Comments on Centers for Medicare and Medicaid Services
Proposed Rules No. CMS-1303-P

As organizations representing a wide range of consumer interests, we are pleased to have the opportunity to comment on the proposed rule CMS-1303-P to create an exception to the physician self-referral prohibition in section 1877 of the Social Security Act. This rule addresses the donation to physicians of health information technology (HIT) to receive and transmit prescription drug information and/or for electronic health records software and training services. We recognize the potential of HIT to improve health care quality. Furthermore, we support efforts by the Department to promote the use of HIT by physicians and other health care providers, and are encouraged by the prospect of reduced errors and higher quality if e-prescribing is implemented. Below are our comments on the proposed rule.

Pre-interoperability Electronic Health Records Exception: §411.351(w)

This section would provide an exception to the Stark patient self-referral statute for donations of electronic health record technology made prior to the adoption of product certification criteria by the Secretary. We oppose this provision and recommend it be deleted entirely in the final regulations.

The Department is moving aggressively to put product certification criteria for ambulatory care in place in 2006. Promoting investment in this technology before DHHS adopts those criteria may seriously impede reaching the goal of a common platform – a goal which is part of the rationale for making this exception. Furthermore, allowing the exception to be in effect prior to certification could encourage providers and manufacturers to press for delay in adoption of the certification standards in order to avoid having to make new investments or to retain the market advantages they have created by installing their systems in physician offices. The Department should delay the effective date for the exception until the certification criteria are adopted.

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

This segment of the proposed regulations would provide an exception to the Stark statute for donations of electronic health records software if the donation is made after the product certification criteria are adopted and if the software is compliant with the certification requirements. We support the intent of this exception but have some concerns about some of the text.

Subsection §411.357(x)(4) requires that neither the selection of the physician nor the amount or nature of the items and services donated can turn on the volume or value of

referrals or other business generated between donor and recipient. The section then enumerates six specific criteria that a donor might use that would be deemed compliant with the exception requirements:

1) total volume of prescriptions the recipient writes;
2) size of the medical practice;
3) number of hours the physician practices medicine;
4) extent of use of automated technology in the recipient's medical practice;
5) if the donor is a hospital, whether the physician is on its staff; or
6) another method that "is based on any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties."

This section is the heart of the proposed rule. The widespread adoption of EHR and EP technology can bring great benefits to patients, providers and insurers. Health information technology can help reduce medical errors, encourage patient activation and adherence to recommended regimens, and provide tools to evaluate clinical effectiveness, population health status, and the quality of medical care. The drive to promote the wider use of EHR and EP technology should not, however, trump the consumer protection or program integrity brought by the antifraud and abuse prohibitions. Donors should not be allowed to selectively fund physicians based on the volume of their prescribing, size of practice, or whether they are likely to be high users of technology since these could be proxies for the generation of referrals and revenue. We therefore recommend the following changes:

- Eliminate item #6, above. It is too open-ended and subjective and could become a major loophole.

- Our preference would be to require that donors offer the technology to all their physicians. In the case of hospitals that would be all physicians with privileges; for MCOs, all physicians in the MCO network; for group practices, all physicians in the group. In the case of an MCO, where it might be impractical to include all network participants, donors could be permitted to give priority to those physicians or clinics that have a certain percentage of their patients in the MCO. Similarly, for hospitals the alternative might be all physicians with privileges of a general category such as: a) practice privileges, or b) admitting privileges.

- Add a new exception that permits the donation to a physician or clinic that provides a certain level of uncompensated charity care or a combination of charity care and Medicaid patients. It is these providers – the community clinics, solo practitioners in rural communities or medically underserved areas – who are least likely to have the resources to make the health information technology investments on their own.

In the preamble to the proposed regulations the Department asks for comments on a cap on the value of the EHR donation, either a maximum percentage of the value of the

technology (which would require the physician to share the costs) or the lower of a fixed dollar amount or the percentage of value. We believe it would be hard to use a fixed dollar amount cap. The cost of technology will change over time and vary depending on the nature of the system. A cap on the percentage of the value of the technology being donated appears to be the more viable option. The physicians or clinics with high Medicaid and/or charity care caseloads should be exempted from cost-sharing.

Subsection 417.357(x)(9). This subsection requires that any donated EHR software contain electronic prescribing capability that complies with the electronic prescription drug program standards under Medicare Part D at the time the items and services are furnished. In the preamble the Department states that it "wants to ensure that integrated packages that could positively impact patient care are not excluded from the post-interoperability exception." We support the development of software in ways that promote avoidance of medical errors, improve quality of care, and/or enhance public health preparedness. It would be desirable that, as the Secretary adopts additional standards for EP, and for EMR systems, any donations qualifying for this exemption also have to comply with those standards without the necessity that the Department amend these regulations. We suggest the Department consider that possibility in shaping the final regulations.

Sunset section 411.357(x) entirely at a designated date. The rationale for allowing an exception to antifraud prohibitions decreases with the passage of time. Physicians may not purchase EHR technology now, but in the future having such technology will be a standard and necessary part of medical practice. At that point there will be no need for third parties to donate such technology. Furthermore, if interoperability becomes the norm, incompatibility across a network of providers ceases to be an issue. We therefore strongly urge that this entire section authorizing the Stark law exception for EHR be eliminated not later than five years from the date of publication of the final regulations. Alternatively, the sunset date could be delayed for up to two additional years if the Secretary makes an administrative finding that there is still a need for the exception to promote adoption of EHR technology.

While we support some limited exceptions to the physician self-referral prohibition for donation of EP and EHR technology, we believe these exceptions will have only a modest impact on the expansion of their use. Of much more importance are the standards harmonization and product certification efforts the Department already has underway. Equally important will be direct funding of loans and grants to states and providers and financial incentives for the adoption of HIT being incorporated in federally supported health care programs, including Medicare, Medicaid, FEHBP, TriCare, and SCHIP.

Thank you for considering our comments.

National Partnership for Women & Families
AFL-CIO
American Federation of State, Federal and Municipal Employees
Consumers Union
Department for Professional Employees, AFL-CIO
National Consumers League
Service Employees International Union