August 3, 2007

Jonathan White, MD
Health IT Director
Agency for Healthcare Research and Quality (AHRQ)
540 Gaither Rd.
Rockville, MD 20850

Dear Dr. White:

The American Health Information Management Association (AHIMA) welcomes the opportunity to respond to the request for information on a National Data Stewardship Entity (NHDSE).

AHIMA is a not-for-profit professional association representing more than 52,000 health information management (HIM) professionals who work throughout the healthcare industry. HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

AHIMA and its members participate in a variety of projects with other industry groups and Federal agencies related to the use of healthcare data for a variety of purposes, including direct care, quality, performance, and patient safety measurement and reporting; research, population health, and administration. In each of these areas, we deal with both primary and secondary data use. It is from these perspectives that we provide our response.

AHIMA thanks AHRQ for this opportunity to submit our recommendations on the issue of data stewardship for secondary data use. If AHIMA can provide any further information, or if there are any questions or concerns in regard to this response and its recommendations, feel free to call me at (312) 233-1135 (office), or at (708) 250-4374 (cell), or email me at donald.mon@ahima.org. If I am not available, please contact the individuals listed at the bottom of this letter.

Sincerely,

Donald T. Mon, PhD
Vice President, Practice Leadership

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Development of a National Health Data Stewardship Entity

Response to Request for Information

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August 3, 2007

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1.0 Executive Summary

The Agency for Healthcare Research and Quality (AHRQ) is seeking information on a National Health Data Stewardship Entity (NHDSE). The American Health Information Management Association (AHIMA) appreciates the opportunity to respond to this RFI.

There is a definite need for a NHDSE. Data stewardship operating rules and requirements for ensuing standards will help reduce cost, increase operational efficiency in the secondary data use life cycle, and improve the accuracy of measures and reports based on secondary data, which in turn, will help key stakeholders make better policy, management, and treatment decisions.

Role of a NHDSE

There are four major areas of secondary data use: (1) Quality, performance, and patient safety, (2) Research, (3) Population Health, and (4) Administration. A NHDSE must support all areas of secondary data use, not just quality and performance measurement. A NHDSE should set uniform rules and the *requirements* for ensuing standards for data stewardship, rather than perform the actual data stewardship activities (i.e., aggregation), or develop technical and other standards (e.g., HL7 documents and messages) itself. It should not: (1) Endorse quality measures as done by NQF, (2) develop quality measures for accreditation or certification purposes, as is now done by the Joint Commission, NCQA, and the various medical societies, (3) develop the actual standards, which should be done through standards development organizations (SDOs), (4) harmonize technical standards developed by SDOs, which should remain the purview of the Health Information Technology Standards Panel (HITSP), and (5) certify data stewardship requirements for EHR systems, which should remain the purview of CCHIT.

The NHDSE must work with other central authorities. The central authority at the highest level should be AHIC, and in the future, its successor. Having all the central authorities receive direction from AHIC will ensure coordination and priority of activities across the various domains. A NHDSE should also work with central authorities that are on its level, some of which are not currently in existence. For example, a central authority for the vocabulary, terminology, and classification domain does not exist, but its need has been raised. The NHDSE will benefit by the central authorities' resolution of the issues within their domains. For example, as a central authority for vocabulary, terminology, and classification resolves some of the issues surrounding the appropriate terms or codes to be used in the EHR, the NHDSE could refer to that resolution in its operating rules or requirements for standards.

Given that there are a number of structures that are not in place for secondary data use, much less data stewardship, the NHDSE must assume certain advocacy roles, including the following: (1) Call for the establishment of a counterpart central authority, if it will help both that domain and data stewardship succeed, (2) identify the need and requirements for pertinent laws and regulations, and (3) identify the data stewardship requirements for health information exchange.

A NHDSE must have a sense of urgency so that it can respond "at the speed of business" to pressing secondary data use issues today. However, given its relationships with other secondary data use and standards setting organizations, it does not have full control over the timelines or the process in which standards can be delivered. Thus, the challenge for the NHDSE will be to develop a road map that anticipates the timely delivery of standards, and to collaborate with its partners effectively to meet those deadlines.

Government funding is the most effective way to launch a NHDSE. However, a NHDSE must complete the development of, and implement, its sustainability model after Year 1 to reduce or eliminate its reliance on government funding. User fees and sales of educational services could be revenue streams that sustain a NHDSE.

Operational Goals

Operationally, a NHDSE should target the following short, medium, and long term goals:

- Short-term (1 year)
  - Establish the NHDSE organizational structure.
  - Seek support and input from key private and public stakeholders in each of the four categories of secondary data use to establish national coordination in a transparent process with other public-private entities to set uniform rules and the requirements for standards for data stewardship.
  - Establish principles that address each area of data stewardship (i.e., confidentiality, privacy, and security; data quality; data collection and aggregation; etc.)
  - Establish a process for receiving requests, inquiries and complaints.
  - Establish a process for existing data sets to conform with NHDSE operating rules and policies
  - Charge the NHDSE to develop a detailed matrix to achieve mid- and long-term goals.
  - Initiate an industry-wide education campaign that communicates accountability for collecting and delivering high-quality data for secondary use.
  - Identify the need for counterpart central authorities (e.g., one in the vocabulary, terminology, and classification domain) that will increase the success for the industry to comply with data stewardship operating rules and standards

- Mid-term (2-3 years):
  - Develop a sustainable business model to support the goals and desired outcomes of the NHDSE.
  - Seek and gain industry agreement on data collection and use data across all categories of secondary data.
  - Establish a mechanism to allow for data set modifications and enhancements.
  - Engage standards development organizations to incorporate data stewardship requirements into existing standards.

- Long-term (5 years):
  - Continually assess the use and support of data stewardship rules and standards.

Guiding Principles

A NHDSE should consider adopting the following principles as it performs its scope of work:

- Practical solutions are needed for collecting and aggregating health information from the largely paper based world that still exists today. At the same time, a vision and an implementation plan (road map) for data stewardship needs to be developed as adoption of electronic health record systems (EHR-S) increases.

- The same data, operating rules, and standards for one area may benefit the other areas as well. A NHDSE should help the industry capitalize on this leverage.
- Privacy and confidentiality should be used as design principles that guide the development of data stewardship policies, operating rules, standards, and practices.
- Data quality must be the target, not data validation. Promoting data quality on the front end will benefit data quality and data aggregation processes on the back end.
- Data content standards and standard data definitions reduce cost and increase efficiency.
- EHR systems and architectures should be designed to collect data once and repurpose many times, including secondary data use.
- Best practices for collecting and maintaining health information on the front end will greatly aid data stewardship throughout its lifecycle.
- "Who owns the data?" should not be the key question on everyone's mind. In the electronic environment, the more pertinent question is, "What are the rights of the various stakeholders to access, use, and control health information for a given circumstance?"

Data Stewardship Issues and Concerns That Must Be Addressed

There are many practical data stewardship issues and concerns that must be addressed. These include:

- Compliance is a major issue because no matter how excellent operating rules and standards may be the industry will derive few benefits from them if there is little or no compliance. Currently, there is no incentive or a means to enforce compliance with data stewardship operating rules and standards stemming from the NHDSE.
- There is an increasing use of secondary data for commercial purposes. The primary question related to the use of secondary data for commercial purposes is whether there is an effective means for vendors to comply with the data stewardship operating rules and standards set forth by the NHDSE.
- There is little requirement to aggregate data in a central repository—whether at the national or regional level—that multiple stakeholders can use for their specific secondary data purposes. A NHDSE must work with health information exchange entities to support the collection of aggregate data over a network of networks without using a central repository.
- Privacy is a major issue for secondary data. For example, there is a difference between patient-identified and patient-identifiable data. Data is patient-identified if the individual is disclosed by the data. Data is patient-identifiable if the identity of the patient can be derived or inferred from the data, with or without the assistance of computers and artificial intelligence. This distinction is important because it raises the question as to whether or not secondary data has been sufficiently anonymized without risk of breaching a person's right to privacy. These principles should be verified through legal review and should be incorporated into data stewardship operating rules and standards.
- Standardized content of clinical documents and standard definitions of data will greatly facilitate downstream data collection and data aggregation, increase data quality, and give tremendous guidance to CDOs, entities that build products based on secondary data needs, and EHR system vendors. Moreover, collecting data in the EHR as discrete, structured, and computable data, relying on the use of codes to the greatest extent possible will increase the

timeliness of analyses and provide better opportunities to enhance quality at the point of care, as well provide benefits for secondary data use. Given that secondary data will benefit from standard data content and data definitions on the front end, it is important that the NHDSE be engaged in their development.

- The conversation must change from ownership of the data to rights to access, use, and control secondary data. Providers legitimately use health information for reimbursement, credentialing, legal defense, and quality management. Thus, patients must understand that they have never had *exclusive* ownership of their health information, where ownership is defined as "the ability to exercise complete sovereignty over information—to disclose, sell, destroy, alter, or determine who shall have access to it at will." This fact must be incorporated into data stewardship operating rules and requirements for standards and included as part of the NHDSE's public awareness campaign. Providers, on the other hand, must understand that the patient has rights regarding medical information, which generally fall into the following categories: the right to access or obtain copies of the information, the right to request amendments or corrections (but not the right to alter or delete information that is part of a legal record), and the right to control disclosures and restrict access by third parties (but not when required by law such as for public health reasons or population health studies). Again, this fact must be incorporated into data stewardship operating rules and standards and included as part of the NHDSE's clinician education and public awareness programs.

2.0 Introduction

The Agency for Healthcare Research and Quality (AHRQ) is seeking information on a National Health Data Stewardship Entity (NHDSE). The American Health Information Management Association (AHIMA) appreciates the opportunity to respond to this request for information (RFI). Founded in 1928 to improve the quality of medical records, AHIMA is the premier association of health information management (HIM) professionals. AHIMA's 52,000 members are dedicated to the effective management of personal health information needed to deliver quality health care to the public.

2.1 Reaction to the *Proposed Mission*

As stated in the RFI, the *Proposed Mission* of this public/private entity is to:

> "...set uniform operating rules and standards for sharing and aggregating public and private sector data on quality and efficiency; offer guidance on implementation of such national operating rules and standards; and provide a framework for collecting, aggregating and analyzing data, to afford means of more effective oversight of health care data analyses and reporting in the United States."

AHIMA recommends two revisions to the *Proposed Mission*.

2.1.1 NHDSE Should Set Uniform Rules and *Requirements* for Standards

AHIMA agrees that the NHDSE should set uniform operating rules, rather than perform the actual data stewardship activities (i.e., aggregate the data). The current wording of the *Proposed Mission* conveys that distinction well.

However, as currently worded, it sounds as though the NHDSE "sets standards," which could be construed as technical standards, such as HL7 messages. In keeping with our understanding of the spirit of the *Proposed Mission*, the NHDSE should set *requirements* for standards, rather than develop technical standards itself.

In addition, while the NHDSE should set the rules for aggregation, it can not and should not police the actual aggregation of data. There are many organizations that collect and aggregate data on a local, state, or national basis, private and public. HIPAA and state privacy rules, as well as extensions of these rules currently under discussion by the American Health Information Community (AHIC), should provide input into the standards and guideline developed by the NHDSE. Likewise, laws and rules establishing or covering data aggregators should address their stewardship of the data entrusted to their care. But, oversight of an aggregator's compliance with confidentiality and security of data should remain the responsibility of those entities delegated that authority under the law or regulation that empowered them to collect data in the first place. The principles developed by the NHDSE regarding the actual aggregation of data should provide guidance to those federal and state agencies whose role it is to oversee compliance with confidentially requirements.

