American Hospital Association

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

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

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of its 4,800 member hospitals, health care systems, other health care organizations, and 33,000 individual members, appreciates the opportunity to comment on the proposed rule outlining an exception to the Physician Self-Referral, or "Stark," regulations. These regulations, together with the anti-kickback regulations, pose a significant barrier to hospitals and physicians working together to realize the promise of health information technology (IT) to improve the coordination and quality of patient care.

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

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

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

The AHA appreciates the initial steps taken by the Centers for Medicare & Medicaid Services (CMS) in setting out these proposed rules. However, the AHA urges CMS to broaden the scope of these exceptions. Under the proposed rules, hospitals still will risk penalties and will not feel confident enough to work with physicians to help them build their IT capacity and expand the exchange of health information for clinical care.

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

Policy goals

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

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

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

Providing an exception to the Stark rules for e-prescribing and EHRs will accelerate physician use of health IT. Patients will benefit from wider IT use and better integration of hospital and physician information systems, resulting in improved coordination of care, reduced medical

errors, and reduced repeat tests. The President and others in the Administration have noted the urgency for progress in this area.

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

Pre- and post-interoperability periods

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

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

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

Given the uncertainty surrounding certification, the AHA urges CMS to adopt a single exception without the certification requirement, not two exceptions for the pre- and post-interoperability

periods. CMS and the HHS Office of Inspector General (OIG) could revisit the exception at a later date to require compliance with interoperability standards once they have been agreed upon. This would allow the standards to be developed, tested and implemented, and give CMS and the OIG the opportunity to review the arrangements that have been made in the interim. It also would also put vendors on notice that progress toward interoperability is essential. This single exception would need to broaden the scope of covered technology and address other specific concerns noted in the comments below.

Breadth of regulatory authority

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

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

E-prescribing exception

Specifically, the proposed rules provide an exception for stand-alone e-prescribing systems. While the AHA understands that the Medicare Modernization Act of 2003 (MMA) directed CMS to develop an exception specifically for e-prescribing, hospitals are not likely to take advantage of an e-prescribing-only exception to the Stark laws because it is too narrow.

Hospitals and physicians need to exchange clinical information across the spectrum of care, including ambulatory, inpatient, post-acute and long-term care. For the greatest impact on quality and patient safety, e-prescribing should be an integrated piece of the full EHR, so that patients' diagnoses, allergies and treatments are accessible and known when prescriptions are made. In addition to being too narrow, the proposed rules provide an exception for stand-alone e-prescribing systems that are generally not found in the market.

Pre-interoperability EHR exception

The AHA has concerns with several elements of the proposed regulations contained in the pre-interoperability section, most of which will apply to all three of the proposed exceptions.

Defining "necessary"

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

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

Covered technology

The proposed rule narrowly defines the covered technology as EHR software that does not include administrative functions but does include e-prescribing modules that conform to

Medicare Part D standards just published. Directly-related training is the only permitted support under the proposed rule.

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

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

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

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

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

Standards

The AHA urges that CMS not require that permitted support conform to the BioSense (Public Health Information Preparedness) standards. BioSense is a national program to advance a new type of biosurveillance at the national, state and local levels, and includes certain public health information reporting standards. These standards have not been widely discussed or adopted industry-wide. More research is needed on their appropriateness for the private sector and readiness for implementation. In addition, requiring compliance with these standards while the broader standardization and certification efforts are underway could prove counterproductive.

Permissible donors and selection of recipients

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

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

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

to help physicians adopt EHRs, hospitals will need to choose which physicians they work with at the beginning of the exception, and how they roll out their donations.

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

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

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

Cap on value

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

physicians can be determined accurately only by considering needs and understanding associated benefits and costs of the use of specific technology.

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

Other conditions

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

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

Post-interoperability exception

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

In addition, certification requirements in the post-interoperability period must accept CCHIT criteria as sufficient for the purpose of the exception even if CCHIT has limited criteria for interoperability. While the proposed rule mentions CCHIT, it does not clearly state that only one certification process will be used. It would be confusing and burdensome if the Secretary established a separate certification mechanism for the purposes of the Stark exception.

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

The AHA stands ready to provide any assistance to remedy the concerns outlined. Questions about our comments can be directed to me, Chantal Worzala, senior associate director of policy, at (202) 626-2319 or cworzala@aha.org, or Lawrence Hughes, regulatory counsel and director, member relations, at (202) 626-2346 or lhughes@aha.org.

Sincerely,

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