CMS-1303-P-1 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Phillip Lowe **Date & Time:** 10/25/2005

Organization : Lowes Therapy

Category : Physical Therapist

Issue Areas/Comments

Background

Background

Physicians are choosing to start PT Clinics to supplement their income.

Issue

Background

Private Practice of PT Clinics owned by PT's will continue to decline and become extint.

Collection of Information Requirements

Monopolies with Physician ownership will result.

Provisions of the Proposed Rule

Consumers will loose their choice of clinics.

Regulatory Impact

Loss of private PT clinics. Decreased options to patients. Referral for profit. Consumer abuse.

CMS-1303-P-2 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : **Ms. Cynthia Edmondson** **Date & Time:** **11/04/2005**

Organization : **Client of MQMB**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

SSI & SS receipent of MQMB.

GENERAL

GENERAL

The current system is grosly inefficient refering obsolete PROVIDERS over the 800 hotline. I don't believe in "passing the buck" to them. MEDICAID employees can do as MEDICARE employees do. They send out a letter to update PROVIDERS information annually and not rely on the PROVIDER, hopefully, one day to inform them. As a results, "BA HUMBUG" to you MEDICAID for continuing giving out caustly false information to the clients throught the State of Texas! This is the age of information, not mis-information! Get it right or pull the plug on the 800 number.

Cynthia Edmondson
202 Red Oak Cir
Austin, Texas
78753

Issue

Background

Life's experiences on several occasions for various MD's referals.

Collection of Information Requirements

Personal use of "the system" in which I experienced unprofessional outdated information freely given, as well as mailed to me. Attempted to contact the "PROVIDERS" to no avail. Time and money waisted. Very frustrating! This information is also freely given on the web sight as well. It is false, outdated and useless. Again, a waste of time, money (copies).

Provisions of the Proposed Rule

Reform needed for Client PROVIDER list to be efficient, updated reguarly, current & true.

Regulatory Impact

This is a travisty. The government should not opperate so inefficiently. It's another big waste of time and money for all

involved. Imagine, the entire State of Texas clients having to search for a physician who takes MQMB. First, call BENEFITS/POLICY 1-88-252-8263 in order "to find out what Medicaid pays for, or to find a provider". All correspondence is false! Waste!

CMS-1303-P-3 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : **Ms. Rebecca Marshall** **Date & Time:** **12/02/2005**

Organization : **American Academy of Pediatrics**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1303-P-3-Attach-1.DOC

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American Academy of Pediatrics

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Statement Submitted in Response to:
Centers for Medicare and Medicaid Services
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

On behalf of the American Academy of Pediatrics

Introduction

The American Academy of Pediatrics (AAP) is pleased to submit this response to the Centers for Medicare and Medicaid Services Proposed Rule on Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements. The AAP and its member pediatricians dedicate their efforts and resources to the health, safety, and well-being of infants, children, adolescents, and young adults. The AAP has approximately 60,000 members in the United States, Canada, and Latin America. Members include pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. The mission of the American Academy of Pediatrics is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults.

The use of Electronic Health Records (EHRs) and the functionality of electronic prescribing will produce improvements in health care and foster more transparency and health care information availability for patients. Although we support the use of these technologies, we understand there are presently many obstacles to their acceptance and implementation.

Misalignment of certain benefits and costs

One significant obstacle, especially for outpatient care, is the misalignment of certain benefits and costs. Presently, the practicing physician must bear the bulk of the expenses, with no ability to recoup expense from groups that may gain the largest benefits—that is, patients and larger health care organizations. To decrease these obstacles, we enthusiastically support the spirit of the new safe harbor under the federal anti-kickback statute for certain electronic prescribing

technology, as required by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law No. 108-173). However, in the language presented, concerns arise that specific regulatory decisions might minimize the effectiveness of the exception designed to increase acceptance of electronic prescribing technologies. These concerns are enumerated in this communication.

CMS-1303-P BACKGROUND

Coverage of replacement technology

The section "Electronic Prescribing Exception," §411.357(v), defines to whom this exception pertains and what nonmonetary remuneration is included. Correctly, this section includes not only hardware but also software, Internet access, training, and support. However, in such a rapidly changing world, there must be assurances that the rules will not curtail donations because version upgrades that are necessary to keep pace with evolving functional and computer communication standards and with expectations of the users are inappropriately characterized as "replacements." Specifically, the rule states the definition of "necessary" is not intended to limit provision of equipment to "enhance the functionality." However, there are also descriptions that the rule will limit providing equipment when the physician already has equipment that "could run the new software." The rule should clearly state that upgrades to make the equipment on par with currently available systems would be covered in this exception.

Sole use restriction

This same section details description of the "used solely" requirement of this exception. The rule appropriately identifies that clinicians will likely want to use a single system, single device, and

single Internet connection for these functions. However, the specific limitation as described is problematic. The allowance that clinicians may use these donated tools for other purposes and even purchase additional tools from the sponsor for fair market value is a helpful addition. Requiring the primary function of the tools to be for electronic prescribing, or as later described an EHR, may raise a large secondary obstacle. In fact, no acceptable metric exists to quantify and assign the relative amount of use for the enumerated function compared with other functions. Fear of misuse may add a real or perceived barrier to the rule utilization.

Interoperability

The importance of interoperability is discussed not only for electronic prescribing but also in the sections pertaining to EHRs. Although interoperability is intended to decrease the influence of the sponsor on the recipient of the donation, interoperability also supports many organizations' efforts to increase system usefulness in general. Moreover, the specific technical guidelines for interoperability could not be included at this time, because they have yet to be developed. Thus, because technical standard-based designs are vital for future complete system interoperability, the AAP strongly encourages the inclusion of this requirement.

Interoperability criteria are used to separate specific provisions of the exemption relative to the EHR into two periods. The first period, "pre-interoperability," is the time prior to the Secretary's adoption of product certification criteria, and the second is after the interoperability criteria have been specified, or the "post-interoperability" period. It appears that the intent is to dramatically limit the scope and degree of the allowable donations in the "pre-interoperability" period.

Although we agree that this certification is important, we are concerned that significant constraining limits, especially during the early period, will only further delay implementation.

Presuming that system interoperability will be clearly defined in the future, there should be consideration for the costs of transferring data and moving to a new system, which may be significant. Significant expense occurs not only when moving from a paper to an electronic system but also when moving from one electronic system to another. The AAP urges that consideration for necessary migration support should also be included in this exception.

Certification

The AAP agrees that covered systems for both EHRs and electronic prescribing should be certified in accordance with the product certification criteria adopted by the Secretary (sections §411.357(x)(2) and §411.357(x)(9)). However, the AAP cautions that the certification process may discriminate against software that is useful for pediatricians. The special requirements of Pediatric Electronic Medical Records have been clearly spelled out,[1] and physicians who treat children should be required to have systems that incorporate these features. Again, this will not only diminish the sponsoring organizations' influence but also ensure that systems in the community provide adequate functionality.

If additional resources are needed to move from a noncertified system to the new certified system, those resources should be covered in this exception. As discussed before, this may include not only new equipment and software but also other support services.

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[1] American Academy of Pediatrics, Task Force on Medical Informatics. Special requirements for electronic medical record systems in pediatrics." *Pediatrics*, 2001;108:513-515

Electronic prescribing additional functionality

The AAP supports the requirement that electronic prescribing be a component of any covered EHR. In addition, the AAP believes that it would further increase the implementation if the electronic prescribing is not limited only to drugs. It should also allow, though not require, the ability to order other prescription-based medical products and services, such as laboratory tests, supplies, and equipment. Inclusion of full ordering functionality will increase the use of electronic prescribing systems, therefore increasing benefits. Inclusion of full ordering functionality will also minimize the potential quagmire when using computerized EHR equipment that has many logical ordering (and other) functions, but only a subset are covered in the ruling and no metric exists to separate the different functions' relative usage.

Impact of caps

Another important specific of the rule addresses methods for adding caps on total value of the provision. Wisely, the authors of the rule have included both the cost of equipment and direct services (ie, Internet connectivity) and the cost of training and support. The methodology and specifics of the cap are crucial components of the system. Although the authors identify that sponsors may not want to accept the entire responsibility of a system, partial responsibility should not be an assumption and should not be included as a component of calculation of the cap. If a sponsoring organization does want to accelerate implementation by paying the entire value, this should not be restricted by the rule. In addition, any cap should be flexible enough to include all aspects of implementation and ensure that it is large enough to support a real-world,

integrated system. Theoretical, scaled-down versions can be frustrating, even dangerous, in health care workplaces.

Further description of allowable value caps seems to suggest an interest in linking the three separate components of the rule change: electronic prescribing, "pre-interoperability" period EHRs, and "post-interoperability" period EHRs. With rules in place to take into account presently available systems, it seems illogical to limit the allowed value for a present system because a previous donation had been made. To obtain the functionality needed for an EHR in the "post-interoperability" period, the value needed is not diminished by the fact that previously, there were donations in the "pre-interoperability" period except when the original equipment could be reused. Real-world considerations must be in place when calculating the value needed to implement a system. In fact, health care computer technology is evolving so quickly this decade that "old" systems can become truly obsolete in only 2 to 3 years.

Medicare versus Medicaid rules

It is very possible that state Medicaid regulations may prohibit support for physicians accepting Medicaid, even though the support may become acceptable under Medicare. Because pediatricians mostly take Medicaid and very little Medicare, if at all, they may get unequal support versus other clinicians, and a "digital divide" may occur as a result. This is a significant concern for pediatricians and was one of the top 10 resolutions passed at the recent AAP Annual Leadership Forum. The resolution required the AAP to ask for parity in Medicare/Medicaid support of electronic clinical information systems. Any changes in rules should be adopted equally for both Medicaid and Medicare.

The final comment refers to the discussion of potential inclusion of related software that would improve patient health care integration but is not necessarily included in either electronic prescribing or EHRs. Three important related utilities include software and interfaces with other organizations, such as immunization registries; support for Personal Health Records to give patients more control and access to their health information; and software for the analysis of quality of patient care. Certified EHRs should include all three utilities.

In conclusion, the AAP believes that the proposed exception has the potential to significantly stimulate the implementation of electronic prescribing and EHRs. With proper attention to the details described above, this accelerated implementation of electronic prescribing will not jeopardize the original goals and protections provided by the original physician self-referral prohibition in section 1877 of the Social Security Act (the Act).

