

**Health Information Technology Policy Committee:
Information Exchange Workgroup
Summary of the Web Conference October 20, 2009**

PARTICIPANTS

Simon Charles, representing Judith Faulkner, Epic Systems Corp.
Connie Delaney, University of Minnesota, School of Nursing
Gayle Harrell, Former Florida State Legislator
Charles Kennedy, WellPoint, Inc.
Frank Nemec, Gastroenterology Associates, Inc.
Michael Klag, Johns Hopkins University, Bloomberg School of Public Health
Deven McGraw, Center for Democracy & Technology
Latanya Sweeney, Carnegie Mellon University
Martin Laventure, Minnesota Health
David Goetz, Tennessee
Micky Tripathy, Massachusetts
Jonah Frohlich, California
Steven Stack, MD, American Medical Association
Jodi Daniel, ONC
Kelly Cronin, ONC
Judy Sparrow, ONC

KEY TOPICS

1. Opening

The Information Exchange Workgroup convened a hearing on the exchange of laboratory data. Invited panelists made presentations. Judy Sparrow, ONC, called the roll. Deven McGraw, Chair, Information Exchange Workgroup, welcomed the participants. She reviewed the charge of the Workgroup and the Policy Committee, saying that the Committee's charge is to recommend policy and technical requirements to support Health Information Exchange (HIE) as "both a verb and a noun." In August, the Workgroup submitted recommendations on the meaningful use of HIE, including both transport and context. The Workgroup did not want to chill innovation and realized that business and legal issues are as important to HIE as are the technical issues. Today's hearing, according to the Chair, is the initial effort to obtain information on the business and legal challenges to HIE. Later, the Workgroup will examine issues around e-prescribing.

Micky Tripathi, Co-Chair, repeated the welcome and pointed out the importance of exchanging lab test results and e-prescriptions in order to move to the next level of information exchange. He said that the face-to-face hearing was an important opportunity to hear from different categories of providers of lab and EHR services.

Background

Kelly Cronin, Office of the National Coordinator for Health Information Technology (ONC), used a PowerPoint presentation to explain the importance of the exchange of lab data to patient

outcomes. She described current practices and listed the major barriers and challenges to the exchange of lab data. She summarized HHS efforts to promote HIE such as the following:

- ASPE, AHRQ, and ONC Studies
- AHIC Workgroup Recommendations
- AHIC –ONC Use Cases
- HITSP, and CCHIT Work
- NHIN Trial Implementations

She concluded by saying that she expected the panel presentations to help in defining the roles of the Federal and state governments.

Angela Brice-Smith, Centers for Medicare & Medicaid Services (CMS) spoke about four aspects of the Clinical Laboratory Improvement Amendments (CLIA). First, CLIA was enacted in 1988 to improve accuracy of lab testing results. It provided for waived testing and today 62% of labs in the United States are waived. CLIA specifies that test results are to be submitted to the authorized person for treatment purposes. But it does not prohibit reporting to a second person at the same time. Second, she described the infrastructure for CLIA enforcement. Enforcement is based on the statute and its regulations; the state operations manual, which consists of interpretative guidances to be used in inspections; survey and certification memoranda; and agreements with the states around the performance of inspections. Enforcement is carried out by Federal central and regional offices and state personnel. Third, she spoke about the challenges concerning CLIA's relationship to EHR and HIE. She explained that CMS staff was thinking about these challenges and today's meeting was an opportunity to obtain ideas about the definition of authorized persons to order tests and receive results. State laws vary greatly in what is permitted. Also, physician offices vary greatly in their IT capacity. Even in medical centers, there is not necessarily communication across all lab operations. Finally, she noted that CMS does not view CLIA as a barrier to exchange. Clinicians would need to provide their electronic exchange addresses in order for simultaneous exchange to the authorized persons and the information exchange. Labs' responsibilities do not change when exchange occurs. She said that CLIA's authority ends when the lab test results are received by the authorized persons. According to Brice-Smith, "simultaneously" is the key concept to exchange.

Q and A

Brice-Smith reiterated that CMS does not see CLIA as a "significant" barrier. Pending approval of legal counsel, guidances can be used to revise what is currently permitted. CMS staff members were asked to remain for the remainder of the presentations in order both to hear the testimonies, many of which were expected to state that CLIA *is* a significant barrier, and to answer questions. In response to a question about the extent to which EHR certification would protect the labs, she said the staff would need to examine that issue.

