Citizens' Council on Health Care

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July 21, 2007

P. Jon White, MD
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

RE: Request for Information (RFI) on proposed National Health Data Stewardship Entity

Dear Dr. White,

Citizens' Council on Health Care is responding to your request for information (RFI), dated June 4, 2007 in the Federal Register (pages 30803 – 30805). Below you will find a Summary Statement, comments regarding several of our key concerns, and one very URGENT Action Request.

SUMMARY STATEMENT

We believe the proposed National Health Data Stewardship Entity (NHDSE) would open wide the vaults of private medical data, authorizing the exposure of more than 300 million Americans to unwanted disclosures and research, potential embarrassment, fear in and outside the doctor's office, privacy violations, genetic discrimination, breaches in the confidential patient-doctor relationship, profiling and surveillance, outside controls on the practice of medicine, and health care rationing. The proposed NHDSE would:

- Nationalize ownership and control of private patient data.
- Eliminate the exercise of individual privacy, consent, and data ownership rights.
- Abolish current state medical privacy laws that actually protect patient privacy.
- Eliminate the power of state legislators to enact future medical privacy laws.
- Authorize a multitude of secondary uses of data unrelated to the direct care of patients.
- Expand government access to private medical data.
- Place control over access to and use of confidential patient medical records data in the hands of unelected and unaccountable bureaucrats, corporate executives, and political appointees in a centralized bureaucracy far from the people whose privacy is violated—and whose access to medical care would be threatened by statistics-based health care rationing decisions.

The Citizens' Council on Health Care does not support the proposed National Health Data Stewardship Entity, requests an extended deadline for public comments and improved public notice, and calls into question the legal standing of the RFI. CCHC also calls on the AHRQ to fully support individual privacy, consent and data ownership rights in any future health data proposals.

SEVEN KEY CONCERNS

The Public Has Not Been Informed—and SHOULD BE!

Despite a call for public input in the RFI, and the fact that the stated purpose is to *"advance health data exchange and use,"* it does not appear that AHRQ has made a real attempt to gather the public's opinion on this very important matter. First, the agency's choice of publication date was sure to mean less public input and discussion. The RFI was issued on June 4th, a time when the public is distracted with vacations, children out of school, and the fun of summer activities.

Second, AHRQ appears to have done little to notify the public:

- The last press release on the AHRQ website press room is dated April 17, 2007.
- There is no section on the AHRQ home page that lists current proposals for public comment.
- In a web search for the RFI, the only item that came up on the AHRQ website using "NHDSE" or "stewardship" in the search engine was the Summary document from a discussion of the "HHS Transparency Initiative" at an AQA Invitational Meeting.
- Neither the RFI nor the link to the *Federal Register* document could be found on AHRQ's website.

As the AHRQ undoubtedly knows, the public does not read the *Federal Register*—most do not even know it exists—and most have never heard of the AHRQ to look there for a public comment notice. They read the newspaper and watch the news on television and the Internet. If it's not there, they'll never know about it—or respond.

Even the media seems unaware of the Request for Information from the public. From our research, it appears that the only news reports on this proposal were in sources unfamiliar to the general public:

> June 6 – *GovernmentHealthIT*: "Health analysts see need for health data steward"
> July 6 – *SmartBrief*: "Agency considered to set standards on health care quality data"
> July 13 – *iHealthBeat*: "Federal IT Group To Study Secondary Uses of Health Care Data"

ACTION REQUEST: If AHRQ sincerely wants the public's opinion and not just input from organizations already "at the table" and "in the know":

- a press release should immediately be released.
- a FAQ sheet provided.
- the public comment period *significantly* extended.

Elimination of State Medical Privacy Laws and Citizen RIghts

The proposed National Health Data Stewardship Entity would undo current federal law, which permits state legislatures to write and enact strong medical privacy laws that protect patient privacy. As stated in the RFI, the NHDSE is proposed to be an entity with all-encompassing national authority:

> [A] public-private national health care data stewardship organization with oversight of the various uses of healthcare data….

The NHDSE would also lead to the collective elimination of the citizen's ability to exercise privacy, consent, and ownership rights over medical record information—including genetic information and DNA. Nowhere in this entire document is the word "consent," the term "patient consent" or the term "patient rights" to be found. The NHDSE would essentially define ownership, consent and privacy rights, if any. While NHDSE could choose to give hospitals or health plans or even researchers ownership rights to patient data, our research found the most likely outcome would be the elimination of all individual and corporate ownership rights replaced by national oversight and "stewardship" duties performed by the unelected directors of the NHDSE.

NHDSE would essentially "own" the medical data of 300 million Americans because the decisions of its directors would control the use and disclosure of all private health data.

