Consumers Union
Nonprofit Publisher of Consumer Reports

Statement of Consumers Union

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before

Subcommittee on Health
The Committee on Energy and Commerce
U. S. House of Representatives

on

Legislative Proposals to Promote Electronic Health Records and A Smarter Health Information System

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Mr. Chairman, Members of the Committee:

Thank you for inviting us to testify today. Consumers Union is the independent, non-profit publisher of *Consumer Reports,* and we work on a wide range of health issues, including prescription drug safety and effectiveness, health insurance and health care costs.

The Potential

We strongly support the movement toward electronic systems of health records (EHR) and information exchange. By harnessing the power of modern information technology systems we can improve the quality of American health care and moderate health costs by:

- reducing errors,
- eliminating service duplication,
- promoting pay for performance, and
- providing the data necessary to evaluate the true comparative effectiveness of various treatments and drugs.

As just one example of the tremendous improvements in quality and cost savings that are possible, Consumers Union has been conducting a national campaign to promote the disclosure of hospital infection rates (www.StopHospitalInfections.org). Each year, there are about 2 million patients who acquire infections in hospitals, and about 90,000 die. The increased cost to the health care sector is in the tens of billions of dollars. We have been working at the state level to pass laws to require hospitals to report their rate of infection in the belief that public disclosure will prompt hospitals to adopt effective methods to reduce their infection rates. Electronic medical records technology and the public disclosure of more types of de-identified patient care data will make it easier for consumers to reward those who provide quality.

The Critical Need to Ensure Privacy

While there can be important public and private benefits of creating an effective electronic medical records system, we believe (and polls demonstrate[1]) that the American public will not support, fully use, or benefit[2] from the great potential of such systems unless more is done—now--to ensure the privacy, security, and appropriate use of medical information. This requires enabling patients to decide when, with whom, and to what extent their medical information is shared. As Dr. David Brailer, head of the Office of the National Coordinator for Health Information Technology, responded March 3 to a letter (see Attachment #1) from consumer groups, "we will achieve our goal of widespread [EHR] adoption only if patients are confident that their health information is private and secure." Today, it is not private or secure.

This concern should especially resonate with public officials such as you, who are so subject to prying eyes and gossiping tongues.[3] I think we all have to admit that there is no hack-proof database or system. Once our medical data is moving electronically, it is subject to threats from hackers, identity thieves and others. That is simply a fact of life, re-confirmed almost daily by new stories of financial and medical record data violations.[4] Beyond the likely scenarios of security breaches, the value of electronic health information is such that many organizations will want to exploit secondary data sources for private financial gain, rarely (if ever) with patient knowledge, let alone consent.

So what can we do to minimize concerns and improve privacy in electronic health records?

The American public needs to be given meaningful control over their medical records. That means they must have a right to keep their records private and that

[1] See as just one example Caroline Broder, "Survey: Consumers Concerned About Control, Access to Medical Info," *Healthcare IT-News*, January 18, 2006.

[2] For example, polling of Americans shows 63% to 75% would not participate in, or are concerned about loss of medical privacy in an electronic system. See work of Professor Alan Westin, February 23, 2005; California Health Care Foundation, January 2000; and 65 Federal Register 82,466.

[3] Testimony of Joy Pitts, Assistant Research Professor, Georgetown University, July 27, 2005 before the Ways and Means Health Subcommittee, citing the Rep. Velasquez and former President Clinton examples, page 2. See also Robert Dallek's An Unfinished Life (p. 261ff) for a description of LBJ's efforts to obtain medical information on JFK and how Kennedy avoided certain important medical tests so as not to have a medical record.

[4] As HHS said in the Federal Register, "there is no such thing as a totally secure [electronic information] system that carries no risk." 68 Federal Register at 8,346. For very recent examples of hacking and intentional misuse of data, see *Information Week*, March 9, 2006, "PIN Scandal 'Worst Hack Ever'; Citibank Only the Start," and *The Washington Post*, March 14, 2006, Business Section, page 2, "Datran Media Settles Probe."

they cannot be forced to give up control of their most private medical information as a condition of treatment.

The penalties for violations of privacy are inadequate and have major gaps.[5] There must be strong enforcement of privacy and security laws, and if a person's privacy is compromised or violated, they should be notified of that breach and have a private right of action.

