Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

April 13 – 14, 2016

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
April 13 - 14, 2016, Summary Report

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RECORD OF ATTENDANCE

(Roll call found Ms. Susan Sheridan and Dr. Qian-Yun Zhang absent both days of the meeting.)

Committee Members Present

Dr. Burton Wilcke, Jr., Chair
Dr. Ramy Arnaout
Dr. Sheldon Campbell
Dr. Monica de Baca
Dr. Gwendolyn Delaney
Dr. Keith Kaplan
Dr. Roger Klein
Dr. Elizabeth Marlowe
Ms. Helen Mills
Dr. Elizabeth Palavecino
Dr. Richard Press
Ms. Anita Roberson
Ms. Maureen Rushenberg
Dr. John Sinard
Dr. Hardeep Singh
Ms. Paula Vagnone
Mr. Andy Quintenz, AdvaMed (Liaison Representative)

Committee Members Absent

Ms. Susan Sheridan
Dr. Qian-Yun Zhang

Ex Officio Members

Ms. Karen Dyer, CMS
Dr. Alberto Gutierrez, FDA
Dr. Reynolds Salerno, CDC

Designated Federal Official

Dr. William (Bill) Mac Kenzie, CDC

Executive Secretary

Ms. Nancy Anderson, CDC

Record of Attendance – cont'd

Centers for Disease Control and Prevention (CDC)

Dr. J. Rex Astles
Ms. Suzette Bartley
Ms. Diane Bosse
Dr. Andrew Bryan
Dr. Roberta Carey
Dr. Bin Chen
Dr. Nancy Cornish
Ms. Laura Conn
Dr. Marie Earley
Mr. Steve Ethridge
Dr. Lin Fan
Ms. Susan Fuller
Ms. Maribeth Gagnon
Dr. Babita Ganguly
Mr. Manjula Gama-Ralalage
Ms. Nicole Gregoricus
Ms. Rachel Greenberg
Dr. Harvey Holmes
Dr. Thomas Hearn (Retired)
Ms. Stacy Howard
Dr. Micheal Iademarco
Dr. Lisa Kalman
Dr. Wesley Kennemore
Dr. Jin Kim
Dr. Maja Kodani
Dr. George Lathrop
Dr. Elizabeth Leibach
Ms. Gladys Lewellen
Dr. Ira Lubin
Ms. Ma Xiaoyue
Dr. Bereneice Madison
Mr. Kevin Malone, Esq.
Mrs. Allison McAlister
Ms. Leslie McDonald
Mr. Wadzanai Mboko
Dr. Toby Merlin
Ms. Graylin Mitchell
Dr. Atis Muehlenbachs
Mr. Urmil Parekh
Dr. Nicole Rankine
Dr. John Ridderhof
Dr. Paramjit Sandhu
Ms. Megan Sawchuk
Ms. Theresia Snelling
Mr. Jonathan Spencer
Ms. Heather Stang
Ms. Sonya Strider
Ms. Erin Stone
Ms. Vickie Sullivan
Dr. Julie Taylor
Mr. Thomas Taylor
Ms. Angela Thompson
Ms. Monica Toles
Ms. Elizabeth Weirich
Ms. Karlyn Wilson
Dr. Laurina Williams
Ms. Teneva Williams
Dr. Yang Xia
Mr. Jonathan Zhong

Department of Health and Human Services (Agencies other than CDC)

Dr. Steve Phurrough, CMS
Ms. Julia Appleton, CMS
Dr. Peter Tobin, FDA
Ms. Rebecca Hong, NIH

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 30 public citizens attended one or both days of the meeting. The meeting was also available by webcast.

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC) -BACKGROUND

The Secretary of Health and Human Services is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory Committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health pertaining to improvement in clinical laboratory quality and laboratory medicine. In addition, the Committee provides advice and guidance on specific questions related to possible revision of the CLIA standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic submission of laboratory information.

The Committee consists of 20 members, including the Chair. Members are selected by the Secretary from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Administrator, Centers for Medicare & Medicaid Services; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions.

Due to the diversity of its membership, CLIAC is at times divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary may not follow their advice due to other overriding concerns. Thus, while some of the actions recommended by CLIAC may eventually result in changes to the regulations, the reader should not infer that all of the Committee's recommendations will be automatically accepted and acted upon by the Secretary.

CALL TO ORDER AND COMMITTEE INTRODUCTIONS

Dr. William Mac Kenzie, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Deputy Director for Science, Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Office of Public Health Scientific Services (OPHSS), CDC, welcomed the Committee and the members of the public, acknowledging the importance of public participation in the advisory process and took a roll call of the members present. Dr. Burton Wilcke, Chair, CLIAC, welcomed the Committee and called the meeting to order. All members then made self-introductions and financial disclosure statements relevant to the meeting topics.

Dr. Mac Kenzie recognized the four outgoing CLIAC members who also received letters of appreciation signed by the CDC Director for their service on the Committee. The members were Dr. Keith Kaplan, Ms. Paula Vagnone (Snippes), Dr. Burton Wilcke, and Dr. Qian-Yun Zhang.

Dr. Wilcke reminded the Committee that CLIAC seeks suggestions for candidates to the Committee at any time. Suggestions for consideration for the 2017 year can be provided by emailing CLIAC@cdc.gov. Each slate of nominees is carefully selected in an effort to assure that the Committee meets the required balance of stakeholders with respect to laboratory medicine, pathology, public health, clinical practice and consumers. The slate of candidates must also maintain the Committee's balance with respect to gender, geographic distribution, and minority representation.

Dr. Wilcke conveyed that the agenda topics included updates from the CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) as well as an update from the CLIAC liaison to the CDC Office of Infectious Diseases Board of Scientific Counselors (BSC). In addition, there would be presentations and discussions on the Medicare advisory panel on clinical diagnostic laboratory tests, on laboratory interoperability, and an update on clinical laboratory biosafety. There would also be discussion on future CLIAC topics.

