May **XX**, 2006

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

The American Health Information Community (AHIC) identified and prioritized several "breakthroughs", health information technology applications that could produce a specific tangible value to healthcare consumers. The Electronic Health Record (EHR) Workgroup was therefore charged as follows:

> **Broad Charge for the Workgroup:** Make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.
>
> **Specific Charge for the Workgroup:** Make recommendations to the Community so that within one year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties.

The Workgroup's deliberations highlighted a number of key issues with respect to the specific charge:

1. Necessary steps in the migration from a provider focused system to a patient focused system with respect to the flow of laboratory information.
2. Urgent need for endorsed, adopted and interoperable vocabulary, messaging and implementation standards for laboratory results and data exchange.
3. Clinical Laboratory Improvement Amendments of 1988 (CLIA) and HIPAA regulations which present potential barriers to electronic laboratory results data exchange in a patient-centric manner, particularly in more stringent states.
4. Technical considerations relating to privacy and security with respect to patient and provider authorization and authentication, including accurate patient identification and linkage to patient specific information.
5. Aligned business cases for the multiple stakeholders involved.
6. Assessment, monitoring and research of early adopters' experiences and identification of best practices.

This letter provides both context and recommendations for how these issues can be addressed to enable widespread access to historical lab data in a patient centric fashion.

BACKGROUND AND DISCUSSION

Widespread EHR Adoption and Availability of Historical Laboratory Results

In his January 2004 State of the Union Address, President George W. Bush highlighted the importance of information technology in health care when he stated, "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care." In April 2004, the President issued Executive Order 13335 calling for widespread adoption of interoperable EHRs within 10 years, and established the position of National Coordinator for Health Information Technology.

Effective use of EHRs has the potential to positively influence both the quality and cost of health care for the Nation. The EHR can improve quality by presenting clinical information and comprehensive patient data to the clinician at the point of care. This facilitates more informed decisions in a shorter time frame. Additionally, the cost of care can be decreased by streamlining data collection, decreasing the likelihood and associated cost of medical errors and by reducing resources used for duplicative or unnecessary information capture and testing.

Despite these benefits, the Nation has been slow to adopt EHRs as highlighted in the recent work of the Health IT Adoption Initiative. This group evaluated both the quality and the results of all EHR adoptions surveys and found that overall physician adoption was approximately 17 percent[2].

A recent AHRQ sponsored report that reviewed 286 studies focused on HIT adoption identified a large number of barriers to the implementation of HIT. These barriers were classified as:

- Situational barriers: including the high cost of purchasing and implementing EHRs as well as developing the necessary interfaces between EHRs and other Health Information Technology (HIT) systems on a custom basis.
- Cognitive and/or physical barriers: including users' physical disabilities and insufficient computer skills
- Liability barriers (including confidentiality concerns)
- Knowledge and attitudinal barriers[1]

Another short term barrier is the lack of comprehensive electronic data on any one individual. Laboratory results have the unique feature of currently existing in electronic format, though they are generally transmitted to physician offices by fax. Since these results are a component in 70% of clinical decisions, timely and easy access to comprehensive laboratory information is of high value to clinicians.

The ability to easily access this information through an electronic health record at the point of care would greatly enhance the value of the EHR to the clinician. Unfortunately, the current environment precludes this type of easy access to comprehensive information: most labs will only provide results to the ordering clinician; while results exist in electronic format, they cannot be transmitted directly to an electronic health record without customized and expensive interfacing; many states prohibit labs from providing results to any one other than the ordering clinician; and there are no clear technological solutions for how patients determine the degree to which their

laboratory information can be made available to multiple providers. Addressing these barriers would realize significant value to the purchasers and users of electronic health records and, therefore, increase adoption.

