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 and uses that could produce a specific tangible value to healthcare consumers. The adoption of Electronic Health Records (EHRs) was recommended as a top priority for the work of the Community. Therefore, an AHIC EHR Workgroup was formed to analyze barriers and formulate a plan to increase EHR adoption within the delivery system, while initially focusing on one specific area of value to practicing clinicians.

The charges for the AHIC EHR Workgroup were therefore both broad and specific to something which could be achieved in the near term.

> **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.
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> **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. The need to migrate from a provider-focused system to a patient-focused system with respect to the flow of laboratory information.
2. The 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 States with more stringent interpretations of these regulations.
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. 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

### Status of the Broad Charge: Widespread EHR Adoption

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.

"The ability of Electronic Health Records (EHRs) to improve the quality of care in ambulatory care settings was demonstrated in a small series of studies conducted at four sites (three U.S. medical centers and one in the Netherlands). The studies demonstrated improvements in provider performance when clinical information management and decision support tools were made available within an EHR system, particularly when the EHRs had the capacity to store data with high fidelity, to make those data readily accessible, and to help translate them into context specific information that can empower providers in their work."[1] Despite these benefits, the Nation has been slow to adopt EHRs as highlighted in the recent report of the HIT Adoption Initiative. This group evaluated the results all EHR adoption surveys, including those judged to be low or indeterminate quality, which showed that EHR adoption is likely to be between 15% and 27% and probably closer to 15% of all outpatient physicians[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[1]. They classified the barriers 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

Cutting across all of these categories, however, may be the need for a major structural and ideological reorganization of clinical medicine as it is now practiced in the majority of settings to be able to integrate itself with and enjoy the benefits of HIT.[1]

**Status of the Specific Charge: Why Lab?**

***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; 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 increase adoption.***

**AHIC EHR WORK GROUP RECOMMENDATIONS:**

**I. Laboratory Results: Central focus**

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 test. However many significant barriers to the "patient-centric model" will need to be overcome, including the development of interoperability standards as well as addressing state laws governing the release of laboratory data among others. Thus, the "patient-centric model" contrasts with 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" will need to be developed. 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 current needs of the current environment while adopting the tools and technologies to support the "patient-centric model" as they are developed and implemented.

> ***Recommendation 1.0*** The ultimate goal, "pure vision" is patient-centered electronic laboratory results, with a recognition that there is an evolutionary path from current

business practices toward that goal. ONC, in addressing the specific charge to the EHR/Lab workgroup, shall ensure that electronic laboratory data is transmissible in a patient-centric environment, permitting all laboratory results on a specific patient to be available to all authorized providers of care.

## II. Laboratory Results: Standards

Systems must be able to receive lab test results when requested by patient or authorized healthcare providers. We need standards that have been refined to work together efficiently to create a single coordinated, comprehensive and non-overlapping set. The lack of easily implemented, usable standards is the primary barrier to creating this system, but fortunately, this is a barrier that can be overcome with focused attention and action. By incorporating HITSP endorsed standards and implementation guides into its certification process for EHRs, CCHIT certification will 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 electronic health record (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].

After recommendation from HITSP, assuming that the standards are feasible, open and not proprietary, the process is fully participatory, and the end result is acceptable to the laboratory industry, Federal health care delivery systems should begin adopting these standards in a reasonable timeframe. Doing so will drive further adoption within the private sector. Federal healthcare systems 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 certification.

***Recommendation 2.1*** ONC, in addressing the role of standards to facilitate the exchange of electronic laboratory data, should recognize and actively promote adoption of those standards endorsed by HITSP as the basis for vocabulary, messaging, and implementation guidance for electronic transmission of laboratory test results.

***Recommendation 2.2*** In carrying out their work, HITSP must consider CLIA and HIPAA regulatory requirements**.**

## 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. Most states require that clinical laboratories disclose test results only to the ordering physician or his designee. If a state law does not define the term, CLIA defines "authorized person" as the person who orders the test. As a result, despite generally permissive provisions in the HIPAA Privacy Rule, most state laws prohibit clinical laboratories from disclosing test results to anyone other than the ordering physician or his designee.

As a practical matter, it is extremely difficult for clinical laboratories or entities conducting disease management or chronic care improvement initiatives to obtain from ordering physicians authorizations for laboratories to release thousands of test results to these entities. Disease management and chronic care improvement activities that could be taking place based on test result information is being hampered. In lieu of pre-emption of state laws, CLIA implementations must be consistent with both state and federal regulations.

> ***Recommendation: 3.0*** ONC, in addressing the specific charge to the EHR/Lab Workgroup, shall seek to address barriers to the flow of laboratory result information from laboratories to persons or entities other than the clinician ordering the test, when access to laboratory results is needed by such persons or entities for legitimate purposes such as disease management or chronic care improvement. Specifically, ONC should seek to resolve those hurdles currently created by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), HIPAA, and State laws.
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> ***Recommendation 3.1*** ONC should work with 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.
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> ***Recommendation 3.2*** CMS should publish CLIA guidance that clarifies the broad definition of authorized parties**.**

## IV. Laboratory Results: Privacy and Security

Health information can only be accessed with adequate security and privacy if there are clear means for verifying the identities of those accessing and altering data. The lack of defined standards for security and the lack of an accepted hierarchy of trusted authentication agents impede the development of the NHIN and associated cost-effective data communication systems. 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.

For health care to realize the greatest benefit from digitization, clinicians and patients must be able to trust that each person using an EHR is who they say they are. 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 an anonymous and secure fashion is critical to the national research enterprise, public health surveillance, and bio-preparedness.

The existence of contradictions within the patchwork of state privacy laws also prevents the nation 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*** ONC shall support the development of a national authorization & authentication infrastructure for both patients and HIT systems users. At a minimum, this system should allow patients to opt in or out of data sharing and to designate a surrogate who could authorize access to their data.
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> ***Recommendation 4.1*** The work group has noted that legal constraints in HIPAA and State laws specify that labs can release data on patients only to the provider who has ordered the test. To address these constraints, the work group recommends that ONC review State and Federal laws so that polices can be developed to make them more consistent and compatible with sharing laboratory data in a patient-centric manner.
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> ***Recommendation 4.2*****:** ONC should include in its contract with HITSP incentives to develop or endorse a methodology to match an individual patient to his or her information across multiple systems.

## V. Laboratory Results: Assessment, Monitoring & Research

The provision of a patient–centric laboratory data resource 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 5.0*** 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.
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> ***Recommendation 5. 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/
XXXX
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*