Dr. Wilcke noted that during the November, 2015 CLIAC meeting, a recommendation was made that "CDC should review the process by which CLIAC creates, reviews, and edits official Committee recommendations to allow a public forum for the shared development and drafting of proposed recommendations prior to the meeting to facilitate more effective Committee discussion." Dr. Mac Kenzie introduced Ms. Gladys Lewellen and Mr. Kevin Malone who spoke on this topic.

Improving the Effectiveness/Efficiency of CLIAC Meetings ***Addendum 01***

Gladys G. Lewellen, MBA, MPA
Committee Management Specialist
Federal Advisory Committee Management Branch
Management Analysis and Services Office
Office of the Chief Information Officer
Centers for Disease Control and Prevention

Kevin M. Malone, JD, MHSA
Senior Attorney
Office of the General Counsel
Office of the Chief Information Officer
Centers for Disease Control and Prevention

Ms. Lewellen began her presentation with an overview on the role of federal advisory committees and CLIAC's role specifically related to the Committee's charter. She noted that meetings and activities must be planned within the parameters of the Committee's charter. In addition, the discussion, deliberations, and subsequent advice and recommendations to agency officials must be consistent with the charter. Ms. Lewellen provided the Committee with the definition, description, and role of subcommittees and workgroups illustrating how each would function in the Committee's operations. She noted the main distinction between a non-chartered subcommittee and a workgroup is that workgroups are generally temporary in nature and currently are not subject to public notice and open meeting requirements. She related the same requirement that applies to subcommittees for presentation of work products to the parent committee also applies to the outcomes, tasks, or projects of workgroups. The role of a workgroup is to serve as a fact finding body that gathers information, analyzes relevant issues and facts, and drafts proposed positions for final deliberation by the chartered advisory committee. Workgroups do not participate in decision-making. Ms. Lewellen stated that 41 CFR, Section 102-330A of the Federal Advisory Committee Act (FACA) provides guidance that permits agencies to engage committees to produce advice and recommendations that may: result in the creation, rescission, or modification of regulations, policies, or guidelines affecting CDC's business; result in significant improvements in service or reductions in cost; or provide additional perspective or viewpoints affecting agency operations. Ms. Lewellen explained how the FACA recommendation process flows and concluded her presentation by stating all recommendations are included as a part of the Management Analysis and Services Office's (MASO) annual comprehensive review to the President and to Congress and become a part of the official records in the General Services Administration (GSA) database.

Committee Discussion

- One member asked about the expected response from HHS on CLIAC recommendations. Ms. Lewellen responded that HHS has established a process for MASO to follow. When a committee recommendation is sent to the HHS Secretary, senior advisors review the incoming correspondence. Generally, the HHS Secretary's response to the recommendation is an acknowledgement or an expression of appreciation to the committee members for the value that they bring to agency operations. If the recommendation is from a mandated advisory committee then MASO may receive specific guidance regarding next steps, which often includes a request from the Secretary for the CDC Director to review the recommendation and make a determination regarding implementation.

- The Chair noted that official recommendations from CLIAC are routed through CDC directly to the HHS Secretary. He inquired how the routing differs when a recommendation pertains more directly to CDC, CMS, and FDA. Ms. Lewellen replied there is nothing to preclude a specific recommendation to any of the agency officials in the CLIAC charter.
- A member asked if it was possible to make CLIAC recommendations mandatory requirements. Ms. Lewellen stated that unless there is a specific statutory authority or presidential directive to the contrary, the recommendations are advisory only and the agency officials, to whom the committee reports, make the decision about accepting or implementing the recommendation. Mr. Malone added that the recommendation would also be sent to the appropriate component of the department for consideration.
- Another member asked if there is a process for tracking CLIAC recommendations and subsequent agency actions. Ms. Anderson responded that recommendations are tracked and periodically DLS provides reports to CLIAC. New Committee members are provided the recommendations as part of their orientation.
- Two members and the Chair asked if each CLIAC meeting could begin with an overview of the status of previous recommendations, especially as they apply to the agenda topics for that meeting. Another member suggested including the updates as part of the CDC agency updates and one asked if the table of recommendations could be posted for the public on the CLIA webpage. Ms. Lewellen noted at the end of each fiscal year all federal advisory committees prepare an annual comprehensive review which is available online at GSA's FACA Database (http://www.facadatabase.gov/). Dr. Mac Kenzie agreed to provide the update and added that a list of prior recommendations and outcomes could be provided either annually or at each meeting. He also said that CDC will work on publishing the table. Ms. Anderson commented that the table dates back to 1992 and includes all formal CLIAC recommendations. She added that CDC receives useful advice from CLIAC discussions even when those discussions do not result in a formal recommendation.
- One member asked if there were any restrictions on communication among Committee members outside of the official CLIAC meeting, for example, if some members wanted to communicate prior to a meeting to agree on the language for a proposed recommendation. Ms. Lewellen responded when such a request is received from the DFO or program staff, MASO confers with the Office of General Counsel since there are very few exemptions to the open meeting requirements for FACA committees. She added that communication regarding administrative matters such as meeting and travel arrangements is considered an exemption or exception to the law.
- Several members asked how workgroups were formed. Ms. Lewellen replied the committee's DFO in collaboration with the Committee Chair can establish a workgroup to focus on a particular issue or a Committee member, as part of the deliberation on any agenda item, can recommend forming a workgroup. In either case, the committee will discuss the charge and deliverables for the workgroup and vote on its establishment. Ms. Lewellen reminded the members that workgroups add operating costs to the committee's budget, so a discussion about subject matter expertise needed, the size of the workgroup, and the logistics of forming a workgroup needs to take place. Mr. Malone added that given the administrative cost to the committee, the ultimate decision to establish a workgroup would be by the DFO in

collaboration with the Committee Chair. He added, the workgroup charge should be within the scope of the subject matter of the charter of the parent federal advisory committee.