We appreciate the ability to comment on this important rule change.

CMS-1303-P-4 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mrs. Nancy Payne **Date & Time:** 12/08/2005

Organization : Allina Hospitals & Clinics

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1303-P-4-Attach-1.DOC

December 8, 2005

Mark B. McClellan, M.D., Ph. D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1303-P
Mailstop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Physicians' Referrals to Health Care Entities with which They have Financial Relationships; Exceptions for Certain Electronic Health Records Arrangements, Federal Register, Tuesday, October 11, 2005.

Dear Dr. McClellan;

Allina Hospitals & Clinics is a not-for-profit system of hospitals, clinics and other health care services dedicated to meeting the lifelong health care needs of communities throughout Minnesota and western Wisconsin. With eleven hospitals, 65 clinics, 14 community pharmacies and four ambulatory care centers, we play a prominent role in the well-being of our communities.

We are currently engaged in implementing a world class electronic health record and practice management system called Excellian. We believe that Excellian is a significant enabler that helps us fulfill our mission of serving our communities by providing exceptional care, as we prevent illness, restore health and provide comfort to all who entrust us with their care. To that end, Allina has developed an affiliate strategy to reach out to our independent physician practices and encourage them to participate in the development of a community health record. Through the affiliate strategy, Allina seeks to provide effective tools to facilitate a positive patient and physician experience across the continuum of care while complying with all laws and regulation governing business with affiliates.

Allina and its affiliated clinics recognize the unquestionable power and benefit of an electronic community health record. However, the effective implementation of such a robust tool is time consuming and very expensive. Further, it requires a paradigm shift for medical practitioners and presents many change management and productivity issues.

In an effort to bring the power of an electronic health record to our affiliates and extend the benefits to the communities we serve, we are respectfully commenting on the proposed changes in order to enable Allina to more easily engage our independent physician

practices to create a solution that is fair for all participants. Thank you for your review and consideration of the following comments.

e-Prescribing

It is very difficult for us to address this section of the proposed rule independent of the electronic health record. Our goal is to implement an integrated approach and find the focus on e-prescribing unnecessarily limiting. Our major concern is that this portion of the rule restricts our ability to work with our physicians on an integrated model when we can only support equipment that is **necessary and used solely** for e-prescribing. We understand the intent of the MMA as it relates to e-prescribing, and would suggest that you drop the restriction in totality, or if you must have a restriction that you change the language from "used solely" to "used substantially."

Covered Technology

Covered technology should include devices that go beyond the typical CPU, monitor and keyboard. Hand-held devices, personal computers, servers and any other connections should be covered. We are concerned that the exclusion in the pre-interoperability standards for billing, scheduling and office management software do not support an integrated approach that would create much efficiency for the medical practice and would feed into hospital systems for quality reporting and billing accuracy. By CMS supporting an expansion of the criteria to include such systems, you may find a significant reduction in billing errors and the ability to see data that crosses the continuum of care from an acute episode to follow up in the primary care or specialty office. Integrated systems are essential to improve the quality and safety of patient care. Please do not be short-sighted in this exception. We vehemently ask that CMS consider the inclusion of integrated technology under the exception. Finally, we believe the rule should be clarified to state that covered technology includes not just software but also access to data processing services. This is intended to ensure that the exceptions will extend to systems which house electronic health record technology on central servers to which providers may obtain secure remote access.

Effective training and education is key to the adoption and utilization of technology. Training is not a one time event. We seek further clarification on the ongoing nature of training as upgrades in software or hardware take place. We also ask that you are more explicit in including ongoing help desk support and systems maintenance under the exception.

Value of Protected Technology

We disagree with the establishment of a cap on the dollar amount that we can provide under the exception. At this point, the technology is too new and is changing too quickly to know where to set an appropriate cap. We feel that it would be very difficult to find a bright line on this issue. While we want to work closely with our physician partners in supporting their utilization of the technology, we are limited by our own financial resources and do not feel that the government needs to set the bar. If a cap is necessary, we are more comfortable with a percentage being used rather than a specific dollar amount.

CMS will need to be clear on the actual cost limitations versus the value of the technology to the physician. Any methodology that focuses on the value of the technology to the physician would be very difficult to administer and would introduce considerable ambiguity into the rule.

Fraud and Abuse

- **Donors**

We ask that CMS expand the list of donors and recipients and think beyond the walls of the hospital or individual physician office. Why would clinical labs not be included? Are RHIOS's included? What about nursing homes? Please include language that clearly includes group practices, along with individual physicians, as permitted recipients of donated technology.

- **Value of Referrals**

While we recognize that the pre-interoperability exception's reference to the volume or value of referrals resembles similar provisions in other Stark exceptions, we believe that in this context a more flexible approach is needed. While a hospital should not donate technology based on the volume or value of referrals from a physician group, it should be permitted to establish selection criteria that will allow for the donation to benefit the greatest number of patients in the hospital's community. Such criteria, while not referral-based, may lead to selection of recipients with whom the hospital has a high volume of patients in common. We believe that clarifications such as those found in the post-interoperability exception for determinations that are not deemed to be based on the volume or value of referrals should be included within the pre-interoperability exception as well. This would help to speed the adoption of integrated technologies without adding significant risk of abuse.

Certification

As to the certification by physicians regarding technical or functional equivalency, we would support certification by physician office not by individual physicians. We suggest that the physician certification take into account items and services "taken as a whole" as one piece of functionality may be equivalent but all of the physician's or groups existing items and services, taken together, are not working toward an integrated solution.

As to certification of technologies according to criteria adopted by the Secretary, we would like a timeframe to be established within which an existing technology could become certified. In the case of our electronic health record system, we can only offer the version that is in production. We need a grandfather clause to include time after standards are adopted to implement, such as, "no later than 2 years after the effective date of criteria adoption by the Secretary."

Additional Suggestions for Changes to the Rule

§411.357 Exceptions to the referral prohibition related to compensation exceptions.

(w)(2) Please add "intended" to limit or restrict…

(w)(5)(iv)Please add physician "or group practice".

(w)(8) Delete the entire section or add "unless part of an integrated solution," after the last comma.
(w)(9) Delete this section and add under the e-prescribing language. This is not necessary in addressing the Stark exception.

In closing, we would like to suggest that CMS do further work to develop a cleaner exception. The conditions and limitations of the proposed changes will limit more than necessary the opportunities to extend the benefits of technology development, purchase and implementation. The lack of attention to integrated systems solutions is a grave mistake and will not support the changes that must take place in order to reduce the long term costs related to lack of information sharing between providers in the continuum of care for a patient. If you have any questions please feel free to contact me at 612-262-4912.

Sincerely,

Letter Sent Electronically

Nancy G. Payne, RN
Director Regulatory Affairs

CMS-1303-P-5 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Dr. Mark Leavitt **Date & Time:** 12/09/2005

Organization : CCHIT

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issue

Background

Please see attached document

Provisions of the Proposed Rule

Please see attached document

CMS-1303-P-5-Attach-1.PDF

CMS-1303-P-5-Attach-1.PDF

CMS-1303-P-5-Attach-1.PDF

The Certification Commission
for Healthcare Information Technology

December 8, 2005

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attn: **CMS-1303-P**
P.O. Box 8010
Baltimore, MD 21244-8010

(Submitted electronically via www.cms.hhs.gov/regulations/ecomments)

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

*Comments on **Background** Section of document.*

CCHIT strongly supports the decision by CMS to simultaneously propose exceptions at §411.357(w) and §411.357(x) for electronic health records software and training services that are not covered by the MMA-mandated exception (page 10 of document).

We believe the MMA-mandated exception, standing alone, would have insufficient impact on health IT adoption or the quality and safety of care, for two reasons:

- First, while there is good evidence that the cost of hardware, software and training for electronic health record systems is a significant barrier to adoption by physicians, there is no such evidence that cost is the major barrier to standalone e-prescribing systems; in fact, free giveaways of e-prescribing systems by payers have demonstrated very low acceptance by physicians.

- The MMA-mandated exception requires that the e-prescribing hardware, software and training be used ***solely*** to receive and transmit electronic prescriptions. The exception does not require e-prescribing to include basic screening for drug interactions, contraindications, allergies, or dose correctness, and thus omits the tools needed to improve drug safety. In addition, as currently structured, the MMA-mandated exception would encourage greater fragmentation of electronic patient information rather than integration. Without tying in the patient's diagnoses, laboratory results, and other data, along with decision support tools to utilize this information for prescription checking, a standalone e-prescribing system provides only a small part of the potential available in an electronic health record, and would fail to achieve the full potential benefits to quality and safety.

Comments on "Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: §411.357(w) and §411.357(x) (page 33 of document)

CCHIT reiterates its support for including these exceptions to support the adoption of electronic health records (EHR). We believe there are clear circumstances in which a hospital, group practice, Medicare prescription drug plan, or Medicare Advantage plan can donate electronic health record technology to physicians, which could help accelerate the adoption of interoperable health IT and improve the quality and safety of care, without risk of program and patient abuse. We wish to add, however, that these exceptions alone will not suffice, and that widespread health IT adoption will require pay-for-performance incentives within the healthcare reimbursement system.

Comments on the concept of pre- and post-interoperability exceptions (page 34).

Since the rule proposes differing requirements for the period before and after the Secretary of HHS adopts product certification criteria, we would like to provide updated information on the timing and availability of product certification.

CCHIT is engaged in developing the Compliance Certification and Inspection Process for Electronic Health Records under HHS Contract #HHSP233200454102EC. Certifying EHR systems for ambulatory care – the domain of physician office practices, the target of the proposed exception – represents our first scope of work under that contract. The contract requires CCHIT to publish proposed certification criteria by December 30, 2005, and to complete a pilot test by February 28, 2006. CCHIT published its proposed criteria on November 30, 2005, one month ahead of contract deadline, and is on track for the timely completion of the pilot test as well. This should lead to inspection of ambulatory EHR systems beginning in March 2006, with official certification results available in June 2006. In addition, while the standards for ePrescribing are still being finalized, we anticipate beginning certification of ePrescribing within EHRs on September 30, 2006.

While we cannot predict the interval between CCHIT's deliverables and the Secretary's adoption of product certification criteria, we recommend CMS and OIG consider a scenario in which certification criteria are in place ***before*** the proposed rule takes effect, making the need for a "pre-interoperability" exception moot. This could simplify the process of formulating the EHR exception.