KEY RECOMMENDATIONS:

I. Laboratory Results: Provider and Patient Centric models

The ultimate goal is to make laboratory data available in a "patient-centric model" where a patient's laboratory results data are available to all authorized providers of care regardless of where or when the information was generated. This would enable patients to benefit from more coordinated and complete health care delivery, as well as reduce the cost associated with duplicate and unnecessary tests. Thus, the "patient-centric model" extends availability of information beyond the existing business environment where laboratory data results are available in a "provider-centric model" (i.e. only the laboratory data ordered by a specific provider for a specific patient are available for review). The work group recognizes that an evolutionary path from the "provider-centric model" to the "patient-centric model" requires the adoption and use of data standards which allow more efficient flow of information. This will enable the suppliers and users of electronic laboratory results data to use standards which promote interoperability and lower costs of specialized interfaces to meet the needs of the current environment while adopting the tools and technologies to support the "patient-centric model" as they are developed and implemented. A "patient-centric" model will also require addressing both technical and legal privacy and security issues.

> ***Recommendation 1.0*** **HHS should take immediate steps to facilitate the adoption and use of endorsed standards and incentives needed for interoperability of lab results within the current provider-centric environment. ONC shall work with multiple stakeholders to develop a detailed work plan to achieve patient-centric information flow of laboratory data in 2007.**

II. Laboratory Results: Standards

Systems must be able to receive electronic lab test results when requested by patient or authorized healthcare providers. The lack of easily implemented, usable standards is a primary barrier to this flow of critical information.

By incorporating HITSP endorsed standards and implementation guides into its certification process for EHRs, CCHIT certification can reduce the cost of laboratory interface development, which is a significant barrier to EHR adoption. Laboratory-to-practice connectivity has been an elusive goal that has prevented leveraging the benefits of HIT interoperability in the small practice setting and has frustrated clinicians and vendors seeking to implement EHR systems. Much has been blamed on the high cost of custom interfaces that are estimated at $30,000 to $50,000 per laboratory and $20,000 per interface in a group practice office[3].

Once HITSP has endorsed standards for laboratory result vocabulary, messaging, and implementation, Federal health care delivery systems should begin adopting these standards in a reasonable timeframe. Doing so will drive further adoption within the private sector. Additionally, federal agencies should positively incentivize adoption of HITSP-endorsed standards and implementation guides in contracts for health care.

> ***Recommendation 2.0*** **HITSP should identify and endorse vocabulary, messaging and implementation standards for reporting the most commonly used laboratory test results by September of 2006 so as to be included in the CCHIT interoperability criteria for March 2007 certification. HITSP must consider CLIA and HIPAA regulatory requirements as appropriate.**
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> ***Recommendation 2.1*** **Federal delivery systems should develop a plan to adopt the HITSP endorsed standards for laboratory data interoperability by December 2006.**
>
> ***Recommendation 2.2*** **Federal Agencies and Departments with health lines of business should include the use of HITSP approved standards in their contracting vehicles where applicable.**

III. Laboratory Results: CLIA/ HIPAA Options

The HIPAA Privacy Rule generally permits the disclosure of protected health information (PHI) by covered entities to health oversight agencies, to other healthcare providers, and to other covered entities and their business associates, for purposes of disease management and chronic care improvement. However, the HIPAA Privacy Rule does not pre-empt more stringent federal or state laws governing the release of such information. Regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) require that clinical laboratories disclose test results only to "authorized persons" (individuals authorized under State law to order tests or receive test results, or both), and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test, e.g. reference laboratories. Many states require that clinical laboratories disclose test results only to the ordering physician or his designee.

In order for electronic historical laboratory results to be available in a patient-centric fashion to authorized providers of care, various architectural models (web portals, RHIOs, etc.) must be evaluated with respect to CLIA and HIPAA.

> ***Recommendation: 3.0*** **ONC should review the possible models for the exchange of historical lab information and determine which would require CLIA/ HIPAA guidance, regulatory change, or statute change.**
>
> ***Recommendation 3.1*** **ONC should engage the National Governors Association and other state based organizations to resolve variations in "authorized**

persons" under various state clinical laboratory laws, as a resource for clinical laboratories seeking to define access rights to electronic laboratory data.