She acknowledged that CMS was aware of the considerable variation across states in CLIA enforcement. CMS has tried to address the lack of consistency by issuing guidances, clarifying information, and training surveyors. The goal is to standardize enforcement. When consistency is identified as an issue, CMS attempts to identify the cause and to issue new policy statements. When complaints are received, CMS staff reviews the enforcement data to determine if the inconsistency is due to state law or surveyor error. Surveyors are required to address all

components of the regulations and guidances. Their job is more difficult when paper records are not available. There are now issues of how to select a sample from electronic records. 53% of waived tests are done in physician offices; not all have current IT. And the number and proportion of waived tests has increased greatly over time. Even in hospitals, not all waived tests are captured in the EHR, for example, tests conducted by nurses on the floor. It is difficult to predict how long it will take to convert to EHR.

Regarding what changes can be made by guidance versus regulation, she said that because it can take up to 3 years, CMS tries to avoid changes in regulations. When legal counsel issues an opinion that a proposed interpretative guideline is not inconsistent with the regulations, a new guidance is issued. If newly proposed standards were not in conflict with CLIA, a guidance could be issued. As to whether CLIA has authority to impose standards of nomenclature, she said that would depend upon the specifics of the definitional change.

CLIA staff has had many discussions about the privacy and security of data, in particular about who is responsible after the lab results are delivered and enter the public realm. One member asked if ONC certified EHR and set up a certification standard for lab transmission into EHR, and if CMS staff were satisfied that in fact that transmission standard could be met, could decisions about implementation and enforcement then be delegated to the states under the statute. The answer indicated that CMS looks at state law to determine if it is more stringent in its protection of privacy and confidentiality than is Federal law. To usurp state law would likely require regulatory change.

Although one member commented that CLIA seems provider- rather than patient centric insofar as the provider can determine who is to receive the test results, Brice-Smith pointed out that CLIA was enacted to increase accuracy of reporting, about which patients were voicing concerns. CMS is a payor. Therefore, labs have an incentive to comply. She said that under CLIA patients can receive reports and can specify additional persons, such as other providers, to receive the reports simultaneously.

Another CMS staff person stated that after the hearing, CMS will examine what needs to be done and will look at the statutory and regulatory authority to determine what CMS can address in interpretative guidances. ONC or other offices in HHS may be able to act where CMS does not have the authority.

Part I: Business Issues related to the Electronic Exchange of Laboratory Data

Mike Nolte, GE Health Systems, submitted written responses to the Workgroup's questions and a written statement. He began by pointing out the exchange of lab test results is a key element in the improvement of patient safety and care; the absence of standards is a major impediment to that improvement. He made the following suggestions:

- A standard mechanism for exchanging lab information should be implemented and certified both for laboratories and EHR to ensure accurate and efficient mechanisms for getting the right patient results to the right provider.
- GE supports the standards specified by the ANSI/HITSP Capability 126 and recommended by the HIT Standards Committee which were recognized by HHS in

January 2008 and the ongoing work of ANSI/HITSP to meet the laboratory orders extensions request given to it by ONC.

- Leveraging infrastructures such as standards-based HIE and other standards-based information exchange technologies can eliminate the extensive point-to-point lab to EHR communications infrastructures that currently exist. Secure, centralized mechanisms for transporting data, can eliminate the burdensome high costs associated with maintaining many individual connections.
- HIT policy and regulatory decisions must be as simple and clear as possible and issued with considerable advance notice in order to create a predictable path for providers and vendors.

Vasu Manjrekar, eClinicalWorks, submitted a written statement but did not respond in writing to the Workgroup's questions. He began by describing eClinicalWorks diverse client base and explained that most practices that go live with the EHR also request electronic lab interface with at least one lab company. Establishing a functional electronic lab interface presents many challenges. Implementing, testing, and validating a lab interface for a practice with national reference lab companies takes from 4-14 weeks. Before starting any lab interface implementation, a practice has to go through an interface approval process with the lab company. This approval is a business decision. CLIA regulations are interpreted by labs to mean that they are responsible for verification of the format of the electronic results viewed by the clinician within the EHR, requiring them to test and validate each individual interface for a practice. This is a manual, redundant, and time consuming process which often results in significant delays. Since nomenclature varies across labs, the practice staff must manually map the compendiums for all labs with which it does business. These and other barriers are increasing the backlog as providers implement EHR. Manjrekar was not allowed to finish his statement due to time constraints.

