



July 26, 2007

P. Jon White, M.D.  
Health IT Director  
Agency for Healthcare Research and Quality  
540 Gaither Road  
Rockville, MD 20850

**Re: AHRQ RFI – National Health Data Stewardship Entity**

AcademyHealth, as the nonpartisan, professional society for nearly 3,800 health services researchers, policy analysts, and practitioners, welcomes the opportunity to respond to the request for information filed June 1, 2007 in the *Federal Register* on the creation of a National Health Data Stewardship Entity (NHDSE). Given the implications of this proposed entity for our mission to support the development of research and data needed to inform health policy and practice, we are pleased to offer the following thoughts for your consideration on behalf of our members, the research community, and the public more broadly.

AcademyHealth views the development and dissemination of secondary health data as a public good. We commend the Agency for Healthcare Research and Quality (AHRQ) for seeking information on establishing a public/private NHDSE to establish uniform operating rules and standards for the disclosure, use, and sharing of those classes of public and private sector data—data that by law cannot be released for general use under the Freedom of Information Act (FOIA). In our view, virtually all secondary data, particularly data related to the performance of programs under the Department of Health and Human Services administrative authority, do not fit into any FOIA disclosure exemptions and therefore should be made rapidly available upon request. At the same time, we also believe that a government policy of affirmatively making such data available without the need for a FOIA request and in a format that lends itself to research and analysis would advance research, analysis, and the goal of information transparency. Such an affirmative step balances the goal of using data to support important public policy goals with the need to protect personal health information privacy as well as the proprietary concerns of private entities.

At the same time, we remain concerned about the overall process for securing and using health data in health services research more broadly. Researchers often face difficulties gaining access to and using programmatic data—data that are required to be reported as a program performance matter and enjoy no specific exemption under law. Other restrictions to data access appear to be the result of regulatory policies and administrative practices that impose additional and, in our view, unnecessary burdens unrelated to privacy, security, or other legitimate agency interests on data that by law are

already in the public domain because they are part of a required program reporting system.

In the interest of data transparency and the growing bi-partisan support for expanded comparative effectiveness research, **AcademyHealth recommends that as AHRQ considers the establishment of an NHDSE, it also evaluate the entity's role in ensuring that population health data, as well as data generated by federal health care programs, are made public, and that all public data sets are made readily available to researchers who enter into agreements that ensure privacy, security, and compliance with applicable human subject research requirements.**

Specifically, this new NHDSE should not only bring clarity and transparency to the existing set of rules and regulations pertaining to secondary data use, but also expand the possible field of available data by increasing clarity, and applying structure and guidelines to stewards of data currently outside the purview of the existing “rules” framework (i.e., Health Insurance Portability and Accountability Act). We believe that this would represent a critical step toward addressing the uncertainty, confusion, and misinformation that currently inhibits access to important health data.

We caution that careful consideration will be required to ensure that the new NHDSE enhances rather than unnecessarily restricts appropriate access to secondary health data. Imposing greater limitations on permissible research uses of federal data, and further restraints on the publication and disclosure of research results, would be an unacceptable outcome of this initiative.

## Context & Definitions

In the emerging age of electronic health information exchange, there is great potential for expanded information sharing and heightened learning. The volume of health information available electronically is expected to increase exponentially, as is the number and type of contributing sources. We believe that the goal, in fact, should be to foster an information sharing environment that enables multiple users to generate knowledge and make better health care and policy decisions by analyzing data from a variety of different sources. In light of this important public policy goal, AcademyHealth supports the establishment of policies, standards, and operating rules that will support meeting the country's goals for health and health care while also respecting personal health information privacy and the proprietary concerns of private entities. Therefore, we generally support the creation of an NHDSE to guide such efforts.

In thinking about an entity that would be tasked with establishing parameters with respect to (as indicated in the RFI) the collection, aggregation, analysis, and sharing of health information for secondary purposes, we think it helpful to establish some working definitions. We offer for your consideration below definitions of secondary use of health data and data stewardship proposed by the Data Stewardship Working Group of the American Medical Informatics Association.