<u>The proposed NHDSE appears to be a mechanism primarily intended to nationalize ownership of private patient data, and undo the current authority of state legislatures to protect patient privacy, uphold individual consent, ownership and privacy rights, and restrict outside access to private medical records.</u>

Surveillance, Rationing of Medical Treatment, and Assaults on Citizen Privacy and Freedom

According to the **Proposed Mission**, this national entity would set uniform (national) rules and standards for sharing and aggregating patient data "to afford means of more effective oversight of health care data analyses and reporting in the United States." In effect, the NDHSE could facilitate or enable:

- Surveillance and outside monitoring of all patients and doctors
- Patient and doctor profiling
- Health care rationing – use of patient data to build so-called "evidence-based" and statistics-based rationale for the purpose of denying medical services and controlling the practice of medicine.
- Expanded government access to private patient data
- Subjection of patients to medical, genetic, and other research projects without consent

Also, as opposed to what is stated in the **Proposed Precepts** section, a national bureaucracy **cannot**:

- "be objective in its decision making." These would be bureaucrats, corporate executives and political appointees.
- "weigh carefully the views of its constituents." It has no constituents. Directors are unelected.
- be "timely" in its decision-making. It is a bureaucracy.
- "preclude placing any particular interest above the interests of the many stakeholders who rely on health care information."

There are more than 300 million Americans. That means there are more than 300 million different interests with regard to the use of individual medical record data, including the very legitimate **right to refuse**. The rights of consent, refusal and ownership protect the privacy and freedom of individuals. Yet as noted previously, there is no mention of patient consent or patient rights in the RFI document.

The **Proposed Characteristics** of the NHDSE mentions that decisions would be made by "consensus." This is not a comfort to the 300 million individuals who would be affected by these decisions. Individual citizen preferences and rights do not often survive bureaucratic consensus decision-making, and are often trampled by it, as happened with the so-called HIPAA "privacy" Rule which now allows a broad range of disclosures of patient data without patient consent.

The proposed NHDSE would further erode the patient's rights of consent and refusal and instead place decisions about exercising those rights in the hands of NDHSE directors whose very position at the NDHSE table would allow them to make decisions for more than 300 million people based primarily on *their own* judgments, preferences, biases and agendas.

Unelected All-Controlling Bureaucracy

The NHDSE would be established as a centralized public-private bureaucracy governed by a small group of unelected bureaucrats, corporate executives and political appointees. They would have sole control over the public's private medical records data but as a public-private entity, no accountability to the public.

There would be little any member of the public could do to oppose or undo the actions and decisions of the NHDSE, including the authorizing of myriad secondary uses of the public's private data.

Secondary Uses of Data Without Patient Consent

It is clear from our research that advocates for gaining extensive access to patient data for secondary uses—uses unrelated to the direct care of the patient—see the proposed NHDSE as the vehicle to make it happen.

Although the RFI specifies that the intended mission of the NHDSE is related to the collection and analysis of performance data from hospitals, clinics, and individual physicians for monitoring the undefined terms of "quality and efficiency"—just one of the many possible secondary uses—the Proposed Mission's

discussion of possible additional uses is much more diffuse. In fact, one has to read the entire RFI carefully before the following disturbing statement is found in the middle of a long paragraph near the end of the document:

> **It is recognized that the role of a NHDSE might extend to domains *beyond* health care performance measurement.** *[my emphasis]*

AHRQ then asks commenters to suggest other domains. Our research finds that plans for a stewardship entity and plans for enabling "secondary uses" of data often go hand in hand. For example, the American Medical Informatics Association (AMIA) provides the following six principles for a National Framework for Secondary Use of Health Data:

- Transparency of policies and practices
- *Stewardship rather than ownership*
- Consensus on privacy policy and security
- Public awareness
- Comprehensiveness
- National leadership[1] *[my emphasis]*

The AMIA provided an expansive Taxonomy (list) of potential "secondary uses of data" at its July 2007 conference. The list of secondary uses was more than 2 pages long with the following headings:

a. Provide background data for system to implement real-time decision support for a specific patient based on repository of observations on similar patients…
b. Protect and enhance public health [includes 24/7 bio-surveillance of ER visits, and reports to government on wellness, people with cancer and other medical conditions, patients exposed to secondary smoke, weight, height and blood pressure, etc.]
c. Conduct Health Research [includes outcomes research, treatment effectiveness, health services research, health technology assessment, identification of candidates for clinical trials, and genetics research ("Link medical data to pedigree and family tree data")]
d. Manage and improve the quality of patient care [includes risk-profiling of patients]
e. Support quality assessment [includes national reporting of physician compliance with quality measures]
f. Support and analyze financial activities
g. Create and test knowledge assets and decision support algorithms [includes development of order sets]
h. Develop security and confidentiality algorithms ["develop and test de-identification routines"]
i. Support market research [includes "targeting patient advertising, marketing and sales"]
j. Track clinical training activities
k. Credential health care providers
l. Detect illegal and inappropriate activity [includes monitoring physician prescribing patterns]
m. Use patient data for patient-specific knowledge seeking
n. Use data to develop interoperability and interchange specification
o. Use data for personal health management [includes maintaining the personal health record]

Secondary uses are releases, disclosures, linking, sharing and analysis of patient data for purposes other than the direct care of the patient. Such purposes could be opposed by or harmful to the patient. In addition, secondary uses mean additional disclosures and transmissions. Once a patient's private data has been disclosed, it cannot be "undisclosed". The patient's data could be sent anywhere, including outside the United States—and outside the laws and courts of the United States.