Comments on the risk of program abuse posed by a DHS entity's provision of valuable technology to physicians (page 34).

We do not agree with the statement, "The provision of electronic health records technology poses greater risk of abuse than the provision of limited electronic prescribing technology, because electronic health records technology is inherently more valuable to physicians in terms of actual cost, avoided overhead, and administrative expenses of an office practice." Although ultimately EHRs may increase the efficiency of an office, in the near term they are disruptive to workflow and frequently require additional staff rather than fewer. This is one reason why adoption has remained so low.

Instead, we believe the risks of program abuse should be separately analyzed for each of the elements in obtaining, implementing and supporting an EHR system. We would identify the following three elements and their risks:

- Computers and network equipment (i.e., "hardware") can be used for many purposes and has some resale value, although it depreciates rather rapidly. Therefore, we believe that donation of hardware may pose some risk of abuse.

- Donation of EHR software, training, and implementation assistance, in contrast, does not carry significant risk of patient or program abuse. These products and services can not serve other functions, and can not be resold by the practice or "taken back" by the donor. Converting an office from paper to electronic records by installing software, retraining staff, and re-engineering workflows is a labor-intensive and even painful process for the practice. We do not believe it could act as a "perk" to induce or reward a higher volume of referrals.

- Ongoing technical support, generally paid for on a monthly or annual basis, is a third essential element in obtaining and using EHR systems. CCHIT believes that donation of ongoing support could pose a risk of abuse for two reasons: it creates a dependency of the physician upon the donor – a 'crash' of an EHR system that was no longer supported would have a devastating effect on the practice -- and second, the fair market value of such support is very difficult to establish.

In summary, CCHIT believes that if the exception focuses on donation of EHR software, training, and implementation, the risk of program or patient abuse is negligible. We believe the risks are higher for donation of general purpose computing hardware as well as for long-term ongoing system support.

Comments on the value of protected technology (page 42)

CMS is contemplating placing a cap on the aggregate value of the technology donated. We share CMS' concerns about the risk of donating multifunctional, resalable hardware, but we reiterate our position about the low risk of abuse when software and training are donated.

As long as the donation is focused on software and training, we suggest that a cap in the value of donated technology could be counterproductive -- disadvantaging smaller offices and primary care practices most in need of help, and/or encouraging the adoption of less sophisticated EHR systems that do not fully achieve quality and safety improvement goals.

Estimates vary regarding the purchase cost of electronic health record systems, but the figures range from $15,000 to $35,000 or more per physician. As a rule of thumb, approximately 1/3 of the investment goes to hardware, 1/3 to software, and 1/3 to training and implementation consulting. Unfortunately, the small offices that represent the

slowest adopters of health IT experience the highest per-physician cost because of their inability to spread the cost among many providers. A fixed per-physician cap could increase rather than decrease that 'adoption gap.'

We also suggest CMS bear in mind that healthcare IT investment, as a percentage of revenues, is small compared to other industries. Hospitals spend 4-5%, and physician offices less than 1% of revenues, while other knowledge-driven industries invest 10% or more in IT. When payment systems are realigned to reward quality, the appropriate amount of health IT investment could be several times higher than it is now. Besides limiting total provider investment in health IT, an exemption with a fixed cap might inhibit capital investment in health IT research and development.

Comments on requiring that electronic health records include a CPOE component (page 49)

Computerized Provider Order Entry (CPOE) is a functionality within electronic health record systems. Prescriptions are the most frequent "order" entered in the physician offices, and this functionality has been covered by the e-prescribing requirements. However, advanced EHRs with full CPOE can also accept orders directed to laboratories, imaging centers, medical equipment suppliers, physical therapists, and other ancillary service providers. The practicality and availability of CPOE in ambulatory EHRs will evolve over time, and CCHIT's certification criteria will require increasing levels of full CPOE capability as it becomes feasible. Instead of touching upon this specific functionality in the proposed rule, we believe decisions on the appropriate timing and depth of CPOE functionality required in a physician office EHR is best left to the deliberations of the certifying body.

Thank you for this opportunity to comment.

Respectfully submitted,

Mark Leavitt, MD, PhD
Chair, Certification Commission for Healthcare Information Technology (CCHIT)
233 N Michigan Avenue, Suite 2150
Chicago, IL 60601

CMS-1303-P-6 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Charles Bailey **Date & Time:** 12/09/2005

Organization : Texas Hospital Association

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment for comments on proposed rules.

CMS-1303-P-6-Attach-1.DOC

December 9, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Re: Proposed Rules, 42 CFR 411.357, Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements

Dear Dr. McClellan:

The Texas Hospital Association, on behalf of its 437 member hospitals, is submitting the following comments on the proposed rules published in the October 11, 2005 issue of the *Federal Register* that will establish new exceptions to the physician self-referral prohibition for electronic prescribing and electronic health records arrangements.

As a general matter, the THA supports the proposed electronic prescribing and electronic health records exceptions, but would encourage CMS to broaden the scope of these exceptions. As noted in the preamble of the rules, the development and use of e-prescribing and EHRs will promote patient safety and efficiency in the delivery of health care services and to the extent that the rules can be modified to expand on and clarify permitted donations of technology to physicians, we believe that the rules will accomplish their objective. In Texas there is considerable variance in the use of technology and particularly e-prescribing and EHR technology by physicians ranging from no or minimal use of electronic technology to very sophisticated systems that have been implemented by large group practices and any efforts to promote electronic technology will benefit patients and the health care delivery system generally.

With respect to the e-prescribing technology, it should be noted that the new exception likely will not promote any significant level of hospital donation of e-prescribing hardware or software to physicians because e-prescribing will assist physicians with their orders for outpatient prescriptions and most outpatient prescriptions are not made through hospital pharmacies. Thus, health plans and pharmacy retailers are more likely to derive cost and other benefits from e-prescribing and these companies may be more willing to donate this technology to physicians. As a consequence, our comments will focus more on the Sections 411.357(w) and (x) of the proposed rules that relate to EHRs; however, many of our remarks will be responsive the comments that have been solicited on certain provisions of the e-prescribing rules in Section 411.357(v).

Software or directly related training services

The first part of Section 411.357(w) provides that the exception applies to non-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary and used to receive, transmit, and maintain electronic health records if certain conditions are met. Unlike the proposed rule for e-prescribing, this provision does not include the providing of hardware or connectivity services. We believe this is a concern and will impede the adoption of EHRs. While many physicians may have personal computers in their offices, some physicians may not have the financial resources to upgrade their hardware or add a server, network cabling or high-speed Internet services in order to better utilize the EHR software. The acquisition of upgraded or new equipment likely will be a more significant financial hurdle for primary care physicians and physicians in smaller or rural areas of Texas.

Therefore, THA recommends that Section 411.357(w) be revised to allow the donation of hardware and other types of information technology associated with EHRs. In addition, THA recommends that consideration be given to the inclusion of information technology support services to the listing of services that might be donated. THA supports the inclusion of training within the exception and we believe that on-going IT support services are essential to the use of this new technology. Such support services are relatively inexpensive and will enhance the likelihood that physicians will be able to successfully use EHR technology.

Donations Limited to Hospital Medical Staff

Proposed Section 411.357(w)(1)(i) would protect donations of EHR technology provided by a hospital to physicians on its medical staff and it is noted in the preamble that CMS does not intend for this exception to apply to physicians who already practice at other hospitals to join the medical staff of a different hospital. While THA understands the concern that this type of donation may present, prohibiting such donations will not allow hospitals to use its promotion of EHR technology as a physician recruitment tool. If this subsection is not modified to address physician recruitment, it would be helpful for CMS to provide guidance on how the donation of EHR technology might be allowed under the physician recruitment provision in Section 411.357(e).

Interoperability

Proposed Section 411.357(w)(2) will prohibit donors of EHR technology from taking any actions to disable or limit interoperability of any donated technology. THA strongly supports this provision and we agree with CMS that that an interoperability requirement will reduce the possibility that hospitals with substantial financial resources will offer free or reduced price technology to a referring physician as a means of maintaining or increasing that physician's referrals to the hospital.

Written Agreement

Proposed Section 411.357(w)(5) requires the donation of EHR technology to be made pursuant to a written document. While this requirement will impose some administrative costs, THA supports this provision because the benefits of a more formalized arrangement outweigh any additional costs. We also strongly support the inclusion of a physician certification that the items and services donated are not technically or functionally equivalent to those that the physician already possesses or has already obtained. We believe that the certification is important and will make physicians consider the legal risks associated with a violation of these rules. Further, we

would disagree with the suggesti n in the preambl to the rules that the execution of an agreement is a mere formality that will be ineffect ve as a safeguard against fraud and abuse.

To address the concerns expressed in the preambl of the rule that some physicians may intentionally divest themselves of EHR technolo y that they already possess in order to shift costs to a donor of the new technology, we woul l recommend that the certification be expanded to include language that the physician has not di vested their existing EHR technology.

Other Conditions

THA also would support the inclusion of additional requirements within the proposed exception, including: (1) eligibility to receive a donation of technology or services, nor the amount or nature of the items or services, may not be determined in a manner that takes into account the volume or value of the recipient's referrals to the donor; (2) the donee may not make receipt of the items or services as a condition of doing business with the donor; and (3) the items or services donated are of a type that can be used for any patient without regard to payor status.

Inclusion of Billing, Scheduling and Office Management Software

Proposed Section 411.357(w)(8) will prohibit the donation of billing, scheduling, or other similar general office management or administration software or services. THA opposes this provision because it will unnecessarily limit the effectiveness of any software donated to physicians. Today, most vendors of EHR software are bundling other management and administrative applications into the software because the integration of multiple programs is more cost-effective and because this integrated software improves the efficiency and effectiveness of the physician's decision making process and practice. The donation and use of more comprehensive EHR software programs also will reduce the complications typically encountered with the interface between different software applications.

While the proposed rules allow a broader donation of items and services once EHR certification criteria are established, this distinction between the pre-operability and post-operability periods is inappropriate and will delay the donation of EHR technology to physicians. Thus, THA would urge CMS to adopt a single exception without the certification requirement and once the interoperability standards are established the rules could be amended to require compliance with those standards.