- *Secondary Use of Health Data:* The non-direct care use of personal health information including – but not limited to – analysis, research, quality measurement, safety measurement, public health, payment, provider certification/accreditation, marketing, and other strictly commercial activities. In

other words, data used for any purpose other than the direct care of an individual patient.

- *Data Stewardship*: Data stewardship encompasses the responsibilities and accountabilities associated with managing, collecting, viewing, storing, sharing, disclosing, or otherwise making use of personal health information.

## **Guiding Principles & Policy Context**

We believe that a reasonable set of guiding principles are be essential to the success of this new data stewardship entity, and would encourage that the establishment of such principles should be the first order of business for this new entity. These principles should serve as the basis against which all possible policies, standards, and rules are evaluated, and could provide rationale and safeguards for legitimate secondary uses. In addition, they would validate the role of trusted data stewards, thereby facilitating more appropriate data exchange. Once established, we would expect these principles of data stewardship to apply to all personnel, systems, and processes engaging in the activities outlined in the proposed scope of work set forth in this RFI.

We would also counsel that the principles and policies established by the new NHDSE for secondary data use should be developed within the context of an over-arching policy framework that establishes privacy and security parameters for the Nationwide Health Information Network (NHIN). It is envisioned that the NHIN will facilitate development of interoperable networks of electronic health records, personal health records, and other types of health data aggregators. In turn, these networks will enable disclosure of significantly greater quantities of longitudinal and more complete health data, thereby increasing the likelihood that sensitive information will be shared. We believe that failure to establish appropriate policies with respect to privacy and security up front could have an unintended chilling effect on the availability of these critical data for appropriate uses.

## **Proposed Mission & Scope of Work**

While we support the establishment of this new NHDSE, we are concerned by the seemingly artificial boundaries imposed by establishing rules and standards for uses related solely to quality measurement. If such an entity is created to look at issues surrounding secondary data use, it should not be so limited in scope. Therefore, we would strongly urge that the appropriate scope of activities for a NHDSE be broader to include data on population health and on the access and cost of care, among others.

As a practical matter, it would be difficult to categorize data being singularly quality related as data used for quality purposes may also be used for other secondary purposes. From a policy perspective, to focus only on quality measurement uses of data is to ignore other important uses for secondary data. We believe it would be unwise to invest this level of resources for an activity that fails to address secondary data use more broadly. Decisions about use—be it for quality reporting, or the assessment of health system performance, or other purposes—would inform data stewards' responsibilities with respect to collection, aggregation, analysis and sharing. Failure to establish a set of policies for all secondary uses of data would, we believe undermine the public's confidence in the new NHDSE as a trusted data steward.

## Structure

If a new NHDSE is created, or if an existing entity is given a new health data stewardship role, a number of issues related to organizational structure and oversight should be considered:

- Openness and Transparency: Any national entity responsible for establishing parameters around the secondary use of health data should operate in a manner that is open and transparent to the public. This is particularly critical given that data generated by federal and state (i.e., public) health care programs will be included under the purview of this new entity.
- Accountability: We view secondary health data as a public good. We therefore believe that the NHDSE should be accountable to the public through congressional oversight, and at least partially funded through general appropriations. To assure accountability, mechanisms should be established to identify and address misuse of data or non-compliance with established rules and procedures.
- Broad Stakeholder Involvement: Given the number of and type of entities contributing data in a networked environment, and the range of end users for those data, we believe this effort should allow for stakeholder involvement. This would enhance transparency of the methods and process, promote public acceptance of operating rules and standards, and enhance support for the entity's overall mission.

The leadership of AcademyHealth stands ready to work with AHRQ to develop an NHDSE that would meet this important responsibility. Please contact Emily Rowe, our director of government relations (202.292.6743; [emily.rowe@academyhealth.org](mailto:emily.rowe@academyhealth.org)), or me with any questions you may have regarding our recommendations.

Sincerely,



W. David Helms, Ph.D.  
President & CEO