundant technology. Next, GNYHA has observed implementation of both EHR and CPOE technology in a few of our member hospitals. Each is a major, multi-year undertaking requiring an enormous clinical transformation and monetary investment. We fear that mandating implementation of both systems at once would overwhelm already taxed hospitals and deter them from developing either.

GNYHA proposes a definition of "electronic health records."
GNYHA supports the following definition of "electronic health records": Electronically originated and/or maintained clinical health information, that may incorporate data derived from multiple sources and that replaces the paper record as the primary source of patient information." We believe the widespread adoption of this definition will help providers tailor their work in this area.

b. Sunset Provision
GNYHA addresses concerns relating to sunset provision and proposes adoption of clinical data exchanges as means of decreasing this concern.
GNYHA understands the OIG's and CMS's concern in this area and agrees that there could be unintended negative effects related to the pre-interoperability EHR exception and safe harbor. One way to counter that negative effect would be to take this opportunity to promote the development of community-wide clinical data exchanges. Fostering such exchanges decreases the possibility of closed or isolated systems both in terms of the specific legal protections afforded and in terms of identifying a desired policy goal; health providers would better understand HHS's overall health IT objectives and act accordingly, in a way that integrates the need for an ultimately open national system.

C. ADDITIONAL SOLICITATION OF PUBLIC COMMENTS: COMMUNITY-WIDE HEALTH INFORMATION SYSTEMS

The OIG has requested input on whether a safe harbor enabling participation in community-wide health information systems (or clinical data exchanges) is necessary and prudent. GNYHA strongly supports the creation of such a safe harbor and believes it is critical to the successful development of such projects. Clinical data exchanges perform a critically important function for patients' quality of care by making patient data available across institutional boundaries and at the point of care, where the data are needed most. Clinical data exchanges are also pro-competitive in that they bring together health care providers from across a community to enable better patient care.

Currently, however, would-be participants are somewhat paralyzed by the fear that they will be punished under the Stark and anti-kickback laws (among others) for taking part in these relatively novel projects. Despite progress in this area, there is still a paucity of legal guidance regarding community-wide health information systems, such that attorney cannot confidently inform their client that proposed actions will pass legal and regulatory muster, particularly when it comes to providing the technology and additional resources necessary to bring such a project to life.

Therefore, GNYHA would recommend the creation of a safe harbor and a revised exception that are compatible and include the following elements:

1. **As noted above, clinical data exchange entities should be approved as donors of necessary items and services to develop a clinical data exchange;**

2. **As necessary, a list of acceptable recipients should be flexible enough to allow for the rolling inclusion of healthcare entities within a community, such as hospitals, physician practice groups, pharmacies, home health agencies, long term care facilities, clinics, and patients, as such groups and individuals are brought into the data exchange;**

3. **There must be flexibility in the stakeholders that may be included at any point in time, particularly as the data exchange is being developed;**

4. **There should be specific definitions and adequate explanation of critical elements.**

Conclusion

GNYHA once again thanks the OIG and CMS for the opportunity to submit these comments and looks forward to their inclusion in the final rules.

22

American
Clinical Laboratory
Association

December 12, 2005

VIA Hand Delivery

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1303-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File code CMS-1303-P

Dear Sir or Madam:

Attached please find an original and two copies of the American Clinical Laboratory Association's comments on the Proposed Rule addressing Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements under the physician self-referral prohibition. 70 Fed. Reg. 59182 (Oct. 11, 2005).

If you have any questions, please do not hesitate to contact me.

Sincerely yours,

Alan Mertz /ED

Alan Mertz,
President

1250 H Street, N.W. • Suite 880 • Washington, DC 20005 • (202) 637-9466 Fax: (202) 637-2050

Comments of the American Clinical Laboratory Association on the Exceptions for Electronic Prescribing and Electronic Health Records

American Clinical Laboratory Association

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed rule issued October 11, 2005 regarding the exceptions for certain electronic prescribing ("e-prescribing") and electronic health record ("EHR") arrangements under the Stark physician self-referral law ("Proposed Rule").[1] ACLA is an association representing independent clinical laboratories throughout the United States including local, regional and national laboratories. Clinical laboratories perform millions of tests each year for physicians and other health care professionals, many of which are reimbursed by the Medicare program. Thus, ACLA members will be significantly affected by these proposed changes.

I. Introduction

For many years clinical laboratories have been the leaders in developing and implementing health information technology systems and connectivity. Laboratories have developed electronic systems and interfaces that connect most physician offices across the country. Other organizations that are now working to establish electronic health standards have solicited assistance from the lab community because its work in developing electronic lab test requisitions and results technology has laid the foundation for the efforts now underway.

Further, ACLA members devote conscientious effort and significant resources to ensure that their provision of electronic laboratory test requisition and result technology is in compliance with all applicable laws and regulations. Pursuant to a specific exception to the Stark physician self-referral prohibition, clinical laboratories are permitted to provide "items, devices, or supplies that are used solely to...collect, transport, process, or store specimens for the entity providing the item, device, or supply, or...order or communicate the results of tests or procedures for such entity."[2] This narrow exception permits laboratories to provide laboratory test requisitions and results to physicians in proprietary formats without charge, but still requires laboratories, like all other health care providers, to charge fair market value for any additional functionality. This separate exception specifically for clinical laboratories confirms that laboratory providers have an important role to play in the widespread implementation of health information technology systems.

Although our comments address the wide range of issues raised by the Proposed Rule, ACLA believes the key issue is whether entities other than those currently identified can be permissible Donors. If the categories of permissible Donors are not expanded, then the exceptions must be drafted narrowly to avoid favoring certain types of providers over others. To do so would bestow upon these providers an unwarranted competitive advantage in the marketplace, and would lead to physicians and other providers choosing services on the basis of

[1] 70 Fed. Reg. 59182 (Oct. 11, 2005).
[2] 42 U.S.C. § 1395nn(h)(1))(C).

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the donated technology that they would otherwise have to pay for, rather than based on the quality and timeliness of the Donor's services.

Although the proposed exception for e-prescribing is similar to the proposed exceptions for electronic health records, we address each of the exceptions separately below.

II. Electronic Prescribing Exception: § 411.357(v)

Laboratories have invested hundreds of millions of dollars in health information technology and already provide laboratory test requisition and results hardware, software, and connectivity services to physicians across the country. As required by federal fraud and abuse laws, these systems are strictly limited to laboratory functionality, although e-prescribing functionality can be provided if purchased by the Recipient at fair market value. While laboratory testing accounts for only three percent of health care spending (and two percent of Medicare expenditures), it is estimated that it has an impact on 70 percent of the medical decisions made in this country. Therefore, clinical laboratories will play a crucial role in any efforts aimed at achieving widespread adoption of e-prescribing and interoperable electronic health records technology.

A. *Donors and Recipients*

The Proposed Rule would define Donors as hospitals with respect to their medical staff, physician group practices with respect to their group members, and PDP sponsors/MA organizations with respect to pharmacists, pharmacies, and other prescribing health care professionals.[3] However, the list of Donors must be expanded to include clinical laboratories and other types of health care providers. Although permitting providers to donate technology outside their area is a departure from past guidance, if the goal of these efforts is widespread interoperability, then the list of permitted Donors must be expanded.

This is especially imperative if the agencies are going to expand the type of technology that could be donated (e.g., to permit Donors to include at no extra charge e-prescribing technology that is used to transmit prescription information regarding items that are not drugs, such as lab tests, or to include multi-functional technology). It is fundamentally unfair to permit the currently proposed Donors to provide other types of technology, but to restrict other health care providers from providing any technology that permits capabilities going beyond the performance of their business. This would create an extremely unlevel playing field, which is neither what Congress intended when it included the e-prescribing provision in the MMA, nor the direction that the Department of Health and Human Services ("HHS") should be moving with respect to e-prescribing and electronic health records.

If laboratories are not permitted Donors under the Proposed Rule, the likely result would be separate standalone systems in a Recipient's office for receiving and transmitting electronic prescription information and for other types of health information technology connectivity – such as software and hardware that laboratories provide to physicians for the sole purpose of obtaining laboratory test requisitions and transmitting laboratory results in that company's proprietary

[3] *See* Proposed 42 C.F.R. § 411.357(v)(1).

formats. Having differing systems for individual functions would serve as an impediment, rather than a catalyst, to increased technology adoption by physicians, who do not want multiple incompatible and non-interoperable systems in their offices.

In addition, laboratory results are definitively linked to e-prescribing information for pay-for-performance purposes, physician quality, HEDIS measures, and in other ways that improve quality of care and preserve limited health care resources. Permitting a single electronic system that offers both lab results and e-prescribing capability will act as an enabler for pay-for-performance and other quality measures. Furthermore, since laboratories already connect hundreds of thousands of physicians, including rural physicians, allowing laboratories to offer e-prescribing technology in accordance with this new exception will have only an incremental cost impact and will allow the physician to retain a system he/she already knows and uses.

Thus, if the Centers for Medicare and Medicaid Services ("CMS") intends to allow any providers to be Donors of e-prescribing items and services, we believe that laboratories (as well as other providers) should be protected as permissible Donors for e-prescribing items and services.

B. *Covered Technology*

The Proposed Rule would limit the scope of the exception to only those items and services that are "necessary and used solely to receive and transmit electronic prescription information."[4] CMS is soliciting comment on whether the exception should be expanded to protect qualifying e-prescribing technology that is used for the transmission of prescription information regarding items and services that are not drugs (e.g., laboratory tests or supplies), and/or whether the Proposed Rule should include an additional exception for multi-functional hardware or connectivity services.

1. Covered Technology Should be Limited if Donors are Restricted

If CMS decides to limit the exception to the currently proposed Donors (which are the donors identified by the statute), then CMS must limit the type of technology eligibie for donation to only e-prescribing technology used for drugs. All other functionality could only be offered if the Recipient pays fair market value for the items or services.

As discussed above, allowing the proposed Donors to provide e-prescribing technology used for the transmission of prescription information regarding items that are not drugs or creating an additional exception for multi-functional hardware would give these providers an unfair competitive advantage by allowing them to provide items and services with additional functionality for no charge. Today, laboratories provide laboratory test requisitions and results functionality without charge, but, for compliance reasons, charge fair market value for any additional functionality.[5] Therefore, to avoid unfair advantage caused by a waiver of the fraud and abuse laws for some but not all providers, hospitals, group practices, PDP sponsors and MA

[4] *See* Proposed 42 C.F.R. § 411.357(v).
[5] *See* 42 C.F.R. § 1395nn(h)(1))(C).

plans should be required to charge for other types of technology or multi-functional hardware and services at no less than fair market value.

It would be bad public policy to permit these entities to offer technology that can be used to order laboratory services while at the same time denying laboratories the right to offer e-prescribing items or services. If hospitals, group practices, PDP organizations and MA plans could give away both e-prescribing and laboratory results software at no charge, physicians would, by government policy, be placed in the untenable position of having to choose between continuing to pay fair market value to the laboratory provider for e-prescribing capability or dropping their existing laboratory test requisition software in return for free e-prescribing and laboratory software from their hospital, group practice, PDP organization or MA plan. Government policy might, in effect, induce some physicians to change service providers on the basis of the donated technology that they would otherwise have to pay for, rather than based on the quality and timeliness of the Donor's services.

2. Covered Technology Should Not be Limited if Donors are Not Restricted

However, if CMS chooses to expand the definition of Donor to include other types of health care providers, including clinical laboratories, then we believe permitting the donation of additional functionality would be appropriate because all providers would be treated equally and none would be unfairly advantaged. Hundreds of thousands of physicians are already using electronic laboratory requisition and results software. Permitting laboratories to add e-prescribing technology to that package will spur quicker adoption of health information technology than permitting the currently proposed Donors to offer laboratory software. Simply stated, the fastest possible adoption of e-prescribing will occur if laboratories are added to the list of Donors.

Allowing laboratories to offer e-prescribing software (and other functionality) will save physicians from having to make room for two separate systems in their offices – one for e-prescribing and one for laboratory test requisitions and results. Allowing laboratories to offer e-prescribing items and services will also give physicians the option to use the laboratory platform he/she is familiar with to access e-prescribing, which will speed adoption of the functionality. Furthermore, allowing laboratories to offer e-prescribing will let laboratory requisitions and results be integrated with drug orders and also give physicians access to all stored laboratory data.

Thus, ACLA recommends expanding the "necessary and used solely for" language and adopting an additional exception for multi-functional technology to take advantage of this opportunity to encourage interoperability.

3. The Exception Should Not Include a Technical or Functional Equivalence Requirement

In addition, CMS is proposing to limit the exception so as not to protect arrangements in which a Donor provides items or services that are technically or functionally equivalent to items

and services the Recipient currently possesses or has obtained.[6] The Donor could not "have actual knowledge of...or act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and services that were technically or functionally equivalent to those donated by the entity."[7] Many physicians already possess such items or services by paying laboratories or other vendors fair market value for this extra functionality. Thus, including this restriction as part of the exception would only serve to penalize physicians who have already expended the effort and resources to implement health information technology that improves patient care. These "early adopters" with preexisting software (whether obtained for free or at a cost) should be rewarded with the same opportunity to benefit from donation opportunities as other providers.

Physicians may switch from one technology to another for a variety of different reasons, including the ability to further improve patient care with a different health information technology item or service. Restricting the ability of providers to make changes only ties them to current vendors. Any concerns in this area can be addressed by: (1) expanding the list of permitted Donors of e-prescribing items and services to include laboratories, and (2) limiting the value of the technology to the Recipient, as discussed more fully below, instead of precluding donations to early adopters. Furthermore, ACLA believes the concept of technical or functional equivalence is problematic. First, there is no clear definition of what is "technically or functionally equivalent." This determination is very subjective, especially in light of rapidly changing technology, which will make it extremely difficult for Donors and Recipients to comply with this standard. In addition, even if there was a sufficient definition, health care providers do not have the resources to evaluate and document the technical or functional "equivalency" of existing hardware and software.

C. *Other Conditions*

The Proposed Rule includes a number of other conditions that must be satisfied before an entity could take advantage of the exception. We address several of these below.

1. Interoperability of Technology

The Proposed Rule notes that interoperability can serve as an important safeguard against fraud and abuse and mitigate the risk that a donation could be a means of maintaining or increasing referrals from a Recipient to a Donor.[8] To the extent that the hardware or software can be interoperable, the Proposed Rule would prohibit Donors from taking any actions to disable or limit that interoperability or otherwise impose barriers to compatibility.[9] CMS is soliciting comment on its approach to interoperability, including its proposed definition of "interoperable" as "the ability of different operating and software systems, applications, and networks to communicate and exchange data in an accurate, secure, effective, useful, and consistent manner."

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[6] Fed. Reg. at 59184-5.
[7] *See* Proposed 42 C.F.R. § 411.357(v)(8).
[8] Fed. Reg. at 59186.
[9] *See* Proposed 42 C.F.R. § 411.357(v)(3).

ACLA supports the Proposed Rule's approach to interoperability. However, we suggest that CMS consider adopting a slightly different definition of interoperability. The National Alliance for Health Information Technology ("NAHIT") has developed a definition of interoperability for use in policy and legal contexts, which is similar to the one being proposed by CMS, but which we think would be more useful in this context. NAHIT defines interoperability as "the ability of different information technology systems, software applications and networks to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged."[10] Since more than 50 major organizations have already endorsed this definition, and it provides a more comprehensive approach to defining interoperability, we recommend that CMS adopt this definition.

2. Volume or Value of Referrals

Another condition of the proposed exception relates to the selection of Recipients. The Proposed Rule states that neither the eligibility of a physician to receive items from a protected Donor, nor the amount or nature of the items received, could be determined in a way that takes into account the volume or value of the physician's referrals or other business generated between the parties.[11] This would not preclude selection criteria based upon the total number of prescriptions written by a physician, but would preclude criteria based upon the number or value of prescriptions written by the physician that are dispensed or paid by the Donor.[12]

If laboratories and other providers are permitted Donors, ACLA believes that as long as the items or services meet the rest of the conditions of the proposed exception, it should be permissible for Donors to select Recipients based on certain criteria that would allow the donated technology to be targeted to those who need and would use it most. This is the approach proposed for both the anti-kickback safe harbor and the Stark exception for post-interoperability electronic health records, both of which discuss specific criteria that could be taken into account when selecting Recipients.[13] Thus, we recommend that CMS revise proposed § 411.357(v)(6) to require that eligibility for, and the amount of, items and services is not "determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties." (emphasis added). Also, as in the post-interoperability electronic health records safe harbor and exception, certain criteria should be deemed not to directly take into account the volume or value of referrals or other business generated between the parties. These criteria would include the:

- total number of laboratory requisitions by the physician;
- size of the physician's medical practice (e.g., total patients, total patient encounters, or relative value units); and
- total number of hours that the physician practices medicine.

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[10] This definition was adapted from the IEEE definition of interoperability, and legal definitions used by the FCC (47 C.F.R. § 51.3), in statutes regarding copyright protection (17 U.S.C. § 1201), and e-government services (44 U.S.C. § 3601). *See* http://www.nahit.org.

[11] *See* Proposed 42 C.F.R. § 411.357(v)(6).

[12] Fed. Reg. at 59187.

[13] *See* 70 Fed Reg. 59015, 59023; *see also* Fed. Reg. at 59190.

Donors must be permitted to consider these criteria in selecting Recipients so that they can adequately cover the cost of donated equipment and connectivity. These same criteria would also permit a provider or supplier to remove e-prescribing items or stop providing services if the donee no longer met conditions of eligibility. Although this approach would be a departure from other exceptions, as pointed out in the Proposed Rule, it would help to promote adoption of health information technology while discouraging direct correlations with federal health care program referrals.