Inclusion of E-prescribing Software

THA supports the requirement that the donated electronic health records software must have an electronic prescribing component. Further, it seem reasonable for the exception to permit the electronic prescribing component of electronic health record software to be used for the transmission of prescription information on items and services other than pharmaceuticals, such as, medical supplies, durable medical equipment or diagnostic testing. While most physician orders will be for pharmaceuticals, the technology should also be used to expedite other types of physician orders.

Inclusion of a Computerized Provider Order Entry Component

While a computerized provider order entry (CPOE) is a key component of electronic health records software, the THA has concerns with a requirement that CPOE be included within the EHR software. Many of the more generic CPOE programs that have been developed to date have not proven to be effective unless these "off-the-shelf" programs are further customized to

meet the needs of specific medical specialties or practices and there is the concern that until the interoperability standards are established there will complications encountered with use of the CPOE component . However, THA would recommend that CMS consider requiring that the EHR software have the capability to collect data associated with the quality measures that will be used as a part of the pay-for-performance initiative being developed by CMS.

Cap on Value of Donation

As noted in the preamble to the proposed rules, CMS is soliciting public comment on whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor and whether a cap (fixed dollar amount or percentage of the value of the donated technology) is needed to protect the program against abuse. THA would support a cap on the value of a donation, but believes that a fixed dollar cap will be unworkable and may preclude reasonable and appropriate donations by hospitals. Capping the donation based on the percentage value of the donated technology seems more reasonable and will require that physicians have some financial commitment to the technology.

Thank you for the opportunity to provide comments on these rules. If you have questions or wish to discuss our comments, please contact me at 512/465-1038 or cbailey@tha.org.

Sincerely,

Charles W. Bailey
General Counsel

CMS-1303-P-7 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Dr. Barry Arbuckle **Date & Time:** 12/09/2005

Organization : MemorialCare Medical Centers

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-7-Attach-1.DOC

MEMORIALCARE®

December 9, 2005

Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington DC 20001

RE: CMS-1303-P

Dear Dr. McClellan:

As President and Chief Executive Officer of MemorialCare Medical Centers (MemorialCare), and the Chair of the MemorialCare Physician Society, we offer joint comments on the proposed Centers for Medicare and Medicaid Services (CMS) rules, intended to afford hospitals increased flexibility to assist our physicians in technology adoption under the present Stark Law.

MemorialCare Medical Centers is a five-hospital, not-for-profit, health care system in Los Angeles and Orange Counties. MemorialCare is engaged in a unique partnership with our physicians. The Physician Society was created in order to provide our independent physicians a leading role in the clinical direction of the enterprise and empower them with a direct link to hospital administration, to drive our organization through evidence based, best practice medicine guidelines and protocols to all our patients for the best possible outcomes.

With this one-of-a-kind partnership in place, MemorialCare will launch our Electronic Health Records (EHR) system, an initiative entitled, MC*21, in mid-2006. Each step of building, designing and validating system content and workflows was done in the presence and at the advice of many of our physician partners MC*21 will transform the way MemorialCare delivers health care services to our communities by increasing patient safety, upgrading the processes and systems which support our caregivers, and offer our patients better information, choices and outcomes. The ultimate success of MC*21, including its interoperability, and benefit to our communities is greatly dependent upon our physicians full utilization of the program and extends well beyond CPOE (computer provider order entry).

E-prescribing will be an integral piece to MC*21. Integrating e-prescribing will require costly software and hardware, as well as extensive training. The vast majority of our physicians are not associated with large medical groups that are better positioned to supply the capitol required to participate. Therefore, it is incumbent upon MemorialCare to support our physicians with software and training so that they will apply the programs appropriately. Any comprehensive EHR is extremely complex, and cannot succeed without this proper training.

The Stark law's current exceptions are not specifically applicable to Health Information Technology. The potential flexibility offered in the proposed rule changes will also allow MemorialCare to work closer with our physicians. While MemorialCare fully supports such flexibility, we request CMS to consider expanding the limits outlined in the proposed changes to include additional items and services that can be provided. As health care costs continue to rise, MemorialCare is also concerned about the impact on the value of the items and services that need to be provided. Further examination of these equally important issues is warranted.

To reiterate, MemorialCare and the MemorialCare Physician Society jointly support the CMS proposed rules changes as outlined in CMS-1303-P for e-prescribing and EHRs. Final adoption of these rules will help solidify MemorialCare's EHR - MC*21 as a successful tool in increasing quality care and patient safety.

If MemorialCare may be of any further service, please feel free to call either Dr. Barry Arbuckle at 562/933-9708 or Dr. David Lagrew at 562/933-1800.

Sincerely,

Barry S. Arbuckle, Ph.D.
President and Chief Executive Officer
MemorialCare Medical Centers

David C. Lagrew, Jr., M.D
Chair
MemorialCare Medical Centers
Physician Society

CMS-1303-P-8 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Dr. Barry Arbuckle **Date & Time:** 12/09/2005

Organization : MemorialCare Medical Centers

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-8-Attach-1.DOC

MEMORIALCARE®

December 9, 2005

Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington DC 20001

RE: CMS-1303-P

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MemorialCare Medical Centers is a five-hospital, not-for-profit, health care system in Los Angeles and Orange Counties. MemorialCare is engaged in a unique partnership with our physicians. The Physician Society was created in order to provide our independent physicians a leading role in the clinical direction of the enterprise and empower them with a direct link to hospital administration, to drive our organization through evidence based, best practice medicine guidelines and protocols to all our patients for the best possible outcomes.

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The Stark law's current exceptions are not specifically applicable to Health Information Technology. The potential flexibility offered in the proposed rule changes will also allow MemorialCare to work closer with our physicians. While MemorialCare fully supports such flexibility, we request CMS to consider expanding the limits outlined in the proposed changes to include additional items and services that can be provided. As health care costs continue to rise, MemorialCare is also concerned about the impact on the value of the items and services that need to be provided. Further examination of these equally important issues is warranted.

To reiterate, MemorialCare and the MemorialCare Physician Society jointly support the CMS proposed rules changes as outlined in CMS-1303-P for e-prescribing and EHRs. Final adoption of these rules will help solidify MemorialCare's EHR - MC*21 as a successful tool in increasing quality care and patient safety.

If MemorialCare may be of any further service, please feel free to call either Dr. Barry Arbuckle at 562/933-9708 or Dr. David Lagrew at 562/933-1800.

Sincerely,

Barry S. Arbuckle, Ph.D.
President and Chief Executive Officer
MemorialCare Medical Centers

David C. Lagrew, Jr., M.D
Chair
MemorialCare Medical Centers
Physician Society

CMS-1303-P-9 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mrs. Lee Ann Stember **Date & Time:** 12/09/2005

Organization : National Council for Prescription Drug Programs

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-1303-P-9-Attach-1.DOC

National Council for Prescription Drug Programs
NCPDP

December 9, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1303–P
PO Box 8010
Baltimore, MD 21244–8010

Re: CMS 1303-P NPRM (42-CFR Part 411) – Comments

Dear Centers for Medicare & Medicaid Services:

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements NPRM.

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,300 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

II. Provisions of the Proposed Rule

A. Exception for Certain Arrangements Involving Electronic Prescribing Technology: § 411.357(v)

"Electronic Prescribing Exception: § 411.357(v)" (F.R. page 59184)

1. Protected Non-Monetary Remuneration

a. "Necessary" Non-Monetary Remuneration

We believe that restricting the exception to "necessary" items and services is important to minimize the potential for abuse. However, we recognize that the donors of the items and services will not necessarily know which items and services the physician already possesses or has obtained. Accordingly, §411.357(v)(7)(iv) would require the physician 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. The physician must update the certification prior to the furnishing of any necessary upgrades or items and services not reflected in the original certification. We are concerned that the certification process would be ineffective as a safeguard against fraud and abuse if it is a mere formality or if physicians simply execute a form certification provided by the DHS entity. The certification must be truthful, and we are proposing at § 411.357(v)(8) that the DHS entity must 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. We are soliciting comments about other ways to address this concern.

We are also concerned that there may be a risk that physicians would intentionally divest themselves of functionally or technically equivalent technology that they already possess in order to shift costs to the DHS entity. We are soliciting public comments on how best to address this issue.

NCPDP Recommendations: Physicians are more likely to adopt multifunctional technology (i.e. that which assists them in managing multiple aspects of their practice) than technology with the sole function of electronic prescribing. Limiting donations to electronic prescribing functionality limits the usefulness of the safe harbor and exception. Hospitals will be unlikely to pursue donations with this limit in place, given that the incentive for hospital donors would be to capture all of the efficiencies offered by electronic healthcare applications. Hospital have no stake in the outpatient prescribing done by physicians in their office practices, and will only be interested in providing this technology to physicians if they can also enhance the existing relationships between the hospital and their staff physicians (such as through enhancing the ability to order tests and receive results electronically, share records, transact business relating to admission of patients, etc.). Likewise, physicians will not be interested in embarking on the installation, training and practice disruption associated with the adoption of a new system unless they perceive that, in the long term, doing so will enhance the efficiency of their practices. Electronic prescribing cannot be approached in a vacuum, and the market will not do so. The perception that pervades the discussion in the proposed rules that physicians will embark on these disruptions simply to replace existing functionality, ignores this reality. Therefore, all the discussion around certifying to the "necessity" of any donated technology is superfluous and will serve only to discourage potential donors by increasing legal fees and the perceived risk that donors will later be prosecuted for violating fuzzy legal restrictions. "Necessary" should be defined as any system, which includes all the components, required for a physician to be enabled to prescribe electronically, whether or not other functionality is available or incorporated.

Likewise, physicians will not be interested in embarking on the installation, training, and practice disruption associated with the adoption of a new system unless they perceive that, in the long term, doing so will enhance the efficiency of their practices. Electronic prescribing cannot be approached in a vacuum, and the market will not do so. The perception that pervades the discussion in the proposed rules that physicians will embark on these disruptions simply to replace existing functionality ignores this reality. Therefore, all the discussion around certifying to the "necessity" of any donated technology is superfluous and will serve only to discourage potential donors by increasing legal fees and the perceived risk that donors will later be prosecuted for violating fuzzy legal restrictions. "Necessary" should be defined as any system, which includes all the components, required for a physician to be enabled to prescribe electronically whether or not other functionality is available or incorporated.