2.1.2 Proposed Mission Should Extend Beyond Quality and Performance

The current wording of the Proposed Mission states that the NHDSE should "...set uniform operating rules and standards for sharing and aggregating public and private sector data on quality and efficiency…" Stated that way, it sounds as though the NHDSE's purview is solely quality and efficiency. AHIMA asserts that the NHDSE could provide multiple benefits to all areas of secondary data use, not just quality and efficiency. The tone of our response is based on this premise. In the sections below, we will further expand on this assertion and provide recommendations.

2.2 Major Themes in This Response

Our response contains the following major themes:

- The NHDSE should set uniform rules and the *requirements for* standards for data stewardship, rather than perform the actual data stewardship activities (i.e., aggregation), or develop technical and other standards (e.g., HL7 documents and messages) itself. With regard to the actual oversight of a data aggregator's compliance (see 2.1.1 above) the NHDSE could coordinate or facilitate responses to concerns or complaints that an entity did not follow the rules, principles, or standards developed by the NHDSE, but an NHDSE would not have policing powers to control compliance without a designation by law.
- Practical solutions are needed for collecting and aggregating health information from the largely paper based world that still exists today. At the same time, a vision and an implementation plan for data stewardship needs to be developed as adoption of electronic health record systems (EHR-S) increases.
- There is significant overlap in the data across the various areas of secondary data use. The same data, operating rules, and standards for quality, performance, and patient safety measurement and reporting may benefit the other areas as well. The industry must capitalize on this leverage.
- Privacy and confidentiality should be used as design principles that guide the development of data stewardship policies, operating rules, standards, and practices.
- Data quality must be the target, not data validation. Promoting data quality on the front end will benefit data quality and data aggregation processes on the back end.
- Data content standards and standard data definitions reduce cost and increase efficiency across the entire work flow described in the *Proposed Scope of Work*. Uniformity of these data content standards and the process of aggregating data provide sending and receiving organizations a better chance for achieving administrative simplification.
- EHR systems and architectures should be designed to collect data once and repurpose many times, including secondary data use.
- Best practices for collecting and maintaining health information on the front end will greatly aid data stewardship throughout its lifecycle.
- "Who owns the data?" should not be the key question on everyone's mind. In the electronic environment, the more pertinent question is, "What are the rights of the various stakeholders to access, use, and control health information for a given circumstance?"

2.3 Focus and Organization of This Response

We chose to focus this response on the application of HIM principles, guidelines, and practices to data stewardship. AHIMA can provide additional information, including aspects of data stewardship outside of the application HIM, upon request.

This response is comprised of three major sections. In Sections 3.0 and 4.0, we have suggested some revisions to the *Proposed Scope of Work* and *Proposed Characteristics* respectively. In Section 5.0, we have tied the general issues raised in Section 3.0 Scope of Work and Section 4.0 Characteristics to the specific issues related to the 25 questions in the *Information Requested* section of the RFI.

3.0 Scope of Work

RFI *Proposed Scope of Work*: A wide range of activities need to be undertaken to advance health data exchange and use, including the development of measures and setting data transmission/IT technical standards. While all of these activities are important, the entity's responsibilities would primarily focus on specific issues relating to data collection, aggregation, analysis, and sharing.

AHIMA agrees with the *Proposed Scope of Work* outlined in the RFI. However, we recommend adding the following two attributes to the initial set of nine in the scope of work: (1) Confidentiality, Privacy and Security, and (2) Data Content and Data Standards.

In the subsections below, we will comment on each of the eleven attributes that comprise the *Proposed Scope of Work*. These eleven attributes should be part of a framework to assess the suitability of existing organizations that might fulfill the role of the NHDSE (see Section 5.25 of this response).

As previously mentioned AHIMA asserts that the NHDSE should set uniform rules, and guidelines, and the requirements for standards for data stewardship, rather than perform the actual data stewardship activities or develop the actual data standard(s). To that end, while our comments below may at times appear to delve into data stewardship activities, they are discussed simply to identify the issues behind the policies, operating rules, standards, and practices which the NHDSE must address.

3.1 Uses of Data

For the purposes of this response, we have organized the uses of secondary data into four major areas: (1) quality, performance, and patient safety measurement and reporting, (2) research, (3) population health reporting, and (4) administration. The various purposes within each of these major areas are reflected in Table 1. This table helps us establish the distinctions between each of these areas and how they may impact NHDSE operations, as well as the development of data stewardship operating rules and requirements for standards.

Table 1
Examples of Secondary Data Use by Area and Purpose

Area	Purpose	Examples
Quality, Performance, & Patient Safety Measurement and Reporting	• Quality improvement • Public reporting of quality data • Accreditation and certification • Patient safety • Consumer satisfaction	• JCAHO: ORYX® • NCQA: HEDIS • CMS – Hospital Quality Alliance (HQA) – CAHPS Hospital Survey (HCAHPS) – Hospital Mortality Measures – Physician Quality Reporting Initiative (PQRI) – Doctors Office Quality Information Technology (DOQ-IT) – Nursing Home Minimum Data Set (MDS) – Home Health Outcome and Assessment Information Set (OASIS) – Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) – Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) • Payers & Employers: Pay-for-Performance – CMS, Insurers – Bridges to Excellence – Leapfrog • Patient safety organizations • Institute for Healthcare Improvement (IHI) 5 Million Lives Campaign • Medical specialty quality measurement programs • State/local quality measurement programs
Research	• Clinical research • Clinical trials research • Health services research • Evidenced-based medicine	• Structure, process, and outcomes research • Investigational research/trials (e.g., drugs, devices, technology, procedures) • Utilization of health services
Population Health Reporting	• Population health status • Public health reporting • Biosurveillance	• Registries (e.g., cancer, diabetes) • Report cards • Vital statistics (e.g., STDs, birth and death rates) • FDA: Adverse drug events
Administration	• Reimbursement Review and Management (not the actual process of reimbursement) – Fraud management – Reimbursement policy – Coverage decisions • Other Policy • Accreditation • Credentialing	• MEDPAR • Uniform Hospital Discharge Data Set (UHDDS) • Uniform Ambulatory Care Data Set (UACDS) • Claims Reporting (NUBC/NUCC) • Payment Error Rate Measurement (PERM) Program • Hospital Payment Monitoring Program (HPMP)

In addition to the federal government and other major programs (e.g., JCAHO ORYX®, NCQA HEDIS) reflected above, the NHDSE must recognize the increasing use of secondary data for **commercial purposes**. In some respects, such commercial uses can be considered an *application* of secondary data, and would be similar to an application produced by a not-for

profit entity. For example, a government agency can generate a basic report on the utilization of health services, while a commercial enterprise can produce a value added report.

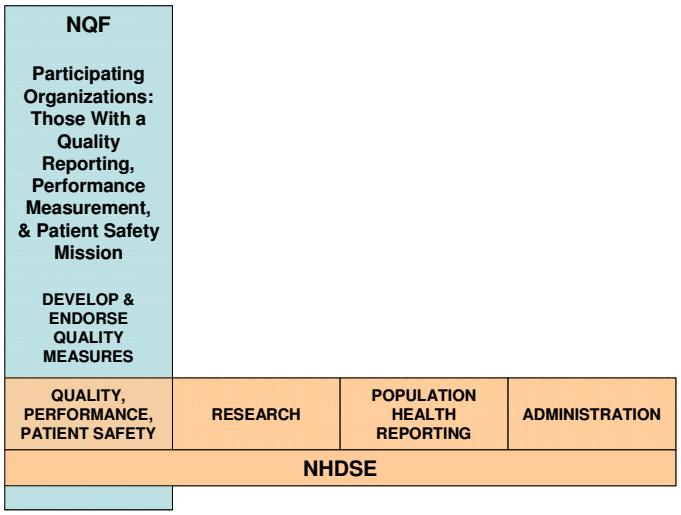
Commercial enterprises—such as consulting firms, group purchase organizations, and software vendors—are marketing a variety of products based on secondary data, ranging from local or cohort specific benchmarking to assistance in determining certificate of need. The use of secondary data for commercial purposes raises the following concerns:

- These commercial enterprises may not be covered entities, and thus are not required to follow HIPAA privacy and security rules, or other laws and regulations protecting the confidentiality of health information
- Currently, there is no incentive for commercial enterprises to comply, nor a means to enforce compliance, with data stewardship operating rules and standards stemming from the NHDSE.

Identifying the scope of secondary data use is one of the first major decisions the NHDSE must make because it drives many key decisions regarding roles and responsibilities; relationships with other entities; organizational priorities, infrastructure, and skill set; governance; and sustainability.

There are ramifications for the NHDSE if, as the *Proposed Mission* implies, its scope of data use is solely quality and efficiency measurement and reporting rather than the entire spectrum of secondary data use (see Figure 1). Constraining the scope of data use also limits the NHDSE's scope of work, which, at first blush, provides some benefits for NHDSE.

Figure 1
Scope of Secondary Data Use Drives Key Decisions

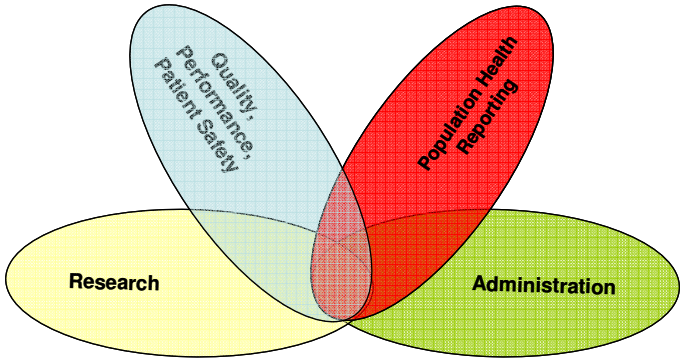


Such a decision would result in fewer entities for which the NHDSE would have to collaborate (i.e., only those engaged in quality, performance, and patient safety) and what they would do together. For example, many organizations such as NQF, AQA, HQA, the Joint Commission, NCQA, QIOs, AMA, medical societies, and so on, are working to: (1) establish a starter set of quality measures, (2) identify and prioritize the data elements in the EHR that support quality and performance measurement, and (3) identify the gaps in data elements. The NHDSE could contribute to these efforts by developing the respective data stewardship operating rules and requirements for standards and not be compelled to focus on the other areas of secondary data use.

Limiting scope of work is usually an excellent management technique to ensure success of an organization or project. However, we recommend broadening the scope to the entire spectrum of secondary data use (the horizontal row in Figure 1) rather than limiting it to quality, performance, and patient safety (the vertical column in Figure 1) for the following reasons.

