Response of the American College of Physicians to the Request for Information Published November 15, 2004, by the National Coordinator for Health Information Technology

Development and Adoption of a National Health Information Network

January 14, 2005

General

1. The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of health care in America. Please provide your working definition of a NHIN as completely as possible, particularly as it pertains to the information contained in or used by electronic health records. Please include key barriers to this interoperability that exist or are envisioned, and key enablers that exist or are envisioned. This description will allow reviewers of your submission to better interpret your responses to subsequent questions in this RFI regarding interoperability.

The National Health Information Network (NHIN) should be constituted as public infrastructure, such as roads and sewers. One reason for this approach is that health information technology (HIT) interoperability may have greater potential to improve patient safety than it has to save money. Another reason is that potential developers of products and services require a reliable and stable base platform on which to build. This low-level infrastructure could be little more than a set of layered standards for all exchanges of health information. The network would consist of a federation of regional networks exchanging data using the Internet. For the most part, clinical data would remain under the control of the data sources.

There must be a single authority that directs the development and enhancement of the required standards. Choosing among existing standards that were not designed to operate within an overall framework has proven to be inefficient and incomplete. In addition, there is a clear need for some centrally provided services, such as vocabulary and service registration and location. This will not be a one-size-fits-all set of standards. The standards must accommodate multiple methods of interaction.

The NHIN is a necessary precursor to the universal implementation of electronic health record (EHR) systems, especially in ambulatory practice. Clinicians in small and medium-sized ambulatory practices are justifiably reluctant to invest time, effort and resources in implementing EHR systems that are not immediately interoperable with external services. The existence of the NHIN, coupled with significant changes in payment and incentives, could dramatically impact the market for, and the implementation of, EHR systems in clinical practices. The NHIN is a necessary, but not sufficient, precondition to EHR system uptake in primary care.

Key Barriers

System disparities

- Rural and inner-city clinicians as well as small and primary care practices will need substantially more support, guidance and assistance. The system must be established and operated with an eye toward who will be the potential winners and losers. For example, rural Regional Health Information Organizations (RHIOs) will require substantially more funding.

- There are differences in the types of practices, patient populations, referral patterns and network needs in rural areas as opposed to urban areas that can strongly affect the type of network structure that best meets system needs.

  In urban areas there are often multiple hospitals/facilities and several large multispecialty group physician practices that work with more than one hospital. The patient population often moves among several systems in relatively short distances. There is often strong broadband Internet infrastructure.

  In contrast, the distances serviced by one or a few regional hospitals in rural areas may be large, but the patient population and physician population is in a more closed network structure with less crossover with other systems. Nearly all patient care may occur between a consistent provider infrastructure with many small physician practices, solo physician practices and one regional hospital. Many of these rural areas also still have limited access to broadband Internet, making it easier and more efficient to access data in a central repository model than in a distributed model.

  The differences between the needs of rural and urban networks can significantly affect the type of network models that would work best and be most financially viable. Rural networks might be best served by a central repository model that can meet the needs of the relatively closed provider network and allow adequate access speeds, even when broadband Internet access is limited or less efficient. Urban areas, on the other hand, may need a more distributed model with communication among multiple information repositories because of the political concerns of larger multispecialty groups and multiple hospital systems.

  As a result, the overall national network infrastructure probably needs to be a combination of both models, where distributed communication among urban systems reaches out to the rural central repositories to allow sharing of patient information.

Reimbursement policies

- The burden of implementation must not become another unfunded regulatory mandate on physician practices.

- Physicians are penalized for investing in HIT solutions to improve patient care. Current Medicare payment policies do not reimburse for the increased practice

expenses and investment of physician and staff time required to convert to systems of care supported by EHRs. The Medicare program's sustainable growth rate (SGR) will trigger across-the-board cuts that will make it impossible for most office-based physicians to invest in EHRs.

- Primary care services continue to be systematically undervalued. Fewer physicians are choosing general internal medicine and family practice at a time when *more* primary care physicians should be trained to take care of an aging population with its higher incidence of chronic disease.

- Medicare's policy of paying on a per-procedure/visit basis fails to recognize physician work that falls outside of the procedure or visit, including coordination and care of patients with chronic disease. E-mail and telephone communications generally are not separately reimbursable under Medicare, even though such communications may reduce the need for face-to-face office visits. Physicians are not rewarded for achieving quality improvements or system-wide savings that may result from better coordination of care.