Phil Marshall, WebMD, submitted written responses to questions. He also submitted a copy of a Consensus Letter to the Office of Civil Rights and the Centers for Medicare and Medicaid Services on the Need for Expanding the Rights of Individuals to Access their Test Results (dated October 20, 2009), which his organization and many industry leaders and other important people had signed. To date, more than 100 signatures have been obtained. The letter outlines the way in which in combination the HIPAA Privacy Rule, the CMS rule 42 C.F.R. § 493.1291, and state laws have put test results in a uniquely restricted category compared to other protected health information and has restricted patients' access to their health information. The letter goes on to describe the rationale for and potential effects of the following recommendations.

- Remove subsection (a)(iii)(A) from 45 C.F.R. § 164.524 and eliminate the disparate treatment of lab test results compared to other protected health information under HIPAA.
- Change 42 C.F.R. 493.1291(f) to the following: "Test results must be released only to (a) authorized persons, (b) if applicable, the individual responsible for using the test results and the laboratory that initially requested the test, and (c) upon request, the test subject." This change clarifies that individuals can receive their results upon request.

Tim Ryan, Quest Diagnostics, provided both a written statement and written responses to questions. He said that he was representing the American Clinical Laboratory Association

(ACLA). He spoke about the financial burden imposed by EHR vendors' and HIEs' expectations that labs should pay for the EHR interface license fees and the cost of implementation of each installation. He went on to describe the effects of CLIA's requirement that laboratories perform validation of each EHR lab interface. He concluded with recommendations summarized as follows:

- Make bi-directional standardized lab interfaces part of the national certification criteria for EHR systems, including functionality pertinent to all the lab order data needed for proper testing, patient matching, and billing.
- Either amend the CLIA regulations or clarify them through the CLIA Interpretative Guidelines that the laboratories are responsible only for ensuring that the data transmitted to the initial receiving EHR or HIE is accurate and contains all of the required CLIA information.
- Require EHR vendors and HIEs to adhere to a standard test compendium framework and format, which is fully integrated into the EHR system.
- Clarify the CLIA regulations to enable the performing laboratory to certify a vendor's laboratory interface by version and not for each individual practitioner installation.

Susan Neill, Texas Department of State Health Services, submitted responses to the Workgroup's questions in writing. She said that she was representing the Association of Public Health Laboratories (APHL) and would not repeat points made by the previous speakers. She described efforts by public health labs to improve their capacity for the electronic exchange of data. For the past 4 years, several state public health labs have been involved in the Public Health Laboratory Interoperability Project (PHLIP) designed to implement data standards and electronic messaging systems. The purpose is to establish electronic exchange of test orders and results for surveillance and disease control. She emphasized that from the surveillance perspective the ability to monitor test orders is as important as exchanging information on test results. A change in the volume of orders is considered an indicator of a change in health conditions or of a possible outbreak. A major public health surveillance concern is the vast disparity in the capability for electronic messaging across the country. This disparity characterizes not only state and local public health departments, but also doctors' offices, clinics and hospitals. Some state labs have state-of-the-art technology and highly qualified staff; others function at a very rudimentary level. Even some Federal labs can only report by mail or fax.

Q and A

In response to a question about the redundant of data, the representative from eClinicalWorks explained how work flow varies across practices; for example, there are differences in physician preferences as to how lab results are delivered. Another questioner noted that the lab representatives said that the EHR vendors should be responsible for addressing this variation, but the EHR vendors say the labs should be responsible. One of the panelists responded that a comprehensive framework should be developed. A common vocabulary would mitigate some problems, but not all. Labs complain about the lack of consistency in patient identifiers. Also, ordering data may not be clear. Many versions of HL 7 are in use.

Another question focused on the CLIA requirement that the interface with the EHR be validated. A vendor representative said that his company works with practitioners on the display of results and compliance with guidelines.