3. Cap on Value of Technology

According to the Proposed Rule, CMS believes that it is appropriate to limit the aggregate value of the qualifying e-prescribing technology that a Donor could provide, and is considering whether to limit the aggregate fair market value of all items provided to a Recipient from a single Donor.[14] The Proposed Rule states that a monetary limit is appropriate, but is soliciting comment on all aspects of the cap idea. ACLA does not believe that there is a consistent or appropriate way to determine fair market value or establish a monetary cap that would accommodate all situations. While a fixed cap is impractical due to the changing nature and cost of acquisition of technology, ACLA recommends that CMS limit the design or utility of the donated technology by requiring that it not have more than incidental value to the Recipient, beyond the function for which it is intended (i.e., e-prescribing).

4. Documentation Requirements

The Proposed Rule would require these arrangements to be set forth in a written agreement that:

- is signed by the parties;
- specifies the items and services to be furnished by the Donor to the Recipient;
- covers all of the e-prescribing items and services to be furnished; and
- contains a certification by the Recipient that the "items and services are not technically or functionally equivalent to items and services the Recipient already possesses or has obtained."[15]

As discussed above, ACLA disagrees with the underlying policy of restricting donations based on functional equivalence. However, even if this policy is included in the final exception, we do not believe certification for this particular requirement should be singled out to be mandated or required since it is no more important than any of the other requirements of the exception.

II. Electronic Health Records Exceptions: § 411.357(w) and § 411.357(x)

In addition to the exception for e-prescribing, CMS is also proposing exceptions to the self-referral prohibition to promote open, interconnected, interoperable electronic health records systems that help improve the quality of patient care and efficiency.[16] CMS is proposing to establish two separate EHR exceptions – one for the time before the Secretary has adopted

[14] Fed. Reg. at 59186.
[15] *See* Proposed 42 C.F.R. § 411.357(v)(7).
[16] Fed. Reg. at 59187.

product certification criteria, including criteria for interoperability, functionality, and privacy and security of EHR technology (the "pre-interoperability" exception), and one for after these standards have been established (the "post-interoperability" exception).

A. *Pre-Interoperability Electronic Health Records Exception: § 411.357(w)*

It is bad public policy to encourage pre-certification activities if the overarching goal of these efforts is interoperability. Allowing multiple, proprietary systems and services to flourish will slow the development and adoption of interoperable technology. The certification standards will eventually become the floor for standards in this area, and they are not far off in the future. In fact, the Certification Commission for Healthcare Information Technology ("CCHIT") has just published its proposed final criteria for certifying ambulatory electronic medical records systems.[17]

Thus, we recommend that the Proposed Rule either be amended to eliminate the pre-interoperability exception or incorporate a general concept of interoperability into the pre-interoperability exception, even if certification is not yet required. To do otherwise could lead to the proliferation and protection of proprietary standards (i.e., closed systems), which could ultimately slow the adoption of technology and impede the goal of widespread interoperability. ACLA recommends that this interoperability concept be based on accepted, consensus-driven standards that are already in place, such as the EHR-Lab Interoperability and Connectivity Standards ("ELINCS"), a national standard for the delivery of real-time laboratory results from a lab's information system to an electronic health record (and part of the CCHIT certification criteria). Other interoperability standards adopted by the federal government agencies as part of the Consolidated Health Informatics initiative could also be incorporated into the Proposed Rule, to the extent they have been widely accepted in the private sector.

1. Donors and Recipients

The Proposed Rule would define Donors as hospitals with respect to their medical staff, physician group practices with respect to their group members, and PDP sponsors/MA organizations with respect to pharmacists, pharmacies, and other prescribing health care professionals.[18] However, the list of Donors must be expanded to include clinical laboratories and other types of health care providers. Although permitting providers to donate technology outside their area is a departure from past guidance, if the goal of these efforts is widespread interoperability, then the list of permitted Donors must be expanded.

This is especially imperative if the agencies are going to expand the type of technology that could be donated (e.g., to include e-prescribing technology that is used to transmit prescription information regarding items that are not drugs, such as lab tests, or to include multi-functional technology). It is fundamentally unfair to permit the currently proposed Donors to provide other types of technology, but to restrict other health care providers from providing any technology, especially when it relates to the performance of their business (e.g., lab requisition and results software). This would create an extremely unlevel playing field, which is not the

[17] *See* http://www.cchit.org/final_criteria.htm.
[18] *See* Proposed 42 C.F.R. § 411.357(w)(1).

direction in which HHS should be moving with respect to e-prescribing and electronic health records.

The argument for inclusion of clinical laboratories as permitted Donors is even stronger with respect to the proposed EHR exceptions than for the proposed e-prescribing exception. Laboratory test results constitute the majority of a patient's medical record; therefore, clinical laboratories have a more direct relationship to EHRs than any other provider group. Further, there is no reason to omit clinical laboratories from the list of permitted Donors of EHR technology merely because Congress omitted them from its list of Donors of e-prescribing technology; due to differences in their functionality, different considerations arise with respect to each type of technology, and Congress has not yet expressed its intent regarding an exception for EHRs.[19]

If laboratories are not permitted Donors under the Proposed Rule, the likely result would be separate standalone systems in a physician's office for receiving and transmitting EHR and electronic prescription information and for other types of health information technology connectivity – such as software and hardware that laboratories provide to physicians for the sole purpose of obtaining laboratory test requisitions and transmitting laboratory results in that company's proprietary formats. Having differing systems for individual functions would serve as an impediment, rather than a catalyst, to increased technology adoption by physicians, who do not want multiple incompatible and non-interoperable systems in their offices.

In addition, laboratory results are definitively linked to e-prescribing information for pay-for-performance purposes, physician quality, HEDIS measures, and in other ways. Permitting a single electronic system that offers EHR, lab results, and e-prescribing capability will act as an enabler for pay-for-performance and other quality measures. Furthermore, since laboratories already connect hundreds of thousands of physicians, including rural physicians, allowing laboratories to offer EHR and e-prescribing technology in accordance with this new exception will have only an incremental cost impact and will allow the physician to retain a system he/she already knows and uses.

Thus, laboratories (as well as other providers) should be protected as permissible Donors for EHR technology. If some providers are permitted Donors under the new exception, then all health care providers should be permitted Donors provided their additional extra-functional applications meet appropriate standards applicable to the module or component of the technology at the time of the donation and they are interoperable. If some providers are permitted to be Donors under the Proposed Rules, we strongly believe that it is necessary to allow additional Donors, including laboratories, to provide technology that provides additional functionality to avoid upsetting existing business and clinical relationships, and to encourage the faster adoption of this technology by leveraging already-existing electronic and connectivity solutions.

[19] We note that in the many different versions of health care information technology legislation pending before and/or passed by the House and Senate, laboratories are included as covered providers.

2. Covered Technology

The Proposed Rule would protect EHR software "necessary and used solely to receive, transmit, and maintain electronic health records" and directly related training services, so long as the software included an e-prescribing component.[20] CMS is soliciting comment on whether the exception should be expanded to protect qualifying e-prescribing technology (as a required component of the EHR) that is used for the transmission of prescription information regarding items and services that are not drugs (e.g., laboratory tests or supplies).[21]

a. Covered Technology Should be Limited if Donors are Restricted

If CMS does not expand the list of Donors, then hospitals, group practices, PDP sponsors and MA plans should only be permitted to provide software that is "necessary and used solely to receive, transmit, and maintain electronic health records." Similarly, if laboratories and other providers are not permitted to donate e-prescribing items and services, then the proposed exception should not permit hospitals, group practices, PDP sponsors and MA plans to offer items that are not drugs – such as supplies or lab tests – without charging fair market value for the added functionality. As discussed above, it would be bad public policy to permit hospitals, group practices, PDP sponsors and MA plans to offer lab items and services while at the same time denying other providers, such as laboratories, the right to offer e-prescribing items or services.

b. Covered Technology Should Not be Limited if Donors are Not Restricted

However, as discussed above, if CMS chooses to expand the definition of Donor to include other types of health care providers, including clinical laboratories, then we believe permitting the donation of additional functionality would be appropriate because all providers would be treated equally and none would be unfairly advantaged. Hundreds of thousands of physicians are already using electronic laboratory requisitions and results software. Permitting laboratories and other providers to offer other HIT software in addition to that used to receive, transmit, and maintain EHRs (e.g., laboratory requisitions and results software and e-prescribing software) will speed adoption of technology and encourage interoperability.

Not including laboratories as permitted Donors will lead to separate systems in a physician's office for receiving, transmitting and maintaining EHRs and other existing types of connectivity – such as software and hardware that laboratories provide to physicians for the sole purpose of obtaining laboratory test requisitions and transmitting laboratory results in that company's proprietary formats. Having differing systems for individual functions will impede adoption of technology by physicians, who do not want multiple incompatible and non-interoperable systems in their offices. Further efforts should take advantage of and look to build upon this existing technology, which so many physicians and hospitals are already using, and not make them suddenly obsolete.

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[20] *See* Proposed 42 C.F.R. § 411.357(w).
[21] Fed. Reg. at 59188.

In summary, if laboratories are not permitted Donors, then for purposes of an exception only, we do not believe laboratory test requisition and result functionality should be necessary software or a core function of an EHR. However, if laboratories are permitted Donors, we believe it would be acceptable to include such functionality as a core function. Any other approach would put one type of provider – clinical laboratories – at a competitive disadvantage to permitted Donors.

c. The Exception Should Permit CPOE

In addition, CMS is soliciting comment on whether the exception should require the EHR software to include a computerized provider order entry ("CPOE") component.[22] However, it is unclear what CMS means by "CPOE." In this context, we understand CPOE to mean a sophisticated order entry application integrated with other systems including pharmacy and lab – and including sophisticated decision support capabilities.

Without further clarification of this concept, it is difficult to provide substantive comments. ACLA would be concerned if the exception required a particular type of CPOE, since there are many different varieties. However, we believe it should be permissible to include CPOE as part of the EHR software.

d. The Exception Should Include a Definition of EHR

ACLA also recommends that CMS develop or adopt a definition of "electronic health record" to ensure that Donors and Recipients understand the parameters of the proposed exception. We believe that the definition should include any component or module of an EHR that is interoperable. Software and hardware items that are modular and interoperable should be deemed permitted technology for the EHR exception.

e. The Exception Should be Limited to EHR Technology

Finally, the proposed exception would not protect the provision of other types of technology, including any billing, scheduling, or other similar general office management or administrative software services, or software that might be used by a Recipient to conduct personal business or business unrelated to the Recipient's medical practice.[23] ACLA is opposed to permitting donations of technology beyond what is necessary and used solely to receive, transmit, and maintain EHRs, even after interoperability is achieved. Permitting such donations would create too broad an exception, and therefore would invite providers to engage in prohibited conduct.

3. Interoperability

CMS is requesting comments on whether it should require that protected software comply with relevant Public Health Information Network preparedness standards, such as those related

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[22] Id.
[23] Id.

to BioSense.[24] ACLA believes that this is an important step, but notes that there is still no standardization of public health reporting at the state and federal level. There are over 3,000 public health agencies in the U.S. and the content and format of mandated reporting to the state health agencies is different from state to state. In addition, disease metrics that are reportable to the Centers for Disease Control and Prevention are currently designed for routine disease surveillance, which is currently a function that is completely separate from the capabilities of BioSense. We believe that more developmental work must be done before compliance can be mandated. Until more standardization is achieved, the exception should not require that software comply with these preparedness standards.

4. Value of the Protected Technology

The Proposed Rule would limit the aggregate value of the protected software and training services that a Donor could provide to a Recipient. CMS is soliciting comments on how a cap might work in this context.[25] As discussed above, ACLA does not believe that there is a consistent or appropriate way to determine fair market value or establish a monetary cap that would accommodate all situations. Donors and Recipients should have the flexibility to choose the extent of technology based upon their individual circumstances, although there must be limits such as those that would be imposed by the "necessary and used solely for" language. Furthermore, while a fixed cap is impractical due to the changing nature and cost of acquisition of technology, CMS could limit the design or utility of the donated technology by requiring that it not have more than incidental value to the Recipient, beyond the function for which it is intended (i.e., EHR or e-prescribing).

In addition, many physicians already possess items or services used for e-prescribing by paying laboratories or other vendors fair market value for the extra e-prescribing capability. These "early adopters" would be penalized under the current proposed exception because they already possess the items or services that the permitted Donors would be offering for no charge and thus could not make the certification that the items and services are not technically or functionally equivalent to items and services the Recipient already possesses or has obtained. To avoid penalizing these physicians, laboratories should be permitted Donors of EHR and e-prescribing items and services and should be permitted to offer the e-prescribing component without charge.

5. Other Conditions

As with e-prescribing, the Proposed Rule for EHRs would require that neither the eligibility of a physician to receive items from a protected Donor, nor the amount or nature of the items received, could be determined in a way that takes into account the volume or value of the physician's referrals or other business generated between the parties.[26]

If laboratories and other providers are permitted Donors, ACLA believes that as long as the items or services meet the rest of the conditions of the proposed exception, it should be

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[24] Id.
[25] Fed. Reg. at 59189.
[26] *See* Proposed 42 C.F.R. § 411.357(w)(4).

permissible for Donors to select Recipients based on certain criteria that would allow the donated technology to be targeted to those who need and would use it most. This is the approach proposed for both the anti-kickback safe harbor and the Stark exception for post-interoperability EHRs, both of which discuss specific criteria that could be taken into account when selecting Recipients.[27] Thus, we recommend that CMS revise this standard to require that eligibility for and the amount of items and services is not "determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties." (emphasis added). Also, as in the post-interoperability EHR safe harbor and exception, certain criteria should be deemed not to directly take into account the volume or value of referrals or other business generated between the parties. These criteria would include the:

- total number of laboratory requisitions by the physicians;
- size of the physician's medical practice (e.g., total patients, total patient encounters, or relative value units); and
- total number of hours that the physician practices medicine.

Donors must be permitted to consider these criteria in selecting Recipients so that they can adequately cover the cost of donated equipment and connectivity. These same criteria would also permit a provider or supplier to remove EHR items or stop providing services if the donee no longer met conditions of eligibility. Although this approach would be a departure from other exceptions, as pointed out in the Proposed Rule, it would help to promote adoption of health information technology while discouraging direct correlations with federal health care program referrals.

In addition, the Proposed Rule would require these arrangements to be set forth in a written agreement that:

- is signed by the parties;
- specifies the items and services to be furnished by the Donor to the Recipient;
- covers all of the EHR items and services to be furnished; and
- contains a certification by the Recipient that the "items and services are not technically or functionally equivalent to items and services the Recipient already possesses or has obtained."[28]

As discussed above, ACLA disagrees with the underlying policy of restricting donations based on functional equivalence. However, even if this policy is included in the final exception, we do not believe certification for this particular requirement should be singled out to be mandated or required since it is no more important than any of the other requirements of the exception.

6. Sunset Provision

CMS is considering whether to sunset the pre-interoperability exception once the post-interoperability exception becomes effective. The Proposed Rule solicits comments discussing whether the pre-interoperability exception could have the unintended effect of impeding the

[27] *See* 70 Fed Reg. 59015, 59023; *see also* Fed. Reg. at 59190.
[28] *See* Proposed 42 C.F.R. § 411.357(w)(5).

adoption of interoperable EHRs by promoting closed or isolated systems that effectively tie physicians to particular providers or suppliers.[29]

ACLA shares the concern raised by CMS that a pre-interoperability exception for extra-functional health information technology items or services could lead to closed or isolated systems or systems that tie physicians to particular providers or suppliers. However, if the system were truly interoperable and did not contain restrictions, public policy should encourage the adoption of this technology, if possible. Many providers are aware that standards are coming and can be expected to choose systems that will be able to communicate on an interoperable basis. Alternatively, they may choose suppliers who will commit to adapt the systems when standards become final.

CMS should encourage outside or self-certification of the various components of full-blown EHRs – such as laboratory requisition and results subsystems – to encourage the spread of interoperable, rather than closed or isolated, systems. Until standards are adopted and implemented, there is a danger that Donors will continue to promote systems that are not intended to be interoperable and will serve as barriers to interoperability in the future.

B. *Post-Interoperability Electronic Health Records Exception: § 411.357(x)*

As discussed above, ACLA recommends that CMS expand the categories of permitted Donors to include clinical laboratories. In addition, the Proposed Rule suggests that Donors should have more latitude in making donations once interoperability and certification standards have been established.[30] ACLA is concerned that even after these standards are in place, Donors will still compete for business based on the additional items and services they can provide to physicians, rather than the quality of the health care services they provide. This type of situation is highly susceptible to abuse, and from a practical perspective, ACLA is concerned that prospective donees could make the donation of technology a condition of doing business with a Donor. Thus, ACLA recommends that CMS limit the technology that can be donated in the post-interoperability period to items and services that do not have more than incidental value to the Recipient, beyond the function for which they are intended.

IV. Conclusion

ACLA appreciates the opportunity to comment on the Proposed Rule. We look forward to working with CMS to finalize and implement the proposed exceptions. Please do not hesitate to contact us should you have any questions about these comments or need any further information.

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[29] Fed. Reg. at 59188.
[30] Fed. Reg. at 59190.

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

David B. Snow, Jr.
Chairman, President & CEO
Medco Health Solutions, Inc.