- Dr. Mac Kenzie asked whether the Committee could utilize workgroups with a defined scope to draft potential recommendations for deliberation by the Committee. Mr. Malone clarified that workgroups can be used to further discuss topics and provide advice back to the Committee. He emphasized that workgroups are not subject to the public access requirements of FACA because they do not directly advise the federal government. The workgroup reports to the federal advisory committee which then deliberates and votes in a public forum.
- A member inquired whether a web-based public portal could be set up to discuss agenda topics before the official CLIAC meeting. Mr. Malone responded that, in such a situation, questions could arise as to whether or not an official meeting subject to FACA is taking place. He added workgroups are valuable for these types of discussions.
- The Chair inquired about interim CLIAC meetings to provide a more timely recommendation on agenda topics. Ms. Lewellen responded that if there is an impending recommendation that requires action by the Committee, interim meetings can be called by the DFO. Interim meetings are subject to all FACA public access rules including announcement in the Federal Register. She noted that interim meetings that are teleconferences or webcasts must be open to the public. Mr. Malone added that it is not common to have interim meetings except in cases of pressing issues such as Zika virus where a decision may be needed within a few weeks' time.

AGENCY UPDATES AND COMMITTEE DISCUSSION

Dr. Wilcke reminded the Committee of the change in procedure for agency updates indicating that the time allotted for agency updates had been decreased and CLIAC members had been asked to review each agency presentation prior to the start of the meeting.

Centers for Disease Control and Prevention (CDC) Update ***Addendum 02***

Reynolds M. Salerno, PhD
Director
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Office of Public Health Scientific Services (OPHSS)
Centers for Disease Control and Prevention

Dr. Salerno, the new DLS Director, began with a brief overview of his background at Sandia National Laboratories in Albuquerque, New Mexico. He provided information to the Committee on two funding opportunity announcements (FOAs) available through DLS; one being a quality improvement initiative utilizing a medical data warehouse to

link laboratory information to patient and system outcomes, and another focused on improving waived testing performance and outcomes through partnerships. Dr. Salerno announced the completion of an educational booklet that resulted from a CLIAC discussion in August 2012. The booklet targets facilities with a CLIA Certificate for Provider-performed Microscopy Procedures (PPM).

Committee Discussion

- Several Committee members voiced appreciation for the PPM booklet citing the need for guidance in physicians' clinics on regulatory requirements for PPM tests.
- A member inquired about the plan to track distribution of the booklet. Ms. Anderson noted that DLS has methods to track the number of print copies distributed and will research methods to track the number of online downloads.
- Another member suggested creating an online training similar to CDC's "Ready? Set? Test!" training for waived testing. The same member suggested providing an editable format of the PPM booklet for organizations to customize for their needs.
- A member suggested improving funding for research on clinical operations and quality improvement studies and asked if CLIAC could have a role in making a formal recommendation to HHS to look at potential funding in the area of laboratory and quality improvement with a connection to patient and system outcomes similar to the medical data warehouse FOA. Dr. Salerno responded that studying ways to improve the operations of clinical laboratories around the country and to better link the work of clinical laboratories to the public health system is a critical responsibility of DLS. Recommendations from the Committee on studies to specifically pursue this would be appreciated.

Centers for Medicare & Medicaid Services (CMS) Update ***Addendum 03***

Karen Dyer MT (ASCP) DLM
Director
Division of Laboratory Services
Survey and Certification Group
Centers for Medicare & Medicaid Services (CMS)

Ms. Dyer provided the Committee with a brief overview of the current CLIA statistics and survey deficiencies. She informed the Committee that the CMS document "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services" was updated in January, 2016. She noted the implementation of the Individualized Quality Control Plan (IQCP), effective January 1, 2016. Ms. Dyer provided a brief review and common themes among the four primary CLIA modernization proposals from the American Medical Association, the Association for Molecular Pathology, the College of American Pathologists, and the Diagnostic Test Working Group. She reviewed the President's Precision Medicine Initiative® (PMI) in which researchers, providers, and patients work together to develop individualized care and noted it has resulted in an issue with researchers wanting to provide genomic test results obtained in a non-CLIA certified research laboratory to study participants. On the quality control topic, she noted that CMS now allows for on-board control materials, external controls that are place on-board

the analyzer. She commented that CLIA will now allow primary source verification (PSV) as a process to confirm laboratory personnel credentials and educational experience. Finally, Ms. Dyer noted the transition from face-to-face to virtual on-line CLIA basic surveyor training.

Committee Discussion

- The AdvaMed liaison asked if the rate of increase of Certificate of Waiver laboratories could be included in future meeting updates. Ms. Dyer agreed to provide that information.
- One member asked about the inclusion of CLIAC in the decision making process on issues such as PSV and on-board quality control noting that CLIAC has not discussed these issues in the past. Ms. Dyer responded that the PSV and quality control decisions were made internally at CMS based on discussions with surveyors and accreditation organizations.
- A member, commenting on the PMI, said studies are needed on the impact of releasing complex test results, such as those for genetic tests, directly to the patient, to understand how patients comprehend and use the information.
- Dr. Gutierrez commented that the PMI was introduced on January 20, 2015, as a Presidential Initiative which includes funding to the National Institutes of Health (NIH) to build a national, large-scale cohort of volunteers who would donate DNA to be sequenced and maintained in a large database for researchers. He added there are many issues including that of researchers who do not work in CLIA-certified laboratories coupled with study participants who are interested in getting their test results and understanding what they mean.