A discussion ensued as to whether the lab or the EHR should be certified for the exchange. One panelist explained that both should follow the standards framework so that when the information gets loaded into the EHR system initially and for further updates, there is an easy technological solution. Currently, the majority of the EHR vendors and hospitals do not have the technology in place to be automatically loaded into the system. The manual process is onerous and time consuming. A common architecture would be helpful. Quest has different compendiums because over the years it has acquired firms with different compendiums. LOINC and SNOMED are not internally consistent because they have evolved over time. One solution would be to define and assign a code to new tests through the FDA approval process. The PHLIP engaged five public health labs in developing common code for influenzas. Doing so was very complex. According to a panelist with experience in California, providers, including hospitals, had a very limited capability to use LOINC. They required extensive technical assistance. If LOINC were required, incremental implementation should be considered.

One member asked how the industry could accept such extreme complexity. Panelists responded that many efforts were underway to reduce complexity. However, there is danger in oversimplification. For example, there are different interpretations as to what LOINC codes can be used for (results and orders codes). Several participants were skeptical that meaningful use criteria for 2011 could be achieved given the current state of affairs.

It was suggested that since an estimated 200 tests account for an estimated 95% of the lab volume, standardization could begin with these tests and be implemented incrementally. ACLA is reportedly working on creating a framework for this approach. One panelist suggested that ACLA's efforts could perhaps be facilitated by an independent body insofar as the labs are not always privy to technical innovations and knowledge of medical practice.

Matching issues can occur when orders arrive in electronic format. Sometimes the orders are incorrect. When providers use a format designed by labs, there are few matching errors. Variation in EHR creates problems. Variation in patients' names can be a problem. It was recommended that certification be based on the labs' format. Matching patient names is not only an issue for labs; the issue needs to be resolved at a higher level.

The 30-day requirement for patient's receipt of test results is unreasonable in an electronic environment; the period should be shortened. Release should be immediate. There is no need for this special treatment of lab results under the law. Panelists were not sure if simultaneously delivery to the patient or others would resolve this issue. There appears to be confusion as to how the law should be interpreted.

The United States has delayed in the adoption of standards. Therefore, a proliferation of vocabularies has occurred. Even the national labs exhibit this variation. The problem is becoming more serious due to the increasing complexity of tests. Since a few hundred tests make up the vast majority of the volume, there is a need to capture key elements of the process in all EHR. Although most of the panelists appeared to agree that standards for data and exchange were needed, one panelist continued to insist that a framework must first be developed.

Asked to describe what would happen if CMS required the 2011 criteria to be implemented by the first quarter of 2010, one panelist said that implementation of a results-only code would be very expensive. One panelist recommended that the Workgroups help by clarifying standardized coding. Some central body needs to be in charge of this function similar to how billing codes are managed by CMS.

Asked if standards should include interpretative data, such as the normal range, panelists reported that the concept of normal range varies by lab. Of course, normal range also varies per patient, which gets into clinical decision support. Ranges vary by specimen and testing methods. The development of a previously referenced “framework” would address such issues.

Part II: Business Issues related to the Electronic Exchange of Laboratory Data

Laura Rosas, New York City Primary Care Information Project (PCIP), submitted written responses to the Workgroup’s questions and a written statement. She described PCIP as overseeing the largest community EHR implementation in the nation. 1500 providers are using a prevention-oriented EHR, with another 2500 in the pipeline. PCIP partnered with eClinicalWorks to create a fully integrated EHR that supports preventive care, chronic disease management, and surveillance reporting to public health agencies. She reported that the lab interface was one of the greatest problems encountered in the project. Implementing, testing, and validating a lab interface for a PCIP practice takes 10-14 weeks. CLIA regulations reportedly are a significant problem in completing lab interfaces. After pointing out the specific sections of CLIA that impede electronic interfaces, she made the following suggestions for modifying the regulations to recognize hub-to-hub interfaces and allow for more streamlined approval of each new practice being added to the master interface.

- Hubs should be certified and validated by laboratories and EHR vendors working together to ensure appropriate accuracy, privacy and security and related standards and requirements.
- Once validated, these hubs should bear the responsibility and liability of the lab result transmission from the point of receipt at the hub to the provider’s EHR.
- Decreasing the regulatory constraint on the laboratory, and increasing oversight on the EHR vendor should encourage laboratories to implement interfaces even to practices that may not have a high volume of orders.