Mark Merritt
President & CEO

December 12, 2005

DEC 12 2005

The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: File code CMS-1303-P

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the proposed rule to create exceptions for certain electronic prescribing and electronic health records arrangements, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

PCMA commends the Centers for Medicare & Medicaid Services (CMS) for recognizing that electronic prescribing provides the promise of improved patient safety, reduced health costs, and increased quality and efficiency of care for all Medicare beneficiaries.

PBMs have pioneered the most sophisticated e-prescribing infrastructure and other health-information management tools to help employers, health insurers, and others improve outcomes, promote safety, and reduce costs. Using these innovative approaches to e-prescribing PBMs will continue to push e-prescribing to its full potential. By expanding a 21st century technological infrastructure to the prescribing process, PBMs are putting critical information at the fingertips of physicians and helping make medical errors due to poorly written paper prescriptions a thing of the past.

Overall comments

PCMA is supportive of the goals to create incentives for physicians to utilize e-prescribing, including the donation of equipment and services to physicians. Congressional intent is clear that the goal is to provide an avenue where stakeholders could donate necessary equipment to physicians to perform e-prescribing without fear of violating anti-kickback statutes or Stark self referral. The rules for donating equipment need to be straightforward, clear, and practical in the business world where donors and physicians operate. CMS and OIG should be cognizant of these goals when issuing a final set of safe harbors and exceptions.

While the proposed rules make important steps in providing legal safeguards for donating equipment, we believe the limited scope of the safe harbor and self referral exceptions require CMS and the OIG to use additional authority that is not constrained by Section 1860D-4(e)(6) of the Social Security Act (SSA) to issue a separate, broader safe harbor and self referral exception.

Such a new issuance would create a favorable environment that attracts the largest number of donors and ensures physicians are not tasked with administrative processes that create barriers to accepting the equipment.

In addition, it is equally important that the two NPRMs are flexible in their interpretation of the governing statutes to ensure that any perceived risk of abuse is balanced with a functioning set of safe harbors and exceptions that is free from unnecessary administrative barriers to allow for congressional intent to be fulfilled.

PCMA's comments will combine remarks on the two proposed rules- "Medicare Program; Physicians' Referrals to Health Care Entities With Which They have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements" and "Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute."

The areas of focus for comment are the following:

- **Recommendation for issuing a new safe harbor and self referral exception.** This recommendation expands what covered technologies would qualify for an additional safe harbor and self referral exception--beyond the proposed e-prescribing safe harbor and exception--using existing statutory authority.

- **Require that donated equipment include e-prescribing, but should not need to be "used solely" for e-prescribing nor a "substantial use" of the equipment be used for e-prescribing.** These are limiting factors in the proposed rules that will dissuade both donors and physicians from giving and receiving equipment.

- **Establishing an appropriate balance between the potential for fraudulent "abuse" and the need to donate and receive equipment.** Such a balance requires eliminating unnecessary burden on donors and physicians to justify giving and receiving equipment.

- **Expanding the types of entities that can qualify as donors as well as ensuring high volume prescribers can receive donated equipment.** Any organization interested in promoting adoption of Health IT should be allowed to donate equipment. High volume prescribers are exactly the groups that will accrue the most efficiencies and savings from donated e-prescribing.

Recommendation for issuing a new safe harbor and self referral exception (CMS Preamble II.A.1.b, p. 59185; OIG Preamble II.A.1, p. 59019).

CMS and OIG have stated interest in establishing an additional safe harbor and exception for multi-functional hardware or connectivity services under the authority established by sections 1128B(b)(3)(e) and 1877(b)(4) of the SSA. PCMA is in favor of such an additional safe harbor and exception and recommends it be broad enough to cover practice management functionalities

such as, but not limited to: billing, scheduling, administrative functions, etc. As stated in the proposed rules, donors are likely to donate equipment that is multifunctional and manages their entire practice as opposed to just a single aspect such as e-prescribing. This would be more efficient than the fragmented approach described in the proposed rules.

CMS and OIG have also stated they are considering how to apply the "substantial use" criteria for a new safe harbor and exception. PCMA believes such criteria are unnecessary and not supported by existing statutory authority under sections 1877(b)(4) and 1128B(b)(3)(e) of the SSA.

Section 1860D-4(e)(6) established that the safe harbor and exception covers equipment and technology that is "necessary and used solely" for e-prescribing. Both proposed rules describe the "used solely" framework to cover donated technology if "substantial use" of this technology is for e-prescribing (See specific comments about "substantial use" below). Since CMS and OIG would utilize existing statutory authority --and not authority under sec. 1860D-4(e)(6)-- for this additional exception, it does not follow that the technology would need to be "substantially used" for e-prescribing.

PCMA recommendation: CMS and OIG should establish an additional new safe harbor and self referral exception under existing statutory authority. This will ensure inclusion of equipment that consists of physician practice management functions, without requiring that "substantial use" of the equipment be for e-prescribing.

Require that donated equipment include e-prescribing, but should not need to be "used solely" for e-prescribing nor a "substantial use" of the equipment be used for e-prescribing (CMS Sec. 411.357(v), Preamble II.A.1.b., p. 59185; OIG 1001.952(x), Preamble II.A.1., p. 59017).

The proposed rules establish a narrow interpretation of the statutory term "used solely." While we do support that equipment must have the capability to do e-prescribing, or be "necessary" for e-prescribing, we do not believe the "used solely" criteria is required to ensure the necessary safeguards. As the proposed rules state, physicians tend to "prefer to use multifunctional devices" that include various practice management functions including billing, practice management functions, etc.

Since a majority of the e-prescribing equipment comes bundled with other IT technologies, such as those mentioned above, the safe harbor and self referral exceptions would only cover a portion of the costs.

The proposed rule states that other uses are permitted for some of the technology, assuming "substantial use" of the equipment is for e-prescribing. While this appears to create some flexibility in the use of the donated technology, it is unclear how a determination of "substantial use" would be made by either the donor or the physician. Creating such a burden of proof raises a legal barrier that neither physician practices nor donors are likely to pursue.

PCMA recommendation:
1) Require that e-prescribing be included as part of the donated equipment, but that equipment need not be "used solely" for, or that a "substantial use" of the equipment is for, e-prescribing.

2) Practice management functionality must be allowed as part of donated equipment. Clearly the proposed rules go beyond the authorizing legislation on numerous occasions by citing the authority under sections 1877(b)(4) and 1128B(b)(3)(e) of the SSA. This same authority should be used to ensure more flexibility, not less.

Establishing an appropriate balance between the potential for "abuse" and the need to donate and receive equipment (CMS Preamble II.A.1.a, p. 59185; OIG Preamble II.A.1, p. 59018).

CMS and OIG consistently state throughout the proposed rules that they are concerned about "minimizing the potential for abuse" to the point of believing that physicians may actually sell older equipment they currently possess in order to shift costs to a donor entity who may be providing new equipment for free. In order to achieve the goal of more donors utilizing Health IT equipment as well as increasing the number of recipients of Health IT equipment, including e-prescribing technologies, it is important that CMS and OIG develop safe harbors and self referral exceptions with a balanced and reasonable perspective of "risk of abuse".

It is also important to note that with some donors of e-prescribing equipment, in particular health plans and PBMs, there is no risk of abuse since the nature of the relationship between this group of donors and a physician would not entail opportunity for a kickback or self-referral. In fact, both of these types of donors have incentives to limit utilization of service, which is counter to the fears of kickbacks and self referrals.

Functional equivalence (CMS Sec. 411.357(v)(7(iv), OIG Sec. 1001.952(x)(7)(iv)).

As part of receiving e-prescribing technology, a physician must provide a "certification" that it does not have items that are technically or functionally equivalent to the items being donated. It is unreasonable to assume physicians will be able to evaluate all of their current IT capabilities to determine the verification that this proposed section requires.

The NPRM already provides ample protections against any abuse within the proposed rule, specifically at sections 411.357(v)(6) and 1001.952(x)(6). In addition, such verification is inconsistent with other existing safe harbors or self referral exceptions.

PCMA recommendation:
Delete 411.357(v)(7)(iv) and 1001.952(x)(7)(iv).

Expanding the types of entities that can qualify as donors as well as ensuring high volume prescribers can receive donated equipment

Eligible entities for donating covered equipment (CMS Sec. 411.357(v)(1); OIG Sec. 1001.952(x)(1)).

The list of eligible entities that can donate equipment within the statute includes PDPs, MAPDPs, hospitals, and group practices. With reasonable safeguards in place throughout the proposed rules, we believe this list should be expanded to include any entity that has an interest in donating health care technology. Such an expansion would ensure the maximum number of entities can donate equipment and therefore increasing the number of physicians that have the equipment. It is of particular importance that those involved with the prescribing and claims administration process, such as PBMs and pharmacies, be allowed to donate equipment. These entities are at the forefront of developing the IT systems to support e-prescribing, and are engaged with physicians on a direct level to increase the utilization of e-prescribing.

PCMA recommendation:
Expand the definition to include any entity that may benefit from the efficiencies of donating equipment.

Choosing recipients-Ability to donate equipment to high volume prescribers (CMS Preamble II.A.3.b., p. 59187; OIG Preamble II.A.3., p. 59021).

Donors should be allowed to take into account the volume, and/or cost of prescriptions written for their populations, since donors will want the benefits of e-prescribing (i.e. fewer errors, greater efficiency) to accrue to their patient populations. By providing e-prescribing technology, donors can provide physicians with the entire formulary and cost structure of the plan while they are choosing the drugs to prescribe their patients. Those practitioners that prescribe high cost branded medications would have real time awareness of all the options under the plan including cheaper preferred brand drugs or generic alternatives. The benefits of having all this information at the point of prescribing would go directly to the patient in the form of lower out of pocket spending.

In addition, donors must be able to justify their expenditures for the equipment to show a tangible benefit (unless they are charities.) For some donors, such as health plans, there is no kickback or self referral value associated with donating equipment to a high volume prescriber.

PCMA recommendation:
Donors can consider the volume and value of prescriptions written by physicians, particularly to a donor's patient/plan population.

Additional Comments

Dollar limit or cap on the value of donated equipment (CMS Preamble II.A.3.b., p. 59186; OIG Preamble II.A.3., p. 59020).

We believe that consideration of a cap on the value of donated equipment would be arbitrary and unnecessary given the lack of incentive for most parties to induce referrals. The fact that technology must be "necessary" for e-prescribing, must be interoperable, and must allow prescriptions to be sent to any appropriate pharmacy provides sufficient safeguards. Any cap, particularly as potential donors and recipients are becoming aware of the new safe harbors and exceptions, would simply limit donor's ability to provide optimal technology, which would discourage their participation.

PCMA recommendation:
No cap or limits on the value of donated equipment.

In conclusion, I look forward to working closely with CMS and OIG on this important set of issues to create necessary incentives for stakeholders to increase the use of e-prescribing.

Sincerely,

Mark Merritt

24

CALIFORNIA
HOSPITAL
ASSOCIATION

Providing Leadership in Health Policy and Advocacy

December 9, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

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

Dear Dr. McClellan:

The California Hospital Association (CHA), on behalf of its nearly 500 member hospitals, health systems and ancillary providers, appreciates the opportunity to comment on the proposed rule outlining an exception to the physician self-referral regulations, or "Stark law." These regulations, together with the anti-kickback regulations, pose a significant barrier to hospitals and physicians working together to realize the promise of health information technology (IT) to improve the coordination and quality of patient care.

The proposed rule seeks to give hospitals more flexibility with protections from prosecution under the Stark law when they provide physicians on their medical staffs with certain IT items and services under three scenarios:

- Provision of resources for e-prescribing;
- Provision of electronic health records (EHR) software and directly related training in advance of national standards for interoperability; and
- Provision of EHR software and directly related training after national standards for interoperability have been adopted and incorporated into a certification process.

The proposed rule defines the protected arrangements, including those between hospitals and members of their medical staff who routinely furnish services at the hospital. Conditions include limitations on the covered technology, a requirement that the donated items are not "technically or functionally equivalent" to items the recipient already has, and documentation requirements. The exception also states that the donor must not consider the volume or value of referral or other business generated between the physician and the donor, and must comply with the anti-kickback statute.

CHA appreciates the initial steps taken by the Centers for Medicare & Medicaid Services (CMS) in setting out these proposed rules. However, we urge CMS to broaden the scope

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of these exceptions. Under the proposed rule, hospitals still will risk penalties and will not feel confident enough to work with physicians to help them build their IT capacity and expand the exchange of health information for clinical care.

Our comments first address larger issues, such as the policy goals, the separation of pre- and post-interoperability periods, the need for a parallel anti-kickback safe harbor, and the Health and Human Services (HHS) Secretary's breadth of authority to propose an exception; and then turn to specific aspects of the proposed regulations.

Policy Goals

The President has set forth a bold goal of electronic health records for all Americans by 2014. However, many physicians are wary of IT investment because of its costs and risks, and because their staffs lack experience. Some hospitals' IT systems are more advanced than those of the physicians practicing in their community. These hospitals also have greater access to capital for financing the considerable costs. Recent estimates put the overall price tag at $156 billion for health IT. They also tend to have larger IT staff, and could lend that expertise to help physician offices adopt EHR.

While the use of EHR within hospitals and physician offices promises to improve quality of patient care, even greater benefits can be obtained by sharing information across health care providers so that, for example, emergency department staff have access to medical histories, and primary-care physicians can know what medications were given during an inpatient stay. As noted in the proposed rule, greater sharing of information has many benefits, including improved continuity of care, decreased need for repeat tests, and safer, higher quality care. It also would improve hospitals' ability to report on quality. Hospitals in California are actively pursuing quality improvements, and need the flexibility to use the tools that will improve quality and safety. This includes working with physicians to implement and connect IT systems.

Not all hospitals are in a position to help physicians adopt EHR, but those that are must be given the flexibility to do so. The Stark law imposes severe penalties on hospitals and physicians that violate it, and the fear of violating the law is inhibiting progress in IT adoption. Stark prevents physicians from referring Medicare and Medicaid patients to organizations in which they have a financial interest; this includes inpatient and outpatient care. It is a "strict liability" statute and no element of intent is required for prosecution. Violators also are subject to significant civil money penalties if they knew or should have known that their referrals were prohibited. Stark law violations also may be pursued as violations of the federal False Claims Act.

Providing an exception to the Stark rules for e-prescribing and EHR will accelerate physician use of health IT. Patients will benefit from wider IT use and better integration of hospital and physician information systems, resulting in improved coordination of care, reduced medical errors and reduced repeat tests. The President and others in the Administration have noted the urgency for progress in this area.

While acknowledging the important policy goals articulated by the President and others in the Administration, the proposed rule still considers IT hardware, software and services donation to be a potential vehicle for fraud and abuse. However, the kinds of relationships hospitals form with physicians for IT are different from relationships that would lend themselves to traditional fraud and abuse, where physicians would receive financial benefit each time they referred a patient to, for example, a laboratory in which they had a financial stake. Furthermore, the original Stark legislation also was motivated by a desire to decrease unnecessary and duplicative testing and services. An integrated EHR that allows hospitals and physicians to share test results and other clinical information should further that goal. Thus, a Stark exception that would encourage and facilitate physician adoption and use of EHRs brings about significant benefits for patients, while posing minimal, if any, risk of fraud and abuse. Failure to provide a workable Stark exception risks losing an important opportunity to increase physician use of EHRs and clinical information exchange, which would improve quality of care for all patients.

Pre- and Post-Interoperability Periods

The proposed rule outlines two distinct EHR exceptions — one in the pre-interoperability period and one post-interoperability. The demarcation between these periods would be the adoption of certification criteria by the HHS Secretary. The exception would be slightly broader in the post-interoperability period.

The proposed rule discusses the progress the Certification Commission on Health Information Technology (CCHIT) has made toward developing a model certification process under a grant from the Office of the National Coordinator. Nevertheless, a certification process does not yet exist, and many questions remain. The level of interoperability that currently can be certified is limited, given the current lack of agreement on standards. The operational questions of how products will be certified have not been answered, nor have questions about how widespread certification will be, what it will cost and when it will be achieved. CCHIT has made considerable progress on developing a model process, but adoption of criteria and a certification mechanism by the HHS Secretary may take considerable time.

While hospitals share the goal of achieving interoperability, tying the broader Stark exception to a certification process that does not yet exist will not provide the clarity or flexibility needed for hospitals to feel comfortable. This approach also goes against the policy purpose of spurring adoption today and the need for urgent action. Allowing for more rapid dissemination of EHR to physician offices, though, could increase the demand for interoperability. As physicians get assistance in implementation and discover usefulness, they will also push for interoperability.

Given the uncertainty surrounding certification, CHA urges CMS to adopt a single exception. If concerns remain, CMS and the Office of Inspector General (OIG) could announce their intent to revisit the exception at a later date with a view toward requiring interoperability standards once they have been agreed upon. This would allow the standards to be developed, tested and implemented, and give CMS and OIG the opportunity to review the arrangements that have been

made in the interim. It also would also put vendors on notice that progress toward interoperability is essential. This single exception would need to broaden the scope of covered technology and address other specific concerns noted in the comments below.

Breadth of Regulatory Authority

CMS has used general authority under section 1877(b)(4) of the Social Security Act to propose the EHR-related Stark exceptions. This section specifically exempts from the Stark law's prohibition on certain physician referrals "any other financial relationship that the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." This section, therefore, clearly anticipates the Secretary's determination that a broad array of financial relationships do not risk the kind of abuses the Stark law was designed to deter, and gives the Secretary wide latitude to identify and describe them through regulation. CHA is concerned that CMS has not exercised fully this broad congressional mandate and has proposed EHR-related Stark exceptions that are unnecessarily restrictive, especially in the "pre-interoperable" phase.