The States should have the right to enact privacy laws above and beyond HIPAA's absolutely minimal provisions and that right must not be pre-empted. Privacy needs to be strengthened, not weakened, and we urge you to oppose legislation that would pre-empt stronger State laws or delegate to the Secretary of HHS authority to pre-empt such laws. These State laws offer extra protection and peace of mind to patients with mental health, STD, cancer and other treatment issues. As 30 organizations in the Mental Health Liaison Group wrote Congress on November 15, 2005, adding improved privacy protections to proposed EHR bills is essential in the mental health sector.[6]

Some will say that it is too complex or too expensive to allow people to control their medical information. But that's why computers are so wonderful! They can be designed to deal with huge numbers of variables—like 50 state laws-- and to create special files where certain data (such as a mental health record) is only available to a designated provider on a "need to know basis." If we do not meaningfully address the privacy issue, polls show the public will not trust this system, many will go to a medical underground 'off-the-books'[7], and we will just increase public cynicism about big government and big business controlling our lives. In an age when the talk is of consumer driven health care, and ownership, and empowerment, forcing people to share their most secret personal medical information is not the path to take.

Attached are a set of consumer principles that was developed under the leadership of the National Partnership for Women & Families and that Consumers Union, AARP, and seventeen other groups are supporting.[8] We urge you to include these principles in whatever legislation you may develop.

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[5] Joy Pitts, op. cit., p. 4.

[6] See letter from National organizations representing consumers, family members, advocates, professionals and providers, c/o Peter Newbould, American Psychological Association Practice Organization, 750 First Street, NE, Washington, DC 20002.

[7] Reportedly millions of Americans already forgo sensitive treatments because of privacy concerns. 65 Federal Register 82,778.

Oppose Incentives to Promote Technology Give-Aways that may Distort Health Care Delivery

Assuming true privacy and increased security, we all would like to promote the fastest possible movement to EHRs and a 'networked' health care system so as to benefit from the quality and cost savings potentials. We recommend, however, against making blanket exceptions to the anti-kickback and physician referral laws for donations of EHR systems.

Given the Federal budget situation, it is understandable that some are attracted by the idea that such blanket exceptions might be a 'free' ways to promote EHR technology dissemination. We believe, however, that such action would have a very limited impact on the adoption of EHR systems and would not be good for consumers. This approach is not free—it has a cost, as we describe below.

Most businesses don't give away something of value to another businessperson unless they expect a return on the investment. When a hospital system offers an IT package to a non-affiliated physician group, it hopes the ease of communication between them (and the goodwill generated by the gift) will encourage referrals to its facilities, regardless of whether that facility is the best quality or value facility for the patient.

There is a parallel example in an area we know causes higher and more costly utilization: Why do pharmaceutical companies give free drug samples (and pens and pads of paper, etc., etc.) to doctors? Because in our society and culture, the act of giving a gift, even a trinket, conveys a psychological sense of obligation—"I owe you one." That is human nature. In the case of 'free' drugs, it leads to increased utilization of high cost products. That is what the anti-kickback and physician referral rules tried to deal with: the act of giving something of value creates "ties" that cause referrals and utilization to go up, without regard to need, cost, or quality.

It is worth spending a minute more on the 'free' drug example. There has been a great deal of concern about the way drugs are promoted and the impact that has on costs and quality of care. The January 25, 2006 issue of JAMA (Vol. 295, No. 4, p. 429ff) carried an article by some of America's most distinguished physicians entitled, "Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers," that calls on the nation's teaching

hospitals to lead an ethical revolution and reject all industry gifts, since those gifts distort the practice and integrity of medicine. As the doctors wrote:

> Social science research demonstrates that the impulse to reciprocate for even small gifts is a powerful influence on people's behavior. Individuals receiving gifts are often unable to remain objective: they reweigh information and choices in light of the gift. So too, those people who give or accept gifts with no explicit "strings attached" still carry an expectation of some kind of reciprocity. Indeed, researchers suggest that the expectation of reciprocity may be the primary motive for gift-giving.
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> Researchers have specifically studied industry gifts to physicians. Receiving gifts is associated with positive physician attitudes toward pharmaceutical representatives. Physicians who request additions to hospital drug formularies are far more likely to have accepted free meals or travel funds from drug manufacturers. The rate of drug prescriptions by physicians increases substantially after they see sales representatives, attend company-supported symposia, or accept samples. The systematic review of the medical literature on gifting by Wazana [author of a JAMA article in 2000] found that an overwhelming majority of interactions had negative results on clinical care.[9]

If medical practice is distorted by the relatively small value of drug company gifts, imagine the consequences of large EHR technology "gifts"!

