THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

December 12, 2005

Honorable Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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.

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Dear Dr. McClellan:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the above proposed rule which seeks to establish exceptions to the Stark Physician Self-Referral regulations, which would permit hospitals to: (1) provide hardware, software, and related training to physicians for electronic prescribing ("e-prescribing") and; (2) provide physicians with electronic health records (EHRs) software and related training. The stated goal of these proposed regulations is to speed the process of meeting the "President's goal of achieving widespread adoption of interoperable EHRs for the purpose of improving the quality and efficiency of health care, while maintaining the levels of security and privacy that consumers expect."

CHA heartily endorses the underlying goal of these proposed regulations and believes health care quality, efficiency, and safety can be improved through the use of interoperable health information technology (HIT). However, in their current form, CMS's proposed regulations are more likely to have an undesired chilling effect on spreading the adoption HIT, for a number of reasons, as detailed below.

- **The Proposed Regulations Do Not Support and Further the Administration's Policy of Speeding Widespread EHR Adoption.**

From a policy perspective, the potential gains widespread HIT adoption would hold for patients and the federal government—in terms of increased quality, patient safety, productivity, care efficiency, and reduced morbidity and mortality—would seem to far outweigh any small risk donating this technology to physicians might pose. In fact, while the e-prescribing exception was mandated under the Medicare Modernization Act (MMA), the exceptions proposed for EHRs are entirely discretionary on the Secretary's part, under Section 1877(b) (4) of the Social Security Act. This part of the law authorizes the Secretary to "create regulatory exceptions for financial relationships that he determines do not pose a risk of program or patient abuse." In essence, by proposing the EHR exceptions, the Secretary is already acknowledging that such technology donations by hospitals do *not* constitute a risk of program or patient abuse.

The very positive public health goals of these proposed regulations are further underscored by you in an October 5, 2005 press release, when you stated:

Restrictions on relationships between physicians and other health care entities are very important for assuring Medicare dollars are spent appropriately, but they were never intended to stand in the way of bringing effective electronic health care to patients. We are bringing our rules in line with what we are working together to achieve: an interoperable electronic health care system that benefits patients by improving care, reducing complications, and unnecessary tests and procedures.

In short, the proposed regulations so narrowly define and restrict the terms and conditions under which hospitals may provide e-prescribing and EHR technology to physicians, that hospitals will be discouraged from doing so. In developing its final regulations, **CHA urges CMS to place first and foremost its primary goal of rapid HIT dissemination, by dramatically simplifying its requirements for hospital donation of this technology to physicians, so that the fear of reprisal under Stark (except in truly abusive situations) is all but eliminated.**

- **The e-Prescribing Exception is Too Narrow and Should be Merged into a Single, Expanded EHR Exception.**

CHA acknowledges that the MMA mandated that CMS promulgate a regulatory exception for e-prescribing hardware, software, and related training. However, having hospitals donate such technology to physicians as a stand-alone system would likely encounter stiff resistance from the physician community, as they would have to learn and operate the e-prescribing system totally apart from their existing system of ordering and recording medications. E-prescribing should be an integrated sub-system of an interoperable EHR that communicates patient data seamlessly with all other health care entities. CMS also complicates matters by proposing two separate EHR Stark exceptions for pre- and post-interoperability certification periods. Hospitals and physicians may not want to take on the expense and work of investing in an EHR system that may ultimately have to be replaced once interoperability certification standards are finalized.

To attain its stated goal of rapid dissemination of e-prescribing and EHR technology to physicians, **CHA recommends that CMS simplify its final rule to provide for a single, unified Stark exception which would allow hospitals to give physicians integrated e-prescribing and EHR hardware, software, and related training. Further, there should only be one certification required once final interoperability standards for all HIT components are finalized. Also, CMS should not exclude from "covered technology" the ability of a donated system to perform critical administrative functions, such as patient scheduling, billing, and referrals for necessary health care services.**

- **Other Technical Barriers to Donation of HIT to Physicians—Uncertainty Surrounding the Definitions of "Technically or Functionally Equivalent" and "Necessary" Items and Services.**

The proposed rule creates great burdens for hospitals wishing to donate HIT to physicians, as well as recipient physicians, to assure that donated items or services not be "technically or functionally equivalent" to those already possessed or obtained by a recipient physician. The donated items or services must be "necessary," i.e., not duplicate technology and capabilities the physician already has. CMS, unfortunately, does not explicitly define "technically or functionally equivalent," other than to give a couple of examples. Also, CMS explains that its definition of "necessary" would not preclude a hospital from donating system upgrades, as long as they "significantly enhance the functionality" of the hardware/software the physician already possesses—another term CMS fails to define—leaving the donors and recipients guessing as to what constitutes compliance.