NCPDP recommends that HHS and OIG exercise their existing authority to adopt an exception and a safe harbor allowing for a donation (in the vein of an "isolated transaction") of hardware, software and limited IT support which will allow physicians to migrate to broad electronic healthcare solutions that meet the needs of physician practices broadly. There is no valid reason to adopt narrow exceptions/safe harbors for limited-use electronic prescribing applications, and then later adopt additional rules relating to multi-functional technology, electronic medical records, etc. We believe the benefits of moving physicians to these solutions, for the entire healthcare system, far outweigh any perceived risks, particularly where donations cannot be conditioned on any commitment to refer.

b. "Used Solely" (F.R. page 59195)

We are soliciting public comment about the standards that should appear in an additional exception for multifunctional hardware (including necessary operating system software) or connectivity services. In particular, we are soliciting public comment on methodologies for

quantifying or ensuring that a substantial use of hardware and connectivity services is for the receipt or transmission of electronic prescribing information. We have considered how to quantify "substantial use" with respect to other provisions of the Act and its implementing regulations; here, we are specifically seeking comments regarding an appropriate definition of "substantial use" in the context of electronic prescribing technology and its use. We are also soliciting public comment on the nature and amount of any cap that we should impose on the value of the donated multi-functional hardware or connectivity services.

NCPDP Recommendations: See above recommendation in II. Provisions of the Proposed Rule A. Exception for Certain Arrangements Involving Electronic Prescribing Technology: § 411.357(v) "Electronic Prescribing Exception: § 411.357(v)" (F.R. page 59184) 1. Protected Non-Monetary Remuneration
a. "Necessary" Non-Monetary Remuneration.

3. Additional Limitations on the Provision of Electronic Prescribing Technology

a. Promoting Compatibility and Interoperability (F.R. page 59186)

We are soliciting comments on whether the exception should permit qualifying electronic prescribing technology to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests).

NCPDP Recommendations: NCPDP recommends that restrictions should not be placed on the types of electronic prescribing activities protected or performed. Segregation of drugs versus supplies versus laboratory tests versus other items (like s ervices) c reates s ilos t hat w ill m ake i t v ery difficult to have integrated systems that handle all aspects of electronic prescribing. Creating "silos" is very difficult to maintain, very difficult to determine where there might be overlap, and very confusing for participants in electronic prescribing.

We are considering defining the term "interoperable" to mean the ability of different information systems, software applications, and networks to communicate and exchange information in an accurate, secure, effective, useful, and consistent manner. (See generally 44 U.S.C. § 3601(6) (pertaining to the management and promotion of electronic government services).) We are soliciting public comment about this approach, our definition of the term "interoperable," alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing.

NCPDP Recommendations: NCPDP recommends that the definition of "interoperability" include the use of industry standards as the method to exchange data. When entities exchange data in the same format this ensures interoperable communication. The continuation of electronic prescribing adoption will increase due to the industry being able to react to business needs and solve those problems. One example of this is the "NCPDP-HL7 Electronic Prescribing Mapping" project, w hich bu ilt t echnical c rosswalks f or v endors o f H L7-based systems and vendors of NCPDP SCRIPT-based systems, to allow the communication of electronic prescribing messages. As the industry continues to adopt, business needs will come forward and technology and even regulations must be adaptive, not constrictive. The needs found for sharing data will continue to evolve, and if the intent is to provide healthcare professionals with the best information available, to give better patient safety, the regulations must allow creative solutions.

b. Value of Protected Technology (F.R. page 59186)

We are considering whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor. We believe a monetary limit is appropriate and reasonable to minimize the potential for fraud and abuse. We are soliciting public comment on the amount of a cap that would adequately protect the

program against abuse, the methodology used to determine the cap (for example, fixed dollar amount, percentage of the value of the donated technology, or another methodology), whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services, whether the cap should be reduced over time, and whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations.

We are also interested in comments on the retail and nonretail costs of obtaining electronic prescribing technology and the degree to which physicians may already possess items or services that could be used for electronic prescribing. We have received varying estimates of the costs of implementing electronic prescribing through the comment process for our Eprescribing and the Prescription Drug Program proposed rule published on February 4, 2005 in the ***Federal Register*** *(70 FR 6256). We also have explored the available literature on the costs of implementing electronic prescribing. (See section IV of this preamble.) We caution that the cost of implementing an electronic prescribing program will not correlate necessarily to the amount of any cap if one is established. Moreover, we do not expect that donors will wish necessarily to donate the total amount that the technology costs or, depending on the size of a cap, the total amount ultimately protected in the final rule. Although we are interested in obtaining detailed information about the costs of the full range of technology so as to be fully informed on this matter, we do not expect that the final regulations will protect all possible costs.*

NCPDP R ecommendations: D ue t o t he w ide r ange o f s ystems supporting eprescribing, related software, and hardware necessary to support its functionality, it is difficult to establish a fixed dollar amount as a c ap t o be protected in the final rule. Eprescribing software can be a stand-alone system - at a relatively low cost or part of a very large EMR system with multiple levels of functionality at a very high cost.

It is important that to properly support an eprescribing ability utilizing the proper industry standards as adopted by CMS, the restriction on donors should not be so severe as to inhibit the adoption of eprescribing. It would seemingly be unfair to place a cap on the percentage - since it would for all practical purposes apply unevenly to stand-alone eprescribing software and electronic medical records systems.

For eprescribing adoption to move forward - there could be other restrictions in the agreement regarding movement of business and referral language to adequately protect against fraud and abuse. Donors should be allowed to freely promote the best possible system to drive adoption and utilization of eprescribing, with restrictions regarding referrals, to achieve market penetration and adoption of eprescribing. The systems must, however, be fully compliant with accepted industry standards and approved by CMS as established in the foundation standards - allowing free interoperability across all systems.

B. Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: § 411.357(w) and § 411.357(x) (F.R. page 59187-8)

We are requesting comments on whether hardware, connectivity and related items and services should also be protected under either or both these exceptions, and, if so, under what conditions.

NCPDP Recommendations: NCPDP recommends that HHS and OIG exercise their ex isting au thority t o adopt an exception and a safe harbor allowing for donation (in the vein of an "isolated transaction") of hardware, software and limited IT support which will allow physicians to migrate to broad electronic healthcare solutions that meet the needs of physician practices broadly. There is no good reason to adopt narrow exceptions/safe harbors for limited-use electronic prescribing applications, and then later adopt additional rules relating to multi-functional technology, electronic medical records, etc. We believe the

benefits of moving physicians to these solutions, for the entire healthcare system, far outweigh any perceived risks, particularly where donations cannot be conditioned on any commitment to refer.

1. Pre-Interoperability Exception
'Pre-Interoperability Electronic Health Records Exception: § 411.357(w)'
a. Covered Technology (F.R. page 59188)

We are soliciting comments on whether the exception should permit the electronic prescribing component of electronic health record software to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests). Additionally, we are soliciting comments with respect to whether we should also o r ins tead r equire t hat el ectronic h ealth r ecords software include a computerized provider order entry (CPOE) component. We are proposing at § 411.357(w)(8) not to protect the provision of other types of technology, including, for example, hardware, connectivity services, billing or scheduling software, or software that might be used by a physician to conduct personal business or business unrelated to the physician's medical practice. Although the proposed exception would protect necessary training services in connection with the software, the exception would not protect the provision of staff to physicians or their offices.

We are mindful that there may be particular constituencies, such as rural area providers, that lack sufficient hardware or connectivity services to implement effective electronic health records systems. We are soliciting comments addressing these special circumstances.

In order to protect further against abuse, we are considering including in the final regulations a definition of "electronic health records" for purposes of the exception. We are soliciting comments on how we should draft this definition. In particular, we are interested in public comments that address the types of software that should be protected; the retail and nonretail cost of this software; the ways in which this software is currently marketed (for example, individual applications versus bundled software packages); methods for defining the scope of protected software; and safeguards that might be imposed (either in the definition or separately) to ensure that the exception does not pose a risk of program or patient abuse. Finally, we are soliciting public comment on whether and, if so, how to protect the provision of other kinds of electronic h ealth information technology.

We are proposing to interpret "necessary" in the new exception consistent with our interpretation of the term in section II.A.1 of this proposed rule and to include a comparable provision at § 411.357(w)(5)(iv) to ensure that the exception does not protect the provision of items or services that are technically and functionally equivalent to items and services the physician currently possesses or has obtained. As with electronic prescribing technology, we are concerned that there may be a risk that physicians would intentionally divest themselves of functionally or technically equivalent technology that they already possess to shift costs to donors and we are soliciting public comment on whether and how to address this situation.

NCPDP Recommendations: To comply with the Medicare Drug Improvement and Modernization Act of 2003 (MMA), we agree that electronic health records software should include the ability for a prescriber to write a prescription, and we agree that a consensus-driven third party should certify such technology. We believe that this electronic prescribing technology should be fully compatible with the foundation standards cited in the final eRx rule 42CFR Part 423, Medicare Program; E-Prescribing and the Prescription Drug Program, and any additional electronic prescribing standards promulgated by the Centers for Medicare and Medicaid Services (CMS). We caution the Office of Inspector General (OIG) about using the term CPOE, as its meaning is not universally accepted, has changed over time and is broader in scope than the electronic prescribing technology that is referred to so prominently in the MMA.

2. Post-Interoperability Electronic Health Records Exception (F.R. page 59189-90)
"Post-Interoperability Electronic Health Records Exception: § 411.357(x)"

a. Covered Technology (F.R. page 59190)

We are soliciting public comments on what types of software should be protected under the postinteroperability exception and methods for ensuring that electronic prescribing and electronic health records are the core functions of the donated technology. As with the preinteroperability exception, we propose at § 411. 357(x)(9) t hat t he t echnology protected under this exception must include an electronic prescribing component, and we are soliciting comments with respect to whether we should also or instead require that electronic health records software include a CPOE component.

NCPDP Recommendations: See above recommendation in 1. Pre-Interoperability Exception 'Pre-Interoperability Electronic Health Records Exception: § 411.357(w)' a. Covered Technology (F.R. page 59188)

Conclusion

Thank you for considering these recommendations.