CMS indicates that its proposed exceptions are concerned with the risk of program abuse "that *may* be posed" [emphasis added] by the provision of valuable technology to physicians, pointing out that the provision of electronic health records technology poses a greater risk of abuse because it is "inherently more valuable to physicians in terms of actual costs, avoided overhead, and administrative expenses of an office practice." CMS, however, does not specifically identify any negative impacts resulting from the provision of EHR technology. Rather, CMS describes a significant number of benefits to patient care and quality anticipated from the adoption and use of such technology, including allowing patient information to move with consumers from one point of care to another, permitting clinician access to critical health information as treatment decisions are being made, and reducing medical errors. As CMS acknowledges, these benefits are consistent with national priorities for improving the health care system and CMS' own goals in exploring pay-for-performance options. CHA urges CMS to discard the narrow view used in constructing the proposed EHR-related Stark exceptions, and offer a broad exception consistent with the mandate of section 1877(b)(4). As CMS explains in the preamble to the proposed exceptions, it can continue to evaluate the risks posed by the donation of EHR technology to physicians, and refine or add appropriate safeguards to the exception as the ongoing evaluation necessitates.

E-Prescribing Exception

The proposed rule provides an exception for stand-alone e-prescribing systems. While CHA understands that the Medicare Modernization Act (MMA) of 2003 directed CMS to develop an exception specifically for e-prescribing, CHA believes our hospitals are not likely to take advantage of it because it is too narrow. Hospitals and physicians need to exchange clinical information across the spectrum of care, including ambulatory, inpatient, post-acute and long-term care. For the greatest impact on quality and patient safety, e-prescribing should be an integrated piece of the full EHR, so that patients' diagnoses, allergies and treatments are accessible and known when prescriptions are made. In addition to being too narrow, we would like to point out that the proposed rules

provide an exception for stand-alone e-prescribing systems that are generally not found in the market.

Pre-Interoperability EHR Exception
CHA has concerns with several elements of the proposed regulations contained in the pre-interoperability section. Some, such as those pertaining to defining the terms "necessary" and "used solely," will apply to all three of the proposed exceptions.

Defining Necessary
MMA limited the exception to "necessary" items or services, but CHA believes CMS has defined "necessary" too narrowly. Expressing concerns about increased risks of recipients intentionally divesting themselves of technology items or services they already have, CMS states explicitly that the exception would not cover the provision of items or services that are "technically or functionally equivalent" to those the recipient currently poses or has obtained. CMS, however, indicates that it does not interpret "necessary" to preclude upgrades that significantly enhance the functionality of the item or service. CMS offers no further guidance on the meaning of "technically or functionally equivalent" or what is meant by "significantly enhance the functionality" of the item or service. Rather, the recipient would be required to "certify" that items and services to be donated are not equivalent. Additionally, the donor must not have actual knowledge of, and act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained such equivalent items or services.

Recipients are unlikely to possess the sophisticated level of understanding of capabilities and functionalities of available technology items and services that this standard seems to require. The burden and expense of making such determinations, therefore, are likely to fall primarily on hospitals and others that are donating the technology items and services. Without clearer guidance on the terms used in the regulation and precisely how to make equivalency determinations, hospitals will not have confidence in the proposed exception. For example, if a physician already has a handheld device that would be sufficient to run the requisite EHR software, but would require extensive and costly modifications to enable it to communicate with the hospital's existing information system, would it be characterized as "technically or functionally equivalent?" CMS should offer guidance that enables any physician to make the required equivalency determination without needing to engage expensive technical and legal consultation services. In addition, CMS should facilitate sharing technical information about equivalency across donors and recipients so that they can take advantage of existing information and avoid duplicative efforts.

Covered Technology
The proposed rule narrowly defines the covered technology as EHR software that does not include administrative functions, but does include e-prescribing modules that conform to Medicare Part D standards just published. Directly related training is the only permitted support under the proposed rule.

CHA is concerned with the narrow definition of covered technology. The products on the market increasingly integrate administrative functions with the clinical EHR. From the physicians' point of view, greater efficiencies and clinical benefits will be gained when these functions work together seamlessly. Many situations require merging administrative and clinical data: clinical data must be accessed to support automatic prescription refill authority; clinical data must be aggregated for quality reporting; bills are derived from the clinical record; etc.

Furthermore, while software and directly related training clearly are important to physician adoption of EHR, they are not sufficient. Physicians may not have the technical knowledge or resources to procure, implement and manage all of the necessary items. In addition, as hospitals expand their IT systems, they must incorporate communication and data transfer capability to physician offices into their IT infrastructures. In a wired health care system, physician access to hospital IT systems and communication between hospitals and physicians will be as necessary to providing high-quality care as use of an operating room and recovery suite. Hospitals will need to maintain this IT infrastructure, and protect its security and integrity. For these reasons, hospitals may want to provide other kinds of support to physicians to ensure that implementations are successful and information can be exchanged safely, such as:

- T1 lines or other enhanced broadband connectivity, including those needed to support transfer of medical images and EKGs, particularly in rural areas. This may include related software and hardware, such as routers to speed download times.
- Secure connections and messaging. Without ensuring that physician office systems have adequate security protocols and secure messaging, hospitals could put their own IT systems at risk when they connect.
- Ongoing maintenance and support. If physician office systems are not upgraded and maintained in the same manner as hospital systems, the ability to share clinical data to improve care will not be sustained.
- Interfaces. If a physician office already has an EHR that is not easily interoperable with the hospital system, the hospital may wish to provide the programming and software needed to interface the two systems. This kind of support clearly promotes interoperability, but is not allowed under the proposed exception.

Given the nature of technology, many of these items are multifunctional. For example, physicians could use the connectivity that allows them to exchange data with the hospital to also access general Internet sites. However, it is not practical, and does not promote interoperability, if physician offices must use a connection only to exchange data with a given hospital. CHA urges CMS to define multifunctional connectivity, including related software and hardware, as covered technology. Incremental approaches may be possible, where the technology necessary for connectivity is covered, while any costs associated with additional uses are borne by the physician.

While existing fair market value exceptions, which allow hospitals to sell IT items and services to physicians at the prevailing market rate, could be used for these kinds of arrangements, it is difficult, burdensome and costly for hospitals to make these calculations, particularly when the costs incurred by the hospital often are lower than the market costs due to economies of scale. Lack of technical knowledge and resources may limit physicians' willingness to pursue fair market value arrangements. Difficulties in determining fair market value have prevented hospitals from establishing arrangements with physicians in the absence of a specific IT exception. Given the severity of the penalties, clear guidance is needed.

Standards

CHA urges CMS not to require that permitted support conform to the BioSense (Public Health Information Preparedness) standards. These standards have not been discussed or adopted industry-wide. More research is needed on their appropriateness for the private sector and readiness for implementation. In addition, requiring compliance with these standards, while the broader standardization and certification efforts are underway, could prove counterproductive.

Permissible Donors and Selection of Recipients

Permissible donors are those in the protected arrangement between a hospital and physicians who are members of the medical staff and routinely furnish services at the hospital. However, the growth of hospitalists and intensivists means that many physicians are admitting patients to the hospital, but not furnishing services in the hospital. In these cases, the need for clinical information exchange is even greater, since the hospital-based physician in charge of the patient will not have the same knowledge as the admitting physician. Similarly, many physicians refer patients to hospitals for outpatient care, and would benefit from having electronic access to test results that they can incorporate into their own EHRs. Therefore, CHA urges CMS to change the criteria to physicians on the medical staff whose patients frequently receive inpatient and outpatient care at the hospital.

While allowing hospitals to donate covered technology to members of the medical staff, the proposed rule states that IT cannot be used to entice physicians away from other hospitals. While CHA understands the pro-competitive intent of this restriction, it puts hospitals in a difficult position. Will offering covered technology to all members of the medical staff, including new members, be construed as an attempt to entice physicians away from other hospitals? If so, how can they ensure all physicians are connected? CHA urges CMS to delete this provision and to allow hospitals to work with new members of their medical staff, without being seen as trying to entice physicians from other hospitals.

The proposed rule states that physician-selection criteria may be allowed in the post-interoperability period. We infer from the lack of reference to selection criteria in the pre-interoperability period that this would not be allowed. However, as a practical matter, if they are to help physicians adopt EHR, hospitals will need to choose which

physicians they work with at the beginning of the exception, and how they roll out their donations.

CHA urges CMS to allow selection criteria and protect specific criteria that make operational sense, even if they could be construed as related to volume and value of referrals, as long as those criteria are linked to achieving greater improvements in quality of patient care or greater likelihood of success in increasing physician adoption of IT. The kinds of criteria that hospitals might want to use, and that would need protection, include:

- Participation in hospital quality-improvement activities.
- Participation in medical staff meetings and activities.
- Specialty (the need to exchange data is often greatest for internal medicine or general practice).
- Department (IT systems are often rolled out by department).
- Readiness to use health IT.
- Consistent use of hospital-based IT systems, such as order-entry functions.
- Acting as a physician champion of hospital-based IT systems.
- Willingness to serve as a trainer for other physicians.
- Size of medical practice (it can be more efficient and effective to work with larger practices, which are often more ready to adopt IT).
- Willingness to contribute some resources to the IT project.

CHA is concerned about how CMS and OIG will determine whether or not IT donations are related to volume or value of referrals, as enforcement is not discussed in the proposed rule. We anticipate that the act of increasing information exchange between hospitals and physicians will lead to greater quality of care in the hospital. Consequently, physicians may increase their use of hospitals that provide this better quality of care, and this can only be viewed as a positive outcome for the patient and payers. However, an ex-post-examination of admitting patterns could conclude that the donation was related to volume or value of referrals.

Cap on Value

CMS suggests that it would be "appropriate to limit the aggregate value" of the technology a donor could provide to a recipient under the exception, believing that such a limit would minimize the potential for fraud and abuse. CHA believes that current imposition of any cap on the value of donated technology is, at best, premature and may unnecessarily and inappropriately inhibit widespread adoption. Hospitals' available financial resources necessarily will limit their ability to donate technology and related services to physicians, and we are unlikely to see an explosion of hospital purchases of expensive and unnecessary technology as a result of the creation of an EHR-related Stark exception. Hospitals' choices to extend technology to their physicians are likely to be dictated by careful consideration of specific needs in light of clearly defined goals and objectives for the sharing of clinical information and improvements in quality of care. In an initial period where the goal is to encourage greater technology adoption, the

appropriate level for a cap on the value on any donations to specific physicians can be determined accurately only by considering needs and understanding associated benefits and costs of the use of specific technology.

As the adoption of technology becomes more widespread, CMS can monitor these developments and reconsider the appropriateness of imposing a cap on value, based on a better and more sophisticated understanding of technology costs, and the impact on improved information exchange and enhanced quality of patient care. The imposition of a cap must give careful consideration to the complexity of how value is determined, if the requirement is to avoid unnecessarily burdening donors with the need to obtain costly valuation consultation services and analyses. If CMS' review suggests the need to impose a cap at some later time, CHA urges the agency to put the cap at hospitals' actual costs rather than fair market value to the recipient. Hospitals likely will receive significant discounts due to volume purchases and other economies of scale, and have a better understanding of their own costs. They would require costly and time-consuming outside valuation services and analyses to determine fair market to the recipients.

Other Conditions
CHA applauds CMS for including the condition that physicians cannot make receipt of technology a condition of doing business with a hospital. Not all hospitals are in a position to assist physicians in adopting EHR, and they should not be coerced into doing so.

The proposed rule also requires that covered arrangements not violate the anti-kickback law. Given this condition, the impact of any exception to the Stark regulations on physician use of IT will be minimal if there is not a parallel safe harbor to the anti-kickback regulations. While the anti-kickback statute requires intent of wrongdoing, and is therefore more difficult to violate, the severity of the criminal penalties limit hospitals' willingness to act without specific guidance. CHA is also submitting comments to OIG on its proposed rule.

Post-Interoperability Exception
As we previously noted, CHA urges CMS to provide for a single exception, rather than introducing both pre- and post-interoperability exceptions. However, if CMS chooses to follow this path, it must finalize the post-interoperability rules at the same time as the pre-interoperability rules. Without clear guidance on what to expect in the post-interoperability period, hospitals will not be able to make informed plans. In the proposed rule, CMS states its intention to wait until the HHS Secretary has adopted certification criteria to finalize the post-interoperability regulations. This action will delay urgently needed support for physician adoption of EHR.

CHA recommends that CMS rethink the approach adopted in this proposed rule. A single exception that addresses our concerns will go far toward achieving the policy goal of increasing physician use of IT and expanding information exchange. Without these changes, hospitals will not have the flexibility they need to work constructively with physicians to realize the promise of IT for improving quality of care.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact me at (202) 488-4688 or mholloway@calhealth.org.

Sincerely,

Margot Bligh Holloway

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December 12, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
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200 Independence Avenue, S.W.
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Re: CMS-1303-P; Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Proposed Rule.

Dear Dr. McClellan:

Catholic Healthcare West, on behalf of our 42 hospitals, appreciates the opportunity to comment on the proposed rule outlining an exception to the Physician Self-Referral, or "Stark," regulations.

The Proposed Rules

The proposed rules seek to give hospitals more flexibility with respect to application of the Stark law when they provide physicians on their medical staffs with certain information technology ("IT") items and services under three scenarios:

- Provision of resources for e-prescribing;
- Provision of electronic health record (EHR) software and directly-related training in advance of national standards for interoperability; and
- Provision of EHR software and directly-related training after national standards for interoperability have been adopted and incorporated into a certification process.

The proposed rules define the protected arrangements, including those between hospitals and members of their medical staffs who routinely furnish services at the hospitals. Conditions include limitations on the covered technology, a requirement that the donated items are not "technically or functionally equivalent" to items the recipient already has, and documentation requirements. The exception also states that the donor must not consider the volume or value of referrals or other business generated between the physician and the donor, and must comply with the anti-kickback statute.

Summary of CHW's Comments

We support CMS in the conservative stance it has taken in advance of national standards for interoperability. The narrow pre-interoperability exceptions are appropriate to safeguard against the development of a patchwork of proprietary systems targeted by wealthier hospitals toward strategic referral alliances with physicians in the community.

However, we believe that the exceptions will need to be broadened significantly following the adoption of national standards for interoperability. As currently written, the post-interoperability regulations, together with the anti-kickback regulations, pose a significant barrier to hospitals and physicians working together to realize the promise of health IT to improve the coordination and quality of patient care. Under the proposed rules, hospitals still risk penalties and will not feel confident enough to work with physicians to help them build their IT capacity and expand the exchange of health information for clinical care.

Accordingly, CHW strongly urges CMS to include protection for multi-functional hardware and connectivity in the post-interoperability exception at §411.357(w). Also, in order to ensure that the hardware and connectivity are sufficiently tied to the use of EHR, CMS should consider requiring that the donee physicians convert their existing patients to EHR in phases. This would both ensure that the hardware be used in connection with the EHR, as well as promote the adoption of EHR.

CHW also opposes the imposition of any cap on the value of EHR items or services provided to eligible donees under the post-interoperability exception. So long as the items and services support EHR that is interoperable and capable of connectivity to any hospital or provider, we see little risk in the provision of such donations. The risk of "free riding" by non-donor hospitals should keep unscrupulous providers in check.

These concerns are explored in more detail below.

The Critical Difference Between Proprietary and Interoperable Health IT

The President has set forth a bold goal of electronic health records for all Americans by 2014. The challenge for the President, his Health Information Technology Coordinator, David Brailer, and Secretary Leavitt is that they cannot achieve their HIT initiative without getting the technology into physicians' hands and offices.

Unfortunately, the biggest roadblock to adoption of EHR is cost. Many physicians are wary of IT investment because of its costs and risks, and because their staffs lack IT experience. In virtually all instances, hospitals' IT systems are more advanced than those of the physicians practicing in their communities. These hospitals also have greater access to capital for financing the considerable costs of health IT. (Recent estimates put the overall price tag at $156 billion.) They also tend to have larger IT staffs, and could lend that expertise to help physician offices to adopt EHRs.

Currently, the Stark Law is a major impediment to hospital-physician collaboration on EHR. Stark prohibits physicians from referring Medicare and Medicaid patients to hospitals from which the physicians have received anything of value. It is a "strict liability" statute and no element of intent is required for prosecution. Violators also are subject to significant civil money penalties if they knew or should have known that their referrals were prohibited. Stark law violations also may be pursued as violations of the federal False Claims Act. Simply put, fear of violating the Stark law is inhibiting progress in IT adoption and achievement of the President's goals.

We support CMS in its use of its general authority under section 1877(b)(4) of the Social Security Act to propose the EHR-related Stark exceptions. This section specifically exempts from the Stark law's prohibition on certain physician referrals "any other financial relationship that the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." This section clearly anticipates the Secretary's determination that a broad array of financial relationships do not risk the kind of abuses the Stark law was designed to deter, and gives the Secretary wide latitude to identify and describe them through regulation.

Providing an exception to the Stark rules for e-prescribing and EHRs will accelerate physician use of health IT. Patients will benefit from wider IT use and better integration of hospital and physician information systems, resulting in improved coordination of care, reduced medical errors, and reduced repeat tests. The President and others in the Administration have noted the urgency for progress in this area.