Legal concerns

- Referral regions may cross state lines with conflicting laws that will need to be worked out. Regional networks near state borders will often have patient referral patterns requiring sharing patient information across state borders on a regular basis. These networks will need to be able to meet the requirements of two or more states.

- Barriers exist to electronic information exchange, such as Stark and Drug Enforcement Agency (DEA) regulations

- There is a lack of regulation governing the liability for stewardship and use of clinical information. It is unclear what responsibility physicians may have for information within the system they may not know about. In addition, it is unclear who will be responsible for reviewing and correcting conflicting information or errors in shared patient records. As the primary care provider moves from an environment of information scarcity to an environment where information could become an uncoordinated flood, new legal protections will be required.

Other

- With regard to interoperability, the functionality of ambulatory/primary care EHR systems lacks maturity.

- Data or studies demonstrating the potential benefits and risks of implementing EHR systems and an NHIN are insufficient.

- Standards and specifications needed to operate the network are lacking.

2. What type of model could be needed to have a NHIN that: allows widely available access to information as it is produced and used across the health care continuum; enables interoperability and clinical health information exchange broadly across most/all HIT solutions; protects patients' individually-identifiable health information;

and allows vendors and other technology partners to be able to use the NHIN in the pursuit of their business objectives? Please include considerations such as roles of various private- and public- sector entities in your response.

- The Internet has succeeded beyond the visions of its founders. The standards for data exchange are relatively simple and low-level. The standards for operating the Internet are governed by two voluntary bodies with clearly defined scope, the IETF and the W3C. The key benefit of this voluntary approach has been facilitation of a vibrant and healthy market for developers of products and services. The key drawback is that the resulting infrastructure is not sufficiently reliable, secure and complete to support the requirements of health information exchange. A public authority that directed and funded the development of needed standards and that required the implementation of the standards would reduce many of the current problems with the Internet. In the case of the global Internet, this approach would be impossible. However, in the case of the American NHIN, it seems necessary.

- A model for information exchange will need to include both models based on a central repository (more likely for rural networks) and distributed models (for most urban areas and to share information between urban areas and rural areas).

3. What aspects of a NHIN could be national in scope (i.e., centralized commonality or controlled at the national level), versus those that are local or regional in scope (i.e., decentralized commonality or controlled at the regional level)? Please describe the roles of entities at those levels. (Note: "national" and "regional" are <u>not</u> meant to imply federal or local governments in this context.)

- A national public authority must mandate the standards to be used in the NHIN. Further, this authority must direct and fund the development and enhancement of these standards by voluntary bodies that include representation from all stakeholders. Some services, such as vocabulary and registry, must be operated by a single source. This national public authority needs to assist in breaking down barriers, such as when laws conflict between states.

- Physicians and patients need to play a prominent role in the governing of all regional and national networks to maximize their input in the decisions on use of the information that is gathered and shared between systems.

- Community and regional networks would be responsible for day-to-day activity--such as identifying and authorizing users, developing and publishing registries of clinical information, customizing vocabulary and other interfaces and connecting authorized users to appropriate data--whether the data are stored locally or externally.

- State governments should take an active role in supporting the creation and maintenance of these networks and actively work to remove barriers due to restrictions by their own state laws as well as conflicts with other states.

Organizational and Business Framework

4. What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN? Please describe the kinds of entities and stakeholders that could compose the framework and address the following components:
   a. How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?
   b. How could policies and standards be set for the development, use and operation of a NHIN?
   c. How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?
   d. How could the NHIN be operated? What are key considerations in operating a NHIN?

- A national authority must set the standards for the construction and operation of the network and for the function of regional authorities. The regional authorities will govern the day-to-day operation, maintenance and expansion of their networks. They would also assist in resolving conflicts between state laws.

- Significant and continuing involvement of practicing clinicians in the work of these authorities is crucial. Funding may be required to ensure sufficient clinician involvement.

- Funding, support and assistance will be required to establish and operate rural networks.

- We have a chicken-and-egg problem whereby clinicians are reluctant to use systems that do not yet connect to anything. Accelerating the development of the NHIN should greatly accelerate the uptake of EHR systems by clinicians. This increase in EHR use should drive further development of the NHIN.

    - Funding and support for the loss of income will be required to overcome the initial barriers for physician use of EHRs, especially in small and rural practices.