- Many organizations that request or supply secondary data do not necessarily confine themselves to quality, performance, and patient safety. They may also engage in research, population health reporting, or administration.
- There is significant overlap in the data used, as well as in the operating rules and standards, across all four areas of secondary data use (see Figure 2). An enormous amount of leverage can be achieved if the scope is focused across the entire spectrum of secondary data use because data stewardship solutions for one area will likely benefit the other areas as well.
- Confining the work of the NHDSE and corresponding entities engaged in quality, performance, and patient safety may invite scope creep because these entities will naturally want to capitalize on such leverage so that they can address their other areas of secondary data use more efficiently and achieve a greater return on investment. It should also be noted that while the introduction, implementation, and use of EHRs will significantly increase the body of knowledge in healthcare, providers—those who hold the EHR and are expected to supply the secondary data—will not willingly cooperate if the requestors of secondary data do not develop consistent and relatively painless ways for them to supply the data in both the paper and the electronic environment.
- Broadening the scope of data uses will help to ensure that all four areas are working in concert with each other. Without this coordination, we run the risk that the four moving parts will not work in synchrony and the health care industry will still have to address disparate data collection, aggregation, data sharing, and reporting issues (e.g., inefficient data collection and aggregation, increased cost of reporting secondary data, increased potential for inaccurate reporting due to competing rules and requirements, and so on).

Figure 2
Secondary Data Uses Have Significant Overlap



Broadening the scope of data uses does not preclude the NHDSE from focusing on quality, performance, and patient safety. Wider scope simply implies that quality, performance, and patient safety is but one of four focus areas. In the comprehensive view that Figure 2 depicts, quality, performance, and patient safety could be the top priority across all four areas of secondary data use, and still drive value in the other areas.

The work at the Veterans Health Administration (VHA) demonstrates this point. In advancing evidenced-based care for diabetes, the VHA was able to focus on process and outcome measures (quality), yet use repurposed EHR data as well as claims and other secondary data to support multi-site clinical trials and observational studies (research), and gain insights into their diabetes patients (population health) through their diabetes registry (Kupersmith, et al, 2007).

Another key benefit of a wider scope is the ability to study quality of care from a longitudinal perspective. Among other things, longitudinal data can help distinguish new complications from pre-existing conditions, and evaluate the safety and effectiveness of treatments (Kupersmith, et al, 2007). As discussed during the July 18, 2007 AHIC Quality Work Group meeting, to obtain a

true longitudinal perspective data needs to be collected from multiple data sources across multiple care settings over time. Again, the VHA demonstrated that this is achievable. A key point from this study is that longitudinality was accomplished by culling data from more than one area of secondary data use, not just quality, performance, and patient safety.

Administration (see Table 1) is a major area of secondary data use. One subset of administration is fraud management. In a project funded by the Office of the National Coordinator (ONC), an expert panel developed requirements for the EHR that could help detect and prevent fraud (RTI International, 2007). Prospective and retrospective analyses of EHR and claims data in secondary databases were among their recommendations. Many of the requirements for fraud management are similar to those for quality improvement, representing another point of leverage across the areas of secondary data use. With an estimated $51 to $170 billion lost to fraud annually, recovering those funds represents a significant value to the health care industry. Some of the dollars recovered from this effort could be used to partially sustain the NHDSE.

In addition to the above, there are other issues that must be addressed. Some of those issues are addressed in the recommendations for secondary data use put forth by the American Medical Informatics Association (AMIA, 2007). AHIMA agrees with those recommendations, which are as follows:

- There must be increased transparency of data use. Secondary use of health data must be conducted and managed solely through open and transparent processes.
- Discussions should focus on data access, use, and control, rather than ownership. (See AHIMA's perspectives in Section 3.2 Confidentiality, Privacy, and Security, and Section 3.10 Data Access.)
- There must be continuing discussions on privacy policy and security regarding secondary data use. Consumer awareness efforts on confidentiality, privacy, security, as well as the benefits and challenges associated with secondary data use must be increased in order to obtain public trust.
- A taxonomy of secondary data use must be created. (Table 1 in this response is a primitive example.) The increasingly difficult current and evolving questions related to secondary data use must be addressed in a comprehensive manner. (The discussion surrounding Figure 2 supports this recommendation.)
- Secondary data use must be addressed at both the national and state levels. Lack of coordination between state and national objectives for secondary data use will perpetuate current inefficient processes and high cost.

3.2 Confidentiality, Privacy and Security (Recommended by AHIMA)

Most of the attention on confidentiality, privacy, and security rules, laws, or regulations has been focused on primary data use, with HIPAA addressing how covered entities must handle health information for treatment, payment, and operations. However, many developers and consumers of secondary data are not covered entities, and therefore, fall outside of HIPAA. There has been some discussion at various forums about extending HIPAA rules to secondary data use. We encourage an analysis of how HIPAA may apply to secondary data with a word of caution. There is some misunderstanding today about how HIPAA is applied uniformly across

the states for treatment, payment, and operations (Dimitropolous, 2007). That suboptimal situation could easily be replicated in the use of secondary data.

However, since "there is no universal authoritative source, law, or regulation that addresses and defines stakeholder rights and responsibilities" for secondary data use (Burrington-Brown, et al, 2007), the analysis of extending HIPAA rules is a reasonable place to start. During these deliberations, the linkage between primary to secondary data use should also be considered. For example, public health's requirement to de-identify persons for aggregate data analysis, yet be able to re-identify an individual has data stewardship implications for the collection and aggregation of data at the care setting level.

In addition to the lack of an authoritative source or law, there is much misunderstanding surrounding the issue of "who owns the data." The confusion lies in the distinction between the responsibilities of providers to maintain a health record for legal and business purposes, and the consumers' rights to state who can access, use, and control health information contained in the record (paper or electronic) for treatment, payment, operations, and now, for secondary data use. The situation is exacerbated even further because consumers vary in their perspectives about access, use, and control issues. (Access, use, and control issues are discussed more extensively in Section 3.10.)

To the extent that there is no authoritative source, law, or regulation, and the access, use, and control issues remain unclear to the various stakeholders of secondary data, attention will be diverted from developing data stewardship operating rules and standards. Protecting the privacy and confidentiality of health information must be used as a design principle not only in architecting laws and regulation for secondary data use, but their data stewardship policies, operating rules, standards, and practices as well. Guidelines for balancing the responsibilities of maintaining a legal health record while preserving consumer rights for secondary data use have been explained by Waller and Alcantara (1998) and Burrington-Brown, et al (2007). We strongly urge the incorporation of these guidelines into data stewardship operating rules and standards as they are developed.

3.3 Data Collection

Only 14 to 24 percent of physician offices in the U.S. have implemented EHR systems, with the highest prevalence in large physician practices, and slower adoption rates in smaller physician offices (Gans, et al, 2005; Ashish, et al, 2006). The difficulties in measuring EHR system adoption notwithstanding, only 11 to 17 percent of inpatient acute hospitals have fully implemented, while 50 to 57 percent have partially implemented, an EHR system (Ashish, et al, 2006, AHA, 2007).

The low percentage of EHR adoption means that health information is still largely paper-based today. Regarding secondary data use, the following data collection issues abound in the paper world (AHRQ, 2006).

- Manual data abstraction is a time-consuming effort requiring extensive staffing resources. Employees conducting manual data abstraction must possess a certain level of knowledge and expertise to ensure information is collected and managed properly. Yet the nation has a shortage of trained professionals able to perform this work.
- Concurrent manual data collection and monitoring provides the opportunity to improve quality at the point of care, but generates other challenges. For example, abstractors often

have difficulty locating and obtaining the required medical record data due to restrictions imposed by single-access paper medical records.

- Retrospective data collection contributes to the lack of organizational improvements in patient care at both the individual case and overall population levels. Issues include variances in data definition and capture and the use of real-time measurement for clinical process redesign.
- Retrospective data collection produces outdated analyses, with little or no ability to effectively enhance quality at the point of care.
- Poor legibility or incomplete documentation in paper medical records also affects the ability to obtain accurate, reliable performance measurement data. Illegible documentation impedes an abstractor's ability to understand and interpret the information.

The above issues reflect a work force burden. But there is a financial impact as well. Recent testimony at the June 19, 2007 NCVHS Work Group on Quality (Kallem, et al, 2007) revealed that, for one university medical center, costs increased 72 percent over a 3 year period to $1 million with a corresponding match in human capital, to accommodate the continued increases in secondary data collection work load.

The above issues must be addressed immediately to reduce the cost and improve the efficiency of the majority of organizations that are still collecting data from paper records. The current prevalence of paper and electronic records in the industry provides opportunities to develop practical data stewardship solutions today while setting a vision and an implementation plan as the adoption of EHR systems increases.

One major opportunity would be to capitalize on an EHR system's ability to collect data once at the point of care, and repurpose it for the various secondary data uses identified in Table 1. Currently, it is not known exactly what data in any given EHR system in the market can be repurposed for secondary data use, how much of the data can be used in its native form or needs to be transformed, and how it needs to be transformed, for secondary data use. High priority should be given then to research that conducts the following analysis:

- Data that is currently captured in an EHR system
  - And can be used in its native form to support secondary data use
  - But must be transformed to support secondary data use
- Data that is not currently captured in an EHR system but can be built in over time
  - And can be used in its native form to support secondary data use
  - But must be transformed to support secondary data use
- Data that is not currently captured in an EHR system and is not necessary to include it in the future (i.e., there is no value of the data in the direct care of the patient, or the data must truly be collected outside of direct care)

This type of analysis will be useful in developing a road map for more efficient and cost effective data collection and aggregation.

3.4 Data Validation

Current data validation processes for secondary data use are very labor intensive. For example, The Centers for Medicare and Medicaid Services (CMS) requires hospitals to submit

five randomly selected medical records for abstraction validation each quarter. To validate data abstraction accuracy and monitor compliance with record sampling procedures, CMS's Central Data Abstraction Centers (CDACs) re-abstract the results and compare them to the hospitals' to determine if the data was abstracted correctly. Considerable effort is spent copying medical records for validation, interpreting validation results, appealing validation results, and so on. Such effort becomes a greater concern with organizations trying to collect data for multiple performance measurement systems with different data collection, submission and validation requirements.

There are at least two ways to address the situation. Standardizing the measures will greatly help reduce overall effort. But according to our recommendations, that should remain the work of the NQF and participating organizations in the quality area, and is outside the scope of the NHDSE. Uniform operating rules and requirements for data validation standards, along with standardization and harmonization of the data elements are within the scope of the NHDSE. Working in tandem with standardized measures, operating rules, standards, and harmonization of data elements will greatly reduce such labor intensive efforts.

Though there will be benefits from data validation rules and standards as described above, AHIMA asserts that the appropriate scope of work attribute should be Data Quality, not Data Validation. Data quality subsumes data validation, integrity, accuracy, and completeness, and encompasses both the system functions and the business processes required to achieve it at high level. High data quality must be the target. Otherwise, the products stemming from secondary data uses may be fraught with error and rendered less meaningful.

Operating rules and requirements for standards must address the data quality issues found in the health record (paper or electronic). Promoting data quality in the record (the front end) will benefit data quality and data aggregation processes (the back end) for secondary data use.

EHR systems in general can increase data quality by:

- Capturing discrete, structured, computable data (as opposed to free text), much of which can be accomplished through the use of common medical vocabularies, coding and classification systems
- Adhering to best practices for records management (e.g., providing system functionality to amend health information, rather than overwriting it; and providing audit controls to see how and when pertinent data was changed)

Promoting data quality on the front end will benefit data quality and data aggregation processes on the back end and, therefore, should be a basic tenet advocated by the NHDSE. Requirements of EHR systems to improve data quality should also be developed by the NHDSE. Moreover, the above examples of data quality bring to light a general principle that the NHDSE should be encouraged to follow time and again: Work flow processes to support secondary data use should not be viewed in isolation. Rather, as long as secondary data use derives benefits from activities that are within the scope of work (e.g., increasing data quality), those benefits ought to be pushed up the work flow chain as far as possible so that others can benefit, too.