Food and Drug Administration (FDA) Update ***Addendum 04***

Alberto Gutierrez, PhD
Director
Office of In-Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Dr. Gutierrez began his presentation with a brief organizational update of the OIR. He provided a brief update on the status of three presidential initiatives that OIR has been involved in; the national action plan for combating antibiotic-resistant bacteria (CARB), the Precision Medicine Initiative® (PMI), and the U.S. National Cancer Moonshot Initiative. Dr. Gutierrez reviewed the recent pre-market approvals (PMAs), de novo down-classifications, CLIA waivers by application, and emergency use authorizations (EUAs). He discussed final and draft guidance documents including a postmarket 'Management of Cybersecurity in Medical Devices' draft guidance. Dr. Gutierrez ended his presentation by highlighting two public workshops which occurred in March, "Point of Care Prothrombin Time/International Normalized Ration Devices for Monitoring Warfarin Therapy" and "Patient and Medical Professional Perspectives on the Return of Genetic Test Results."

Committee Discussion

- A member commented that different subsets of language are used between various societies of pathology and oncology in terms of recommendations for testing, and even in terms of the diagnostic descriptions. The U.S. National Cancer Moonshot Initiative could be used to clarify these differences. Dr. Gutierrez responded that the FDA is working with the community to develop material standards and possibly method standards.
- One member asked when data from the cytology workload study would be available. Dr. Gutierrez responded that data evaluation is ongoing with the hope it may be ready to present at the November 2016 CLIAC meeting.
- A member requested additional information on streamlining the processes for antimicrobial susceptibility breakpoint updating as part of the CARB initiative. Dr. Gutierrez responded that this issue is ongoing since breakpoints are listed in drug approval package inserts and changing package labelling is not easily or quickly accomplished. It is dependent on the manufacturer and the FDA doesn't have much leverage in persuading the drug companies to make changes.

CDC OID Board of Scientific Counselors (BSC) Update ***Addendum 07***

Elizabeth M. Marlowe, PhD, D(ABMM)
Committee Liaison to CDC Board of Scientific Counselors
Office of Infectious Diseases (OID)
Assistant Director
Microbiology-Molecular Testing
Southern California Permanente Medical Group
Regional Reference Laboratories

Dr. Marlowe provided a summary on the December 2015 CDC OID BSC meeting. She summarized the key updates from the Center for Global Health, followed by an update from the National Center for Immunization and Respiratory Diseases. She provided highlights from the National Center for Emerging and Zoonotic Infectious Diseases, the Advanced Molecular Detection program, the Infectious Disease Laboratory Working Group, the Food Safety Modernization Act Surveillance Working Group (FSMA SWG) which presented its recommendations for the improvement of foodborne illness surveillance, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. She also related the most current information on the ongoing outbreak caused by *Legionella* as well as on climate change. She ended her presentation with a summary of the updates provided by Dr. Frieden.

PRESENTATIONS AND COMMITTEE DISCUSSION

Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests ***Addendum 05***

Steve Phurrough, MD, MPA
Medical Officer
Hospital & Ambulatory Policy Group
Centers for Medicare & Medicaid Services

Dr. Phurrough provided an overview of the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT), charged with providing CMS advice on issues related to reimbursement for laboratory tests. He briefly reviewed CMS' current laboratory test pricing methodology accomplished by either cross-walking or gap filling. He described the future payment system mandated by Public Law 113-93 Protecting Access to Medicare Act (PAMA) (implementation date - January 1, 2017) which will establish payment rates based on the weighted median of private payer rates. He stated that the statute established an advisory committee, the CDLT, and reviewed its composition, objectives, duties and topic restrictions. Dr. Phurrough ended by noting that the panel met twice in 2015 and will be meeting again this summer (2016).

Committee Discussion

- A member asked which laboratories would be required to report payer data under the new payment system. Dr. Phurrough replied that the proposed rule defines which laboratories will be required to report payer data, including a test-based minimum testing volume or monetary revenue. The final rule will include the definition of an applicable laboratory including which, if any, physician laboratories, independent laboratories, and hospital laboratories must report private payer data.
- Another member asked how the new payment system would compare to the current system. Dr. Phurrough replied that the Congressional Budget Office's (CBO) interpretation of the requirements has indicated this will result in a cost savings for Medicare. However, CMS will not have the answer to this question until after the end of the data collection period.
- One member noted that the impetus for the enactment of the statute was an HHS Office of Inspector General's study that said Medicare was dramatically overpaying for laboratory tests. The member asked if it would have been more cost effective to have simply cut the laboratory fee schedule by a percentage. Dr. Phurrough acknowledged the complexities of the payment system and replied that government agencies are not allowed to lobby Congress to change the statutes but rather take their guidance from Congress.
- A member noted this law addresses what tests cost and asked if there are any upcoming laws focused on what the tests cover. Dr. Phurrough replied that he did not know of any. A member asked if this would be an opportunity to rethink how reimbursement is structured so that payment is not based just on volume but also on

the quality and value of the test. Dr. Phurrough emphasized the separation at CMS between coverage and payment and stated PAMA is focused only on payment.

- One member asked if any thought was being given to paying on a sliding scale that would take into consideration how beneficial the test was to the patient. Dr. Phurrough stated he was unaware of any statutory mechanism that would allow variable payments for laboratory tests based upon the circumstance in which they were provided.
- Another member opined that while value based pricing sounds great, it would be almost impossible to implement.
- A member commented that as the price reimbursement for legacy test methodologies decreases, laboratories trying to maintain a cost margin may acquire less robust, lower cost tests. An unintended consequence of this could be a decrease in the quality of testing. The member asked if there is any verbiage in the statute that says if a significant cost savings is not achieved an adjustment to the statute or regulation will be made. Dr. Phurrough replied there are no thresholds written into the statute. However, there is a requirement in the statute to assess the implementation and results of the new program and Congress could provide additional guidance at that time. After the first year of implementation an assessment on the difference in utilization and on the total expenditures based upon those differences, prices, and utilization will be undertaken.
- The Chair asked how the quality of the test affects the price of the test. Dr. Phurrough replied that currently CMS does not have the authority to ensure that the test being paid for has value. The CDLT committee may, at some point, discuss the issue as part of their coverage policy discussion. However, Congress will have to enact a new law addressing this before CMS will be able to implement test pricing base on clinical utility.
- The Chair noted that some tests serve both a personal health and a public health function and asked whether this was being considered. Dr. Phurrough responded the committee may focus on coverage issues in the future.
- A member noted that insurance company negotiations result in lower prices for some tests and higher prices for others and asked if this will be taken into consideration. Dr. Phurrough replied the final rule will discuss how discounts should be handled. However, when the private payer data is reported, it is expected that both of those rates will be seen and included in the weighted median.
- Another member asked if there was any consideration at the rule-making level or in the CDLT committee for specifying transparency of the submitted data. Historically, particularly for new diagnostic tests, contractors set prices which appear to be low, (gap-filling process), but the data used for those determinations are not scrutinized. Dr. Phurrough replied the gap-filling process is different from the PAMA mandated process. The gap-filling process will continue on some level, therefore, efforts are being made to improve it. For PAMA, in the proposed rule, it is specified that the data are to be submitted in an online database which will be available to those submitting the data. The proposed rule requested public comments on how transparent the data should be and those comments are being reviewed. A decision will be published in the final rule.