    - The federal government and private payers must also be willing to implement changes in reimbursement policies to encourage mainstream adoption and use of NHIN and long-range sustainability of the use of EHRs and the network.

    - Clinicians need to have access to objective, unbiased information and consultative help on evaluating readiness of EHRs, making selection decisions and obtaining the full benefits of EHR functionality.

    - A process of certification is needed to assure all systems meet certain standards of functionality in the clinical practice setting as well as interoperability for sharing clinical information in regional and national networks.

    - Absent these four actions, adoption will continue to be slower than many desire and sustainability will be at risk.

5. What kind of financial model could be required to build a NHIN? Please describe potential sources of initial funding, relative levels of contribution among sources and the implications of various funding models.

- The federal government must fund the central authority.
- The federal government and other payers must provide start-up funding for regional networks and EHR adoption, especially in rural and small physician practices.
- Payers must provide incentives for HIT adoption and continued use of EHRs to improve quality of care and to maintain sustainability of the network. Medicare, as the nation's largest single payer, must take the lead on restructuring payment policies to create such incentives.
- Funding through Quality Improvement Organizations (QIOs) working with educational groups and physician organizations should be sufficient to help physicians adopt EHRs, adopt clinical practice change and share information through information networks.

6. What kind of financial model could be required to operate and sustain a functioning NHIN? Please describe the implications of various financing models.

- The NHIN will never be "finished." Just as the physical infrastructure will need constant maintenance and repair, the NHIN framework will need constant attention. Changes in technology, medicine and public policy will require significant and potentially costly attention. The ongoing financial model will not vary significantly from the start-up model. There will be an ongoing requirement for federal funding combined with support by multiple stakeholders and incentive reimbursement models.

7. What privacy and security considerations, including compliance with relevant rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are implicated by the NHIN, and how could they be addressed?

- The key concern for clinicians is that they maintain control over the access and use of data for their patients. The clinician must maintain authority to determine who has access to what information and how the information is used.
- Models that delineate the responsibility for a new type of patient record containing information from multiple resources will need to be developed; this model must address error correction and reconciliation of conflicting data (e.g., different problem lists)
- The role of patients in this process also needs to be determined.
- Patient identifier issues need to be addressed. A voluntary national patient identifier should be considered.

- Federal privacy protections need to be in place before implementing a national system of unique identifiers.
- If unique identifiers are created, security of this information must be guaranteed.
- If individual patient identifiers are used, they should not be linked to Social Security numbers.

- The above issues need to be addressed and guidance given on a national level.

8. How could the framework for a NHIN address public policy objectives for broad participation, responsiveness, open and non-proprietary interoperable infrastructure?

- The standards setting process must be open and responsive to identified needs and supported/controlled on a national level.
- The chosen standards must be sufficiently flexible to support multiple modes of interaction.
- Physicians need to take a primary/prominent role in the development of these policies.

Management and Operational Considerations

9. How could private sector competition be appropriately addressed and/or encouraged in the construction and implementation of a NHIN?

- Significant economic incentives for physicians, coupled with the interoperability promised by the NHIN vision, will stimulate a viable market for vendors.
- Minimum standards should be determined on a national level, but choice of specific products should be left to individual physician practices and networks.

10. How could the NHIN be established to maintain a health information infrastructure that:
    a. evolves appropriately from private investment;
    b. is non-proprietary and available in the public domain;
    c. achieves country-wide interoperability; and
    d. fosters market innovation.

- The success of the NHIN will depend largely on the ability of the central authority to be inclusive and responsive, and on continuing financial incentives provided by the federal government and other payers.

11. How could a NHIN be established so that it will be utilized in the delivery of care by healthcare providers, regardless of their size and location, and also achieve enough national coverage to ensure that lower income rural and urban areas could be sufficiently served?

- Incentives must be aligned so that the beneficiaries of the NHIN share proportionately in the costs.

- Legal and regulatory barriers to adoption must be removed.

- New legal protections will be required that address emerging issues of duty and liability concerning actions taken based on increased data availability.

- Rural networks will require substantial up-front investment.

- Start-up costs for EHRs as well as for the formation of local and regional information networks need to be covered for small and rural practices. Reimbursement incentives should be targeted at small and solo physician practices, particularly in underserved and rural communities to sustain the use of EHRs and participation in the regional network.

12. How could community and regional health information exchange projects be affected by the development and implementation of a NHIN? What issues might arise and how could they be addressed?