CHW agrees with CMS that there are different considerations that need to be recognized between pre-interoperability EHR donations and post-interoperability EHR donations. Creation of exceptions for pre-interoperable IT may promote the development and adoption of EHR by physicians, but at the risk of creating a patchwork of closed, proprietary systems that ultimately delay the development and adoption of an interoperable EHR and the public health benefits of interoperability. For this reason, CHW supports a narrow pre-interoperability exception.

By contrast, interoperable IT poses a lower risk of abuse than proprietary IT because there is less risk that its closed nature will be used to direct or steer business to the donor and promises substantially more benefits. Furthermore, the original Stark legislation was motivated partly by a desire to decrease unnecessary and duplicative testing and services. An integrated EHR that allows hospitals and physicians to share test results and other clinical information should further that goal.

More importantly, while the use of EHRs within hospitals and physician offices promises to improve quality of patient care, even greater benefits can be obtained by broadening the sharing of information across health care providers so that, for example, emergency department staff have access to medical histories, and primary care physicians can know which medications were given during an inpatient stay. As noted in the proposed rule, greater sharing of information has many benefits, including improved continuity of care, decreased need for repeat tests, and safer, higher quality care. It also would improve our hospitals' ability to report on quality. We are actively pursuing quality improvements and need the flexibility to use the tools that will improve quality and safety. This includes working with physicians to implement and connect IT systems.

Thus, a Stark exception in the post-interoperability phase that encourages and facilitates physician adoption and use of EHRs would bring about significant benefits for patients while posing minimal, if any, risk of fraud and abuse. In contrast, a failure to provide a workable Stark exception could lead us to miss this important opportunity to increase physician use of EHRs and clinical information exchange, which would improve quality of care for all patients.

There are two issues that need to be addressed. First, the government must develop a standard for interoperability as soon as possible. Until such a standard is in place, there will be disparity in the marketplace, as only wealthy hospital systems are able to fund and build their own proprietary networks. Second, the post-interoperability exception must be substantially broadened. CHW is concerned that CMS has proposed an EHR-related Stark exception that is unnecessarily restrictive in the "post-interoperable" phase.

Covered Technology in the Post-Interoperable Exception

The proposed rule narrowly defines the covered technology as EHR software that does not include administrative functions, but does include e-prescribing modules that conform to Medicare Part D standards just published. Directly-related training is the only permitted IT support under the proposed rule. We are concerned about the narrow definition of covered technology. Increasingly, the products in the marketplace integrate administrative functions with the clinical EHR. From the physicians' point of view, greater efficiencies and clinical benefits will be gained when these functions work together seamlessly.

Many situations require the merging of administrative and clinical data. For example, clinical data must be accessed to support automatic prescription refill authority; clinical data must be aggregated for quality reporting; bills are derived from the clinical record, etc.

Furthermore, while software and directly-related training clearly are important to physician adoption of EHR, they are not sufficient. Physicians may not have the technical knowledge or resources to procure, implement and manage all of the necessary items. In addition, as hospitals expand their IT systems, they must incorporate into their IT infrastructures the capability for communication and data transfer to and from physician offices. In a wired health care system, such access and communication between hospitals and physicians will be as necessary to providing high quality care as the use of operating rooms and recovery suites. In addition, hospitals will need to maintain this IT infrastructure and protect its security and integrity. For these reasons, hospitals will want to provide other kinds of support to physicians to ensure that implementation is successful and information can be exchanged safely. Some examples of such support are as follows:

- T1 lines or other enhanced broadband connectivity, including those needed to support transfer of medical images and EKGs, particularly in rural areas. This may include related software and hardware, such as routers to speed download times.
- Secure connections and messaging. Without ensuring that physician office systems have adequate security protocols and secure messaging, hospitals could put their own IT systems at risk when they connect.
- Ongoing maintenance and support. If physician office systems are not upgraded and maintained in the same manner as hospital systems, the ability to share clinical data to improve care will not be sustained.
- Interfaces. If a physician office already has an EHR that is not easily interoperable with the hospital system, the hospital may wish to provide the programming and software needed to interface the two systems.

This kind of support clearly promotes interoperability, but is not allowed under the proposed exception. Given the nature of technology, many of these items are multifunctional. For example, physicians could use the connectivity that allows them to exchange data with the hospital to also access general Internet sites. However, it is not practical, and does not promote interoperability, if physician offices must use a connection only to exchange data with a given hospital. We urge CMS to define multifunctional connectivity, including related software and hardware, as covered technology. Incremental approaches may be possible, where the technology necessary for connectivity is covered, while any costs associated with additional uses are borne by the physician.

CHW strongly urges CMS to work with other agencies and appropriate stakeholders to quickly define the interoperability standards so that effective adoption of e-prescribing and EHRs can move forward. We urge CMS to rethink the approach adopted in this proposed rule as it relates to the post-interoperability phase exceptions. Without broader exceptions, we will not have the flexibility we need to work constructively with physicians to realize the promise of IT for improving quality of care.

Finally, please note that unless we have corresponding protections with respect to the federal Anti-Kickback Statute and the private inurement rules that apply to tax-exempt organizations, we will continue to experience legal and regulatory roadblocks in this area. Therefore, CHW urges CMS to work with the OIG and the IRS to pursue a coordinated effort to ensure protection.

CHW looks forward to working with CMS on this important endeavor. Questions about our comments can be directed to me or Shelly Schlenker, Vice President of Public Policy and Advocacy at (916) 851-2009 or sschlenker@chw.edu, or Raja Sekaran, Senior Counsel for Regulatory Affairs, at (415) 438-5690 or rsekaran@chw.edu.

Sincerely,

William J. Hunt
President, Group Operations

Charles N. Kahn III
President

December 12, 2005

Mark B. McClellan, M.D., Ph.D.
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Washington, DC 20201

Re: CMS-1303-P; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements

Dear Dr. McClellan:

The Federation of American Hospitals ("Federation") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America which provide a wide range of ambulatory, acute and post-acute services. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule regarding proposed regulatory exceptions to the federal statute imposing limitations on certain physician referrals, which is found at section 1877 of the Social Security Act ("SSA"). (*See* 70 *Fed. Reg.* 59,182 (Oct. 11, 2005) ("Proposed Rule").)

The Federation offers both general comments on the role of the fraud and abuse laws as they relate to the development of health information technology ("HIT") policy and specific comments on the terms of the Proposed Rule.

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I. General Comments

A. The Adoption of HIT Will Benefit Patients and the Healthcare Infrastructure

The Federation agrees wholeheartedly with CMS that implementation of HIT systems will benefit patients and the nation's health care infrastructure. HIT systems will create greater efficiencies, improve quality of care, and reduce medical errors. Moreover, recent studies show that the use of electronic health records ("EHRs") can save the health care system significant dollars in the long run. While hospitals are skeptical about realizing any demonstrable direct savings from EHRs due to the significant expense they will incur, hospitals nonetheless support the adoption of EHRs due to the other benefits they will provide. To achieve this laudable goal, federal fraud and abuse statutes should support, not hinder investment in technology.

B. Applicable Statutory Authority Allows for Broader Exceptions for EHRs

The Federation commends CMS and the Office of Inspector General ("OIG") for taking action that recognizes the need for fraud and abuse protections to help foster the development and adoption of HIT, particularly EHRs. Without such protections, the health care industry will be reluctant to undertake large capital investments to encourage the wide-scale adoption of HIT, which is necessary to help realize President George W. Bush's goal of making EHRs available to most Americans by 2014.

Federal law prohibits physicians from making referrals for designated health services to those facilities in which the physician or a family member has a financial interest, unless an exception applies. (*See* SSA § 1877.) As a strict liability statute, this law prohibits such referrals unless they qualify for a specific exception. The statute contains certain exceptions, and section 1877(b)(4) of the Social Security Act permits regulatory exceptions to be promulgated to protect financial arrangements that do not pose a risk of patient or program abuse.

CMS has proposed one exception related to electronic prescribing, and two exceptions related to EHRs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended the Social Security Act to direct HHS to implement fraud and abuse protections under the anti-kickback statute and the law limiting certain physician referrals for electronic prescribing arrangements, and CMS is implementing such protections under its statutory authority in the Proposed Rule. Also, CMS proposes two regulatory exceptions related to EHRs under its general rulemaking authority.

We submit that under its rulemaking authority, CMS can promulgate EHR exceptions that are broader than those proposed that would significantly enable the healthcare industry to create a workable HIT system. The Proposed Rule's preamble outlines the many benefits that HIT systems provide, while noting only that providing something of value *may* pose a risk of patient or program abuse. The preamble aptly

recognizes that CMS may continue to evaluate the risks posed by HIT donations and may add or modify the terms of the exception as necessary. This is a common activity for a regulatory agency. Under this framework, the proposed exceptions should be expanded to afford greater, more meaningful protections upfront that would still be permissible under this authority. If after implementation, specific concerns arise related to certain practices, appropriate changes can be made at that time to narrow the protections. However, restrictive policies at this juncture will not facilitate an environment in which providers are striving to meet the President's objectives and will only further delay and hinder HIT system implementation.

C. The Goal of Expanding Access to HIT Should Drive Federal Health Information Policy, Not the Fraud and Abuse Laws

We support the decision by CMS and the OIG to act promptly to develop policy in this area and we urge CMS to move expeditiously to issue final regulations on all aspects of the Proposed Rule. However, because CMS and the OIG may be the first to act with final policy and may do so in a way that can influence the HIT landscape, we are concerned about the broader policy implications. Many of the necessary technical aspects of federal HIT policy are not yet in place and will be developed over the next few years. As a result, with final fraud and abuse policy possibly coming sooner than final HIT policy, it is possible that there could be a divergence between those related policies.

Given that possibility, the Federation strongly urges CMS and OIG to promulgate reasonable policies in this area that will encourage HIT systems to be created and then promptly revisit any final fraud and abuse policies when final HIT policies are adopted to ensure that the technical aspects of both policies are aligned. To do otherwise could result in fraud and abuse policy driving HIT policy, which is an undesirable outcome that would hinder quality patient care and innovation. We also recommend that CMS refrain from setting policy on matters deemed to be HIT-focused, as those policy issues are better left to others with the necessary expertise.

D. HIT Arrangements Do Not Raise the Same Concerns as Other Fraud and Abuse Issues

The fraud and abuse laws are designed to protect against financial relationships between providers and physicians that unduly influence referral patterns or that cause over-utilization of services, which results in higher government expenditures. A hospital's interest in investing in HIT is driven by a desire to innovate and improve quality of care and to provide a better platform for pay-for-performance models. Hospitals are investing this area because it is the next step in the natural evolution of the delivery of healthcare. As a result, the Federation believes that HIT investment and the desire to provide an incentive to physicians to participate in such systems do not raise typical fraud and abuse concerns present with other financial arrangements.

It is a very significant business decision for hospitals, particularly large integrated delivery networks, to implement a comprehensive HIT system. For our members, this

decision involves a large capital investment that is likely to affect a company's entire infrastructure nationwide. This is not done to influence the referrals of one or a group of physicians, but to modernize operations to improve efficiencies and quality of care. Once this investment is made, it is imperative for physicians and other health care professionals to participate in order for the system to be effective. By participating in such a system, a physician is not receiving any remuneration for referrals; rather, the physician is assisting the hospital in providing quality care to the hospital's patients.

II. Specific Comments on the EHR Exceptions

The Federation will focus our specific comments on the proposed policies related to EHRs. While supportive of CMS's decision to promulgate regulatory protections for investment in EHRs, we find the current proposals to be of little practical value and unlikely to foster wide-scale investment by the hospital community. This conclusion is explained in more detail below in our specific comments as well as in our responses to certain requests for information contained in the Proposed Rule.

A. Separate Exceptions Are Not Necessary For Pre-Interoperability and Post-Interoperability Periods

The Federation does not believe it is necessary to promulgate separate exceptions for pre-interoperability and post-interoperability periods. For various reasons, the pre-interoperability exception essentially is unworkable, and likely will provide little protection to encourage investment. In our view, the better course is to promulgate one exception, which can follow the general approach of the proposed post-interoperability exception, with one exception. We recommend removing the product certification requirement (*see* 42 C.F.R. proposed § 411.357(x)(2)) until such time as those standards are finalized and determined to be appropriate for inclusion in fraud and abuse standards.

Under our recommended approach, CMS can send a clear message to the field that product certification is highly likely to be a future requirement in the exception, and we are supportive of this message. Also, to the extent there is an enforcement community concern regarding closed systems, this message would discourage providers from developing proprietary systems and actually would help hospitals include protections in their contracts with HIT vendors that will guarantee a move toward compliance with applicable HIT standards as they are issued.

Should CMS decide to issue a final rule with two EHR exceptions, final regulations should be issued simultaneously for both exceptions. Once all product certification criteria are available, donors and donees should be able to immediately avail themselves of the second EHR exception, which is viewed as slightly broader than the first EHR exception. However, the preamble currently contemplates that CMS would not issue final policy on the second exception until product certification criteria are finalized, which means that there would be an unnecessary and inappropriate lag period before the second exception would become effective. (*See* 70 *Fed. Reg.* at 59,190.)

Finally, the shorthand distinction between pre- and post- interoperability made in the Proposed Rule may be misleading. The Proposed Rule appears to indicate that the transition from one exception to the next exception turns upon when there is "certification" for technology. (70 *Fed. Reg.* at 59,817; *see* proposed 42 C.F.R. § 411.357(x)(2).) In this regard, the preamble's discussion of "product certification criteria" goes well beyond just interoperability and also includes functionality, privacy, and security of EHRs. (*See* 70 *Fed. Reg.* at 59,817.) It may be more appropriate to characterize the exceptions as pre- and post- certification.

B. The Scope of the Covered Technology in Both Proposed Exceptions Should Be Expanded

The proposed exception for EHRs protects the provision of "items and services (in the form of software or directly related training services) necessary and used solely to receive, transmit, and maintain electronic health records" provided certain conditions are met. (*See* 42 C.F.R. proposed § 422.357(w).) The Federation has a major concern with this proposed standard, which is included in both the pre-interoperability and post-interoperability exceptions.

For both exceptions to be meaningful, the scope of the covered technology should be expanded to include items related to hardware and connectivity as well as ongoing maintenance services for the system. There are many types of hardware and connectivity items that are necessary to ensuring that the system works correctly. For example, a T1 line or other broadband connectivity is essential to the ability to communicate effectively. We see no persuasive policy reason for treating those items and hardware differently from software under either EHR exception, and recommend both exceptions be expanded to include these additional items.

The proposal also creates an inference that physicians will have sufficient HIT resources in-house to fully support their interface with the hospital EHR system. This is not likely to be the case. In our members' experience, physicians need assistance for a system to function effectively. The exception should allow for donors to provide that support, which will also provide a quality control oversight function. Failure to maintain an adequate system threatens the efficiencies and quality improvements expected from the system and true overall benefits of an HIT system.

C. Definitions of Several Key Terms Require More Flexibility

The definition of the term "necessary" raises concerns under both EHR exceptions. CMS appears to tie the standard for "necessary" with whether the donation would replace a physician's existing system that is "technically or functionally equivalent" to the donated technology. The Proposed Rule requires a physician certification on this issue. (*See* 42 C.F.R. proposed §§ 411.357(w)(5)(iv); (x)(5)(iv).) However, no further guidance is given regarding how this standard should be interpreted. Similarly, the Proposed Rule indicates that a technology is necessary if it "significantly enhance[s] the functionality" of an item or service. Further guidance regarding this term

is also needed. This additional guidance should be flexible. Overly restrictive policy in this area will hinder the willingness to provide the investment the federal government seeks.

Also, the pre-interoperability exception requires that an EHR be "used solely to receive, transmit, and maintain" an EHR. (*See* 42 C.F.R. proposed § 411.357(w).) This "solely" requirement is overly restrictive and is likely to preclude legitimate uses which are consistent with the policy goal of increased efficiencies and improved quality of care. We strongly recommend removing the word "solely" from this standard. Otherwise, this will be one element that will render the pre-interoperability exception effectively unusable.

D. The Donee Group for Hospitals Should Be Expanded Beyond Medical Staff Physicians

The Federation is concerned that limiting the permissible donee group for hospitals to just medical staff physicians will be too restrictive. There are valid reasons to offer protected technology to non-medical staff members. Some referring rural physicians prefer to view an EHR of a patient that the physician referred to the hospital, regardless of whether he/she has privileges at that hospital. Also, fewer and fewer primary care physicians ("PCPs") see value in joining hospital medical staffs, payers do not require them universally to have medical staff membership, and medical staff dues or medical staff application fees are now disincentives to applying for this status.

Hospital communications with these rural physicians and PCPs is good for the continuity of patient care (because the patient ultimately does go back to his/her primary physician) and thus primarily benefits the hospitals in providing services to their communities. For these reasons, we think the overall benefits of expanding a hospital's donee class better enhances the ability to achieve the broad policy goals of HIT.

Current CMS regulations provide physician self-referral protections for qualifying arrangements that are implemented "community-wide." (*See* 42 C.F.R. § 411.357(u).) While this exception has been unworkable for other reasons, a main premise underlying the exception is that the technology must be made available to all health care professionals in a particular area. We believe this premise should be reiterated in the current EHR exceptions.

E. E-Prescribing Readiness Should Not Be a Mandatory Component of an EHR Donation

Both proposed EHR exceptions require that any EHR donation must include capability that complies with the new electronic prescribing standards required under Medicare Part D. This is an example where we are concerned that HIT policy not be driven by fraud and abuse policy. Any HIT donation will depend on many factors in a particular case, and this requirement may stifle investment in those arrangements where electronic prescribing is not seen as significant element.