3.5 Attribution

Many quality improvement systems measure physician performance. Consequently, it is important to attribute a patient, procedure, visit or encounter correctly to the physician.

Currently, there is a lack of consensus in the industry on the methodology to attribute the patient, procedure, visit or encounter to the physician, and which unit of measure (such as the individual physician, the practice, the hospital) should be used (Pacific Business Group on Health, 2005). These issues will become increasingly important as payment and public reporting of physician practice quality becomes more prevalent.

Solving these issues is the purview of the domain experts (the physicians and organizations engaged in quality, performance, and patient safety measurement and reporting). In fact, a road map to develop these solutions has already been proposed (Pacific Business Group on Health, 2005). The NHDSE should work collaboratively with these entities to develop the respective data stewardship operating rules and requirements for standards.

One fundamental outcome of those efforts should be a data stewardship operating rule or standard recommending that accurate attribution to the physician (or whatever unit of measure is appropriate) should be documented in the EHR. Such attribution can be done through the reasonable and appropriate use of authentication and audit controls in the EHR system.

As with data quality, authentication and audit controls provide an excellent example of how a data stewardship operating rule or standard benefits both direct care (primary data use) and downstream secondary data use. Authentication and audit controls have long been accepted as critical components in protecting the privacy and confidentiality of health information. They were also identified as useful requirements for fraud management, and now, as the above example conveys, it is useful for performance measurement as well. This example underscores the multiple benefits that accrue from excellent documentation in the health record on the front end and we recommend that the NHDSE incorporate this into its requirements for standards.

3.6 Data Content and Standards (Recommended by AHIMA)

The lack of standard data content (the components that comprise a clinical document such as a history and physical) and data element definitions remain as two of the most vexing issues in the collection of secondary data. Without standard data content, some data elements necessary for secondary data use may not be collected because they were not contained in the clinical documentation.

Without standard data definitions, data may not be collected with sufficient granularity or with similarity in definitions, resulting in incomplete or erroneous data for the secondary data set. A simple example illustrates this point. In the Uniform Hospital Discharge Data Set (UHDDS) data element 03, Sex, has allowable values of male, female, and no value. In the Medicare Quality Monitoring System (MQMS), this same data element has allowable values of M = male, F = female, and U = unknown (Giannangelo, 2007).

Transforming male to ‘M’ and female to ‘F’ to submit data to both systems is trivial. But it requires effort nonetheless. However, “no value” in UHDDS does not have the same meaning as “unknown” in MQMS, which opens up two potential sources of error. The first is the inadvertent submission of the wrong value (“unknown” was submitted as “no value” to UHDDS or “no value” was submitted as “unknown” to MQMS). Second, there is no way to reconcile the difference if the primary data source did not collect “unknown” and the value for MQMS is submitted as missing. [Note: This is admittedly a simplistic example. In reality, most Care Delivery Organizations (CDOs) do collect “unknown” and can report it. We have simply used this example as a way to illustrate the potential for error in reporting.]

Standardized content of clinical documents and standard definitions of data will greatly facilitate downstream data collection and data aggregation, increase data quality, and give

tremendous guidance to CDOs, entities that build products based on secondary data needs, and EHR system vendors. Given that secondary data will benefit from standard data content and data definitions on the front end, it is important that the NHDSE be engaged in their development. Data stewardship contributions to the effort must include recommendations for:

- The increased use of standard designated vocabularies, terminologies, coding, and classification systems
- The increased use of discrete, structured, and computable data for data that is not coded
- Standard data content of clinical documents
- Standard definitions for data elements required for secondary use

3.7 Data Aggregation

Our points regarding data aggregation surround two separate and distinct issues.

3.7.1 Authorization, Authentication and Audit Controls Must Be Applied to Data Aggregation

There are different methods to aggregate data, including client aggregation, a central aggregation service and an aggregation proxy. For all of these methods, proper authorization, authentication, and audit procedures must be established to ensure that: (1) the individuals accessing the records have been properly approved for the desired access and have properly identified themselves when accessing the data, and (2) there are required audits to track who accessed the data and what actions were done to the data.

3.7.2 No Central Repository of Aggregate Data

Using confidentiality, privacy, and security as a design principle, we strongly recommend that there be no central repository of aggregate data —whether at the national or regional level— that multiple stakeholders can use for their specific secondary data purposes. Once data has been aggregated by the CDO, it is entirely feasible for the CDO to submit it to the entity requiring it, and for that entity (e.g., the Centers for Disease Control and Prevention) to have a repository or registry. This instance is valid because the entity has both an authorized purpose for the data (e.g., disease surveillance) and requirements to protect the privacy and confidentiality of the data (through authorization, authentication, audit controls), and can better control authorized access to the data.

Though similar authorization, authentication, audit, and access controls can be applied to multi-use central repositories, and other technical solutions can be deployed (e.g., data vaults instead of a repository), to protect the confidentiality and privacy of health information, there is still greater potential for security violations or inadvertent mistakes in this approach that result in unintended disclosure or access. In addition, the public's perception may not be as favorable towards a central repository as it would towards a distributed approach.

Secondary data can also be submitted over the nation-wide health information network (NHIN). Therefore, the "no central repository" approach has implications for the NHIN. We strongly recommend that data stewardship operating rules and standards thus adhere to the thin network approach offered by Connecting for Health (2006).

3.8 Methodologies

Two minor comments regarding methodologies:

- Methodological rules and standards for aggregating data, including risk adjustment, measure weights and sample size, are challenging tasks, but appropriate for the NHDSE to address. Data stewardship operating rules and standards must be strict in prohibiting the re-identification of an individual due to low sample size in analytical reporting, while making it permissible for specific public health reasons (e.g., finding a disease carrier) when such purposes are authorized.
- New analyses will continue to be generated from the users of, and the developers of products based on, secondary data. The NHDSE must understand the data requirements for these analyses as they are being planned, so that it can likewise plan for their data collection in the EHR now as well as in the future, and determine whether the data are available and in the correct format to support the analyses.

3.9 Data Analysis

Setting data analysis rules and standards, including those relating to trending, benchmarking, distribution, outlier analysis, correlation analysis, and stratified analysis, are appropriate areas for the NHDSE to address. Caution must be exercised in outlier analyses, so that the privacy of individual outliers is protected (if the outlier analysis is at the person level).

The above analytical techniques will be greatly facilitated by the use of standard data sets that are derived from paper and electronic health records. Data stewardship operating rules and standards should specify the requirements for capturing computable data (coded data or discrete data for data that is not coded) in the paper and electronic records on the front end so that the generation of these standard data sets is both more efficient and sufficient to support the required analyses.

3.10 Data Access

Data access is simply one aspect of confidentiality, privacy, and security. We discussed confidentiality, privacy, and security more broadly in Section 3.2. In this section we focus more narrowly on data access.

There has been much debate in the industry regarding access to health data. Much of this debate revolves around the question, "Who owns the data?" Though it may seem far afield, the question is actually very relevant because there is a belief among some stakeholders that the person owning the data can determine things about the data, including who can access it and what can be done to it when accessed. Data ownership is an extremely complex issue and cannot be fully addressed here. For brevity, we will restrict our comments to key data ownership issues that affect secondary data use, paraphrasing material from Waller and Alcantara (1998) and Burrington-Brown, et al (2007).

- A greater variety and number of stakeholders hold and employ health care data for uses other than direct patient care, the original purpose for which it was created. Providers, for example, legitimately use health information for reimbursement, credentialing, legal defense, and quality management. Thus, patients must understand that they have never had *exclusive*

ownership of their health information, where ownership is defined as "the ability to exercise complete sovereignty over information—to disclose, sell, destroy, alter, or determine who shall have access to it at will." This fact must be incorporated into data stewardship operating rules and requirements for standards and included as part of the NHDSE's public awareness campaign.

- Providers, on the other hand, must understand that the patient has rights regarding medical information, which generally fall into the following categories: the right to access or obtain copies of the information, the right to request amendments or corrections (but not the right to alter or delete information that is part of a legal record), and the right to control disclosures and restrict access by third parties (but not when required by law such as for public health reasons or population health studies). Again, this fact must be incorporated into data stewardship operating rules and standards and included as part of the NHDSE's clinician education and public awareness programs.
- The extent to which the data are de-identified can determine which rights and responsibilities apply to the various stakeholders. Full de-identification with no ability for re-identification allows the information to be accessed and used to a much larger extent because there is less need to control it to protect privacy. Information that has been de-identified with no capability to re-identify can be readily disclosed, sold, or published without risk of breaching a person's right to privacy. These principles should be verified through legal review and should be incorporated into data stewardship operating rules and standards.
- There is a difference between patient-identified and patient-identifiable data. Data is patient-identified if the individual is disclosed by the data. Data is patient-identifiable if the identity of the patient can be derived or inferred from the data, with or without the assistance of computers and artificial intelligence. This distinction is important because it raises the question as to whether or not secondary data has been sufficiently anonymized without risk of breaching a person's right to privacy. These principles should be verified through legal review and should be incorporated into data stewardship operating rules and standards.
- A report that contains aggregated or summarized data generated by an employer from personal health records of many employees may be considered a business record created by that employer. The level of the data—whether it is a discrete record or an aggregate of many discrete records—is a factor in determining who may access it and how it can be used. The laws and policies on this issue are not totally clear, and is an issue for which the NHDSE can provide some guidance.

The question, "who owns the data?" is no longer useful because it is clear that no single person or entity "owns" the information, and the question is not granular enough to offer real solutions. The more appropriate question is, "what are the rights of the various stakeholders to access, use, or control health information under particular circumstances?" The NHDSE should change the conversation accordingly by actively posing the latter question and sorting out the solutions by type of circumstance. Waller and Alcantara (1998) and Burrington-Brown, et al (2007) offer excellent guidance for this discussion. A table from Burrington-Brown outlining the various stakeholders' rights in access, use, and control can be found in Appendix 1.

3.11 Data Sharing and Reporting

Three minor points regarding data sharing and reporting: Data stewardship operating rules and standards should include:

- Guidelines for timely report feedback to clinicians and health care organizations
- Opportunities for providers to review and validate data reports prior to public release of report results
- Clear guidance and technical support to CDOs regarding analysis and public reporting processes

4.0 Characteristics

AHIMA agrees with the *Proposed Characteristics* in the RFI. However, we would add the following three to the initial set of ten *Proposed Characteristics*: (1) Infrastructure to Support the Effort, (2) Organizational Conflict of Interest, and (3) Credibility and Leadership.

In the subsections below, we will comment on some of the thirteen characteristics where we have additional input. These thirteen characteristics should be part of a framework to assess the suitability of existing organizations that might fulfill the role of the NHDSE (see Section 5.25 of this response).

4.1 No Additional Input for Nine of the Initial Proposed Characteristics

We have no additional input for the following characteristics supplied in the RFI: *Objective, Knowledgeable, Trustworthy, Adaptable, Transparent, Timely, Collaborative, and Sustainable*.

4.2 Independent (Characteristic #2)

We suggest expanding this statement to read, "Have a governing structure that is independent of all other business and professional organizations *and government entities*."