- A member asked if one unintended consequence of this law could be an increase in payment rates due to price gouging and if CMS will be monitoring for this possibility. Dr. Phurrough replied there is no way to predict how prices will change as a result of the implementation of this law.
- A member noted that existing data suggest that when physicians are aware of test prices they order less. The member asked if CMS had considered developing an educational tool that would allow ordering physicians and health-care providers access to cost data at the time of ordering. The member commented the expertise of the ordering physicians combined with access to the cost data might help shift utilization and expenses in a medically appropriate way. Dr. Phurrough replied that cost data are publicly available. Another member commented that all electronic health record related order entries should be accompanied by test related costs, so there should be a way to implement such a system.
- A member commented that as more of the laboratory fees have been shifted to the patient's deductible there has been a corresponding shift from over-ordering to occasional under-ordering. The member opined much of the responsibility for appropriate ordering is on the physician but some of it should be shared with the patient, allowing them to take ownership of their health. Dr. Phurrough responded there has been discussion about instituting a deductible for laboratory testing.
- A member asked if databases from commercial software venders could be utilized and shared with CMS. Dr. Phurrough replied Congress has instructed CMS to collect data. The member also noted that if hospital laboratories are not required to report data then the final result will be skewed. Dr. Phurrough responded that the issue of what is an applicable laboratory was among those that engendered the most comments in response to the proposed PAMA rule.
- Another member noted there are a number of codes that Medicare uses but that are not used by the private payers and asked how the median prices will be determined in these cases. Dr. Phurrough replied the proposed rule says under those conditions, CMS will continue to use the cross-walking and gap-filling system, which would be different from the way they are used in the current system. The final rule will discuss whether those codes need to be readdressed on an ongoing basis.

Laboratory Interoperability: ONC Policies and Engagement with Clinical Laboratories ***Addendum 06***

Jon White, MD
Deputy National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)

Dr. White provided a summary of ONC's work to drive the adoption and interoperability of the information systems in health care. He noted that the adoption of health IT, electronic health records (EHRs) in particular, has now expanded to encompass approximately two-thirds of the physician office laboratories (POLs) and 95 percent of the hospitals. He also provided evidence that data exchange has increase in recent years. He stated there has been a tremendous push for interoperability at the ONC in the past two years which is being guided by policy documents. Dr. White briefly described the Federal Health IT Strategic Plan policy document emphasizing that the number one goal

is patient-centered care. He discussed goal four noting that it includes responsibilities for both the public and the private sector and reviewed the four standardization efforts. He discussed the annual Interoperability Standards Advisory (ISA), a non-regulatory approach ONC has developed to drive standardization and interoperability, and provided an example of what is referenced in the document. Finally, Dr. White reviewed the ISA annual process and timeline.

Committee Discussion

- A member, referring to slide three, asked whether the amount of information being exchanged was captured in the American Hospital Association survey. Dr. White replied he did not know the details regarding data captured in this survey.
- One member asked if incentives were needed to encourage the laboratories to use LOINC. Dr. White noted ONC's authority comes from the certification of Health IT; it uses the ISA which is non-regulatory to suggest LOINC be included in certified heath IT. He stated incentives drive the use of standards and interoperability and provided the following examples: 1) ONC coordinates with colleagues in the public and the federal sectors, 2) The Nationwide Interoperability Roadmap addresses drivers and incentives upfront, 3) Information systems are required as part of the underlying infrastructure of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and 4) Healthcare provider organizations need data to be able to take better care of populations and deliver better value to the beneficiaries which acts as a driver.
- Another member noted expertise is needed in order to accurately encode laboratory data using LOINC and SNOMED CT. If there are coding errors and the quality is poor, then precision medicine, pharmacogenomics, and clinical decision support are going to suffer and interoperability will not be realized. This coding expertise is a real obstacle for the laboratories. Furthermore, only hospital laboratories are eligible for meaningful use incentives. The member asked what ONC will do to help adoption of the laboratory guides, LOINC, and SNOMED CT for all laboratories. Dr. White responded informatics expertise is critical, not just in laboratories but across all health care. He said ONC is involved in promoting professional development across all health care disciplines since informatics expertise is critical for the future of laboratories. ONC recognizes that there are areas of health care, such as laboratories, that are not benefited by the incentive program, therefore ONC is collaborating with federal and private partners to develop clinical guidelines and incentives. The member commented while meaningful use is a move in the right direction, it was unfortunate the pathology laboratory was not included in the meetings to create the guidelines. The member stated it will be fundamental to rectify this since 70 to 80 percent of the data in medical records are from the pathology laboratories. The member also noted if wide expansive decisions are being made about health care based on information that is put into digital systems, then it is incumbent to be certain the systems are accurate.
- A member noted that laboratory testing is the single highest volume medical activity, therefore getting it right is important. The member discussed the complexity of information related to laboratory test results and stated laboratory

professionals look at tests in terms of sensitivity, specificity, and positive and negative predictive values, which are integral to how the tests are ordered and used but divorced from the context in which they are transmitted. Dr. White replied ONC is open to suggestions.