The actual burden of "certifying" that items and services being donated by a hospital are not "technically or functionally equivalent" is placed on the receiving physician. CHA does not believe that this is a reasonable burden to place upon physicians, meaning this burden will likely fall upon the donating hospitals—if, in fact, they are willing and able to perform such a complex assessment, and then take the risk that this assessment is 100 percent accurate.

The lack of certainty surrounding the above terms, and the burden on physicians of having to certify that all HIT gifts from a hospital do not in any way violate the proposed Stark exceptions, is extremely daunting for hospitals and physicians alike. As such, **CHA strongly urges CMS in its final rule to eliminate such a piecemeal approach to donation of HIT to**

physicians, which is not only technically complex, but creates compliance concerns that likely will deter such giving to occur, slowing rather than speeding the adoption of such technology. CMS must develop a much more holistic approach to allowing integrated system HIT donations to physicians, so that physicians can concentrate on serving their patients, and not worrying whether some small part of their system unwittingly violates Stark. CHA also believes that placing a cap on donated technology is premature at this point in time, and should require further CMS study, since HIT and its capabilities and costs are rapidly evolving.

- **Permissible Donors and Selection of HIT Recipients**

CHA believes the proposed rule's limitation of only allowing a hospital to donate HIT to members of its medical staff that routinely furnish services at the hospital is not reflective of the way care is practiced in a community, and also undermines the magnitude of patient data which can be exchanged, to the detriment of physician and patient alike. For example, there has been a significant growth in the number of hospitalists and intensivists who admit patients to a hospital, but who do not furnish services there. The hospital-based physicians who treat these referred patients would certainly have need for clinical information exchange from these admitting physicians, yet the proposed rule bars the hospitals from giving these admitting physicians the same technology. Also, many non-staff physicians refer patients to a hospital's outpatient department, and would benefit greatly if they could electronically receive test results back from the hospital for incorporation into their own patient records.

It is clear in the proposed rule that the underlying concern is that hospitals may use the free gift of HIT as an enticement to lure physicians away from other hospitals. CHA does not believe that such a gift, unless it is of extraordinary value, is, by itself, the only factor a physician considers when deciding to practice at a specific hospital. Further, CMS's overriding goal of improving patient care quality and safety by speeding widespread adoption of HIT so that hospitals and physicians are electronically connected cannot be achieved if strict rules exist about which physicians can be HIT recipients. As such, **CHA strongly urges CMS, in its final rule, to liberalize its criteria for physicians eligible for such HIT donations, to significantly increase the electronic exchange of patient information in a community, so that quality of care is optimized.**

- **Lack of Regulatory Synchrony between CMS and the Office of Inspector General**

As you are aware, DHHS's Office of Inspector General (OIG) released a complementary set of proposed regulations to create an Anti-Kickback statute Safe Harbor for e-prescribing technology hospital donations to physicians. Yet, OIG did not offer matching Safe Harbors for CMS's two proposed EHR exceptions. This places hospitals and physicians in a major legal quandary, since the OIG leaves the door open to interpret hospital gifts of EHR technology as a form of kickback for referring patients to a donating facility. **CHA thus urges CMS and the OIG to reach agreement on assuring that all hospital donations of HIT are covered under a single Safe Harbor, eliminating the uncertainty that now exists due to OIG's unwillingness to create a Safe Harbor for EHR donations.**

Summary

CHA believes that the many benefits that will accrue to patients and to the health care system at large, through the widespread adoption of electronic health information technology, is worthy of the massive interest and effort this goal is receiving throughout the U.S. health care sector, at both the private and public level. A recent *Health Affairs* reports shows an interoperable national HIT system would save $78 billion annually, through avoided waste, duplication, reduction of medical and medication errors, reduced morbidity and mortality—all by-products of the increased quality and productivity a national health information infrastructure would spawn.

Secretary Leavitt has stated that national EHR adoption is the "wheel that turns all others," and the proposed rules from CMS and OIG are a clear first attempt to knock down the barriers that stand in the way of this becoming a reality. However, as currently written, these proposed rules do far more to prevent rather than promote this desired outcome. CHA believes that HHS must issue an unequivocal edict that puts its quality and care efficiency priorities above all else, and direct CMS and OIG to draft coordinated final rules that offer a clear, unfettered, and positively incentivized path to an interoperable HIT infrastructure that will benefit all.

CHA appreciates the opportunity to comment on CMS's proposed rule, and hopes our recommendations have been helpful.

Sincerely,

Sister Carol Keehan, DC
President and CEO