4.3 Responsive (Characteristic #4)

We suggest revising the statement to read, "…IT *and health information management (HIM)* standards…" As suggested throughout this response, HIM encompasses confidentiality, privacy, and security, data quality, data content and data standards, records management, and other areas relevant to the scope of work, which argues for its inclusion into the statement.

4.4 Infrastructure to Support Data Stewardship Efforts (Recommended by AHIMA)

We suggest adding this characteristic with the following tagline: "The NHDSE must have the infrastructure to launch and maintain data stewardship efforts."

Infrastructure includes having paid staff, rather than volunteers, to manage the projects it will take on, along with the appropriate tools to develop and maintain the operating rules and requirements for standards, track the myriad activities across the four areas of secondary data use, and monitor the changes to data content and data standards that will occur over time. This characteristic will be important in initially identifying the entities that might fulfill the role and does not eliminate the type of volunteer roles that provide oversight and input into the process.

4.5 Organizational Conflicts of Interest (Recommended by AHIMA)

We suggest adding this characteristic with the following tagline: "The NHDSE as an organization must be free of real or perceived conflicts of interest."

This characteristic is closely associated with, but still different from being *Objective*. It is antecedent to being *Objective.* Before an entity can be objective in its decision making and preclude placing any particular interest above the interests of many, it must itself be free of conflicts of interest.

4.6 Credibility and Leadership (Recommended by AHIMA)

We suggest adding this characteristic with the following self explanatory tagline: "The NHDSE must be viewed by other organizations as being a credible leader in the industry."

5.0 Information Requested

5.1 Need for the NHDSE, Including the Value It Might Bring, and Issues It Might Solve

5.1.1 Need for a NHDSE and the Value It Might Bring

There is a definite need for a NHDSE. As discussed throughout Section 3.0, operating rules and requirements for ensuing standards will help reduce cost, increase operational efficiency in the secondary data use life cycle, and improve the accuracy of measures and reports based on secondary data, which in turn, will help key stakeholders make better policy, management, and treatment decisions.

The need for resolving the myriad data stewardship issues is clear. The key question is, "Does it require the coordinating efforts of a single entity to resolve these issues?" AHIMA concurs and recommends the adoption of a single entity model.

As the IOM points out, a single entity needs to be empowered as a central authority because a system to develop solutions will not "evolve on its own from the vast array of efforts by public, for-profit, and not-for-profit organizations currently under way. This assertion is based on history and a number of realities that characterize the present situation," (IOM, 2006, pp. 66-67). Though the IOM was referring to an entity that would address a comprehensive set of problems found in quality reporting and performance measurement, the "realities" they present clearly apply both to data stewardship—which was, after all, a subset of the issues they explored—and the other areas of secondary data use. Among those realities are the following:

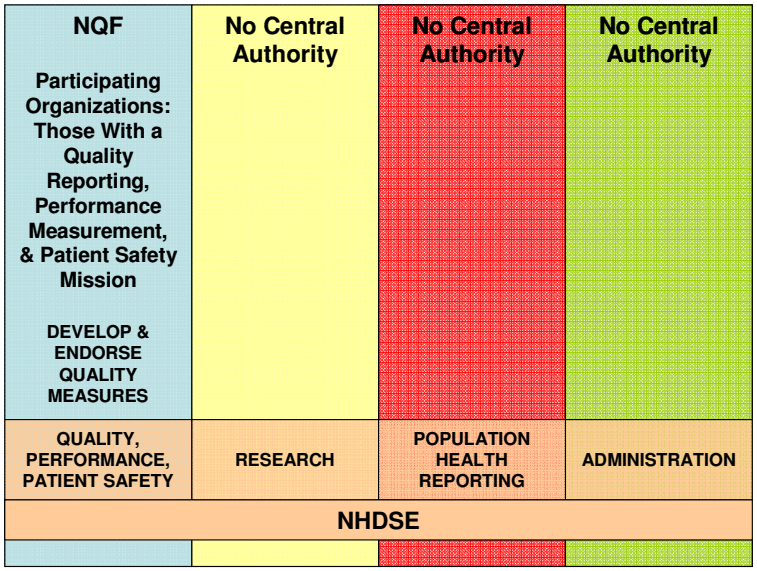
- Existing entities have neither the authority, the overarching leadership, nor the ownership to coordinate data stewardship activities
- Wasteful duplication and inconsistencies will continue, since no single organization or stakeholder group has the standing to require others to comply with operating rules and standards for data quality, data collection, aggregation, and the like
- Public goods, such as investments in data aggregation methods, are unlikely to be addressed adequately because measure development, commercial uses, and other applications of secondary data, which drive data collection and aggregation, compete in the market

If the single entity notion is accepted, the next question is, Should the single entity be a new entity or can it be an existing organization with expanded responsibilities? The single entity can be a new one in the same mold as The Certification Commission for Healthcare Information Technology (CCHIT). However, an existing organization with expanded responsibilities may also be successful. AHIMA recommends the use of the framework in Section 5.25 to discern whether an existing organization has the appropriate characteristics and scope of work attributes to fulfill the responsibilities of a NHDSE.

5.1.2 Issues a NHDSE Might Solve

As we asserted in Section 3.1 Uses of Data, the industry will reap greater benefits if data stewardship issues are addressed across all four areas of secondary data use rather than solely for quality, performance, and patient safety. Thus, AHIMA is recommending the creation of a NHDSE whose charge is to address data stewardship issues across all areas of secondary data use (see Figure 3). Under this model, the NHDSE is not charged with solving the substantive issues within each area of secondary data use (column-wise in Figure 3). Instead, as one of the collaborating organizations, the NHDSE contributes the data stewardship solutions as the central authority and participating organizations resolve the substantive issues. For example, in the quality and performance area, the NHDSE does not itself develop and endorse quality measures. Rather, it contributes to the solution by identifying the underlying data stewardship issues and developing the necessary operating rules and requirements for standards.

Figure 3
NHDSE Fulfills Data Stewardship Responsibilities Across All Four Secondary Use Areas



Interestingly, though there are obvious technical issues to address, non-technical issues, such as compliance and coordination are weightier and must be among the first the NHDSE must solve. Compliance is a major issue because no matter how excellent operating rules and standards may be the industry will derive few benefits from them if there is little or no compliance.

Another major issue is the coordination of data stewardship operating rules and requirements for standards: (1) Across all areas of secondary data use (row-wise in Figure 3), (2) with counterpart activities in the primary data use areas, (3) across state and national initiatives, and (4) with related international activities, since many data stewardship issues are now being addressed globally (e.g., SNOMED-CT). Operating rules and standards will remain silos without careful coordination across these areas and activities.

At the detailed or technical level, among the solutions that must be developed in conjunction with the above stakeholders are policies, operating rules, or standards related to:

- The longitudinal analysis of data gathered from all areas of secondary use (see Section 3.1)
- Extending HIPAA and other confidentiality, privacy, and security laws and regulations for secondary data use, and in particular, organizations that are not now covered entities (see Section 3.2)

- Protecting the confidentiality of health information (see Sections 3.2) and the privacy of the individual, especially regarding ways in which the patient can be re-identified (see Sections 3.8 and 3.9) and secondary data can be accessed (see Section 3.10)
- Collecting computable data in the EHR to increase the timeliness of analyses and provide better opportunities to enhance quality at the point of care (see Sections 3.3 and 3.8)
- Increasing the validity, integrity, accuracy, and completeness of the data to be submitted for secondary use (see Section 3.4)
- Consistently using vocabularies, terminology, coding and classification systems across all applications of secondary data (see Section 3.4)
- Accurately attributing the patient's health information to the physician or other appropriate unit of measure and documenting it in the health record (see Section 3.5)
- Standardizing data content and data definitions to facilitate more reliable data collection, aggregation, and reporting (see Section 3.6)
- Aggregating the data within a health information exchange where no central repository exists (see Section 3.7)

5.2 Desirable Governmental and Private Sector Roles in Health Data Stewardship

AHIMA recommends a public-private collaborative approach to data stewardship. Collaboration amongst the various entities—i.e., institutional providers (hospitals and other facilities); practitioners (physicians, nurses, pharmacists, and other allied health professionals); payers/health plans; health information management, technology, and informatics professionals; employers/purchasers; individuals/consumers; vendors and suppliers (drug and device manufacturers); federal agencies; and non-profit entities—will ensure that key stakeholder points of view will be considered. Such collaboration will foster vital support from the community, which will be especially needed during the startup phase of the NHDSE, and is a critical factor for the NHDSE's continued success.

A collaborative approach also takes advantage of both the combined and complementary strengths and resources of the government and private sector (see Table 2).

Table 2
Roles of Government and Private Sector –Selected Tasks/Activities

Activity/Task	Government	Private Sector
Start up/seed funding	Largely provided by the federal government	
Research	As equal participants in the NHDSE, all entities develop the research agenda identifying topics requiring further research on data stewardship issues	
	Funds core research and demonstration projects	
Development of operating rules and requirements for standards	As equal participants in the NHDSE, all entities provide expert input through work group activity. (Federal entities engage in their role as submitters of secondary data (e.g., from VA and DoD hospitals), as well as from developers of secondary data use products.)	
Implementation of operating rules and standards – front end data collection	Incorporates into CHI standards. Requires VA and DoD care facilities to conform to rules and standards. Requires all entities doing business with VA and DoD care facilities to conform to rules and standards when exchanging health information.	CDO's conform to operating rules and standards (method of compliance to be determined)
Coordination	Ensures that basic tenets, operating rules and standards are threaded into major HIT initiatives (e.g., AHIC, NHIN, HITSP, CCHIT)	
	Coordinates priorities and activities across federal agencies (e.g., ONC, AHRQ, CDC)	
Establish a sustainable funding model	Establish a funding model that would provide long-term sustainability for the NHDSE. Funding can be shared across multiple sectors (including government) as many will benefit from the outcomes of the NHDSE's efforts.	

5.3 Roles and Responsibilities of Existing Entities that Should and Should Not be Fulfilled by a NHDSE

5.3.1 Roles and Responsibilities of Existing Entities That Might Be Addressed by a NHDSE

In the model depicted in Figure 3, Section 5.1.2, there is a clear separation of responsibilities between the NHDSE and existing entities. At the same time, the model shows that the NHDSE must collaborate with a number of organizations across the four areas of secondary data use (discussed in greater detail below). In this separation – collaboration model, the NHDSE need not address any role or responsibility currently assumed by existing entities. This model also allows measure developers and other suppliers of secondary data use products to compete in the market as usual, yet benefit from operating rules and standards. This approach may well sustain their participation in the process.

5.3.2 Roles That Should Not Be Fulfilled by a NHDSE

As previously mentioned, the model is explicit in that the NHDSE does not perform the substantive work in each of the four secondary data use areas. Rather, it supports the activity by identifying and developing the necessary data stewardship operating rules and requirements for standards (see Section 5.1.2). To be explicit then, the NHDSE should **not**:

- Endorse quality measures as done by NQF

- Develop quality measures for accreditation or certification purposes, as is now done by the Joint Commission, NCQA, and the various medical societies
- Develop the actual standards, which should be done through standards development organizations (SDOs)
- Harmonize technical standards developed by SDOs, which should remain the purview of the Health Information Technology Standards Panel (HITSP)
- Certify data stewardship requirements for EHR systems, which should remain the purview of CCHIT

We asserted in Section 3.1 Uses of the Data that the health care industry would reap greater benefits if the NHDSE addressed data stewardship issues for all four areas of secondary data use rather than solely for quality, performance, and patient safety. Under that premise, **the NHDSE should be a new entity that engages the stakeholders from all four areas of secondary data use** (see Figure 3). No existing entity conducts data stewardship operations spanning all four areas of secondary data use. Consequently, one will have to be started.