- One member wondered if a starting place for electronic reporting would be to include in standards implementation guides a manageable subset of LOINC codes covering 90-95 percent of laboratory tests. The member asked if ONC has undertaken the endorsement of the implementation guides that currently exist or considered sharing the knowledge gained from the pilot projects or existing implementation guides with laboratories. Dr. White noted that in addition to working with the standards organizations there have been projects centered on improving some of the standards implementation guides. This endeavor goes beyond the laboratory, but ONC would welcome meeting with laboratory professionals. The member asked if CAP was taking on a formal role in advising and disseminating some of the lessons learned through the pilot projects. Dr. White replied yes, they will be undertaking this role.
- A member noted that on a state level, there are already some systems in place that would be good examples for what's possible with respect to standardization. A good example is Georgia's immunization registry. The member suggested using these existing systems as examples and adding to them. Dr. White replied that was an excellent point and that immunization registries are a great example. ONC would like to collaborate with people that have both the authority and interest at a local level to drive these systems.
- A member, referring to the ONC fact sheet (***Addendum 10***) on the "ONC Health IT Certification Program: Enhanced Oversight and Accountability" proposed rule, commented that the proposed rule may address many of the gaps currently experienced with vendor products. Dr. White replied ONC certifies health IT through regulation which establishes certification criteria. ONC also has a certification program where private sector organizations are certified to determine if vendors meet the criteria of the regulation. Vendors, under the current regulations, publish information using a set format which is publicly available on the Certified Health IT Product List (CHPL). ONC has realized that oversight and transparency could be improved and those purchasing the systems requested more transparency which resulted in the proposed rule that does not name a standard.
- A member asked how the issue of transparency versus confidentiality was being handled; would there be a way to limit access to certain parts of the patient's chart depending on who was viewing it. Dr. White replied part of the statute that created ONC established a chief privacy officer for ONC who works closely with the Office of Civil Rights (OCR) which administers HIPAA and also works with ONC's colleagues across the administration on issues of privacy and security. ONC is concerned with transparency for the patient to make sure they can obtain their information and know how it is being used. In that capacity, ONC has been working very closely with OCR. Significant guidance has been recently issued about an individual's rights, under HIPAA, to access their data. Dr. White asserted HIPAA should never be used as an excuse to deny a patient access to their data. OCR in partnership with ONC has issued guidance on this subject.

- The Chair asked how the public perceives interoperability. Dr. White noted there are actually assumptions that some of these things are already in place. Increasingly the public is indicating they want access to their information and they want to know who has access to their information. People expect their information to be shared with the right people.
- A member noted many people have voiced concerns about the shortcomings of LOINC and expressed the opinion that it is a highly granular coding system that creates substantial difficulties in achieving interoperability. The member added the LOINC code changes when the test methodology changes and it is not clear whether it is important for those tests to have different codes. This can create problems when transmitting the data (making sure the correct codes are being sent) and for the systems receiving the data (interpretation of the codes). The data recipient may not have the transmitter's LOINC code in their information system or EHR depending on the test methodology. The member related a number of studies have shown that the bulk of data that laboratories want to exchange consists of a couple of hundred tests and asked if ONC could create a standard. Dr. White replied there is an Office of Management and Budget (OMB) circular that says the federal government will not create a standard if one already exists in the private sector that is fit for the purpose. It is not an insurmountable barrier but one has to be able to show that something doesn't work. He related the National Library of Medicine (NLM) has been sponsoring LOINC for a long period of time and it has been iteratively developed over time though there are issues that can be raised. Dr. White suggested that ONC might collaborate with Regenstrief and the NLM to address the issue. He said another path might be to investigate whether there is a different resource or national code set that could be made available to laboratories.
- Dr. Mac Kenzie commented that ONC, since its inception, has had a huge amount of work to do and has been asked to take on a tremendous task, often with little power or resources. He added the laboratory portion of the standards has suffered some, particularly given the amount of laboratory data that goes into the EHRs, and asked if it would be beneficial to have a laboratory representative on the ONC's FACAs. Dr. White replied laboratory expertise is included in the work groups.
- Ms. Dyer emphasized that all types of laboratories need to be included in the discussions on EHRs. She stated that one of CMS' concerns from the beginning was LOINC. Many laboratories had never heard of LOINC but they were supposed to be implementing that system. Dr. White agreed.
- The Chair noted there are different kinds of tests being performed to diagnose the same condition, a range of individuals and places where testing is being performed, and variation in the quality of the tests. He asked how this was being factored into semantic interoperability. Dr. White replied that all of those are important to semantic interoperability so they must be part of the standards and implementation whether the electronic data are in a structured or unstructured format.
- Dr. Wilcke, the CLIAC chair, called for formal recommendations. After considering the comments made during the interoperability discussion, the Committee made the following recommendations:

1. To facilitate wider uptake of standards for laboratory interoperability, HHS should endorse and stimulate adoption of an implementation guide/s for laboratory results

reporting (e.g., The EHR-Lab Interoperability and Connectivity Specification (ELINCS) for orders available at: http://www.chcf.org/projects/2009/elincs); and successful pilots that arise from the S&I framework effort (http://wiki.siframework.org/Laboratory+Orders+Interface+Initiative)

2. CLIAC requests that the Office of the National Coordinator for Health Information Technology (ONC) Standards and Policy Committees each include a pathology informatician (pathologist with expertise in clinical informatics) as a committee member.