- The establishment of standards by the NHIN authority should be designed to facilitate the formation of community and regional projects and should not restrict their formation or discourage early adopters.

- The community and regional projects must have a significant role in the deliberations and decisions of the NHIN authority.

- As stated above, issues between state laws and regulations need to be addressed and resolved to facilitate the formation of regional networks across state lines.

13. What effect could the implementation and broad adoption of a NHIN have on the health information technology market at large? Could the ensuing market opportunities be significant enough to merit the investment in a NHIN by the industry? To what entities could the benefits of these market opportunities accrue, and what implication (if any) does that have for the level of investment and/or role required from those beneficiaries in the establishment and perpetuation of a NHIN?

- Health plans and employers (including Medicare and Medicaid) will realize the greatest financial benefit from the formation of local and regional networks as well as the NHIN. They should thus help finance the initiation of the networks, adoption of EHRs in physician practices, and sustained use of EHRs and the network.

Standards and Policies to Achieve Interoperability

(Question 4b above asks how standards and policy setting for a NHIN could be considered and achieved. The questions below focus more specifically on standards and policy requirements.)

14. What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? What could be the characteristics of these entities? Do they exist today?

- Due to the inherent complexity of health care, it seems unlikely that any one Standards Development Organization (SDO) could develop and maintain all the standards needed for interoperability.

- Several existing SDOs operate successfully within a particular domain. This model could be useful if the central authority directed and funded the work done by these domain experts.

- The Certification Commission for Healthcare Information Technology (CCHIT) is a good starting model for developing consensus on standards.

- The key to successful development of interoperable standards is to require that all standards be developed from a single reference model. This will prevent development of conflicting standards, such as HL7 CDA and CCR. The Authority should require that all candidate standards conform to a single common reference model.

15. How should the development and diffusion of technically sound, fully informed interoperability standards and policies be established and managed for a NHIN, initially and on an ongoing basis, that effectively address privacy and security issues and fully comply with HIPAA? How can these standards be protected from proprietary bias so that no vendors or organizations have undue influence or advantage? Examples of such standards and policies include: secure connectivity, mobile authentication, patient identification management and information exchange.

- The NHIN authority should define requirements, identify most appropriate SDOs for each requirement and coordinate the development of the standards.

16. How could the efforts to develop and diffuse interoperability standards and policy relate to existing Standards Development Organizations (SDOs) to ensure maximum coordination and participation?

- The NHIN authority must create and maintain a master framework for required standards and work with SDOs to create compatible standards in their own areas of expertise.

- All interoperability standards should be developed on a single reference model.

17. What type of management and business rules could be required to promote and produce widespread adoption of interoperability standards and the diffusion of such standards into practice?

- Most standards are not specified sufficiently to enable interoperability without further specification.

- Most interoperability standards are not immediately compatible with other standards.

- The NHIN authority must establish appropriate bodies and procedures to address the compatibility and interoperability of chosen standards.

- The NHIN authority must coordinate the release of new versions of implemented standards over time.

18. What roles and relationships should the federal government take in relation to how interoperability standards and policies are developed, and what roles and relationships should it refrain from taking?

- The NHIN authority should define requirements, identify most appropriate SDOs for each requirement and coordinate the development of the standards.
- The NHIN authority must create and maintain a master framework for required standards and work with SDOs to create compatible standards in their own areas of expertise.
- All interoperability standards should be developed on a single reference model.
- The NHIN authority must ensure that standards implementations are sufficiently flexible and voluntary.
- Requirements that favor specific vendors or products should be avoided whenever possible.

Financial and/or Regulatory Incentives and Legal Considerations

19. Are financial incentives required to drive the development of a marketplace for interoperable health information, so that relevant private industry companies will participate in the development of a broadly available, open and interoperable NHIN? If so, what types of incentives could gain the maximum benefit for the least investment? What restrictions or limitation should these incentives carry to ensure that the public interest is advanced?

General

- Authorize the creation of revolving loan programs, grant programs and refundable tax credits for physicians and other health care providers to acquire interoperable health data systems that can accommodate EHRs, electronic prescribing and clinical decision support tools.
- Build into the Medicare physician payment system an add-on code for E/M services to identify that a service was facilitated by electronic health data systems, such as EHRs, electronic prescribing and clinical decision support tools.
- Reimburse telephone and electronic consults (communication between patient/physician or other health care provider) when a distinctly identifiable medical service is provided.