Sincerely,

Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

cc: NCPDP Board of Trustees

CMS-1303-P-10 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Robert Boysen **Date & Time:** 12/10/2005

Organization : Sisters of Charity of Leavenworth Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-11 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Michael Simko **Date & Time:** 12/12/2005

Organization : Walgreen Co.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-11-Attach-1.DOC

Walgreens
The Pharmacy America Trusts

December 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1303–P
PO Box 8010
Baltimore, MD 21244–8010

Re: CMS 1303-P NPRM (42-CFR Part 411) – Comments

Dear Centers for Medicare & Medicaid Services:

Walgreens is pleased to submit the following comments regarding the Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements NPRM.

Walgreens i s t he l eading r etail p harmacy p rovider i n t he U nited S tates. F ounded in 1901, Walgreens operates over 5000 pharmacies in 45 states, including Puerto Rico. Walgreens fills 14% of all prescriptions in the United States. Walgreens operates the most 24-hour pharmacy locations. Walgreens is a leader in pharmacy technology, with all its pharmacies connected by satellite.

II. Provisions of the Proposed Rule

A. Exception for Certain Arrangements Involving Electronic Prescribing Technology: § 411.357(v)

"Electronic Prescribing Exception: § 411.357(v)" (F.R. page 59184)

1. Protected Non-Monetary Remuneration

a. "Necessary" Non-Monetary Remuneration

We believe that restricting the exception to "necessary" items and services is important to minimize the potential for abuse. However, we recognize that the donors of the items and services will not necessarily know which items and services the physician already possesses or has obtained. Accordingly, §411.357(v)(7)(iv) would require the physician 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. The physician must update the certification prior to the furnishing of any necessary upgrades or items and services not reflected in the original certification. We are concerned that the certification process would be ineffective as a safeguard against fraud and abuse if it is a mere formality or if physicians simply execute a form certification provided by the DHS entity. The certification must be truthful, and we are proposing at § 411.357(v)(8) that the DHS entity must 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. We are soliciting comments about other ways to address this concern.

We are also concerned that there may be a risk that physicians would intentionally divest themselves of functionally or technically equivalent technology that they already possess in order to shift costs to the DHS entity. We are soliciting public comments on how best to address this issue.

Walgreens Recommendations:

Physicians are more likely to adopt multifunctional technology (i.e. that which assists them in managing multiple aspects of their practice) than technology with the sole function of electronic prescribing. Limiting donations to electronic prescribing functionality limits the usefulness of the safe harbor and exception. Hospitals will be unlikely to pursue donations with this limit in place, given that the incentive for hospital donors would be to capture all of the efficiencies offered by electronic healthcare applications. Hospital have no stake in the outpatient prescribing done by physicians in their office practices, and will only be interested in providing this technology to physicians if they can also enhance the existing relationships between the hospital and their staff physicians (such as through enhancing the ability to order tests and receive results electronically, share records, transact business relating to admission of patients, etc.). Likewise, physicians will not be interested in embarking on the installation, training and practice disruption associated with the adoption of a new system unless they perceive t hat, i n t he long term, doing so will enhance the efficiency of their practices. Electronic prescribing cannot be approach in a vacuum, and the market will not do so. The perception that pervades the discussion in the proposed rules that physicians will embark on these disruptions simply to replace existing functionality, ignores this reality. Therefore, all the discussion around certifying to the "necessity" of any donated technology is superfluous and will serve only to discourage potential donors by increasing legal fees and the perceived risk that donors will later be prosecuted for violating fuzzy legal restrictions. "Necessary" should be defined as any system, which includes all the components, required for a physician to be enabled to prescribe electronically, whether or not other functionality is available or incorporated.

Walgreens recommends that HHS and OIG exercise their existing authority to adopt an exception and a safe harbor allowing for donation (in the vein of an "isolated transaction") of hardware, software and limited IT support which will allow physicians to migrate to broad electronic healthcare solutions that meet the needs of physician practices broadly. There is no good reason to adopt narrow exceptions/safe harbors for limited-use electronic prescribing applications, and then later adopt additional rules relating to multi-functional technology, electronic medical records, etc. We believe the benefits of moving physicians to these solutions, for the entire healthcare system, far outweigh any perceived risks, particularly where donations cannot be conditioned on any commitment to refer.

b. "Used Solely" (F.R. page 59195)

We are soliciting public comment about the standards that should appear in an additional exception for multifunctional hardware (including necessary operating system software) or connectivity services. In particular, we are soliciting public comment on methodologies for quantifying or ensuring that a substantial use of hardware and connectivity services is for the receipt or transmission of electronic prescribing information. We have considered how to quantify "substantial use" with respect to other provisions of the Act and its implementing regulations; here, we are specifically seeking comments regarding an appropriate definition of "substantial use" in the context of electronic prescribing technology and its use. We are also soliciting public comment on the nature and amount of any cap that we should impose on the value of the donated multi-functional hardware or connectivity services.

Walgreens Recommendations:

See above recommendation in II. Provisions of the Proposed Rule A. Exception for Certain Arrangements Involving Electronic Prescribing Technology: § 411.357(v) "Electronic Prescribing Exception: § 411.357(v)" (F.R. page 59184)
1. Protected Non-Monetary Remuneration
a. "Necessary" Non-Monetary Remuneration.

2. Designated Health Services (DHS) Entities Protected by the Exception (F.R. page 59185-6)

Proposed § 411.357(v)(1)(i) would protect donations of qualifying electronic prescribing technology provided by a hospital to physicians on its medical staff. We intend to protect donations only to physicians who routinely furnish services at the hospital. We do not intend for this exception to protect remuneration used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital. We are soliciting comments on this issue.

...

Proposed § 411.357(v)(1)(ii) would protect donations of qualifying electronic prescribing technology provided by a group practice to its physician members. For purposes of the new exception, we propose to apply the existing regulatory definitions of the terms "group practice" and "member of a group practice" (see § 411.352 and § 411.351, respectively). Further, the inclusion of paragraph § 411.357(v)(1)(ii) does not imply that the provision of the items and services by a group to its members necessarily requires a new exception, because the in-office ancillary services exception or the employment exception would apply in most circumstances, where needed. We believe the Congress included these relationships in section 1860D–4(e)(6) of the Act simply to encourage group practices to adopt electronic prescribing technology. We are soliciting comments regarding whether and h ow a g roup p ractice m ay ap propriately furnish qualifying electronic prescribing technology to a "physician in the group practice," as defined at § 411.351.

...

We are soliciting comments on whether we should use our authority u nder s ection 1877(b)(4) of the Act to protect qualifying electronic prescribing technology provided to physicians by other DHS entities. Most other DHS services do not appear to involve substantial utilization of prescription drugs. We are interested in comments addressing the types of DHS entities that should be included, the degree of need for the protection, and the safeguards that should be imposed to protect against program or patient abuse.

Walgreens Recommendations:

Consistent with the goals of the expanded rule, Walgreens believes the list of donors should be expanded to include clinical laboratories and other types of health care providers. As technology expands, it would be unfair to limit the types of entities protected under the regulation. This would inhibit the progress of eprescribing adoption that CMS should be working towards including eprescribing and electronic health records.

3. Additional Limitations on the Provision of Electronic Prescribing Technology

a. Promoting Compatibility and Interoperability (F.R. page 59186)

We are soliciting comments on whether the exception should permit qualifying electronic prescribing technology to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests).

Walgreens Recommendations:

Walgreens recommends that restrictions should not be placed on the types of electronic prescribing activities protected or performed. Segregation o f dr ugs versus supplies versus laboratory tests versus other items (like services) creates silos that will make it very difficult to have integrated systems that handle all aspects of electronic prescribing. Creating "silos" is very difficult to maintain, very difficult to determine where there might be overlap, and very confusing for participants in electronic prescribing

We are considering defining the term "interoperable" to mean the ability of different information systems, software applications, and networks to communicate and exchange information in an accurate, secure, effective, useful, and consistent manner. (See generally 44 U.S.C. § 3601(6) (pertaining to the management and promotion of electronic government services).) We are soliciting public comment about this approach, our definition of the term "interoperable," alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing.

Walgreens Recommendations:

Walgreens recommends that the definition of "interoperability" include the use of industry standards as the method to exchange data. When entities exchange data in the same format this ensures interoperable communication. The continuation of electronic prescribing adoption will increase due to the industry being able to react to business needs and solve those problems. One example of this is the "NCPDP-HL7 Electronic Prescribing Mapping" project which built technical crosswalks for vendors of HL7-based systems and vendors of NCPDP SCRIPT-based systems, to allow the communication of electronic prescribing messages. As the industry continues to adopt, business needs will come forward and technology and even regulations must be adaptive, not constrictive. The needs found for sharing data will continue to evolve, and if the intent is to provide healthcare professionals with the best information available, to give better patient safety, the regulations must allow creative solutions.

b. Value of Protected Technology (F.R. page 59186)

We are considering whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor. We believe a monetary limit is appropriate and reasonable to minimize the potential for fraud and abuse. We are soliciting public comment on the amount of a cap that would adequately protect the program against abuse, the methodology used to determine the cap (for example, fixed dollar amount, percentage of the value of the donated technology, or another methodology), whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services, whether the cap should be reduced over time, and whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations.
We are also interested in comments on the retail and nonretail costs of obtaining electronic prescribing technology and the degree to which physicians may already

possess items or services that could be used for electronic prescribing. We have received varying estimates of the costs of implementing electronic prescribing through the comment process for our Eprescribing and the Prescription Drug Program proposed rule published on February 4, 2005 in the ***Federal Register*** *(70 FR 6256). We also have explored the available literature on the costs of implementing electronic prescribing. (See section IV of this preamble.) We caution that the cost of implementing an electronic prescribing program will not correlate necessarily to the amount of any cap if one is established. Moreover, we do not expect that donors will wish necessarily to donate the total amount that the technology costs or, depending on the size of a cap, the total amount ultimately protected in the final rule. Although we are interested in obtaining detailed information about the costs of the full range of technology so as to be fully informed on this matter, we do not expect that the final regulations will protect all possible costs.*

Walgreens Recommendations:

Due to the wide range of systems supporting eprescribing, related software, and hardware necessary to support its functionality, it is difficult to establish a fixed dollar amount as a cap to be protected in the final rule. Eprescribing software can be a stand-alone system - at a relatively low cost or part of a very large EMR system with multiple levels of functionality at a very high cost.