Update on Clinical Laboratory Biosafety

Biosafety in Clinical Laboratories ***Addendum 08***

Reynolds Salerno, PhD
Director
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Office of Public Health Scientific Services (OPHSS)
Centers for Disease Control and Prevention

Dr. Salerno began his presentation by noting that safety and health care in the biosciences has been focused more on traditional healthcare workers and research laboratories than on the clinical laboratory and stated the attention needs to be refocused on the risk to the clinical laboratory worker. He presented an overview of the history of biosafety using examples of occupationally acquired infections, increases in laboratory tests needed for diagnosis, and laws passed. He discussed gaps and contradictions in clinical laboratory safety guidelines discovered during the 2014 Ebola outbreak and the current Zika outbreak and the lack of any mention of risk assessment in biosafety guidelines or regulations. Dr. Salerno acknowledged that in 2015, CLIAC recommended to HHS that a number of steps that should be taken to address biosafety gaps in clinical laboratories. HHS responded, acknowledging the recommendations and indicating they would welcome additional comments and suggestions from CLIAC. Dr. Salerno suggested that a biorisk management systems approach to safety, analogous to CLIA's quality management system, should be adopted by laboratories. He emphasized that risk assessment needs to be at the core of this approach and, like CLIA's quality management system, the biorisk management system needs to be performance-based. Dr. Salerno concluded his presentation with a list of questions for the Committee members to consider:

- Are clinical laboratories familiar with the CDC Blue Ribbon Panel's Biosafety Guidelines?
- What is the status of biosafety practices and training in CLIA-certified laboratories?
- How are laboratory acquired infections in CLIA-certified laboratories investigated and reported?

- To what extent do manufacturers assure the safety and decontamination of laboratory instrumentation?
- Can guidelines be developed to help clinical laboratories manage biosafety for unknown diseases?
- How can CMS/FDA/CDC persuade clinical laboratories to adopt a culture of risk assessment?
- What studies should CDC/CMS/FDA conduct to answer the questions above?

Enhancing Domestic LaboratoryBiosafety for Ebola and Other Highly Infectious Diseases ***Addendum 09***

Toby Merlin, MD
Director
Division of Preparedness and Emerging Infections
National Center for Emerging & Zoonotic Infectious Diseases
Office of Infectious Diseases
Centers for Disease Control and Prevention

Dr. Merlin presented an overview of the CDC program to enhance domestic laboratory safety for Ebola and other highly infectious diseases. He began with a review of the gaps discovered in laboratory safety during the 2014 Ebola event. He described the CDC's Epidemiology and Laboratory Capacity (ELC) Program to Enhance Laboratory Biosafety. Dr. Merlin related that 62 supplemental ELC awards were given focused on two specific strategies: enhancing biosafety in the public health laboratory and improving laboratory coordination and outreach with other clinical health laboratories. He also noted the Association of Public Health Laboratories was awarded supplemental funds to conduct other national biosafety activities. Dr. Merlin summarized the accomplishments noting progress has been made in all categories. He related that has been made clear that there are not enough individuals with the appropriate experience and knowledge in biosafety to fulfill the laboratories' needs. He stated biosafety risk management appears to be a new concept for many clinical laboratories. Dr. Merlin ended his presentation with a review of the next steps and noted that the agency did recognize the concerns raised by CLIAC in 2015 regarding biosafety and has begun to address those concerns.

Committee Discussion

- The Chair spoke of a number of common laboratory practices in the 1970's that are now forbidden because they are unsafe and commented that in addition to quality results, safe conduct is needed.
- Dr. Gutierrez discussed the need for manufacturers to show that the recommended decontamination method has been tested and succeeds. This has not been accomplished for all laboratory equipment and it is difficult to see how FDA could institute procedures to review the decontamination information for instruments, especially when gaps may be found in hindsight, as with Ebola. He reminded members that safety issues can occur with laboratory developed tests (LDTs) because the safety of a new test for an emerging disease may not have been studied or the

laboratory does not have the appropriate expertise to verify safety.

- The Chair suggested that Certificate of Waiver (CW) testing sites should also be considered when discussing safety. A member said that for both laboratories that perform only waived testing and those that perform nonwaived testing, manufacturers should provide safety competencies in the form of checklists in addition to the technical competencies needed for their instruments. Many laboratory workers do not take the time to read the instructions when testing and they may not always know how to safely use the instruments. During the later discussion of the recommendation, the Committee agreed that CW sites should not be included but treated separately because they have different safety issues.
- A Committee member discussed the need for better guidance to reduce occupational acquired infections because research and public health laboratories are not good analogs for clinical laboratories, especially those laboratories with high volume chemistry and hematology tests. Risks to both the testing personnel and the patients have to be considered. Emerging infections that occur in laboratories outside the US that do not have the same capacities and capabilities cannot always be used as a source of guidance. Dr. Merlin agreed and stated that until the money designated by Congress for Ebola, there was no funding mechanism available to reach out to the clinical laboratory community. Dr. Salerno asked CLIAC for suggestions and mentioned the possibility of developing some type of publication to highlight the issues. He also stated that more work should be done. Questions need to be asked and data collected to determine what is working or not working and to give laboratories more confidence in their risk assessments.
- Committee members discussed the need for better communication from the CDC and stressed that it does not have to be complete information to be helpful. Current information with periodic updates would be very helpful. Dr. Merlin agreed that better communication is necessary in the future. Other members suggested that CDC consider collaborations with key leaders and professional organizations in the field to develop and pilot new communication strategies, such as the use of trade magazines and listservs.
- A Committee member said guidance was needed for practical issues such as competency testing for health care workers who perform point-of-care testing in isolation rooms; quality control testing needed for dedicated instruments that are in isolation rooms and not in routine use; whether a separate CLIA certificate is required for testing performed in isolation rooms; and whether automated transport systems that remove tube caps before moving specimens potentially containing Ebola virus throughout the core laboratory are considered safe?
- The Chair raised the issue that during the Ebola outbreak, some suggested that standard precautions developed to prevent transmission of HIV or hepatitis may not be adequate for specimens containing highly infectious agents like Ebola virus.
- Sensing the continued urgency of the biosafety issues under discussion, a number of Committee members discussed approaches to increase awareness and implement changes. These included incorporating safety management into the larger quality management frameworks, adding safety to competency training, having one entity "own" the problem to ensure progress, and encouraging accrediting organizations to require that laboratories conduct biosafety risk assessments. One Committee member