AHIMA understands both the realities of the current environment and the practicalities of running such an organization. There may be insufficient industry will and funding to start and sustain an overarching NHDSE. If that is the case, and is decided that data stewardship activities should be solely conducted for quality, performance, and patient safety, then the NHDSE need NOT be a new entity. As the IOM noted, extensive resources "…exist on which to build a national system, including those of national organizations such as the National Committee for Quality Assurance (NCQA), the National Quality Forum (NQF), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as well as numerous state and regional entities" (IOM, 2006, pg 64).

Our recommendation in this instance is similar to the IOM's (2006). However, we are quick to add that the data stewardship support for this national system will still need to be bolstered as much of what has been discussed today in the industry has focused more on standardizing the set of quality measures than on data stewardship.

AHIMA, however, encourages the industry to adopt the NHDSE model which covers all four areas of secondary data use. Granted, there are challenges associated with this model. The NHDSE will not only have to collaborate with NQF and the other participating organizations engaged in quality reporting, performance measurement, and patient safety, it must engage with entities in the other areas of secondary data use as well (see Table 2).

Table 3
Examples of Entities the NHDSE Would Engage Across the Four Areas of Secondary Data Use

Quality, Performance, & Patient Safety	Research	Population Health Reporting	Administration
– NQF – AHRQ – ONC – CMS – AQA – HQA – Medical Societies – Providers – HIM/HIT/Informatics Associations – Payers – Employers – Quality Improvement Organizations (QIOs) – Patient Safety Organizations (PSOs) – Accreditors – Value Exchanges – Health Information Exchanges (HIE) – Vendors – Consumers/advocates	– AHRQ – Practice Based Research Networks (PBRNs) – Clinical researchers – Medical societies – HIM/HIT/Informatics Associations – Pharmaceutical companies – ONC – HIE – Vendors – Consumers/advocates	– CDC – AHRQ – NIH – ONC – State health departments – Providers – HIM/HIT/Informatics Associations – HIE – Vendors – Consumers/advocates	– CMS – ONC – AHRQ – Payers – Employers – Providers – HIM/HIT/Informatics Associations – Vendor – Consumers/advocates

The coordination challenges may be more difficult in this model since there is no central authority in the other three areas of secondary data use as there appears to be in quality, performance, and patient safety. However, it is important to remember that the NHDSE in this model would not do the substantive work in each of the four areas (e.g., developing and endorsing a starter set of quality measures). Instead, it would work collaboratively with the various organizations in each of the four areas to develop data stewardship operating rules and requirements for standards to support all of the areas. The focus on data stewardship will make their work more manageable.

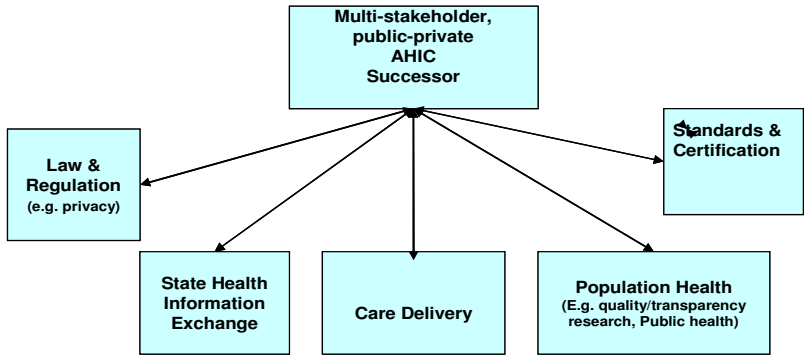
5.4 Relationship of a NHDSE and its Work to Other Quality Improvement Organizations and Activities

As we have asserted throughout this response, the NHDSE should focus its efforts across all areas of secondary data use. Therefore, the NHDSE must develop relationships with those organizations (see Table 3) and participate in those ongoing activities in each of the four areas. As previously stated, the relationship the NHDSE has with each of these organizations is to support their substantive efforts by developing the necessary data stewardship principles, guidelines, operating rules, and requirements for standards. Further details can be found in Sections 2 and 3.

There have many public-private initiatives which have called for the establishment of a central authority within certain domain areas. The NHDSE is itself a central authority for the

data stewardship domain. The central authority at the highest level should be AHIC, and in the future, its successor, in whatever authority and composition it takes on as a result of the current discussion in the industry. As Figure 4 points out, the NHDSE (and all other central authorities) should receive direction from the AHIC (successor). (Note: Figure 1 was used in testimony AHIMA gave to the AHIC in January, 2007. The equivalent in the figure to the NHDSE, which was not conceived at the time of the testimony, is "Population Health.") Having all the central authorities receive direction from AHIC will ensure coordination and priority of activities across the various domains.

Figure 4
NHDSE Receives Direction from AHIC Successor, Coordinates Activities with Other Central Authorities



The NHDSE must work with other central authorities that are on its level, some of which are not currently in existence. For example, a central authority for the vocabulary, terminology, and classification domain does not exist, but its need has been raised (AMIA & AHIMA, 2007). The NHDSE will benefit by the central authorities' resolution of the issues within their domains. For example, as a central authority for vocabulary, terminology, and classification resolves some of the issues surrounding the appropriate terms or codes to be used in the EHR, the NHDSE could refer to that resolution in its operating rules or requirements for standards.

Given that there are a number of structures that are not in place for secondary data use, much less data stewardship, the NHDSE must assume certain advocacy roles, including the following:

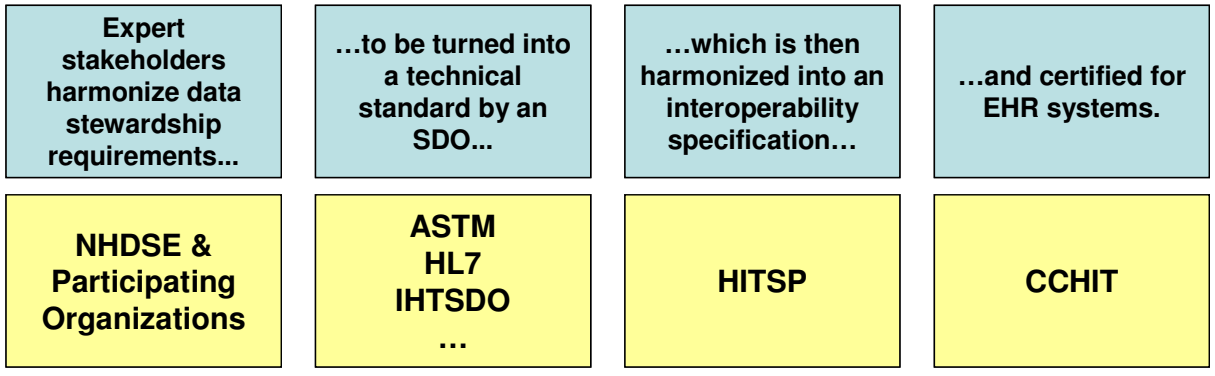
- Calling for the establishment of a counterpart central authority, if it will help both that domain and data stewardship succeed
- Identifying the need and requirements for pertinent laws and regulations
- Identifying the data stewardship requirements for health information exchange

(Note: Its relationship with care delivery is largely captured in Section 3 Scope of Work, when we addressed the connection between the collection of data for primary use and repurposing it for secondary data use. The NHDSE's relationship with standards and certification is addressed in Section 5.5 below.)

5.5 Relationship of a NHDSE and its Work to Other Health Information Standards Initiatives

Consistent with our recommendations in Section 5.3, the NHDSE should not develop or harmonize HIT standards for data stewardship. Rather, the NHDSE should facilitate collaboration among the expert stakeholders across the areas of secondary data use to develop and harmonize data stewardship *requirements* for HIT standards. Focusing on requirements allows the NHDSE to follow the orderly and discrete steps outlined in Figure 5.

Figure 5
Relationship of NHDSE to Other Technical Standards Activities



The NHDSE should be comprised of individuals who use their knowledge of the substantive issues to identify and develop data stewardship operating rules and requirements for standards. Therefore, the NHDSE should not be organized as a standards development organization (SDO). Asking the NHDSE to develop the ensuing technical standards would dilute the valuable resources it needs to stay focused on requirements. In addition, there are excellent SDOs already in existence. Thus, setting up the NHDSE as an SDO is duplicative and not warranted.

Focusing on data stewardship requirements for technical standards enables the NHDSE to remain an independent, objective organization—a customer, rather than a competitor, to the SDOs. It also enables the NHDSE to work collegially within the standards harmonization and certification framework the industry has spent considerable resources on to build in the last few years.

5.6 Key Challenges to the Creation and Maintenance of a NHDSE

Funding will remain the key challenge to the creation and maintenance of the NHDSE. The NHDSE cannot be launched without seed funding from the government. At the same time, the NHDSE must develop a sustainable business model so that the initial investment is not wasted.

Another key challenge is obtaining initial stakeholder buy-in and maintaining their support. Without such support, the initiative may boil down to a regulation, rather than a voluntary effort.

Lastly, the NHDSE must have a sense of urgency so that it can respond "at the speed of business." However, given its relationships with other secondary data use and standards setting organizations (see Figure 5), it does not have full control over the timelines or the process in which standards can be delivered. Thus the challenge for the NHDSE will be to develop a road map that anticipates the timely delivery of standards, and to collaborate with its partners effectively to meet those deadlines.

5.7 Risks of Creating a NHDSE

Making the transition from the current environment to a single entity that will ultimately shepherd and oversee the nation's rules and standards, guidelines, and framework for the secondary use of health care data will be a large and unprecedented undertaking. Within the

current environment there is no mandate for this entity as described throughout this document. As previously noted, the lack of a business model, as well as insufficient funding and an immature infrastructure are risk factors for the NHDSE.

However, the risks of not creating an NHDSE far outweigh the uncertainties associated with its implementation. Within a NHDSE, the industry will maintain the status quo: increased cost, duplication of effort, lack of coordination among measure developers and other reporting bodies, and so on. CDOs are already under tremendous strain to meet the reporting demands of various government agencies and private organizations. Therefore, it is critical to begin the dialogue and movement toward the development of a NHDSE.

5.8 Appropriate Role(s) of a NHDSE in Advancing Quality Measurement

As we have stated throughout this response, the appropriate role for the NHDSE in advancing quality measurement at a higher level is to identify and develop the necessary operating rules and standards to support the entire measure development and endorsement process. Though the NHDSE may not be specifically charged with doing the substantive work in each of the areas of secondary data use, the work that has been outlined for the NHDSE in this response is by no means trivial.

5.9 Appropriate Role(s) of a NHDSE in Characterization and Evaluation of the Comprehensiveness, Accuracy and Reliability of Shared and Aggregated Health Care Quality Measurement Data

As previously stated in Section 3.4, the NHDSE must focus on data quality. Increasing data quality will produce more reliable, accurate, and complete data, which in turn will result in more accurate quality measurements and reports. High data quality at the point of care (the front end) will benefit data quality and data aggregation processes (the back end) for secondary data use. See Section 3.4 for a more detailed explanation.