She concluded by asking the HIT Policy Committee and the CLIA Committee to:

- Require the implementation and use of LOINC codes in laboratory results
- Endorse a standardized coding system for laboratory orders
- Require routine provision of electronic compendium updates to health care providers, payors, and other stakeholders

Sarah Chouinard, Primary Care Systems, Inc. and Community Health Network of West Virginia, provided written responses to the questions. She did not provide written testimony. She said that as a provider of medical care with limited resources in a rural area, she wished to respond to the testimonies presented earlier in the day and to point out that the purpose of HIE was to improve patient care, not simply to digitize medical practice. She gave several examples of ways in which the use of EHR had improved her care of patients. For example, prior to the installation of EHR, it had not occurred to her to send reminders for mammograms. The EHR changed her quality

assurance protocols and helped to focus her efforts. She now views the patient in the context of population health. Her network of community health centers uses a version of the VA Vista as modified by the Indian Health Service for patient management. Use of the EHR helps to engage the patient in self management. She believes that the PHR is the best solution for sharing data across providers. She made four recommendations:

- Focus on standardization
- Continue to develop the master patient index
- Support the consensus letter presented by Phil Marshall, WebMD
- Track and record changes in lab codes, in part to protect from litigation

Raymond Scott, Axolotl Corporation, submitted written responses to the questions. He did not submit a copy of his testimony. He spoke from the perspective of an HIE vendor with 14 years experience and described the implications of separating the generation of lab results from presentation of results. Due to advancements in IT, there are now many ways of delivering and presenting lab test results. It makes sense to separate the responsibility for these two functions. Also, there are different problems regarding ordering tests and delivering results and he said that the delivery problems can be solved more easily. He recommended using LOINC for a consistent coding system. For the problem of correct physician identification, he recommended the use of the national provider identification system. Another issue is the timely delivery of a panel of tests, which require various times frames to complete. Batched delivery is not appropriate given the current IT.

Areg Boyamyan and Jim Timmons, Foundation Laboratory, submitted written responses to questions. Mr. Boyamyan described his company's experience in HIE among California correctional facilities. 170,000 patients are involved. The project was completed in 1 year and reportedly resulted in better care (no data were presented) and an estimated 11% reduction in costs. Repeat tests were reduced by 50% and paperwork by 80%. Telephone costs were a component of the reduction in costs. Training was a big issue; the lack of proper training contributed to errors and user dissatisfaction with the system. The main avenue, in his opinion, for broadening electronic exchange of lab data is to apply HL7 to the standardization of lab result transmissions. He concluded by saying that providing better incentives for doctors, clinics, and diagnostic testing facilities to adopt an electronic data exchange would improve the general architecture of the U.S. health care system as it pertains to patient care and cost of care.

Q and A

The cost of installing a lab interface can range from \$20,000 to \$100,000. Many small providers cannot justify such a cost. Bidirectional interfaces are more expensive. All costs should be made clear upfront. A Web-based system is one way to reduce the costs, but these systems do not integrate well with all functions of the EHR. Physicians may purchase EHR and then ask their hospitals to connect to the labs. An HIE hub may be another solution. In West Virginia, the FQHCs formed a network and purchased a license, which made the interface affordable. Doctors typically use several different labs because of the requirements of the payors. Therefore, a practice must have an interface with several labs and this increases the cost. Labs give priority to the practices that generate the most business. Eventually, this will push small labs and small providers out of business and contribute to concentration of ownership in the lab industry.

Several panelists were of the opinion that, under CLIA, test results could be delivered simultaneously to the HIE and the patient. Sometimes, however, it is preferable for the treating physician to review the test results prior to delivery to the patient.

Of the approximately 9000 LOINC codes, about 200 are useful to the ambulatory care physician. Therefore, focusing on the universal use of these codes would be a major step toward standardization. But the LOINC codes must be made to match with the methodology. It would be possible to convert all test codes to LOINC, but conversion is labor intensive and time consuming.

Regulatory and Policy Issues

Joy Pritts, Georgetown University Health Policy Institute, responded to the Workgroup's questions in writing. She reported on findings from an examination of state law on the release of lab data. The study, which has not yet been released, was commissioned by ONC. HIPAA permits providers to share health information with each other for treatment and operations purposes fairly broadly, but CLIA restricts some of that permitted exchange of information. CLIA says test results may be released only to authorized persons and the individual responsible for using the test results. The individual responsible for using the test is not defined in the statute or regulation, but other rules indicate that the phrase means the person who ordered the test.