It is important that to properly support an eprescribing ability utilizing the proper industry standards as adopted by CMS, the restriction on donors should not be so severe as to inhibit the adoption of eprescribing. It would seemingly be unfair to place a cap on the percentage - since it would for all practical purposes apply unevenly to stand-alone eprescribing software and electronic medical records systems.

For eprescribing adoption to move forward - there could be other restrictions in the agreement regarding movement of business and referral language to adequately protect against fraud and abuse. Donors should be allowed to freely promote the best possible system to drive adoption and utilization of eprescribing, with restrictions regarding referrals, to achieve market penetration and adoption of eprescribing. The systems must, however, be fully compliant with accepted industry standards and approved by CMS as established in the foundation standards - allowing free interoperability across all systems.

c. Other Conditions (F.R. page 59186-7)

We are interested in comments with respect to other potential criteria for selecting medical staff recipients of donated technology. Also, the exception would not protect arrangements that seek to induce a physician to change loyalties from other providers or plans to the donor (for example, a hospital using an electronic prescribing technology arrangement to induce a physician who is on the medical staff of another hospital to join the donor hospital's medical staff for a purpose of referring patients to the donor hospital).

Walgreens Recommendations:

Walgreens agrees that the exception should not induce physician to switch loyalties, however, hospitals that provide technology to physicians that practice at that hospital should not be restricted only because the physician may not be a regular member of that hospital staff. The promotion of eprescribing technology will be inhibited with restricting the ability to provide interoperable systems to physicians from other practices.

B. Exceptions for Certain Arrangements Involving Electronic Health RecordsItems and Services: § 411.357(w) and § 411.357(x) (F.R. page 59187-8)

We are requesting comments on whether hardware, connectivity and related items and services should also be protected under either or both these exceptions, and, if so, under what conditions.

Walgreens Recommendations:

Walgreens recommends that HHS and OIG exercise their existing authority to adopt an exception and a safe harbor allowing for donation (in the vein of an "isolated transaction") of hardware, software and limited IT support which will allow physicians to migrate to broad electronic healthcare solutions that meet the needs of physician practices broadly. There is no good reason to adopt narrow exceptions/safe harbors for limited-use electronic prescribing applications, and then later adopt additional rules relating to multi-functional technology, electronic medical records, etc. We believe the benefits of moving physicians to these solutions, for the entire healthcare system, far outweigh any perceived risks, particularly where donations cannot be conditioned on any commitment to refer

1. Pre-Interoperability Exception

'Pre-Interoperability Electronic Health Records Exception: § 411.357(w)'

a. Covered Technology (F.R. page 59188)

We are soliciting comments on whether the exception should permit the electronic prescribing component of electronic health record software to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests). Additionally, we are soliciting comments with respect to whether we should also or instead r equire t hat el ectronic h ealth r ecords software include a computerized provider order entry (CPOE) component. We are proposing at § 411.357(w)(8) not to protect the provision of other types of technology, including, for example, hardware, connectivity services, billing or scheduling software, or software that might be used by a physician to conduct personal business or business unrelated to the physician's medical practice. Although the proposed exception would protect necessary training services in connection with the software, the exception would not protect the provision of staff to physicians or their offices.

We are mindful that there may be particular constituencies, such as rural area providers, that lack sufficient hardware or connectivity services to implement effective electronic health records systems. We are soliciting comments addressing these special circumstances.

In order to protect further against abuse, we are considering including in the final regulations a definition of "electronic health records" for purposes of the exception. We are soliciting comments on how we should draft this definition. In particular, we are interested in public comments that address the types of software that should be protected; the retail and nonretail cost of this software; the ways in which this software is currently marketed (for example, individual applications versus bundled software packages); methods for defining the scope of protected software; and safeguards that might be imposed (either in the definition or separately) to ensure that the exception does not pose a risk of program or patient abuse. Finally, we are soliciting public comment on whether and, if so, how to protect the provision of other kinds of electronic health information technology.

We are proposing to interpret "necessary" in the new exception consistent with our interpretation of the term in section II.A.1 of this proposed rule and to include a comparable provision at § 411.357(w)(5)(iv) to ensure that the exception does not protect the provision of items or services that are technically and functionally equivalent to items and services the physician currently possesses or has obtained. As with electronic prescribing technology, we are concerned that there may be a risk that physicians would intentionally divest themselves of functionally or technically equivalent technology that they already possess to shift costs to donors and we are soliciting public comment on whether and how to address this situation.

Walgreens Recommendations:

To comply with the Medicare Drug Improvement and Modernization Act of 2003 (MMA), Walgreens agrees that electronic health records software should include the ability for a prescriber to write a prescription, and we agree that a consensus-driven third party should certify such technology. We believe that this electronic prescribing technology should be fully compatible with the foundation standards cited in the final eRx rule 42CFR Part 423, Medicare Program; E-Prescribing and the Prescription Drug Program, and any additional electronic prescribing standards promulgated by the Centers for Medicare and Medicaid Services (CMS). We caution the Office of Inspector General (OIG) about using the term CPOE, as its meaning is not universally accepted, has changed over time and is broader in scope than the electronic prescribing technology that is referred to so prominently in the MMA.

c. Permissible Donors (F.R. page 59188)

We do not believe that providers and suppliers of ancillary services, such as laboratories, are well positioned to advance the goal of widespread use of interoperable electronic health records for patients, nor would they have the same interest in doing so. Nevertheless, we are interested in c omments r egarding w hether o ther c ategories o f donors should be included and why. We are also interested in comments with respect to whether different or alternative conditions should apply to any category of donor. In addition, we note that some donations of electronic health records software and related training services may fit within existing exceptions, including those at § 411.352 (for group practices) and § 411.355(c) (for certain prepaid health plans).

Walgrens Recommendations:

The exception should be expanded to include other services and entities to such as laboratories. As health care technology expands, larger systems such as electronic medical records including complete patient medical information sharing is essential to the promotion and adoption of eprescribing technology. Information sharing is essential to promote the value of adoption. The inclusion of other entities will help promote adoption and utilization of technology and result in overall broad based adoption of eprescribing.

d. Selection of Recipients (F.R. page 59189)

We are proposing at § 411.357(w)(4) a condition, consistent with other regulatory exceptions, that the eligibility of a recipient to receive items and services from a donor, and the amount and nature of the items and services received, may not be determined in a manner that takes into account the volume or value of the recipient's referrals to the donor or other business generated between the parties. We are interested in comments with respect to potential criteria for selecting physician recipients of donated electronic health records software and related training services.

Walgreens Recommendations:

Volume of eprescribing activity should not be criteria to determine the recipient of donated technology. Walgreens agrees with the selection criteria. To adequately promote widespread adoption of interoperable systems, threshold volume levels must not be taken into consideration.

e. Value of the Protected Technology (F.R. page 59189)

We are interested in comments regarding the appropriate amount and methodology of a limiting cap. In addition to an aggregate dollar cap, we are considering two alternative approaches: (1) A cap that would be set at a percentage of the value of the donated technology to the physician (thus requiring the physician to share the costs); or (2) a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the physician. We are soliciting public comment about this approach, including comments on how a cap under this exception would relate to a cap under the exception proposed at § 411.357(v) and how the value of technology provided under the final exceptions would be aggregated. We are concerned that DHS entities may abuse the proposed exceptions for electronic prescribing items and services and electronic health records software and training services by selectively relying on both exceptions to maximize the value of technology provided to physicians as a means of disguising payments for referrals. We believe conditions should be included in the final regulation to prevent this abuse and are considering requiring an overall cap on value, as well as documentation requirements that integrate all technology provided under the final exceptions. We are interested in public comments that address the retail and nonretail costs (that is, the costs of purchasing from manufacturers, distributors, or other nonretail sources) of obtaining electronic health records software and training services necessary to promote the widespread adoption of electronic health records. We are also interested in comments that address the degree to which physicians may already possess items or services that could be used for electronic health records. In addition, we are soliciting comments on whether and, if so, how to take into account physician access to any software that is publicly available either free or at a reduced price.

Walgreens Recommendations:

Because of the emergence of newer and larger broad based technology systems, fixing a dollar amount or cap to donated technology would be difficult and would act to impede eprescribing adoption. As we move toward national interoperable systems, and the emergence of new technologies, early adopters of epresscribing should not be penalized from receiving expanded technology only because it contains an eprescribing component which may be already available to the recipient physician practice.

2. Post-Interoperability Electronic Health Records Exception (F.R. page 59189-90)

"Post-Interoperability Electronic Health Records Exception: § 411.357(x)"

We anticipate that a process to identify product certification criteria, including uniform industry standards for interoperability, functionality, and privacy and security, may be completed in the next year. The health information technology contractors and the American Health Information Community (AHIC) will be considering processes to set standards and to certify and inspect electronic health records technology; these processes and standards will be recommended to the Secretary for recognition and adoption. A certified product will meet all of the criteria adopted by the Secretary, including criteria for interoperability, functionality, and privacy and security, through the process recognized by the Secretary. The post-interoperability exception will protect only the donation of certified electronic health records technology. We are soliciting comments on how these processes under development might impact the scope of a final exception for electronic health records.

Walgreens Recommendations:

Walgreens supports the foundation standards criteria already issued by CMS in regards to eprescribing. The industry is already working towards interoperability across various systems such as the NCPDP Script – HL7 interface and the results of the 2006 pilots to review additional industry standards. Walgreens supports CMS in the continued efforts to identify standards covering all aspects of e-healthcare. The resultant effects of standards adoption will be the promotion and acceleration of adoption e-healthcare.

a. Covered Technology (F.R. page 59190)

We are soliciting public comments on what types of software should be protected under the postinteroperability exception and methods for ensuring that electronic prescribing and electronic health records are the core functions of the donated technology. As with the preinteroperability exception, we propose at § 411. 357(x)(9) t hat t he t echnology protected under this exception must include an electronic prescribing component, and we are soliciting comments with respect to whether we should also or instead require that electronic health records software include a CPOE component.

Walgreens Recommendations:

See above recommendation in 1. Pre-Interoperability Exception 'Pre-Interoperability Electronic Health Records Exception: § 411.357(w)' a. Covered Technology (F.R. page 59188)

c. Permissible Donors (F.R. page 59190)

In new § 411.357(x)(1), we are proposing to protect the same categories of donors protected under the preinteroperability exception as discussed in section II.B.1 of this proposed rule. We are also considering whether to protect additional categories of donors and whether different or alternative conditions should apply to any category of permissible donor. We are interested in comments addressing the types of individuals and entities that should be protected, the degree of need for protection, and the safeguards that should be imposed to protect against fraud and abuse.