F. The Pre-Interoperability Exception Should Not Limit Permissible Items or Services to EHRs

As a general matter, the HIT products on the market often do not focus on just one application. Most products are multiple, interfaced applications which provide a full range of efficiencies and interconnected modules. The pre-interoperability EHR exception prohibits any donated technology from including billing, scheduling or other office management software. (*See* 42 C.F.R. proposed § 411.357(w)(8).) This requirement will preclude many, if not all, products available on the market today. Moreover, given this exception is by definition time limited, products are not likely to change in response to this requirement. As a result, we recommend this requirement be eliminated, because it would render this exception essentially meaningless.

At the very least, the exception should be modified to indicate that the donor may not donate non-EHR technology related to office administration. This would allow physicians to implement an integrated bundle of applications with an EHR, but would require the physicians to pay for the non-EHR applications. We are concerned that under the current proposed language, this possible sharing of costs related to a multi-faceted product may be prohibited.

G. The Proposed Cap on Allowable Technology Should Be Eliminated

The Proposed Rule requests comment on whether there should a cap on the amount of permissible items or services that can be donated. The Federation does not favor a cap for several reasons. Any limit on donations likely would be arbitrary and could easily obstruct the adoption of technology. Also, including a cap essentially would mandate physician investment, which is likely to lead to negotiations over what items and services should be included in the arrangement. Under this scenario, the possibility for compliance concerns grows, as hospitals will be asked to accommodate specific requests to ensure physician participation. This also will impact a hospital's ability to fully implement the system and related applications of its choosing. If deviations from a standard HIT plan were sought in particular markets, this could impact the overall effectiveness of the system's performance and limit the benefit to patients that is intended and obtainable.

Also, if CMS decides not to expand the list of permissible items or services as we recommend above, then to add a cap on top of those limitations would further tie the hands of those entities looking to make investments. Should CMS decide a cap is necessary, we strongly urge that a percentage test be used that relates to the cost of a particular package and that the standard not be a fixed dollar amount. In this regard, we are concerned with the cost figures CMS quotes in the Regulatory Impact Statement.

Anecdotal evidence reflects that the cost of donated technology is significantly higher than the figures reported therein.

H. The Post-Interoperability EHR Exception Should Be Interpreted to Permit a Staggered Rollout of HIT

The post-interoperability exception requires that "[n]either the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that is directly related to the volume or value of referrals or other business generated between the parties." (*See* 42 C.F.R. proposed § 411.357(x)(4).) We urge CMS to interpret this regulation in a manner that gives donors the flexibility to roll out their HIT programs in a manner that makes most sense in a particular situation.

CMS had attempted to do this in its regulation by enumerating specific examples of when a roll out is deemed "not directly related to" referrals or other business. We recommend that CMS eliminate these specific examples, and instead indicate that a donor's staggered implementation of HIT will not be viewed as violating this section. If CMS decides to retain a list of permissible examples, CMS should make clear that this list is not exclusive, and provide further guidance regarding how donors should interpret the standard that the "determination is made in any reasonable and verifiable manner that it is not directly related to" referrals or other business between the parties.

* * * *

Thank you for the opportunity to provide input on this Proposed Rule. Should you have any questions about our comments, please contact Jeff Micklos at (202) 624-1521.

Respectfully submitted,

Charles N. Kahn III
President

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

December 12, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
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Washington, DC 20201

Re: Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements

Dear Dr. McClellan:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the proposed rule entitled "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements" as published in the October 11, 2005 *Federal Register*. MGMA commends the Centers for Medicare & Medicaid Services (CMS) for taking positive and constructive steps toward eliminating legal barriers that may stand in the way of widespread electronic prescription and electronic health records (EHR) adoption.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

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Introduction

Medical group practices are turning increasingly to technology for solutions to the many problems associated with inefficient systems. The use of this technology in the ambulatory setting, particularly the increased use of electronic prescribing and electronic health records, not only will improve access to care and quality of care, but also reduce medical errors. As a strong advocate of increased patient safety and improved efficiencies in ambulatory care settings, MGMA has promoted the

adoption of health technology and the widespread acceptance and use of clinical guidelines and evidence-based clinical decision making. In addition to the clinical benefits associated with health technology, many in the industry anticipate that extensive use of the technology will result in increased administrative efficiencies. However, significant barriers remain before all group practices and others can begin to reap the benefits of this new technology.

A recent study conducted by the MGMA Center for Research and the University of Minnesota School of Public Health highlights the urgency and critical need to address these barriers. More than 3,300 medical group practices participated in the January to March 2005 *Assessing Adoption of Health Information Technology* project, which was funded by the Agency for Healthcare Research and Quality (AHRQ) and published in the September/October edition of *Health Affairs*.

MGMA's research showed that just 14.1 percent of all medical group practices use an EHR, and just 11.5 percent indicated that an EHR was fully implemented for all physicians and at all practice locations. More significantly, the research showed that only 12.5 percent of medical group practices with five or fewer full-time equivalent physicians (FTE) have adopted an EHR. The adoption rate increased with the size of practice; groups with six to 10 FTE physicians reported a 15.2 percent adoption rate, groups with 11-20 FTE physicians reported an 18.9 percent adoption rate, and groups of 20 or more FTE physicians had a 19.5 percent adoption rate. In terms of electronic prescribing capabilities, the MGMA survey reported that less than 25 percent of practices write and reorder prescriptions using some form of computer-based information system.

Additional data revealed that 12.7 percent of groups were in the process of implementing an EHR; 14.2 percent said implementation is planned in the next year; and 19.8 percent said implementation was planned in 13-24 months. The remaining 41.8 percent had no immediate plans for EHR adoption. Among those with no immediate plans for implementation, the difference between large and small groups is striking - 47.8 percent of practices with five or fewer FTE physicians compared with only 20.7 percent of practices with 21 or more physicians. This research data confirms that much work remains to convince and assist physician practices, particularly smaller organizations, with implementation of information technology.

One of the barriers to the increased adoption of health information technology cited in the survey was the Stark regulation's prohibition against hospitals sharing resources with practices. MGMA applauds the government for its decision to create a regulatory exception that should help stimulate the implementation of this important technology. However, while MGMA understands the government's desire to minimize the risk of fraud and abuse in the health care system, we are concerned that CMS constructed the proposed rule in such a narrow and restrictive nature that it will not achieve the government's goal of widespread health information technology adoption. Therefore, we strongly encourage the agency to include the following revisions in the final rule.

"Necessary" Non-Monetary Remuneration

The proposed exceptions would only protect items and services that are "necessary" to conduct electronic prescription drug transactions. We are concerned that CMS took the additional step of proposing to require that physicians certify that the items or services provided are not technically or functionally equivalent to those that the physician already possesses or has already obtained. MGMA does not believe this "certification" requirement is necessary or advisable, and we request that CMS eliminate it from the final rule. MGMA believes the certification requirement could deter physician practices from pursuing arrangements with donors because they cannot state with certainty that items or services are sufficiently different technically or functionally to meet this heightened legal standard. Many practices do not possess the necessary knowledge and expertise to make the determination called for under the certification process. Therefore, practices might view the risk of such a certification too great.

In addition, practices committed to implementing an electronic prescription system or electronic health records under the new Stark exception, but unable to satisfy the certification requirement in-house, may be forced to hire an outside consultant to perform the analysis. MGMA contends that shouldering practices with this financial burden is contrary to the spirit and intent of the proposed exception--to assist providers who do not possess the financial resources to purchase items and services for electronic prescribing. In the event the certification requirement remains in the final rule, MGMA urges CMS to allow any costs associated with the certification requirement to be included as part of the services a donor offers to the practice.

MGMA strongly supports the proposal to permit the replacement of current health information technology systems. There are circumstances where physicians may have old and/or outdated technology that would not have a sufficient level of functionality or interoperability. In fact, many practices have experimented with lower cost technology yet have disbanded the effort. Although they may still have this software or hardware in the practice, it may not be currently used in their interaction with patients. In addition, those practices with outdated technology could benefit significantly from educational and consultative services.

DHS Entities Protected

The proposed rule limits the type of entities that may provide assistance, and the persons to whom assistance can be provided. MGMA strongly recommends that CMS expand the entities protected under the rule. We believe the limited scope of entities protected as proposed would not achieve the mutual goal of government and industry to promote electronic prescribing and electronic health records to the greatest extent possible. Furthermore, we believe the proposed structure would not be practical in today's complex health care system.

The proposed rule protects donations made by a hospital to physicians on its medical staff. MGMA believes this limited language would not serve the interests of providers or patients. Typically, medical groups operate as a cohesive unit, in which all physicians and

other clinicians in the practice access the same health information technology. Under the proposed language, it appears as though only those physicians in a medical group who furnish services at a particular hospital would qualify to receive electronic prescribing or electronic health records hardware and software. Would this mean that other physicians in the group who do not furnish services at the hospital could not access this technology? If so, such a scenario would certainly be neither practical nor reasonable. CMS should clarify or amend the language to ensure that all physicians in a medical group can fully utilize the items donated by a hospital. CMS should also clarify that the items and services may be provided to the group practice itself, rather to "physicians" as the proposed rule specifies.

MGMA also urges CMS to expand the list of donors to permit group practices to donate electronic prescribing and electronic health record technology to other physician practices. Larger group practices are at the center of the health care delivery system in many communities around the nation. These entities should be afforded the same exception as hospitals, with, of course, the same limitations. Furthermore, the list of donors should be expanded to include clinical laboratories and other health care providers that would benefit from an interoperable health care system.

Value of Protected Technology

MGMA does not believe CMS should limit the aggregate fair market value of all items and services provided to a physician from a single donor. We believe that a limit is not necessary to minimize the potential for fraud and abuse. As discussed previously, the exception would only protect items and services that are "necessary" to conduct electronic prescription transactions. The proposal to protect only those items and services "necessary" would seem to sufficiently safeguard against fraud and abuse. As long as the items and services are utilized for the exception's intended purpose, the value of the items and services should not be a consideration.

In addition, MGMA contends that a cap could disadvantage smaller physician practices that do not have the financial resources of larger entities. For example, some medium and large practices might currently have certain software and hardware already in place. Therefore, the value of any additional items and services they need would fall within the cap. However, many small practices currently have no software or hardware in place. Therefore, the value of all required items and services might reach beyond the cap.

In the event that CMS decides to establish a cap, MGMA urges the agency to exercise extreme caution. MGMA believes that many cost estimates currently available underestimate the costs of purchasing and maintaining an electronic prescribing system. According to MGMA's study, the mean electronic health record purchase and implementation cost per FTE physician for all practices is $32,606. Practices with 5 or fewer FTE physicians experience a mean cost of $37,204.

Covered Technology

With MGMA's recent study indicating that only about 14 percent of practices have adopted this technology, we believe that the exception should be broadened to permit donors to offer educational sessions and consulting assistance in addition to hardware, software, Internet connectivity, and training and support services. A critical step in assisting physicians transition to this new technology will be education regarding the functionality that these EHR systems possess, which product and solution best meets the needs of their practice, and how best to implement this complex technology.

In addition, MGMA has found that appropriate consulting services can often make the difference between a successful migration to health information technology and one that fails. How best to transform the workflow of a practice is an important consideration for each organization adopting technology. In most cases, practices turn to outside experts to assist them in developing an approach to workflow change that best suits their individual needs and requirements. This consulting assistance is even more critical when practices decide to purchase lower cost systems that typically require more customization (i.e., clinical templates). It is important to note that should CMS widely release their low cost Vista Office EHR, it is expected that significant consultative services will be required before practices will be able to successfully implement the software.

MGMA also encourages the government to expand the scope of the exceptions to include non-drug prescriptions. Depending on their particular specialty, physicians may prescribe more non-drug health related items than drug-related items. We believe that physicians should be encouraged to utilize electronic means of ordering clinical tests, durable medical equipment, and other critical health-related items.

While we agree that the government should not protect the provision of equipment that would be used for personal, non-medical purposes, MGMA strongly disagrees with the government's assumption that billing and other administrative functions should be excluded. It is clear that much of the return on investment for physicians who incorporate an EHR into their practice is the integration of clinical and administrative systems. Electronic health records that permit the physician to efficiently incorporate billing into the workflow may allow the practice to allocate staff, previously assigned to administrative tasks, to more patient-centered clinical duties. Furthermore, convincing physicians to adopt technology will be much easier if they are presented with the opportunity to improve all clinical and administrative areas of their practice workflow.

CMS should take note that the Certification Commission for health Information Technology (CCHIT), the entity identified by the Department of Health and Human Services (HHS) as the developer of functionality and interoperability EHR certification standards, has identified a number of areas of testing that revolve around administrative functionality and interoperability. As an example of functionality, the CCHIT has listed support for non-medication ordering such as referrals and care management, and scheduling for either the patient or a resource/device. In their interoperability requirements, the CCHIT incorporates a number of administrative and financial data categories including quality improvement reporting, patient identification, patient administration, scheduling, electronic referral authorization, communications with the

practice management system, revenue cycle-related transactions, and query and receiving electronic patient eligibility information. Accordingly, we recommend that the "pre-interoperability" exception be expanded to mirror the "post-interoperability" category to include billing and other administrative software, provided that the core function of the software is the EHR.

Regulatory Impact of Proposed Rule

While the specific impact of these new legal protections is unclear, we are hopeful that they will encourage technology adoption in financially challenged practices. The difficulty will be to assess the impact of such regulatory actions. We recommend that the government fund and oversee a comprehensive and ongoing survey of physician adoption of health information technology. This survey should solicit information regarding why and how practices implement technology and what barriers remain for those that have not yet adopted the technology. We also recommend specifically surveying group practice and hospital utilization of these legal protections.

Conclusion

MGMA appreciates your consideration of these comments and looks forward to working with CMS in pursuit of our common goal of maximizing the number of physician group practices that utilize electronic prescribing and electronic health records. If you have any questions, please contact Robert Tennant or Aaron Krupp in the Government Affairs Department at (202) 293-3450.

Sincerely,

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DEC 13 2005

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December 12, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1303-P
200 Independence Avenue, SW
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Washington, DC 20201

Re: **Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exceptions for Certain Electronic E-Prescribing and Electronic Health Records Arrangements (CMS-1303-P)**

Dear Dr. McClellan:

The Advanced Medical Technology Association ("AdvaMed") commends the Centers for Medicare and Medicaid Services ("CMS") and the U.S. Department of Health and Human Services Office of Inspector General ("OIG") for collaborating on the development of two very important proposed rules to facilitate the dissemination of information technology in the health care industry. We appreciate this opportunity to comment on the proposed rules that would protect the provision of certain information technology hardware, software, and related training services by specific donors to physicians provided certain requirements are met.

Health information technology ("HIT") promises to revolutionize the health care delivery system and have a dramatic effect on patient safety, quality of care, and efficiency. HIT products and applications are greatly expanding throughout vital sectors of the American health care delivery system, including clinical operations, decision support, devices, equipment, distribution, administrative tasks, and the interface with payers. As a result, HIT is helping to significantly reduce medical errors, improve the quality of care, speed the flow of information and documents, and reduce administrative costs.

Digital health information technologies range from Web-based software solutions that encompass the entire medical record to devices with digital components that connect physicians, patients, and heath care facilities. These medical technologies can capture, store, monitor, and transmit information about a patient's health. Many of these technologies help to populate the interoperable electronic health record ("EHR"). The interoperable EHR can lead to significant improvements in quality and cost reductions due to streamlined administrative processes and fewer medical errors. Potential savings to the health care delivery system have been estimated as high as $78 billion to $112 billion a year — and as much as $140 billion a year if those EHR savings are combined with savings from other HIT advances.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually. In particular, AdvaMed represents the innovators of smart medical technologies. Specific examples of these innovations include:

RECORDS	DEVICES	OFF-SITE MONITORING and COMMUNICATION
Application of computer-assisted physician order entry to increase patient safety and health system efficiency.	Infusion pumps that are preventing drug overdoses and enabling health care providers, such as hospitals, to re-engineer their systems to avoid medical errors.	Remote monitoring technologies that are eliminating trips to the doctor and enabling improved monitoring of patients with chronic diseases and improved monitoring of intensive care unit (ICU) patients.
Personal Digital Assistants (PDAs), hand-held devices that allow doctors making rounds to immediately access each patient's complete medical record.	Image-guided or computer-assisted surgery (CAS), which allows surgeons to more precisely position their instruments and to document the procedure. Procedures are shorter and less invasive, and CAS appears to be improving quality of care and reducing morbidity in some cases.	Telemedicine to improve care, for instance, of both rural, less accessible populations and urban populations.
Lab results that are stored and sent to physicians electronically, which streamlines and speeds up testing and retrieval.	Devices with computerized components such as implantable cardioverter-defibrillators (ICDs), which allow heart patients subject to life-threatening cardiac arrhythmias to send vital data to their physicians via a secure Internet connection.	Picture archiving and communication (PAC) systems, which store and permit the transmittal of radiological images such as X-rays when and where they are most needed.

RECORDS	DEVICES	OFF-SITE MONITORING and COMMUNICATION
Pharmacies that are receiving electronic prescription orders from physicians. Pharmacists are prevented from filling orders if critical patient data is missing, potential adverse drug interactions are flagged, and medication alerts are issued for high-risk medications. The electronic record of all of this is available in real time by any authorized health care provider.		Virtual patient visits via e-mail.