The study examined the definition of authorized person under state law. Pritts presented a map to summarize her findings. 26 states are silent on the exchange of information. 16 states specify that test results be released only to the person who requested the test or the designee, or as directed by the person who authorized the test, practically meaning that permission must be obtained to share results across providers. She said that state medical practice laws regulate the release of lab data as well. Clinical lab licensure laws and medical records laws are also relevant. However, the latter often do not define "provider".

State law controls whether the patient may access her own health information directly from a clinical lab. Only six states are clear on patient access. Sometimes the law specifies a waiting period. In seven states, test results can only be released with the permission of the ordering provider.

Don Horton, LabCorp and ACLA, provided detailed written responses to the questions, his written testimony, and exhibits of the specific changes to CLIA recommended by his organizations. He began by saying that his testimony focused on two regulatory issues—"authorized persons" and "final report destination". Regarding the former, he said that ACLA has developed proposed amendments of both the CLIA statute and regulations that would expand the list of "authorized persons" to whom labs can send test results to include covered entities and business associates as defined in the HIPAA Privacy Rule. The proposal would operate as a targeted pre-emption of state authorized person laws; states would continue to be permitted to define "authorized person", so long as they do not exclude covered entities and business associates. The proposed changes would not permit disclosure of any type of test result when disclosure of that type of test is otherwise prohibited (e.g., HIV).

He continued by saying that EHR vendors often modify the test result report transmitted by a clinical laboratory to an ordering provider to customize the appearance of the report on the end user's computer screen. Although clinical laboratories have no control over such modifications, current CLIA regulations hold them responsible for ensuring that the required report elements reach the "final report destination" intact. The same applies to an HIE. In the current electronic health information exchange environment, "final report destination" has become a virtually meaningless term. The clinical laboratory's regulatory responsibility for presentation of the test results should end once the result is provided to the ordering provider's EHR, or to an intermediary contractually obligated to send the results to the intended destination.

Jonah Frohlich, California Health and Human Service Agency and member of the IE Workgroup, submitted a copy of his testimony. He did not respond in writing to the questions. He began by describing the fragmentation of the lab industry. Of the more than 200,000 certified clinical labs in the United States, half are physician office-based, yet they perform only 8% of all tests. Hospital-based labs and independent labs represent 4% and 3% of clinical labs respectively and combined perform more than 75% of tests. Approximately one-quarter of physicians use EHR, but many of them still receive lab results by fax. The data are then manually entered or scanned into the record. Small and hospital-based labs have very limited IT resources and expertise to support electronic lab ordering and results reporting. There is virtually no standardization of lab messaging in the industry today.

Frohlich related his experience working on ELINCS projects. The labs required a great amount of assistance to adopt the LOINC coding scheme. They were unprepared to adopt SNOMED or UCUM; the standard coding schemes for results and units of measures. The lab information systems the hospitals operated had internal "proprietary" codes for test names, and they had little expertise to map these codes to LOINC. He recommended the following:

- Under the Federal EHR certification process, require that EHR systems adopt and use national lab standards such as ELINCS, and display the lab results in a CLIA compliant way
- Under CLIA, require that labs verify whether or not the receiving EHR is Federally certified
- Under CLIA, require labs to send results using the same national standards that EHR vendors are certified against
- Under meaningful use, require meaningful use eligible hospitals that provide outreach lab services to comply with the above as one of their meaningful use criterion.

He concluded by pointing out that to reach the goal that at least 90% of physicians are meaningful users of EHR by 2015, physicians must have working lab interfaces. Under the current regulatory framework, the industry cannot support today's demand and is completely unprepared for this explosion of demand.