What if Congress proposed (though it would not take a law) that companies and providers could give money or equipment to a truly neutral charity in an area (for example, the Red Cross, the American Public Health Association, a State Medicaid Agency) that would then distribute the gift on some basis of need and there would be no tie between the donor and the recipient? I think most potential donors would find lots of reasons why that wouldn't work. And that should tell you everything: the donor wants a "tie" with the recipient that will result in goodwill and increased

[9] Eleven footnote references to sources for statements omitted from quote. For a less scholarly description, see "The Drug Pushers, by Carl Elliott, MD, Ph'D in The Atlantic Monthly, April, 2006: "After awhile even the most steel-willed doctors may look forward to visits by a [drug] rep, if only in the self-interested way that they look forward to the UPS truck pulling up in their driveway. A rep at the door means a delivery has arrived: take-out for the staff, trinkets for the kids, and, most indispensably, drug samples on the house. Although samples are the single largest marketing expense for the drug industry, they pay handsome dividends: doctors who accept samples of a drug are far more likely to prescribe that drug later on. Such gifts do not come with an explicit quid pro quo, of course. Whatever obligation doctors feel to write scripts for a rep's products usually comes from the general sense of reciprocity implied by the ritual of gift-giving."

referrals. For consumers, the problem is that the "tie" and resulting increased referrals may not be the best for the patient because the donor may not be the best or lowest-cost provider in an area. And donors who have the resources to give may just increase their economic dominance in an area, thus reducing future competition and driving up costs.

Look for real solutions to speeding dissemination of IT

There are better ways to encourage more adoption of EHRs. Once progress is made on technology and process standards and there is more agreement on the best hardware and software paths, Congress may want to promote the dissemination of such technology and pay for it in a way that does not distort practice patterns. You might explore with CBO whether, as you try to fix the Medicare physician payment system (SGR), a budget neutral, time-limited way to encourage physician installation of certified EHR could be possible. For example, would CBO score as neutral a system where on a voluntary basis, a physician could greatly increase their practice expense payments for several years so they could more easily finance the installation of a 'certified' EHR system. Then in the next several years they would repay that 'advanced' amount through reduced practice expense payments, on the grounds that the installation of the equipment will reduce paperwork and clerical practice expense in future years. Another encouragement to take advantage of this opportunity would be a requirement that by a date certain all Medicare-Medicaid EHRs would have to be through certified systems.

Congress could also help providers in the future by using the certification process to obtain a discount price for EHR hardware and software.

In summary, we urge you to consider alternatives to encouraging the dissemination of this new generation of equipment in ways that do not weaken the nation's anti-fraud laws.

If Congress feels compelled to proceed with anti-kickback and anti-referral law changes, we urge you to consider limited exceptions based on modifications to the Administration's October 2005 proposed regulations.
These draft regulations would permit exceptions—but not blanket exemptions--to the anti-kickback and physician referral laws for EHR donations. Consumers Union, the National Partnership for Women & Families, and five other national organizations filed formal comments expressing serious concern about the exceptions and urging major changes (see attachment #2).

For example, we recommend changing the regulations to:

--delay the effective date of the exceptions until the product certification process for ambulatory care that the Administration is now aggressively supporting is in place (otherwise you encourage donations that may lead to technological dead-ends and wasted time and effort—e.g., Beta v. VHS competing donations);

--limit the exception to donations to physicians or clinics that provide a certain level of uncompensated charity care or serve a significant number of Medicaid patients; or if that is not possible, require donors to offer the technology to all (their) physicians, not just those who provide high volumes of profitable business;

--sunset the exemptions;

--require recipients to copay a portion of the cost: totally free equipment is likely to sit in the closet. The equipment needs to be something that the recipient wants enough to put some of his own resources into.

Thank you all for your time and attention.

Attachment #1

Health Information Technology – Consumer Principles
March 2006

An interoperable system of electronic health information holds many potential benefits for consumers, including: better coordination of health care regardless of patient location, higher quality and more efficient care, increased system transparency, and patient access to information about providers that allows them to make better decisions. At the same time, such a system raises serious concerns among consumers about personal privacy, data security, and the potential misuse of their information. And while an interoperable system of electronic health information holds great promise, the many possible benefits will not be realized unless appropriate policy measures are established up front.

Consumer protections and potential benefits from health information technology (HIT) should not be left to chance. The success of efforts to promote widespread adoption of HIT, including electronic connectivity and data exchange across health care institutions, ultimately will depend on the willingness of consumers to accept the technology. Given the pervasive concerns expressed by the public about unauthorized disclosure and use of their health information, it is critical to build a foundation of public trust. To that end, as efforts move forward to develop networks for the electronic exchange of information between institutions, there must be a clear, deliberate, and open forum for addressing and setting matters of policy. As organizations representing a broad and diverse set of consumer interests, we believe that the following set of principles should underpin such efforts.

Principles

Individuals should be able to access their personally identifiable health information conveniently and affordably.

- Individuals should have a means of direct, secure access to their electronic health information that does not require physician or institutional mediation.

- Individuals should have access to all electronic records pertaining to themselves (except in cases of danger to the patient or another person).