suggested that laboratories could learn from the patient safety world and outlined the following five-pronged approach to address biosafety:
1. There is a need for funding to stimulate research and discovery in high-risk areas and to learn what we don't know to improve safety.
2. Develop a change package to implement what we know are good biosafety practices, including risk assessments. Note: change package is defined as a catalogue of strategies, change concepts, and action steps that guide participants in their improvement efforts.
3. Provide a mechanism to ensure that good biosafety practices are followed. This could include incentives, penalties, regulation, accreditation, reimbursement.
4. Measure outcomes: periodic measurement and continuous quality improvement are needed to making sure laboratories continue to implement and follow good biosafety practices in the future.
5. Someone needs to be responsible and take ownership of the situation to make sure the steps above take place.

The Committee concluded the biosafety discussion after making the following recommendation:

CLIAC considers the matter of biosafety in clinical laboratories as an urgent unmet national need. We therefore recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that:

- Includes stakeholders from all areas of clinical laboratories (including professional societies), diagnostic instrumentation industry, other relevant Federal agencies, and patient / clinician representatives.
- Recommends areas requiring further research in clinical laboratory safety.
- Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and for emerging infectious diseases.
- Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and to solicit input from the clinical laboratory and broader medical communities.
- Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety.
- Develops a framework for implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices.

Discussion on Forming Workgroups

- The Chair reminded the Committee that a member had suggested that a workgroup be formed to discuss the following topics:
    - HHS should require LOINC coding for a manageable subset of lab test results and consider starter list of 255 lab tests in ELINCS (EHR-Laboratory Interoperability and Connectivity Specification for Orders) page 178: LOINC Common Lab Order Value Set v1.1 http://www.chcf.org/projects/2009/elincs)

    - HHS should require LOINC coding for a manageable subset of lab test results and consider starter list of 255 lab tests in ELINCS (EHR-Laboratory Interoperability and Connectivity Specification for Orders) page 178: LOINC Common Lab Order Value Set v1.1 http://www.chcf.org/projects/2009/elincs)
- Ms. Dyer commented that CMS currently has an interoperability workgroup which met in September 2015 with another meeting planned for summer 2016. The Committee agreed that a CLIAC interoperability workgroup was not therefore necessary.
- A member suggested that a workgroup be formed to discuss the issues surrounding the Institute of Medicine (IOM) report "Improving Diagnosis in Health Care" noting this had been discussed during the November 2015 CLIAC meeting. The member suggested the workgroup's tasks be:
    - Review IOM's recommendations,
    - Review CLIAC's November 2015 meeting discussions and proposed recommendations,
    - Develop background for key recommendations to be discussed during the November 2016 CLIAC meeting.

Future CLIAC Topic Suggestions from the Committee

- Dr. Iademarco discussed the Antimicrobial Resistance Surveillance Task Force that is sponsored by the Council for State and Territorial Epidemiologists and CDC's National Center for Emerging & Zoonotic Infectious Diseases. One of the task force's pressing needs is to understand interoperability issues in the laboratory and Dr. Iademarco suggested that CLIAC could contribute because it has the right expertise represented. One Committee member suggested that the Task Force look at public health laboratories that already do some antimicrobial resistance surveillance. Two Committee members proposed that the Committee receive more information about the needs of the task force and the Committee can discuss them at a later meeting.

Other topic suggestions from the Committee were:

- PMI including information on the concerns about how the tests are being used and the release of test results to the patient population who may not understand the complex results.
- Discuss novel testing platforms and new test methods that are seemingly less invasive for patients but leave questions that need to be answered in a public forum.
- Clinical utility of tests and how this affects post analytic errors
- The new Medicare reimbursement policy and test quality.
- Updates on the CLIA modernization proposals.
- Broad discussion of CLIA modernization to include areas of concern and general principals.

BACKGROUND INFORMATION

Addendum 10
Addendum 11

ACRONYMS

Addendum 12

NOMINATION INFORMATION

Addendum 13

PUBLIC COMMENTS

Addendum 14
Addendum 15

ADJOURN

Dr. Wilcke and Dr. Mac Kenzie acknowledged the staff that assembled the meeting agenda and thanked the CLIAC members and partner agencies for their support and participation. The following are the three Committee recommendations passed at this meeting:

Recommendation on Biosafety:
CLIAC considers the matter of biosafety in clinical laboratories as an urgent unmet national need. We therefore recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that:

- Includes stakeholders from all areas of clinical laboratories (including professional societies), diagnostic instrumentation industry, other relevant Federal agencies, and patient / clinician representatives.
- Recommends areas requiring further research in clinical laboratory safety.
- Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and for emerging infectious diseases.
- Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and to solicit input from the clinical laboratory and broader medical communities.
- Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety.
- Develops a framework for implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices.

Recommendations on Laboratory Interoperability:

1. To facilitate wider uptake of standards for laboratory interoperability, HHS should endorse and stimulate adoption of an implementation guide/s for laboratory results reporting (e.g., The EHR-Lab Interoperability and Connectivity Specification (ELINCS) for orders available at: http://www.chcf.org/projects/2009/elincs); and successful pilots that arise from the S&I framework effort (http://wiki.siframework.org/Laboratory+Orders+Interface+Initiative)

2. CLIAC requests that the Office of the National Coordinator for Health Information Technology (ONC) Standards and Policy Committees each include a pathology informatician (pathologist with expertise in clinical informatics) as a committee member.

Dr. Wilcke announced the fall 2016 CLIAC meeting dates as November 2-3, 2016, and adjourned the Committee meeting.

I certify this summary report of the *April 13-14, 2016*, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Burton Wilcke, Jr., Ph.D., CLIAC Chair Dated: 6/13/2016