Stabilizing Payments

- Replace the sustainable growth rate (SGR) with an update formula based on increases in the costs of providing services. It will not be possible for physicians to make the investment in HIT to support quality improvement if their Medicare payments are reduced by 4 or 5% per year for the remainder of the decade.

- Urge the Centers for Medicare and Medicaid Services (CMS) to eliminate physician-administered drugs from the SGR, retroactive to 1998. This change will eliminate much of the accumulated "cliff" in Medicare physician payments and substantially reduce the costs of a legislative fix.

Expanding Demonstration Projects on Performance Improvement/Creating Financial Incentives for Use of HIT

- Recommend that Congress expand the limited authority and funding given to CMS to institute performance improvement demonstration projects under Section 649 of the Medicare Modernization Act. The Section 649 program provides financial incentives to several hundred primary care physicians in four states who agree to acquire HIT to support quality improvement and have their performance evaluated on evidence-based clinical performance measures. ACP believes that Congress should expand upon this program by making it available in a substantially larger number of states, opening it up to a larger number of practices in each state and providing dedicated funding to reimburse physicians for participating in the demonstration programs without being subjected to Medicare's budget neutrality requirements.

- Recommend that Congress direct CMS to allow for separate payment of e-mail and telephone consultations with patients subject to guidelines on appropriateness. Such separate payments should not result in a reduction in the amount that Medicare currently pays for the office visit because these services usually substitute for a visit.

- Recommend that CMS authorize a separate add-on payment to the Medicare office visit payment when the visit is supported by an EHR that meets certain standards as defined by the Secretary of Health and Human Services. Because HIT is expected to produce annual savings in the range of $30 billion or more per year, ACP believes that the office visit add-on payments should not be subject to budget neutrality limits.

Coordinating Care of Patients with Chronic Disease

- Recommend that Congress authorize CMS to give physicians the option of receiving a management fee for coordinating the care of patients with chronic disease. Physicians who agree to incorporate the Chronic Care Improvement model developed by Edward Wagner, MD, FACP, would be eligible to receive the care coordination fee plus performance based bonus payments. (The use of HIT to improve care of patients is a key feature of the Wagner Chronic Care Improvement model).

- Examine ways to allow physicians to share in system-wide savings that fall outside the Medicare Part B program. Under current Medicare payment policies, physicians are not permitted to share in the savings associated with reduced hospitalizations, drugs, tests or medical devices associated with better management of patients with chronic disease.

- Examine the concept of including a severity-of-care adjustment factor for care of patients with multiple chronic conditions that would be incorporated into Medicare payments for office visits and other evaluation and management services.

20. What kind of incentives should be available to regional stakeholders (e.g., health care providers, physicians, employers that purchase health insurance, payers) to use a health information exchange architecture based on a NHIN?

- It is crucial that involvement of practicing clinicians in the work of these authorities and use of the network be significant and ongoing. Funding may be required to ensure sufficient clinician involvement to participate in network governance organizations and to be able to obtain an EHR, participate in available networks and sustain participation.

21. Are there statutory or regulatory requirements or prohibitions that might be perceived as barriers to the formation and operation of a NHIN, or to support it with critical functions?

- Referral regions may cross state lines with conflicting laws.
- Barriers exist to electronic information exchange, such as Stark and DEA regulations
- There is a lack of regulation governing the liability for stewardship and use of clinical information.

22. How could proposed organizational mechanisms or approaches address statutory and regulatory requirements (e.g., data privacy and security, antitrust constraints and tax issues)?

- The present legal and regulatory barriers are sufficient to severely hamper the chances for the success of the NHIN. Also, new laws and regulations will be required as needs are identified.

- While it is probably outside of the scope of the NHIN authority to make the necessary changes, it is the responsibility of the authority to address these requirements successfully with appropriate external bodies.

Other

23. Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.

- The overall model should include both central repository models for smaller local/rural networks and distributed models for information sharing between regional networks and within larger urban networks.

- Governance should require major participation by physicians.

- Physicians and patient representatives should have major control over how patient data are collected and shared within and between networks.

- Financial models must address the need for financing to get the networks started and to sustain network use.

24. How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?

- Decreased costs for patient care
- Decreased medical errors due to insufficient or inaccurate patient information
- Decreased utilization of medical services