Walgreens Recommendations:

As stated previously

e. Value of Protected Technology (F.R. page 59191)

We are considering whether a larger cap on the value of the donated software would be appropriate. In the discussion of the pre-interoperability exception at section II.B.1 of this preamble, we noted various alternatives we are considering in connection with a limiting cap and outlined issues about which we are soliciting comments. We are considering similar issues, and are interested in similar comments, in connection with the appropriate amount of a cap for interoperable, certified technology donated under the post-interoperability exception.

We are interested in comments regarding the appropriate amount and methodology of a limiting cap. In addition to an aggregate dollar cap, we are considering two alternative approaches: (1) A cap that would be set at a percentage of the value of the donated technology to the physician (thus requiring the physician to share the costs); or (2) a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the physician. We are soliciting public comment about this approach, including comments on how a cap under this exception would relate to a cap under the exceptions proposed at § 411.357(v) and § 411.357(w) and how the value of technology provided under the final exceptions would be aggregated. We are interested in public comments that

address the retail and nonretail costs (that is, the costs of purchasing from manufacturers, distributors, or other nonretail sources) of obtaining electronic health records software and training services necessary to promote the widespread adoption of certified electronic health records systems. We are also interested in comments that address the degree to which physicians may already possess items or services that could be used for electronic health records. In addition, we are soliciting comments on whether and, if so, how to take into account physicians' access to any software that is publicly available either free or at a reduced price.

Walgreens Recommendations:

As previously stated, Walgreens believes the imposition of specific dollar amounts or caps on technology donated will ultimately serve to impede overall adoption. As new technologies emerge and an interoperable healthcare system continues to develop, it would be restrictive and t oo bi nding o n do nors and recipients to limit the value of donated technology.

IV. Regulatory Impact Statement (F.R. Page 59192)
"Regulatory Impact Statement"

B. Impact on Small Businesses (F.R. Page 59196)

We have determined that this proposed rule would not have a significant impact on small entities bec ause it do es no t inc rease r egulatory burden or otherwise meet the RFA standard of "significant impact." While the aggregate impacts would be substantial, it is unlikely that near term effects on individual practitioners would be substantial as a proportion of revenues (for example, a $3,000 remuneration compared to typical practice revenues in the hundreds of thousands of dollars). We expect our proposed new exceptions ultimately to be highly beneficial to physicians, hospitals, and pharmacies (most in each category are small entities), as well as to affected entities and persons who are not "small entities" as defined in the RFA—PDP sponsors, MA organizations, and our beneficiaries. We welcome comment on these conclusions.

Walgreens Recommendations:

Walgreens believes that the proposed rule would not have significant impact on small entities. In addition, Walgreens agrees that the exceptions would be highly beneficial to physicians, hospitals, and pharmacies. As the emergence of interoperable and large scale health systems continue, all entities will benefit from the exceptions proposed in these regulations.

Adoption of eprescribing technologies has already demonstrated significant savings regarding use and adoption and prove a viable investment and positive return to both small practices as well as other entities.

Conclusion

Walgreens commends CMS for its efforts through this proposed rule to achieve adoption of electronic health technology and the resultant positive impact on the United States healthcare system. Walgreens supports CMS and its efforts and is willing to provide support and participation in the adoption of eprescribing, electronic healthcare, and the overall improvement to the adoption and utilization of interoperable nationwide healthcare.

Sincerely,

Michael J. Simko /s/
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CMS-1303-P-12 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Kenneth Raske **Date & Time:** 12/12/2005

Organization : Greater New York Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-12-Attach-1.DOC

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Kenneth E. Raske, President

December
Twelve
2005

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Washington, DC 20201

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,

Kenneth E. Raske
President

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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-

[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, GNY HA b elieves H HS s hould b e f acilitating p articipation b y t hose e ntities t hat a re 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. I n a n e ra o f h ospitalists, it is n ot p ractical t o e xclude do ctors w ho ar e n ot

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.

CMS-1303-P-13 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Ms. Jane Thorpe **Date & Time:** 12/12/2005

Organization : AdvaMed

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1303-P-13-Attach-1.DOC

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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
Room 314G
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).

****

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,

/s/
David Nexon
Senior Executive Vice President

CMS-1303-P-14 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. David Merritt **Date & Time:** 12/12/2005

Organization : Center for Health Transformation

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1303-P-14-Attach-1.PDF

Center for Health Transformation
Better Health, Lower Cost

December 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
P.O. Box 8010
Baltimore, MD 21244-8010

Regarding Proposed Regulation at 42 CFR Part 411

Medicare Program; physicians' referrals to health care entities with which they have financial relationships; exceptions for certain electronic prescribing and electronic records arrangements

The comments to the proposed regulation in question as submitted by The National Alliance for Health Information Technology (NAHIT) are straightforward, detailed, and, most importantly, correct. The recommendations, submitted to CMS on December 8, 2005, reflect a broad consensus throughout healthcare that the regulation as written will not promote widespread adoption of health information technology, and will not promote the creation of a nationwide, interoperable healthcare network.

If the Department of Health and Human Services is to issue a new regulation, it must be clear-cut, concise, and flexible. The proposed regulation should include exemptions and a safe harbor that are available to any willing organization, such as national laboratories, and be much more flexible, such as allowing any type of permitted support.

An effective regulation will play a critical role in building what we call a 21st Century Intelligent Health System. This future will be centered on the individual; every American will be insured; it will be a binary market between individual and provider; costs go down instead of up; consumers will be healthier; providers will be paid on quality not volume; and it will be fully electronic—it simply cannot be built upon paper.

Getting health information technology into the hands of doctors, nurses, and other practitioners is the first step towards this future. Without the changes argued by NAHIT, the efforts by the Department of Health and Human Services to accelerate adoption and the creation of an interoperable health network will fall far short. HHS should reconsider its proposed regulation and strike a balance in the Stark law that advances this vision.

Sincerely,

Newt Gingrich
Founder, Center for Health Transformation

CMS-1303-P-15 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Dr. John Duggan **Date & Time:** 12/12/2005

Organization : American Association of Ambulatory Surgery Centers

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-16 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Dr. John Duggan **Date & Time:** 12/12/2005

Organization : American Association of Ambulatory Surgery Centers

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-16-Attach-1.PDF

American Association of
[redacted]
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Michael A. Romansky, Esq.
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December 12, 2005

Mr. Daniel R. Levinson
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-405-P
Room 5246, Cohen Building
330 Independence Ave., SW
Washington, DC 20201

Re: Proposed Physician Self-Referral Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements (File Code: CMS-1303-P)

Dear Mr. Levinson:

As President of the American Association of Ambulatory Surgery Centers, I appreciate this opportunity to submit comments on the Office of Inspector General's ("OIG") proposed rule to create a safe harbor to the Federal anti-kickback statute for certain arrangements involving electronic prescribing and electronic health records technology, as published in the October 11, 2005 *Federal Register*.

AAASC is a national association dedicated to advancing high-quality, physician-led and patient-centered care in ambulatory surgery centers ("ASCs"). We are committed to using technological advances to improve quality and efficiency in the provision of health care. Our comments primarily reflect the concerns of our member ASCs that, as service providers,we have every bit the vested interest in the adoption of electronic prescribing and electronic health records technology as do hospitals, group practices, and other providers who are proposed in the rule to be afforded safe harbor status.

AAASC applauds the OIG's efforts to promote widespread adoption of electronic health records and electronic prescribing technology. However, we have some concerns with the proposed rule, which are summarized below.

Permissible Donors

The proposed rule limits the classes of donors to hospitals, group practices, prescription drug plan sponsors and Medicare Advantage organizations. According to the preamble, such donors "have a direct and primary patient care relationship and therefore have a central role in the health care delivery infrastructure that justifies safe harbor protection for the furnishing of electronic health records technology that would not be appropriate for other types of providers . . ." See 70 *Fed. Reg.* 59023. ASCs and the physicians who perform surgeries in ASCs have a direct patient care relationship that is dependent on accurate and efficient record-keeping. Accurate record-keeping is of no less paramount concern in the ASC than the hospital or group practice; yet, the proposed rule would not afford physicians who perform procedures primarily in an ASC setting the same protection as their counterparts in hospitals. AAASC strongly urges CMS to include ASCs in the list of permissible donors.

Scope of Electronic Prescribing

One of the criteria for the electronic prescribing safe harbor is that donated items or services be part of, or used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D. However, to encourage use of electronic prescribing technology, the more prescription applications the technology has to eliminate common paper processes, the more likely it will be accepted in the clinical setting. Thus, AAASC recommends that the electronic prescribing safe harbor be expanded to permit qualifying electronic prescribing technology to be used for the transmission of prescription information for drugs as well as non-drug items and services such as devices, supplies and laboratory tests.

Pre-Interoperability and Post-Interoperability SafeHarbors

Hardware and Connectivity

Hardware and connectivity are an integral, and, frequently, the most costly, part of an electronic health record system. The limitation in the pre-interoperability and post-interoperability safe harbors to software and directly-related training services is unduly restrictive because it would require the physicians to pay for hardware and connectivity, thereby discouraging the widespread adoption of electronic health records. AAASC strongly urges CMS to include hardware and connectivity under both of these safe harbors.

Office Management Programs

Many electronic health record software packages come bundled with other office management functions such as billing or scheduling. Growing competition among vendors has made it increasingly difficult to find non-bundled electronic health record software programs. Facilities that purchase

electronic health record software typically do not have the ability (legally or technically) to unbundle the software. Moreover, in a time of burgeoning health costs, it is counter-intuitive for the government to implement any policy which has the effect of encouraging the unbundling of such programs. Therefore, we believe the pre-interoperabilityafe harbor's limitation on software "used solely" to receive, transmit, and maintain electronic health records is unduly restrictive and impractical and should be deleted in the final rule.

In closing, we appreciate this opportunity to comment on the proposed rule. If you have questions, or would like to discuss our comments further, please call our Washington Counsel, Michael Romansky, at 202.626.6270.

Sincerely,

John Duggan, MD
President

Cc: Craig Jeffries
Executive Director