5.10 Appropriate Role(s) of a NHDSE Regarding the Transmission of Shared and Aggregated Data

As previously stated, in our recommended model the NHDSE does not perform data stewardship activities (e.g., collect, aggregate, or transmit the data) itself. Instead, it develops the operating rules and requirements for standards for the transmission of shared and aggregated data. Protecting the confidentiality of health information and the privacy of the individual is a primary concern in the transmission of shared and aggregated data. Thus, operating rules and requirements for standards for data transmission must minimally address confidentiality, privacy, and security.

5.11 Appropriate Scope of Activities for a NHDSE Beyond Quality Measurement

As previously stated, in our recommended model, the appropriate scope of work for the NHDSE is data stewardship for all areas of secondary data use (see Section 3.1). Therefore, the NHDSE must go beyond quality measurement, and address the core issues in research, population health reporting, and administration. The scope of activities within each of these areas of secondary data use is varied. For example, research includes clinical research,

investigational trials, health services research, and evidenced-based medicine. A greater list of these activities can be found in column two of Table 1, located in Section 3.1.

5.12 Key stakeholders Impacted by a NHDSE and Structure for Interactions

Groups that have a vested interest in the successful implementation and sustainment of the NHDSE include key stakeholders from each of the four categories of secondary use (see Table 3 in Section 5.3.2). As previously mentioned, the NHDSE is not charged with solving the substantive issues within each area of secondary data use. Instead, as one of the collaborating organizations, the NHDSE contributes the data stewardship solutions as the central authority and participating organizations resolve the substantive issues.

5.13 Appropriate Governance Model(s) for a NHDSE

The NHDSE governance model should be based upon the ability to establish a trusted relationship with the health care industry. As a result, AHIMA asserts that a joint public-private partnership is required for the NHDSE to be successful.

In assessing and determining which governance framework will be successful for the development and sustainment of the NHDSE, several factors must be taken into consideration. These include considerations regarding 1) source of authority or power, 2) choice of legal entity, 3) governing structure, and 4) approach toward transparency.

5.13.1 Source of Authority

The NHDSE should coordinate uniform rules and requirements for standards for secondary data use. However, under the current environment adherence to such standards is not required in the industry as a whole. While the NHDSE process and functioning might be objective and independent of government or any one segment of the industry, it does not mean that data providers adopt the requirements for secondary data without some move to universal acceptance of the standards. The NHDSE should educate the health care industry and look to piggyback on the Secretary's value based healthcare concept to increase acceptance. The NHDSE should be part of the AHIC cycle that includes the HITSP and CCHIT. This coordination should also provide some strength to the goal of achieving acceptance of the uniform rules and standards for secondary data.

5.13.2 Choice of Legal Entity

AHIMA recommends that the NHDSE be an independent non-profit, public-private entity.

5.13.3 Governing Structure

An inclusive governance process and structure is essential to achieving success. The organizational structure and policies of the NHDSE should be designed to ensure balanced representation from all key stakeholder groups in each of the four major areas of secondary data use. Table 3, Section 5.3.2 contains a preliminary list of stakeholders for consideration and should continue to be expanded as the NHDSE infrastructure is solidified.

Once the organizational phase of development has been established and stabilized, the sustainment phase will serve as long term support for the organization. During the sustainment phase it is recommended that the organization transition to an independent, non-profit organization.

As demonstrated through the CCHIT model, the NHDSE must establish a Board of Trustees who would assume fiduciary responsibility (a requirement for the organization to become a fully independent, nonprofit organization). The responsibilities of the board of trustees would include fiscal oversight and stewardship of assets, organizational strategy, evaluation of senior management, and identification and resolution of any conflicts of interest involving commissioners and management of the NHDSE.

To ensure key stakeholder groups are represented, members from various aspects of the health care community, such as providers, vendors, government representatives, academia, and payers, should be represented on the Board of Trustees (see Table 3 in Section 5.3.2).

To carry out the initiatives, a Board of Commissioners would be selected to represent a wide range of stakeholders, provide strategic direction, ensure objectivity and credibility, provide guidance to and review the reports of the work groups, and approve the final processes for establishing rules and standards for secondary data.

The Commissioners should be made up of at least two representatives from each of the four major areas of secondary data use. The Commissioners should be selected through nominations that are submitted to the Trustees by a joint Nominating Committee made up of internal and external members appointed by the Trustees. Commissioners would serve staggered two-year terms.

Sustainability could be achieved by requiring user fees for those organizations submitting a need to the NHDSE for processing. Funding can also be shared across multiple sectors, including the Federal government (e.g., CMS within the quality area, the CDC within population health reporting), as many will benefit from the outcomes of the NHDSE's efforts. In addition the NHDSE could receive income from the sale of guidance and education materials much like the Joint Commission and the Financial Accounting Standards Board (FASB). This should suffice over time, however, there will be an initial backlog that will require a jumpstart in funding and some of this will have to come from the government. By looking to user fees rather than dues, some of the potential for undue influence (from those who can afford to pay dues) would be removed.

In order to achieve success in the development of a public and private partnership, there are several critical factors to consider:

Characteristics for Success	**Description**
Trustworthy and creditable	Establish leadership that can be trusted through a balanced and open approach that engages noted health care leaders throughout the industry.
Open and transparent	Develop an inclusive governance process that engages a diverse set of HIT stakeholders to ensure broad acceptance of work products. All information and work products should be made available for public comment and processed methodically.
Ability to balance competing pressures	Recognize the natural tensions between key stakeholders and propose solutions that deliver value to everyone involved.
Effective	Capable of establishing the communication channels that will be necessary to enable acceptance in all four secondary data use domains.
Efficient	Establish efficient, low-cost processes for gathering input, developing knowledge, and communicating with stakeholders. The ability to

	conduct business virtually through telecommunication and Internet collaboration technologies is essential.

5.13.4 Approach Toward Transparency

Transparency is viewed as a critical element to the success of the NHDSE and its establishing and issuance of policies, rules and standards for the covered tasks. By implementing a transparent process, the public-private partnership enables the ability to elicit input from key experts, stakeholders and the public during meetings, comment periods, etc. Principles for transparency should include the following:

- Open and transparent: Develop effective mechanisms to provide and receive information from the public as operating rules and standards are developed and implemented.
- Accountable: Report, explain, and justify how operating rules and standards are developed. Regular reports regarding progress and outcomes should be made publicly available.
- Responsive: React in a timely manner to industry input and needs.

Transparency should be achieved in a manner similar to that used by CCHIT so that there is not only industry, government, individual, vendor, and employer involvement, but also posting of pre- and post- materials that go into the requirements for standards.

5.14 Means to Assure NHDSE Objectivity and Independence

The NHDSE can achieve objectivity and independence by being established as a public-private entity that collaborates with a wide range of critical industry stakeholders and where long-term financing is based on end-user fees and services rather than dues or strict government financing. User fees and sales of educational products would provide a revenue stream, allowing the NHDSE to become an independent organization.

Representatives from various groups, such as those noted in section 5.3.2 would be involved in all areas of policy, principles, and process decision making. Paid staff would handle all organizational and processing so as not to overextend the volunteers from industry.

As mentioned in section 5.13, the NHDSE should coordinate uniform rules and requirements for standards for secondary data use. However, under the current environment, adherence to such standards is not required in the industry as a whole. Thus, the NHDSE should educate the health care industry and coordinate its activities with other industry initiatives. This coordination will help the industry accept the uniform operating rules and requirements for data stewardship standards.

5.15 Means to Achieve Trustworthiness in a NHDSE, and How it Would be Achieved

The NHDSE will require the support and trust of all stakeholders from the health care community. Complete transparency and input from the key stakeholders during the processes of creating uniform rules and requirements for standards will further ensure success of the NHDSE. Establishing an open process that enables key stakeholder participation will be paramount in the success and sustainability of the NHDSE.

Regardless of the governance model established for the NHDSE, it is imperative that the NHDSE be free of all real or perceived conflicts of interest. This concept addresses those issues associated with organizations that would expect to have a vested interest in the outcome of

certain decisions or policies decided upon. To maintain the trusted network between the NHDSE and key stakeholder organization, conflicts of interest must be keenly addressed. If a situation occurs where a conflict of interest arises, steps must be taken to ensure the least amount of impact on the organization and the industry at large.

5.16 Recommendations for Achieving Timeliness in NHDSE Decision Making

In the early stages of development, NHDSE activities may not coincide with existing industry efforts related to data stewardship. The NHDSE should be required to develop a road map that outlines opportunities for immediate solutions to existing activities while incorporating future data stewardship goals into a rational sequence of activities (similar to how HITSP and CCHIT are working together to synchronize timing of activities related to standards and certification).

5.17 Recommendations for Achieving Compliance with NHDSE Recommendations, Rules or Standards

Uniform rules and requirements for standards for secondary data use will not facilitate change if they are not understood and implemented effectively. It is important that the NHDSE develop a sound process for achieving consensus among the wide variety of stakeholders, and educate the industry of its rules, requirements for standards, and other outputs.

Compliance with NHDSE rules and ensuing standards should rely on the standards development and certification processes as heavily as possible. See Section 5.5 for a more detailed explanation.

5.18 The Essential External Inputs to a NHDSE

To develop operating rules or requirements for standards effectively, the NHDSE needs input at the business, product, measure, and data level. At the business level, the NHDSE needs to understand the business objectives of the secondary data product (i.e., an individual measure, a reporting system or data set as shown in Table 1, Section 3.1). Understanding the business objectives is critical because the operating rules and ensuing standards must be an enabling force that promotes the consistent use of secondary data in the market.

External inputs are needed at the product, measure, and data level so that the NHDSE can discern the differences among the intended uses of the data, understand what and how data are used across products or measures, and determine whether the data can be derived from the EHR in a native or transformed format. Understanding these issues is a vital step for finding the leverage across the various data uses.

These analyses could be conducted in a number of ways. AHIMA recommends that such analyses be conducted similar to that completed by the NQF Expert Panel, funded by AHRQ. Several examples of reports and data sets that should be included in this type of analysis are included in Table 1, Section 3.1.

5.19 Recommendations for Achieving Organizational Flexibility for a NHDSE

In this rapidly changing health care environment, it is critical for a NHDSE to be robust enough to leverage its efforts across a broad set of activities, yet agile enough to quickly and effectively respond to market and public policy changes. It is just as critical, however, to ensure

that key stakeholder needs are considered when making decisions and changes that will affect the use and management of secondary data.

One practical way to achieve organizational flexibility, yet strike the balance of securing stakeholder input, is to follow CCHIT's model for accommodating change. CCHIT has established new work groups and changed its staffing mix accordingly as it has gone from certifying ambulatory EHR systems to inpatient acute EHR systems, to network components, and now to a variety of expansion areas. A similar process can be adopted by a NHDSE as it first targets quality measurement and moves to public health reporting or other priority.

5.20 The Potential Organizational Infrastructure Needs of a NHDSE

A NHDSE will require funding in its beginning stages to hire staff, establish its initial work groups, develop the first set of deliverables, and draft a sustainable business model. This initial funding is important because it will help the NHDSE focus on providing immediate value to the industry, as well as to its constituents, and give it time to begin addressing all the issues within its scope of work without having to worry so heavily about its existence.

Aside from staff, an essential part of its infrastructure will be the tools to efficiently capture and organize input from a formal public comment process, track the myriad secondary data use activities, and map its operating rules and requirements for standards to secondary reports and data sets.