Misleading Statement

While the Agency's RFI makes a claim that may or may not *technically* be true, it is none-the-less misleading. In the second paragraph, the following statement is made:

> "[T]here are no current plans to issue a related request for proposals [to establish a National Health Data Stewardship Entity]."

True or not, there certainly is a history of moving toward establishing such an entity. Our research finds that the federal government, including AHRQ, has been very involved in groups that have spent several years developing a "data stewardship model."

In 2001, the GAO published a report called "RECORD LINKAGE AND PRIVACY: Issues in Creating New Federal Research and Statistical Information." This report discusses record linkage involving person-specific data, and "strategies for enhancing 'data stewardship.'" It notes that

> [V]arious groups have taken a leadership or coordinating role in efforts to improve techniques and stewardship strategies. These include the
>
> - OMB and its Interagency Council on Statistical Policy […]
> - HHS Data Council and the HHS Office for Human Research Protections and
> - The National Research council and its Committee on National Statistics, as well as the Institute of Medicine, within the National Academy of Science (NAS), among others.

In September 2004, AQA, formerly called the Ambulatory Care Quality Alliance, was formed "to lead an effort for determining, under the most expedient timeframe, how to most effectively and efficiently improve performance measurement, data aggregation, and reporting in the ambulatory care setting." *AHRQ was a founding member.* Just two months later, at a leadership meeting of the American Academy of Family Physicians —another AQA founding member—the director of AAFP gave a presentation titled ***"Toward National Data Stewardship."*** In that presentation Dr. Kibbe statements include the following:

> We are long overdue in enacting a national strategy for data collection, aggregation, management, and reporting on quality processes and outcomes for common, expensive, chronic illnesses.

In 2005, the AQA Data Sharing and Aggregation Workgroup published a "Working Draft" paper called, "Establishment of a Public/Private Entity Currently Referred to as a 'National Health Data Stewardship Board.'" Three members of the Workgroup were from AHRQ.

In 2006, 36 people met as an Expert Panel to draft the American Medical Informatics Association proposal for building a "National Framework for the Secondary Use of Health Data." At least five of those individuals represented government, and one individual represented the National Quality Forum, where AHRQ's director is a board member.

In 2007, this past February, the white paper from that meeting was published in the Journal of the American Medical Informatics Association: "Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper." As noted above, one of the key principles is a focus on data stewardship rather than ownership.

<u>The very fact that this RFI is in the Federal Register now reveals AHRQ's goal of establishing the NHDSE sooner rather than later.</u>

Legal Standing of RFI in Question

The public needs to ask why the AHRQ published the initiative of a private entity in the Federal Register? The Federal Register is a publication of the proposed regulations and the upcoming actions of federal agencies. The AQA, on the other hand, is a private sector coalition that has its phone conferences and meetings staffed by America's Health Insurance Plans (AHIP).[2] Outside of AHRQ and the Centers for Medicare and Medicaid, the members of the Steering Group and the Supporting Organizations of AQA are all private organizations:

- AARP
- AFL-CIO
- American Academy of Family Physicians

- American Academy of Pediatrics
- American College of Physicians
- American College of Surgeons
- American Medical Association
- American Osteopathic Association
- American's Health Insurance Plans
- Association of American Medical Colleges
- Medical Group Management Association
- National Committee on Quality Assurance
- National Partnership for Women and Families
- National Quality Forum
- Pacific Business Group on Health
- The Society of Thoracic Surgeons

Congress has no authority over the AQA. The AQA is not a federal government agency, leaving the legal standing of this entire RFI process in question.

CONCLUSION

We believe the proposed National Health Data Stewardship Entity (NHDSE) would open wide the vaults of private medical data, authorizing the exposure of more than 300 million Americans to unwanted disclosures and research, potential embarrassment, fear in and outside the doctor's office, privacy violations, genetic discrimination, breaches in the confidential patient-doctor relationship, profiling and surveillance, outside controls on the practice of medicine, and health care rationing. The proposed NHDSE would:

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Thank you for this opportunity to comment. If you wish to contact me, I can be reached at #651-646-8935.

Sincerely,

Twila Brase, RN, PHN
President

[1] "Towards a National Framework for the Secondary Use of Health Data." Charles Safran, MD, MS, PowerPoint presentation to the National Committee on Vital and Health Statistics (NCVHS), November 28, 2006.
[2] Elizabeth Hoy, "Who's Who in Performance Measurement Today?" AAO-HNS Bulletin accessed online July 20, 2007.