IV. Laboratory Results: Privacy and Security

Health information can only be accessed with adequate security and privacy if there are clear standards and means for the following:

- Accurate ***identification*** of patients, particularly in a digital environment, is essential for treatment, safety and payment accuracy, and to assure that PHI is not misdirected to misidentified individuals. While the most accurate identification can be achieved through use of unique patient identification numbers, cultural and political considerations make such an approach infeasible, at least in the near future. That being the case, other technologies, policies and procedures must be developed or identified and implemented to assure the lowest possible patient identification error. An alternative to creating unique personal identification for everyone is to define a national standard set of authenticating information required to receive healthcare. Unambiguously identifying patients and linking their information from multiple sources is a major challenge both within and across clinical enterprises. Unless caregivers are able to access linked information on a given patient across the continuum of care, proper and cost-effective care cannot be rendered. Similarly, the ability to link patient data in a secure fashion is critical to the anonymized use of information for national research, public health surveillance, and bio-preparedness.
- For health care to realize the greatest benefit from digitization, clinicians and patients must be able to ***authenticate*** that each person using an EHR is who they say they are. An environment on trust based on secure authentication allows for buy in from providers, patients and other healthcare entities.
- The existence of contradictions within the patchwork of state privacy laws also inhibits ***authorized*** individuals from connecting healthcare information. HIPAA set a minimum national privacy standard but many states have augmented those standards. The resulting cacophony of state laws is fundamentally inconsistent: what is mandated in one state is prohibited in another.

Recommendation 4.0 **A consumer empowerment subgroup comprised of privacy and security members, and members of all AHIC Breakthrough workgroups should develop a consistent set of recommendations on patient identification, authentication and authorization.**

V. Laboratory Results: Advancing Adoption

As the healthcare industry travels this evolutionary path of adoption from provider-centric to patient-centric historical laboratory data exchange, it is imperative that the unique needs and impact on all stakeholders is carefully considered. Although much

discussion has taken place regarding the potential benefits, costs savings, cost shifting and increased costs of interoperable lab results data, a full examination and development of the business case, including identification of incentives for all stakeholders, is required.

> ***Recommendation 5.0:*** **ONC should assess and develop the business case for historical laboratory results data sharing across all adoption models, considering the unique needs and alignment of incentives for all stakeholders**.

VI. Laboratory Results: Assessment, Monitoring & Research

The provision of patient-centric laboratory data resources has the potential to improve the quality and efficiency of patient care. However, it is necessary to prove that these benefits are actually being achieved in practice. It is important also to consider that implementations may vary in their effectiveness and that best practices need to be identified and disseminated as early as possible.

> ***Recommendation 6.0*** **AHRQ should develop a proposed study methodology to measure the extent and effectiveness of the adoption of the first stage of HITSP standards, as well as the adoption and utilization of aggregated patient-centric data as it becomes available.**
>
> *Recommendation 6.1* **AHRQ should research best practices in the implementation and utilization of patient-centric laboratory data stores and how to disseminate this knowledge.**

Sincerely yours,
/s/
XXXX
Co-Chair XXX AHIC Workgroup

Sincerely yours,
/s/
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Co-Chair XXX AHIC Workgroup

References:

[1]*Shekelle PG, Morton SC, Keeler EB. Costs and Benefits of Health Information Technology, Evidence Report/Technology Assessment No. 132 (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-02-0003.) AHRQ Publication No. 06-E006. Rockville, MD: Agency for Healthcare Research and Quality. April 2006*

[2]*HIT Adoption Initiative. Report to the Office of the National Coordinator: An Environmental Scan of the Current State of EHR Adoption Measurement in the United States. The George Washington University School of Public Health and Health Services The Institute for Health Policy at MGH/Partners HealthCare System Division of Internal Medicine at the Brigham & Women's Hospital Clinical and Quality Analysis Group of Partners HealthCare System*

[3] *Jan Walker, Eric Pan, Douglas Johnston, Julia Adler-Milstein, David W. Bates, and Blackford Middleton. The Value Of Health Care Information Exchange And Interoperability. Health Affairs Web Exclusive, January 19, 2005*