- Individuals should be able to supplement, request correction of, and share their personally identifiable health information without unreasonable fees or burdensome processes.

Individuals should know how their personally identifiable health information may be used and who has access to it.

- Individuals should receive easily understood information identifying the types of entities with access to their personal health information and all the ways it may be used or shared. The explanation should include any sharing for purposes other

than the immediate care of the individual, and should explicitly identify intentions for data use such as public health protection, quality improvement, prevention of medical errors, medical research or commercial purposes.

- Access to personal health information must be limited to authorized individuals or entities.

- Tracking and audit trail systems should be in place that permit individuals to review which entities have entered, accessed, modified and/or transmitted any of their personally identifiable health information.

Individuals should have control over whether and how their personally identifiable health information is shared.

- Individuals should be able to opt out of having their personally identifiable health information – in whole or in part – shared across an electronic health information network.

- Individuals should be able to limit the extent to which their health information (with or without personal identifiers) is made available for commercial purposes.

- Individuals should be able to designate someone else, such as a family member, caregiver or legal guardian, to have access to and exercise control over how records are shared, and also should be able to rescind this designation.

Systems for electronic health data exchange must protect the integrity, security, privacy and confidentiality of an individual's information.

- Personally identifiable health information should be protected by reasonable safeguards against such risks as loss or unauthorized access, destruction, use, modification, or disclosure of data. These safeguards must be developed at the front end and must follow the information as it is accessed or transferred.

- Individuals should be notified in a timely manner if their personally identifiable health information is subject to a security breach or privacy violation.

- Meaningful legal and financial remedies should exist to address any security breaches or privacy violations.

- Federal privacy standards that restrict the use and disclosure of personally identifiable health information should apply to all entities engaged in health information exchanges.

The governance and administration of electronic health information networks should be transparent, and publicly accountable.

- Independent bodies, accountable to the public, should oversee electronic health information sharing.

- Consumers should have equal footing with other stakeholders.

Recognizing the potential of electronic patient data to support quality measurement, provider and institutional performance assessment, relative effectiveness and outcomes research, prescription drug monitoring, patient safety, public health, informed decisionmaking by patients and other public interest objectives, systems should be designed to fully leverage that potential, while protecting patient privacy.

Implementation of any regional or national electronic health information network should be accompanied by a significant consumer education program so that people understand how the network will operate, what information will and will not be available on the network, the value of the network, its privacy and security protections, how to participate in it, and the rights, benefits and remedies afforded to them. These efforts should include outreach to those without health insurance coverage.

AARP
AFL-CIO
American Federation of State, County and Municipal Employees
American Federation of Teachers
Center for Medical Consumers
Communications Workers of America
Consumers Union
Department for Professional Employees, AFL-CIO
Childbirth Connection
Health Care for All
Health Privacy Project
International Association of Machinists and Aerospace Workers
International Union, United Auto Workers
March of Dimes
National Coalition for Cancer Survivorship
National Consumers League
National Partnership for Women & Families
Service Employees International Union
Title II Community AIDS National Network
United Steelworkers International Union (USW)

Attachment #2

Comments of Groups on HHS Proposed Regulations on anti-kickback and physician referral[10]

Comments on Office of the Inspector General Proposed Rule OIG-405-P

As organizations representing a wide range of consumer interests, we are pleased to have the opportunity to comment on the proposed rule OIG-405-P that would add a new paragraph (x) to the existing safe harbor regulations at 42 CFR 1001.952. The proposed safe harbor would protect donation of specific items and services for prescribing drugs electronically. The preamble to the regulations also describes the scope of two planned additional safe harbors for electronic health records software and directly-related training services, but the Office has not proposed actual regulatory language for such a safe harbor.

We recognize the potential of health information technology (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 safe harbor.

Pre-interoperability Electronic Health Records Safe Harbor

The Office is considering the creation of a safe harbor 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 not be included 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 safe harbor. Furthermore, allowing the safe harbor 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.

Post-interoperability Electronic Health Records Safe Harbor

[10] This is the comment on anti-kickback proposed rule. Basically identical comments were filed on CMS-1303-P, relating to the physician referral proposed rule.

In a parallel proposed rule, CMS-1303-P, the Department has included the actual text of a proposed regulation to 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; we have outlined our concerns in comments filed today on CMS-1303-P. The Office has asked for comments on its plans for a similar safe harbor, described in section II.B.2 of proposed OIG-405-P. Our comments on the potential safe harbor are similar to those expressed with regard to the Stark exception. For convenience, our views are set forth below in the context of the proposed CMS Stark exception text.

Subsection §411.357(x)(4) [of CMS 1303-P] 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 postinteroperability 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, and

the creation of additional safe harbors under the Anti-Kickback statute, for donations 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