Since there is a considerable amount of secondary data that is reported and many of the data elements vary in their definition, though they seemingly represent the same information, a critical tool will be a data element repository, which should, among other things:

- Catalog meta-attributes (i.e., name, organization/author, objectives, version) of reports, data sets, and individual measures
- Contain a dictionary that identifies the data elements used in similar data sets and compares the varied ways a data element is defined across categories of secondary data use
- Map the data elements to a standard list of data elements in an EHR system (e.g., the ASTM 1384-02a standard) to determine whether reported data can be derived from the EHR in native or a transformed format (see Section 3.3)

It should be noted that data element tools and guidelines exist on some level today (e.g., the United States Health Information Knowledgebase (USHIK), National Institute of Standards and Technology (NIST) inventories, etc.). The NHDSE should explore the feasibility of using these tools rather than developing them from scratch or immediately acquiring commercial tools.

The above mentioned tools will greatly assist the NHDSE in developing policies, operating rules and requirements for standards and in coordinating secondary uses of the data. These activities will require a significant level of effort in the beginning and as the entity matures, and it is important that the NHDSE has the right tools to ensure its success.

5.21 Potential Funding Requirements and Sources of Funding for a NHDSE

As previously stated, initial funding for the start up phase should come from the federal government. Once the NHDSE has determined its business model, its revenues to sustain itself could come from its educational products and service fees, along with some continued government support (federal and state). In terms of government support, funding can be shared

across multiple sectors (e.g., CMS within the quality area, the CDC within population health reporting), as many will benefit from the outcomes of the NHDSE's efforts.

5.22 The Organizational Skill Set Required of a NDHSE

A NHDSE requires strong leadership and experience in the areas of secondary data use. Critical skill sets include the ability to develop and implement a strategic vision, strong program and project management capabilities, and the ability to facilitate, manage, and coordinate public, private and volunteer activities. Since this entity does not yet exist, it is unclear what the final make up of the organization will be. However, experience with other public-private partnerships demonstrates the need and ability to collaborate with powerful stakeholders in the health care industry. The above skill set will be critical for the successful transition to and ultimate management of a NHDSE.

5.23 Priority Activities for NHDSE to Support Data Sharing and Aggregation

To support data sharing and aggregation, we recommend the NHDSE take action to address short-, mid-, and long-term goals upon formation:

- Short-term (1 year)
  - Establish the NHDSE organizational structure.
  - Seek support and input from key private and public stakeholders in each of the four categories of secondary data use to establish national coordination in a transparent process with other public-private entities to set uniform rules and the requirements for standards for data stewardship.
  - Establish principles that address each area of data stewardship (i.e., confidentiality, privacy, and security; data quality; data collection and aggregation; etc.).
  - Establish a process for receiving requests, inquiries and complaints.
  - Establish a process for existing data sets to conform with NHDSE operating rules and policies
  - Charge the NHDSE to develop a detailed matrix to achieve mid- and long-term goals.
  - Initiate an industry-wide education campaign that communicates accountability for collecting and delivering high-quality data for secondary use.
  - Identify the need for counterpart central authorities (e.g., one in the vocabulary, terminology, and classification domain) that will increase the success for the industry to comply with data stewardship operating rules and standards

- Mid-term (2-3 years):
  - Develop a sustainable business model to support the goals and desired outcomes of the NHDSE.
  - Seek and gain industry agreement on data collection and use data across all categories of secondary data.
  - Establish a mechanism to allow for data set modifications and enhancements.
  - Engage standards development organizations to incorporate data stewardship requirements into existing standards.

- Long-term (5 years):

- Continually assess the use and support of data stewardship rules and standards.

5.24 Issues Concerning the AQA Characterizations of a NHDSE

AHIMA has identified no issues regarding the AQA's characterizations of a NHDSE, except for the three characteristics that we have added in Section 4.

5.25 The Suitability of One or More Existing Organizations to Fulfill the Role of a NHDSE

There are a large number of organizations that will play a major role in NHDSE activities, but few organizations currently have both the infrastructure and expertise to oversee all secondary uses of data. An in depth analysis of all key industry stakeholders should be conducted to determine which organization have the infrastructure, expertise, skill set, and assets to assume the role of a NHDSE. First level screening activities should be conducted using a tool similar to the one listed below.

Table 4
Framework to Assess of Existing Entities Who Might Fulfill the NHDSE Role

Proposed Organizations	Functional Area(s) of Expertise - Quality, Performance & Patient Safety - Research Population Health - Reporting - Administration	Supported NHDSE Core Functions									Ancillary NHDSE Functions					Total
		Scope of Work									Scope of Work		Characteristics			
		Data Aggregation	Data Collection	Attribution	Methodologies	Data Analysis	Data Validation	Uses of Data	Data Access	Data Sharing & Reporting	Privacy & Security	Data Content & Structure	Infrastructure to Support Effort	No Organizational Conflict of Interest	Credibility/ Leadership	

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7.0 Appendix A

Stakeholders' Right and Responsibilities for Protected Health Information
(Burrington-Brown, et al, 2007)

Stakeholders		Access	Use	Control
Individual/Patient	**Rights**	To access protected health information (PHI) within 30 days.	With the right to access, the use is up to the patient.	Patient should understand all possible uses of data, including secondary use.
	Responsibilities			
Clinician	**Rights**	Appropriate members of work force have access to the information in order to carry out their duties.	To use or disclose for treatment, payment, or health care operations (unless authorization is specifically required). To disclose as required by law or for public health activities.	*No current national regulation policy exists. Apply stewardship principles to:* justify and explain treatment; identify legal record; identify designated record set.
	Responsibilities	Identify work force members who need access to PHI to carry out their duties. Identify the categories of information they may access.	Make reasonable efforts to limit work force members' access to PHI needed to perform their duties. To use or disclose for treatment, payment, or health care operations. To disclose as required by law or for public health activities.	Have policies and procedures in place to comply with the privacy and security rules. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business.
Provider Organization	**Rights**	Appropriate members of work force have access to the information in order to carry out their duties.	To use or disclose for treatment, payment, or health care operations (unless authorization is specifically required). To disclose as required by law or for public health activities	*No current national regulation exists. Apply stewardship principles to:* justify and explain treatment; identify legal record; identify designated record set.
	Responsibilities	Identify work force members who need access to PHI to carry out their duties. Identify the categories of information they may access.	Make reasonable efforts to limit work force members' access to PHI needed to perform their duties. To use or disclose for treatment, payment, or health care operations. To disclose as required by law or for public health activities.	Have policies and procedures in place to comply with the privacy and security rules. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business.
Referral clinician	**Rights**	Appropriate members of	To use or disclose for	*No current national*

or provider		work force have access to the information in order to carry out their duties.	treatment, payment, or health care operations (unless authorization is specifically required). To disclose as required by law or for public health activities.	*regulation policy exists. Apply stewardship principles to:* justify and explain treatment; identify legal record; identify designated record set.
	Responsibilities	Identify work force members who need access to PHI to carry out their duties. Identify the categories of information they may access.	Make reasonable efforts to limit work force members' access to PHI needed to perform their duties. To use or disclose for treatment, payment, or health care operations. To disclose as required by law or for public health activities.	Have policies and procedures in place to comply with the privacy and security rules. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business
PHR Service Provider	**Rights**	*No current national regulation policy exists. Apply stewardship principles to:* outline policy that allows only appropriate members of work force to have access to PHI in order to carry out their duties.	*No current national regulation policy exists. Apply stewardship principles to:* limit use or disclosure for business operations (unless authorization is specifically required). Disclosure as required by law.	*No current national regulation policy exists. Apply stewardship principles to:* Outline policy that PHI should be under patient control.
	Responsibilities	*No current national regulation policy exists. Apply stewardship principles to:* identify work force members who need access to PHI to carry out their duties; identify the categories of information they may access.	*No current national regulation policy exists. Apply stewardship principles to:* make reasonable efforts to limit work force members' access to PHI needed to perform their duties; to use or disclose for business operations; to disclose as required by law.	*No current national regulation policy exists. Apply stewardship principles to:* outline policies and procedures to comply with the privacy and security rules. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business
Insurance Company	**Rights**	Appropriate members of work force have access to the information in order to carry out their duties.	To use or disclose for treatment, payment, or health care operations (unless authorization is specifically required). To disclose as required by law.	*No current national regulation policy exists. Apply stewardship principles to:* justify and explain treatment; identify legal record; identify designated record set.
	Responsibilities	Identify work force members who need access to PHI to carry out their duties. Identify the categories of information	Make reasonable efforts to limit work force members' access to PHI needed to perform their duties. To use or disclose	Have policies and procedures in place to comply with the privacy and security rules. *No current national*

		they may access.	for treatment, payment, or health care operations. To disclose as required by law.	*regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business
Health Data Exchange	**Rights**	*No current national regulation policy exits. Apply stewardship principles to:* outline a policy that allows only appropriate members of work force have access to the information in order to carry out their duties.	*No current national regulation policy exists. Apply stewardship principles to:* limit use or disclosure for business operations (unless authorization is specifically required); disclose PHI as required by law.	*No current national regulation policy exists. Apply stewardship principles to:* justify and explain business/coverage decisions.
	Responsibilities	*No current national regulation policy exists. Apply stewardship principles to:* identify work force members who need access to PHI to carry out their duties; identify the categories of information they may access.	*No current national regulation policy exists. Apply stewardship principles to:* make reasonable efforts to limit the access of work force member to PHI needed to perform their duties; use or disclosure for business operations; disclose as required by law.	*No current national regulation policy exists. Apply stewardship principles to:* outline policies and procedures in place to comply with the privacy and security rules. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business.
Health Data Bank	**Rights**	*No current national regulation policy exists. Apply stewardship principles to:* outline a policy that allows only appropriate members of work force have access to the information in order to carry out their duties.	*No current national regulation policy exists. Apply stewardship principles to:* limit use or disclosure for business operations (unless authorization is specifically required); disclose PHI as required by law.	*No current national regulation policy exists. Apply stewardship principles to:* justify and explain business/coverage decisions.
	Responsibilities	*No current national regulation policy exists. Apply stewardship principles to:* identify work force members who need access to PHI to carry out their duties; identify the categories of information they may access.	*No current national regulation policy exists. Apply stewardship principles to:* make reasonable efforts to limit the access of work force to PHI needed to perform their duties. Use or disclosure for business operations; disclose PHI as required by law	*No current national regulation policy exists. Apply stewardship principles to:* have policies and procedures in place to comply with the privacy and security rules. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business
Business	**Rights**	Appropriate members of	To use or disclose for	*No current national*

Associates of Covered Entities		work force have access to the information in order to carry out their duties.	treatment, payment, or health care operations (unless authorization is specifically required). To disclose as required by law.	*regulation policy exists. Apply stewardship principles to:* justify and explain business/coverage decisions.
	Responsibilities	Identify work force members who need access to PHI to carry out their duties. Identify the categories of information they may access.	Make reasonable efforts to limit the access of work force to PHI they need to perform their duties. Use or disclosure for business operations. To disclose as required by law	*No current national regulation policy exists. Apply stewardship principles to:* have policies and procedures in place to comply with the privacy and security rules. Return or destroy all PHI at the termination of the contract. *No current national regulation policy exists. Apply stewardship principles to:* identify responsibilities of stakeholders upon sale or transfer of business.