As CMS and the OIG have correctly identified, the physician self-referral or "Stark" Law (the "Stark Law") and the Federal health care program anti-kickback law (the "Anti-Kickback Law") in their current statutory and regulatory form effectively prohibit the provision of HIT to physicians and other health care providers. While AdvaMed believes the two proposed rules (CMS-1303-P and OIG-405-P) are an important first step, we are concerned with the following elements of the proposed rules: (1) Pre/Post "Interoperability" Distinction; (2) Covered Technologies; (3) Protected Donors; (4) Valuing Covered Technologies; and (5) Preemption of State Laws and Regulations. We will address each of these issues separately below.

Pre/Post Interoperability Distinction *(Pre-Interoperability Electronic Health Records Exception, § 411.357(w) and Post-Interoperability Electronic Health Records Exception, § 411.357(x))*

AdvaMed recommends that CMS omit the concepts of pre- and post-certification and pre- and post-interoperability from the proposed rules. A certification process is already being developed and should be implemented in March – April, 2006, which is well within the time frame of this proposed rulemaking process. Certified ambulatory EHRs will meet minimum function, interoperability and security, and reliability requirements. Furthermore, interoperability is not a static condition that can be measured and achieved at a given point in time. Interoperability involves a process of establishing standardized ways to exchange a patient's health information that will continually evolve as standards and software improve.

Covered Technologies. *(Pre-Interoperability Electronic Health Records Exception, § 411.357(w); and Post-Interoperability Electronic Health Records Exception, § 411.357(x))*

AdvaMed recommends that the proposed exceptions for e-prescribing and EHRs be unified into one exception that protects the provision of hardware, software, and related training services. As currently drafted the proposed e-prescribing exception covers

hardware, software and related training services, while the proposed EHR exception only protects software. Hardware, software and related training services are all clearly necessary for e-prescribing and EHRs. However, operating system software, connectivity and effective support services are critical as well to the successful implementation and continued use of an HIT system. The optimum use of HIT requires all of these components in a complete infrastructure. Thus, to parse out different protected technologies for certain functions frustrates the goal of creating a unified infrastructure.

Furthermore, there are systems available today that perform multiple functions, such as e-prescribing and EHRs, but also billing and management functions. As currently drafted, the proposed rules do not protect such systems. All of these functions are necessary to enable physicians and other licensed health care professionals to use common tools for multiple tasks, such as writing electronic prescriptions, scheduling appointments, and billing. All of these elements work efficiently together to improve patient safety, efficiency, and quality management. The proposed rules should encompass these systems in addition to e-prescribing and EHR technologies.

Protected Donors. (*Electronic Prescribing Exception, § 411.357(v), Pre-Interoperability Electronic Health Records Exception, § 411.357(w); and Post-Interoperability Electronic Health Records Exception, § 411.357(x)*)

AdvaMed believes that the list of protected donors should be expanded to include clinical laboratories, pharmacies, health networks, nursing homes, community health centers, and any other sites where patients may interact with the health care system. To promote truly interoperable e-prescribing systems and EHRs, all types of health care providers must be allowed to donate permitted technology. Patient interactions with the health care system are multi-faceted and include visits to physicians' offices, hospitals, clinical labs, pharmacies, etc. Furthermore, to allow certain health care providers to provide covered technology, but not others, creates additional barriers within the health care system. In order to facilitate full adoption and true interoperability, CMS must adopt rules that broaden the dissemination capabilities of all health care providers.

Cap on Donated Technologies. (*Electronic Prescribing Exception, § 411.357(v), Pre-Interoperability Electronic Health Records Exception, § 411.357(w); and Post-Interoperability Electronic Health Records Exception, § 411.357(x)*)

In the proposed rule, CMS requests comments on whether a "cap" should be added to the exception requirements that would limit the aggregate value of the covered technology provided by a single donor to a physician. While AdvaMed understands and appreciates CMS' interest in applying a monetary limit to minimize the potential for fraud and abuse, AdvaMed believes that the strongest deterrent to fraud and abuse is the requirement that covered technologies be certified and interoperable. Furthermore, given the nature of HIT, AdvaMed believes that formulating and applying a specific dollar figure to the covered technology would not only be difficult, but would unnecessarily discourage donors from providing these important technologies. Even if CMS were to consider

adopting a cap, how would the value of HIT be determined? The value of these items and services is quite different from the providers' and physicians' perspectives and the value may change considerably over time depending on whether or not additional elements are added to continue to foster interoperability. Finally, the covered technologies include a wide variety of items and services from hardware to software to training services, all of which have different values depending on whether they are provided separately or in conjunction with each other. However, if CMS does decide to proceed with instituting a cap on the value of donated technologies, AdvaMed encourages CMS to take into consideration both the value and costs of such items and services as well as the fact that the value and costs are dynamic in nature. CMS should err on the side of setting a higher cap so as not to unduly discourage the adoption of HIT and render the exception futile.

Preemption of State Laws and Regulations.

Once finalized, the new exception or exceptions to the Stark Law for e-prescribing and EHRs should pre-empt any state laws or regulations that conflict with the requirements of the new exception(s).

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AdvaMed again wishes to thank CMS for its initiative and efforts related to the dissemination and adoption of HIT. These proposed rules are vital to the continued progress towards an interoperable health care system in which all Americans have EHRs. We appreciate CMS' consideration of our comments and look forward to continuing to work with CMS on this issue.

Sincerely,

David Nexon
Senior Executive Vice President

ADVAMED

2005 DEC 13 AM 8:06

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Mark McClellan, M.D., Ph.D.	David Nexon
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NOTES/COMMENTS:

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

December 12, 2005

Mark B. McClellan, MD, PhD, FACP
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Centers for Medicare & Medicaid Services
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Re: **Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 42 CFR Part 411, CMS-1303-P, (October 11, 2005)**

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, appreciates the opportunity to submit comments on the proposed rule, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements," published in the *Federal Register* dated October 11, 2005. This proposed rule would establish new exceptions under the Federal Physician Self-referral Law for certain arrangements involving the provision of electronic prescribing and electronic health record (EHR) technology. We applaud CMS for its expediency in issuing a proposed rule and urge the final rule to be promulgated as soon as possible.

We want to take this opportunity to acknowledge the importance of providing protections to entities considering the donation of electronic prescribing and EHR technology to other entities struggling to come up with the financial means to make the investment. We also recognize the complexity involved with writing a rule that balances the need to speed adoption of information technology with the need to protect patients from fraud and abuse. We believe the Centers for Medicare & Medicaid Services (CMS) has made a good-faith effort to draft a proposed rule that attempts to strike that balance and we congratulate you on this effort. However, we have significant concerns that the proposed rule does not accomplish what it intends and, in some places, may create unintended consequences that restrict the ability to adopt new technology in the future.

SUMMARY OF COMMENTS

- ACP appreciates the efforts CMS has made in the proposed rule and we urge the prompt and efficient release of the final rule.
- Congress and the Administration must take a greater leadership role in offering financial incentives to providers to accept the increased costs (one-time and ongoing) and practice workflow changes (ongoing) required as part of HIT implementation.
- We are particularly concerned the proposed requirement for the Recipient to "certify" technology poses an undue financial burden and should be either clarified or withdrawn.
- ACP requests flexibility in defining the criteria for "used solely" to avoid the unbundling of multi-use devices, resulting in an added expense.
- CMS should be as inclusive as possible when considering adding potential qualified Donors and Recipients.
- Permitted donations should be broadly interpreted to include any equipment (especially hardware), item, information, right, license, intellectual property, software, training, education or service necessary for developing, implementing, operating or facilitating the adoption of electronic prescribing or EHR.
- We are not supportive of placing a cap or aggregate limits on the amount of technology a Donor may provide.

GENERAL COMMENTS

ACP is well aware of the potential benefit of electronic prescribing and EHRs to the health of Medicare beneficiaries -- and ultimately all Americans -- in terms of decreased medical errors, increased clinical quality of care, and reduced costs for all stakeholders. We strongly support overall efforts in Congress and the Administration to speed the adoption of uniform standards for health information technology (HIT). In particular, ACP supports the efforts of the American Health Information Community (AHIC) and its confirmation of the activities of the Certification Commission for Healthcare Information Technology (CCHIT) to develop a process to certify specific HIT products that meet or exceed a specified level of functionality, interoperability and security.

Within the College, we are firmly committed to providing practicing internists with practical tools to help them improve quality and incorporate quality measures into their practices. ACP's Physicians Information and Education Resource (PIER) provides ACP members -- at no cost to them -- access to "actionable" evidence based guidelines at the point of care for over 300 clinical modules. ACP's-own Practice Management Center has developed resources to help internists in the decision-making process on electronic health records and is leading an initiative to provide internists with tools and best practices to help them redesign their office processes to improve health care quality.

While we believe the CMS proposed regulations represent a necessary step toward facilitating the implementation of technology, we do not believe it will result in significant

widespread HIT adoption. We do not believe the majority of potential Donors protected by the proposed exceptions have the necessary financial resources to make a major impact regarding implementation of this technology. Without sufficient financial assistance from the federal government, particularly to those in small physician practices, we will simply be unable to achieve a smooth transition into a fully-integrated HIT society. Therefore, we believe it is essential to fund initiatives that encourage HIT integration into all health care sectors.

To this end, ACP strongly believes that the Congress and the Administration must take a more active leadership role by offering significant financial incentives for practitioners to accept the increased costs and burdensome practice workflow changes that will be required as part of HIT implementation. Such incentives should include grants, loans, and refundable tax credits to account for the expensive start-up costs for implementation. In addition, there must be recognition of the on-going costs for training, maintenance and periodic upgrades inherent in operating a HIT system. These costs can be addressed by providing a modest Medicare add-on payment for physicians who employ HIT as part of overall quality improvement efforts. These same provisions can be found in the bipartisan legislation, H.R. 747, "the National Health Information Incentive Act." In addition, we believe the Department of Health and Human Services should act to expand the pay-for-performance Medicare Modernization Act (MMA) Section 649 demonstration to encourage greater participation from small physician practices. We believe that offering meaningful financial incentives is the most effective way to improve quality and expand the use of HIT, especially in small practices.

While ACP does not believe the proposed rule will dramatically increase the overall adoption of HIT, there are enough potential Donors with the financial means considering this option and, therefore, several minor refinements and clarifications should be made in order to yield the greatest possible benefit. In order to have any amount of success, however, it is absolutely essential that the Anti-kickback Statute safe harbors and the Self-referral Law exceptions are completely in line with another.

ACP offers the following comments to the proposed rule:

SPECIFIC COMMENTS & RECOMMENDATIONS

"Necessary" Nonmonetary Remuneration (§ 411.357(v) and (w))

According to the proposed rule, the exceptions would not protect arrangements in which a Donor provides items or services that are "technically or functionally equivalent to items and services the Recipient currently possesses or has obtained." In addition, the proposed rule would require the recipient to "*certify*" that the items and services to be provided are not technically or functionally equivalent to items or services the recipient already possesses or has obtained.

The College believes that the proposed criterion for "technical and functional equivalent" is ambiguous and needs further clarification. In an environment where advances in technology are constant, this would be a very difficult standard in which to comply. More importantly, we are particularly concerned that the requirement to "certify" that the items are not "technically or functionally equivalent to items or services the Recipient already possesses or has obtained" will amount to an unnecessary and costly burden for physician practices and other Recipients. The vast majority of physicians will be unable to make such a determination without hiring an outside expert in the informatics field with the requisite knowledge.

Particular issues CMS needs to clarify in the final rule regarding the "certify" provision are: What types of information should be included in the certification? What are the penalties for innocently misstating the technical or functional equivalency of the item or services? Who decides if and to what extent the Recipient misstates the certification? And, given the technical expertise required to make this certification, CMS should also clarify if it is appropriate to seek outside advice and whether those fees could be paid for by the Donor, and applied to the aggregate limit or cap (should one be adopted)?

Given the multiple complexities and uncertainties surrounding the certification requirement and ambiguity of items that are "technical and functional equivalent," we strongly believe the undue burden and added expense required runs counter to the intent of the MMA to further promote the implementation of this technology. ACP strongly recommends CMS reconsider this requirement, or remove the obligation to "certify" altogether.

In addition, ACP seeks further clarification of CMS's concern about the risk of Recipient's intentionally divesting themselves of functionally or technically equivalent technology that they already possess to shift the costs to Donors. We do not believe there is substantial risk of intentional divesting technology, however, there may be innocent situations that unfairly trigger a violation of the proposed rule. For example, Recipients may have some form of technology that, because of its inherent complexities, the practice is not using it to its full potential. A Donor that offers the Recipient a more "user friendly" system along with the necessary training and supports – something the Recipient desperately needs in order to recognize the technology's full-use – should not be in violation of the rule, especially if the Donor is aware of the situation.

In addition, there may be a situation where a Recipient relocates or is recruited by a Donor to another geographic area. In that case, if the Recipient divests all of its practice assets, including technology, and accepts the Donors technology should that Recipient (or Donor) be in violation of the law? We believe CMS should clarify this restriction and draft a rule that is more flexible.

Finally, CMS includes in the proposed rule "Necessary" definition examples of 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 electronic prescribing information. We recommend that this definition implicitly include connectivity services, help desk services and operating system software. Inclusion

of items such as these will support the optimum use of information technology while not impinging on efforts to combat fraud and abuse.

"Used Solely" (§ 411.357(v) and (w))

The College seeks clarification of the requirement that items and services donated must be "used solely" for the transmission or receipt of electronic prescribing information. We believe that narrowly proposed "used solely" criteria will limit the effectiveness of the proposed rule to facilitate the implementation of HIT. For example, many physicians are currently dissuaded by the 'business case' and practice workflow changes necessary to add electronic prescribing or other forms of technology to their practices. In most practice settings, single purpose electronic prescribing technology is of limited value. While the donation of requisite electronic prescribing hardware, software, and training may affect a change in this position, the inclusion of increased functionality in the donated system (e.g., email capacity, Internet capability, etc.) would further facilitate increased participation by Recipients.

Furthermore, the "used solely" requirement may have the unintended effect of pressuring vendors to "strip-down" already integrated software packages, a practice known as "unbundling," resulting in less office efficiency and ultimately increased practice costs arising from the need to purchase additional technology separately. We are, therefore, requesting consideration of protections that cover increased functionalities in the donations. This would be consistent with the proposal to create an additional exception to protect the provision by Donors to Recipients of some limited hardware (including necessary operating system software) and connectivity services that are 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.

Finally, while ACP greatly appreciates CMS elaborating on what qualifies as "used solely" to a broader "substantial use" definition as it applies to limited hardware and connectivity services, we still believe that even this term would benefit from further clarification. In order to avoid percentages or other confusing criteria, we recommend CMS allow for more flexibility in allowing multi-purpose devices.

Comments on Other Qualifying Technology

CMS is soliciting comments on whether the exceptions should protect qualifying electronic prescription technology that is used for the transmission of prescription information regarding items and services that are not drugs (e.g., supplies or laboratory tests). ACP strongly supports the expansion of exceptions to protect prescription information on items and services that are not drugs. We believe these can include prescriptions for laboratory tests, supplies and durable medical equipment (DME).

Other Donors and Recipients Protected by the Exceptions

The College strongly supports the expansion of the exceptions to include other categories of Donors and Recipients within health care that can facilitate the implementation of electronic prescribing and EHRs. We understand CMS was simply responding to the drafting of the MMA legislation and we hope broadening the scope of qualified Donors and Recipients will be received favorably. We are also aware that Section 1877 of the Act restricts CMS to regulatory authority over physicians, we do believe, however, non-physicians and other health care providers should be excluded from protection.

Specifically, we recommend the inclusion of clinical laboratories and other types of health care providers such as nursing homes, durable medical equipment (DME) providers, community health centers, and other long term care facilities as potential Donors and Recipients of this technology. The College also supports the inclusion of certain other provider organizations, such as Network Providers or other entities that operate, support or manage Network Providers; physician-hospital organizations or physician organizations; Regional Health Information Organization (RHIOs), or others designed to enhance the overall health of the community.

Another area that needs further modification involves the requirement that hospitals can only donate technology to physicians on its own medical staff. This strict requirement runs the risk of the hospital providing technology to only certain members of a group practice, potentially isolating other "members of the group practice" who do not have privileges to the Donor hospital. In order to promote continuity of care and avoid a situation where only part of a practice is wired, we believe Donors should be allowed to donate technology to all "members of a group practice," including those who do not routinely provide services to the Donor. We believe that as long as other safeguards are in place to not otherwise impose barriers to compatibility, there is little risk of fraud or abuse. (*It should be noted that this area will also come into play as Donors incorporate selective donation criteria*).

Similarly, we believe a group practice should be able to provide technology to "independent contractors" providing services within the group or persons who are not physicians. In many cases, especially in emergencies, other providers within the group practice may cover for independent contractors in their absence and it makes sense that all records of patients are readily available to the practice, regardless of the status of the treating provider.

In sum, ACP strongly believes that in order to facilitate the distribution and implementation of electronic prescribing and EHR technology, the definition of Donors and Recipients should be drafted as broadly and inclusively as possible. It is unfair to permit certain Donors to provide technology, but restrict other providers from providing that same technology. We do not believe this was the intent of the Congress in drafting this provision, and therefore, recommend CMS broaden its definition.

Proposed Pre-and-Post-Interoperability EHR Exceptions (§411.357(w) and (x))

The pre-interoperability and post-interoperability exceptions would at least protect electronic health records software (that is, software that is essential to and used solely for the transmission, receipt, and maintenance of patients' electronic health records and electronic prescription drug information) and directly-related training services, provided that the software includes an electronic prescribing component. ACP requests that the elements covered by the exception for EHRs be further clarified and expanded. More specifically, it is unclear from the proposed rule whether the donated costs of an EHR system operating within an Application Service Provider (ASP) model would be covered by the exceptions. We seek clarification here.