Walter Sujansky, Sujansky & Associates, submitted written responses to the questions. He did not provide a copy of his testimony. He reported that his company led the implementation of ELINCS in the outpatient setting and participates in HITBE. He agreed that with regard to the CLIA issue, laboratories have limited resources to verify that the electronic results are being displayed correctly. Therefore, they give priority to practices that provide them larger testing

volume with the result that small practices experience significant delays in installing interfaces. He said that the need for standardizing test results extends beyond the LOINC coding of the test. Interoperability is impeded by the absence of highly specific messaging standards. The HL7 standards allow variances that must be resolved with each new interface. He believes that if a highly constrained implementation guide were built into EHR and laboratory systems, the interface would be simplified. He went on to say it is not necessary to have a universal patient ID to correctly match patient results to patient records as the results are reported back to the EHR from which the order originated.

Q and A

Responding to one member's concern about the ACLA's recommendation to allow lab results to be sent to "any covered entity or business associate", the representative said that this change would give lab providers parity with other health care providers in the exchange of protected information.

Pritts' study did not examine variation in enforcement across states. However, the National Academy for State Health Policy is looking at enforcement in a subset of states. The states were selected to be representative of the categories identified by Pritts. Preliminary results suggest that enforcement varies. She found no indication that state laws affect the CLIA delivery requirements. Asked what could be done to simplify the requirements, Pritts said that in her opinion many of the changes in CLIA discussed by the panelists could be made under the rule-making authority of the secretary. Participants continued to discuss several of the differences in the recommendations put forward by the panelists.

A member inquired about the possibility of prioritizing the tests that reportedly make up 95% of lab volume.

Several panelists reiterated that it is not realistic to expect providers to meet the 2011 requirements for meaningful use in exchange of lab data given the current environment. Asked to identify the major barriers, one panelist referred to the requirement that labs visually verify the display on the receiving end. If the requirement were changed to accept verification via certification of acknowledgment of the transaction, a major barrier would be eliminated.

Several questions directed to Pritts focused on the possibility of changing HIPAA to eliminate the CLIA carve out. She explained that HIPAA preempts state law except where state law is more stringent. Panelists noted that since all states recognize the right of patients to obtain data from providers, it is not necessary for lab data to go directly from the lab to the patient. On the other hand, studies indicate providers may not always discuss these data with their patients, which is the ideal practice. One member indicated that the Workgroup may want to consider the relative importance of patients' direct receipt of their lab test results compared to providers' ability to interface with labs.

One panelist recommended hospitals with outreach lab services deliver lab results using the same Federal standards that EHR vendors are required to use and adopt as part of the certification process. It may be a burden to hospitals, but otherwise many small and rural providers without other options are left out, thereby weakening the safety net. Questions were asked about the cost

to hospitals. In California, the cost of each implementation of ELINCS was reportedly about \$15,000. It was pointed out that monies are available through ARRA.

Public Comment

Judy Sparrow, ONC, announced the opportunity for 2-minute public comments, to be heard via telephone or the Web.

Toni Mattoch, America's Blood Centers (ABC) urged the Workgroup to consider the needs of the blood centers, which are regulated under CLIA, either by accreditation or a state licensure program approved by CMS. The blood centers are a critical component of the health care system and play an important role in public health surveillance. They are affected by the lack of standards for the transfer of information from blood centers to hospitals. ABC obtained approval from the international HL7 organization to work on a blood center extension of that standard. He asked that the blood centers be included among those entities eligible for HIT funding. He said that he was submitting a written copy of his testimony.

Jason Dubois, ACLA, responded to points raised during the hearing. He described efforts on the part of the lab industry to standardize orders and test results. The lack of success led the ACLA to turn to the development of the framework, which was referenced earlier in the testimonies. A draft framework will be released for public comment by the end of the year.

Daniel Vreeman, Regenstrief Institute, referred to a paper he published on an analysis of past frequency volume. A relatively small number of tests make up a vast majority of total volume and frequency. The results of this study can be used as a practical step forward in standardization.

Tyle Shang, physician and lab director, Montefiore Medical Center, spoke about the need for a framework. She expressed hope that the Workgroup's recommendations lead to a clarification of the CLIA rule on verification and encourage the standards bodies to work on a testing cycle.

The meeting concluded with the Chair repeating the invitation for participants and observers to submit information and recommendations by October 31.

5. Next Steps

The Workgroup is scheduled to meet via Web conference November 3. A hearing on e-prescribing will be held November 20 from 9 am to 3 pm, preceded by a Workgroup meeting on November 19.

SUMMARY OF DECISIONS AND ACTION ITEMS:

None made