Furthermore, it is unclear whether the "help desk" or the consultation that is routinely required with the implementation of an EHR system within a practice is covered by the proposed exceptions. This service is vitally important to the success of implementation. It is also not clear whether clinical decision support technology (e.g., PIER) is included under the proposed exceptions. We believe that this type of clinical decision support technology is an important element in any effective EHR system and should be covered by the exceptions.

Finally, the College strongly suggests that permitted donations be broadly expanded to include any equipment (especially hardware), item, information, right, license, intellectual property, software, training, education or service used for developing, implementing, operating or facilitating the adoption of EHR and other HIT and the electronic exchange of health information by physicians and other health care providers. In addition, we favor CMS take the position requiring all donations meet or exceed the CCHIT-approved certification levels of functionality, interoperability, and security. We believe that the significant benefits of facilitating implementation of technology by including this broad category of CCHIT-certified donations within the exception far outweigh the potential for increased abuse.

Selective Criteria (§411.357(x)(4))

CMS is proposing that neither the eligibility of a recipient to receive items and services from a protected Donor, nor the amount or nature of the items or services received, may be determined in a manner that takes into account the volume or value of the recipient's referrals or other business directly generated between the parties. The proposed rule further clarifies that this exception does not preclude selection criteria that are based upon an indirect measure of business generated by the recipient (e.g., the total number of prescriptions written by a recipient of electronic prescribing hardware or software).

The College supports the need to exclude from the exception donations that are a condition of doing business with the Donor, or are a direct result of the volume or value of the amount of business generated by the recipient to the Donor. We are concerned, however, about the further elaboration that permits selection based upon indirect measures of business generated. We believe that most Donors will employ such selection criteria that

will potentially disadvantage small physician practices -- which generate relatively limited business – in competing for donations included in the proposed exceptions. We suggest that the proposed rule include incentives for donations covered by the exception to promote donations to small (especially in rural and underserved) practices.

Value of Protected Technology

ACP is greatly concerned about limitations on the aggregate fair market value of all items and services provided to a Recipient from a single Donor and the belief that a monetary limit is appropriate and reasonable to minimize the potential for fraud and abuse. First, we do not believe the risk for fraud and abuse is high and, more importantly, we believe that setting such limits would unnecessarily discourage potential Donors from providing technology.

The College questions the need for caps or aggregate limits to be placed on donated technology to meet the requirements of the exceptions. There is real question as to how such limitations would implemented, calculated, monitored, and adjusted from year-to year. A more basic question, however, is whether the standard to be used for calculating the cost would be the *fair market value* to the Recipient, or what the *actual cost* is to the Donor, keeping in mind large Donors would be able to leverage economies of scale by buying in bulk. In addition, the per-physician implementation cost to a small physician practice will be much higher than for a medium-to-large physician practice. Therefore, setting a per-physician cap or limitation could greatly disadvantage the smaller practice and limit their overall eligibility. It also should be noted that donation value involves many other variables that CMS should consider. For instance, there are fees for software licenses, IT support and training, processing, implementation, hardware, connectivity, and other elements. So, if CMS is inclined to adopt a cap or aggregate limitation, we urge consideration of all the expenses (initial and ongoing) involved.

While we recognize CMS's fraud and abuse concerns, we believe the proposed rule already contains sufficient protections that alleviate the need for a cap or aggregate limits. The placement of a cap or aggregate limitations would only serve to stifle the implementation of electronic prescribing and EHR technology. We are particularly concerned that a cap, without proper consideration of all the variables, will significantly disadvantage smaller practices that need the most financial assistance. We, therefore, do not believe a cap is warranted or necessary at this time.

Definitions of 'Interoperability' and 'Electronic Health Record'

ACP supports CMS's use in the proposed rule of "interoperability" as "the ability of different operating and software systems, software applications, and networks to communicate and exchange data in an accurate, secure, effective, useful, and consistent manner." We believe this proposed language sufficiently defines the term.

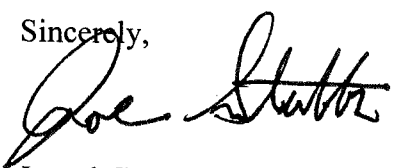
The College suggests, however, that you reconsider the use of the term "electronic health record (EHR)." This term, as used in the proposed rule, is inconsistent with terminology used within the information technology industry and, its use to refer to several different concepts, is confusing to the reader. An EHR typically refers to the broad concept of the sum total of all the health care data that exists regarding an individual within the electronic universe. This may include an individual's personal health record, their history of medication use stored by a drug plan, medical records electronically stored by their primary physician, electronically stored imaging results stored in the local hospital etc. An EHR system refers to any system (e.g., e-prescribing, electronic medical record, personal health record) that is a component within the individual's EHR. An electronic medical record (EMR) system typically refers to patient-centric, electronically maintained information about an individual's health status and care that focuses on tasks and events directly related to patient care, and is optimized for use by clinicians. It is also limited in scope to the continuum of care within a single clinical delivery system. This EMR system definition is based upon a definition offered by the Gartner Consulting group for a computer-based patient record (CPR). In most instances throughout the proposed rule, we believe you are technically referring to an EMR system rather than an EHR, however, the final rule should make a clarification.

CONCLUSION

While we commend CMS for submitting a proposed rule allowing the promotion of electronic prescribing and electronic health records, we strongly urge the OIG and CMS to make the necessary clarifications and promulgate the final rule as expeditiously as possible. Donors and Recipients need to have the necessary comfort to engage in these types of arrangements and the final rule should do nothing to discourage such engagements.

Again, ACP greatly appreciates this opportunity to comment on the proposed standards. Please do not hesitate to contact Neil Kirschner, Ph.D., Senior Associate, at (202) 261-4535 and nkirschner@acponline.org or Patrick Hope, Esq., Legislative Counsel, at (202) 261-4541 and phope@acponline.org if you have any questions regarding these submitted comments.

Sincerely,



Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

Michael D. Maves, MD, MBA, Executive Vice President, CEO

December 12, 2005

Mark B. McClellan, MD, PhD, FACP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1303-P
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: *Medicare Program; Physicians' Referrals to health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;* 70 Fed. Reg. 195, 59182 (Oct. 11, 2005); File Code CMS-1303-P

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to provide its views on the Centers for Medicare and Medicaid Services' (CMS) proposed rules concerning *Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements*, 70 Fed. Reg. 195, 59182 (Oct. 11, 2005)

I. General

The AMA appreciates the Centers for CMS's efforts to foster the development and utilization of health information technology (HIT) by proposing exceptions to the Stark self-referral laws for electronic prescribing technology. The AMA is optimistic that e-prescribing and other health information technology can achieve the promise of improving patient safety and increasing administrative efficiency.

The AMA supports legislation and other appropriate initiatives that provide positive incentives for physicians to acquire health information technology. We believe that the creation of safe harbors for assisting physicians with the adoption of HIT is necessary in order to facilitate wide-spread usage of such technology. While the AMA supports assistance to physicians purchasing HIT, it strongly believes that such assistance cannot unreasonably constrain physicians' choices regarding which HIT system to purchase. In addition, the AMA believes that any assistance must promote voluntary rather than mandatory sharing of Protected Health Information (HIPAA – PHI) with the assisting facility consistent with the patient's wishes as well as applicable legal and ethical considerations.

In order to encourage voluntary electronic prescribing in the Medicare program, the Department of Health and Human Services should be fully aware of the future Medicare environment for physicians. Initial standards for e-prescribing will be in place by January 1, 2006. And, by law, e-prescribing standards must be in place by April 1, 2009. The 2009 standards include broad HIT requirements such as the ability to identify drug interaction, warnings, or cautions; the ability to provide information on lower cost therapeutically appropriate alternatives; and the ability to provide information that relates to the medical history of individuals. At the same time, CMS actuaries predict five percent annual payment reductions for physicians for six years, starting in 2006. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. This means that by 2012, physicians will be paid about 26% less than in 2005, while practice costs will have increased significantly.

Moreover, a recent study by Robert H. Miller, et al, published in *Health Affairs* September/October 2005 issue, found that initial electronic health record costs were approximately $44,000 per full-time equivalent (FTE) provider per year, and ongoing costs were about $8,500 per FTE provider per year. Initial costs for twelve of the 14 solo or small practices looked at, ranged from $37,056 to $63,600 per FTE provider. With these potential costs and this financial environment, it will be extremely difficult for physicians to allocate the resources necessary to invest in new technologies. The AMA is confident that e-prescribing has significant potential benefits to physicians and their patients, but is commensurately concerned that investments in e-prescribing technology and electronic health records will be difficult given the dramatic reimbursement reductions forecast in Medicare.

While the AMA appreciates CMS's efforts to encourage e-prescribing by creating exceptions to the Stark laws, given the limited financial and technologic resources of many physician practices, we are concerned that these exceptions are not sufficiently broad to encourage widespread and successful adoption of e-prescribing technology. To this end, the AMA believes that both CMS and the OIG should adopt final rules that reflect liberal exceptions that will better achieve the ultimate promise of e-prescribing – improved efficiency, patient safety, and health care quality.

A. Electronic Prescribing Exception: § 411.357(v)

1. Protected Non-Monetary Remuneration

a. "Necessary" Non-Monetary Remuneration

Pursuant to the proposed rule, allowable non-monetary remuneration includes hardware, software, internet connectivity, training, and support services. Given the enormous costs related to implementation of HIT, the AMA strongly believes that the list of acceptable donations should be more expansive. The AMA thinks that in addition to the aforementioned allowable non-monetary remuneration, the safe harbor should include donations of maintenance, associated costs related to implementation, upgrades, as well as any costs associated with licenses, right s of use, or intellectual property.

There will be numerous unanticipated costs associated with implementation and use of e-prescribing technology. In addition, there will be extended maintenance fees incurred as a result of the 24-hour-day, 7-day-a-week online technical support required by physicians' schedules. And, due to the ever-changing nature of the technology industry, there will undoubtedly be costs associated with upgrading any and all e-prescribing technology in the future. Any Stark exception for donations of e-prescribing technology, therefore, should address not only the costs of acquisition, but the costs of implementing, maintaining, and upgrading e-prescribing technology.

The regulations also require that physicians determine what technology they possess. Specifically, physicians must certify that any technology they receive is not technically or functionally equivalent to any existing technology. While the AMA recognizes CMS's concern regarding divestment and replacement of technology, we believe that requiring such a certification, and effectively banning physicians from utilizing the exceptions to obtain potentially more efficient and effective e-prescribing technology, will create an additional financial burden on physicians and will be at odds with the goal of encouraging e-prescribing by outfitting physicians with the most useful technology.

Requiring physicians to certify existing technology capabilities is an enormous financial and administrative burden on physicians. Many physicians do not know the capabilities of the technology they possess or how their technology relates to the technology being offered by donors. Assessing these capabilities takes both time and expertise. Acquiring the expertise to determine technological capabilities would require time away from patient care for physicians, or in the alternative, money to hire an outside expert, both of which would further deter those physicians already skeptical about implementing new e-prescribing technology.

Moreover, the AMA is concerned about the administrative process associated with a certification. We believe that such a requirement would raise numerous questions and complications, including: what, exactly, the certification would attest to; who would be liable for the information in the certification when a physician relies on someone in his/her

office, or relies on an outside expert for making technological determinations; what the repercussions for misinformation on a certification would be; who would be responsible for determining that the information was incorrect; how the person or group making that determination would determine whether the incorrect information was submitted intentionally or just the result of a lack of knowledge or mistake; and whether there would be a right to appeal that decision. These questions, and more, surround any proposal to force physicians to certify technological information for which they do not have the expertise, and would lead to additional apprehension and skepticism on the part of the physician.

Finally, the AMA believes that a prohibition on donating technology to physicians that already have similar technology would ultimately hinder the goals of widespread usage of e-prescribing technology. Such a prohibition could bar qualified physicians from receiving technology that could result in standardization among all physicians working at a single donating hospital. It could bar physicians who have outdated, outmoded, or unusable technology from accepting updated, user-friendly technology. And, it could bar physicians that might have the capability to support e-prescribing technology, but not the knowledge or incentive to put it into practice, from receiving realized technology that would encourage them to e-prescribe. It is at odds with the goals of these regulations to restrict physicians from receiving technology that would most strongly encourage extensive adoption of e-prescribing.

b. "Used Solely"

Under the proposed regulation, the technology provided to physicians must be "used solely" for the transmission or receipt of electronic prescribing information. This limits donated hardware and software to that necessary and used solely, to transmit and receive electronic prescribing information to/from a drug program that meets CMS program standards. The AMA is concerned that such a strong limitation will constrain software interoperability and hamper the widespread implementation of electronic health records and e-prescribing.

Requiring technology to be used solely for e-prescribing where such technology may have electronic health record or other health information usages will hinder the types of quality and IT initiatives that CMS intends to encourage. Further, the proposed language would either exclude or require the dismantling of such common technologies as hardware and software suites containing email applications, office systems, internet capability, and connectivity. This prohibition would severely limit the types and brands of technology that could be donated and would likely result in the incurring of additional delays and expenses related to stripping multi-function technology. In addition, it would require physicians to maintain two completely separate systems. The AMA does not believe that it is practical to require physicians to acquire or use software and hardware solely for electronic prescribing. Requiring a stand alone system creates all sorts of unnecessary complexities and confusion and would be another obstacle to encouraging the worthy goal of broad adoption of e-prescribing technology.

Finally, the AMA urges CMS to broadly interpret qualified prescriptions. The AMA believes that permissible e-prescribing should not be limited to pharmaceuticals. Rather, allowable prescriptions should include non-pharmaceutical prescriptions such as physical therapy, imaging, durable medical equipment, and laboratory tests.

2. Designated Health Services (DHS) Entities Protected by the Exception

Under the proposed regulations, donors and recipients include hospitals to members of their medical staffs, group practices to physician members, Prescription Drug Program (PDP) sponsors and Medicare Advantage (MA) organizations to physicians. The AMA believes that donors and recipients should be broadly defined in order to encourage the greatest number of physicians to implement and utilize e-prescribing technology. We are concerned that restricting the donors and recipients as proposed, will exclude many physicians, including those who are not affiliated with any hospital, those who have privileges but are not members of a hospital staff, and those who are employees of a hospital that is not willing or able to donate. And will, in addition exclude health plans, labs, and networks as donors. Furthermore, the enumerated donors and recipients do not account for those physicians who may work with several potential donors, creating a situation whereby the donors might be encouraged to compete against each other, or to the contrary, no donor feels truly responsible for supplying the technology.

In addition, the AMA believes that the restrictions will create unnecessary burdens and complications for physician networks, Independent Physician Associations (IPA), and group practices. The proposed rule does not appear to allow donations to physician networks, IPAs, and group practices. This could easily result in a situation whereby only one or a small number of physicians in a physician network, IPA, or group practice are members of a hospital medical staff, and thus the only ones permitted to utilize the e-prescribing technology. Not to mention where members of a group practice, physician network or IPA are members of different hospital medical staffs and thus offered different, potentially incompatible technology. Moreover, the AMA believes that the proposed rule unnecessarily prohibits donations by group practices to physicians who are not members of the group, physician networks, and IPAs, even where physicians in group practices share patients with such physicians or need to be clinically integrated with a physician network or IPA. The AMA believes that donations to and from physician networks, IPAs, and group practices should be included in any exception or safe harbor. Allowing all entities that bill Medicare to donate electronic health records and e-prescribing technology to any physician or group of physicians would go a long way toward implementing interoperable electronic health records on a national scale.

3. Additional Limitation on the Provision of Electronic Prescribing Technology

b. Value of Protected Technology

While the AMA appreciates CMS's efforts to reduce the threat of fraud and abuse, we do not think that a cap on the value of protected technology should be imposed. Imposition of a cap would unquestionably result in costs being passed on to physicians. Because there is no

way of knowing what the costs of products will be in the future, or even what products will be available, a specific monetary cap could easily be exceeded by new, more advanced technology. Such a situation would result in physicians being forced to cover all costs that exceed the cap. This threat is compounded by the absence of any language in the proposed rules that accord physicians a choice with regard to the donated technology. Without any input as to the technology being donated, physicians could easily be faced with a product donation that exceeds the cap and be required to choose between absorbing the additional cost or rejecting the donation in whole. Such a situation is even more likely where the cap is based on the value of the technology to the physician as opposed to the cost to the donor, and the donor is able to obtain valuable technology at reduced rates. Thus, the AMA does not believe that a cap is necessary so long as any non-monetary remuneration that is donated is done so without limiting or restricting the use of the e-prescribing technology to services provided by the donating entity, and so long as it does not take into account the volume or value of referrals.

The AMA believes that the proposed exceptions to the Stark self-referral laws should be broad and encourage rapid adoption of e-prescribing technology. CMS should craft definitions, limitations, and conditions that address realistic concerns about program and patient abuse without being unnecessarily restrictive. Such latitude is necessary in order to overcome considerable physician trepidation and realize the promise of e-prescribing and electronic health record technology.

We are pleased that CMS is moving forward with adoption of exceptions to the Stark self-referral laws for e-prescribing and we support CMS in this effort. We appreciate the opportunity to provide our views on the implementation of the proposed rule and look forward to working further with CMS on this important matter. Should you have any questions regarding these comments please contact Anders Gilberg, Assistant Director, Federal Affairs, by phone, 202-789-4688, or by email, Anders.Gilber@ama-assn.org.

Sincerely,

Michael D. Maves, MD, MBA