

HLWI Advisory Group Meeting
Thursday, March 15, 2018
10:00 - 11:00 am

Via Conference Call
Call-In Number: 1-800-882-3610
Passcode 6506506#

AGENDA

<u>ITEM</u>	<u>TIME</u>	<u>SUBJECT</u>	<u>REPORTING</u>	<u>PAGE</u>
I.	10:00 - 10:05 am	WELCOME AND INTRODUCTIONS A. Introductions and welcome	Co-Chairs Hamill/Foltz	2
II.	10:05 - 10:10 am	APPROVAL OF THE MINUTES A. Approval of the minutes from the November 9, 2017 HLWI conference call	Hamill/Foltz	5
III.	10:10 - 10:30 am	LANDSCAPE UPDATES A. All members: emerging issues and trends B. LFS update	All	
IV.	10:30 - 10:45 am	CLIA RFI/COMMENTS A. Megan Howard will review the CHA Response to a CMS Request for Information: (Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the CLIA)	Howard	7
I.	10:45 - 10:55 am	LEGISLATIVE UPDATE A. A review of laboratory and workforce legislative proposals	Martin	10
II.	10:55 - 11:00 am	OTHER BUSINESS A. Schedule next in-person meeting	Martin	13
III.	11:00 am	ADJOURNMENT	Hamill/Foltz	

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HLWI Advisory Group Meeting
Thursday, November 9, 2017
10:00 - 11:00 am
Via Conference Call
Draft Minutes

Participants:

Sharon Arase, Dolapo Afolayan, Danny Arimboanga, Patricia Buchner, Laurie Byrne, , John Ferguson, Dora Goto, Tim Hamill, Susan Kazarian, Peggy Kollars, Valerie Ng, Sonia Maljian, Cindy Martin, Jason Pedro, Deanna Reinacher, Sarah Rutschmann, Jennifer Schiffgens, Karla Theis, Sharon Wahl, Cindy Wong

CHA Staff:

Michele Coughlin, Megan Howard, Cathy Martin

Regional Association Staff:

Lisa Mitchell, Rebecca Rozen

Welcome and Introductions

Dr. Hamill welcomed participants and new member Deanna Reinacher and the meeting began at 10:04 a.m. Individual member introductions followed.

Approval of Minutes from September 13, 2017 meeting.

Dr. Hamill requested that participants bring forth any changes to the meeting minutes from the March meeting. No changes were requested.

- It was moved, seconded and the minutes from the September 13, 2017 meeting were approved.

Landscape Update

Megan Howard from California Hospital Association's Washington, D.C. office provided the workgroup with an update on the on the new CLFS rates that are set to take effect in January 2018. Megan stated that these new payment rates will be significantly lower and are expected to represent a 30% reduction in payment rates in the state of California. She explained the final rates could be released as early as next week. Megan shared some of the advocacy efforts CHA had taken to oppose the rate reductions that included joining 30 other national associations to ask CMS to suspend the lowered rates. She explained that DataSuite reports would soon be released modeling the impact of the proposed changes, and that these reports may prompt questions. She suggested that members email her with any questions they may have and stated that email was the best way to reach her at mhoward@calhospital.org. She further explained that if CMS took the position to suspend the proposed rates, that CHA would send communications to members alerting them to the situation.

Valerie Ng asked about AB 659 and its impact to laboratories. A brief workgroup discussion ensued and the group was informed that the governor signed the bill in September 2017 and the law would take effect in January 2018. Under this law, laboratories would be required to report every 3 years, rather than every year, thereby creating a reporting reduction.

Cindy Wong Cindy informed the committee about the development of a CBC analyzer recently categorized as waived. She reported that the FDA recently approved an automated hematology analyzer that can be operated by unlicensed personnel, though staff licensure may still be required for operation in California.

Valerie Ng will send a link to the HLWI

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583997.htm>

Dora Goto brought up the topic of the new state policies on issuance of qualifying letters to graduates taking ASCP exams. She mentioned that, as of October 16, qualifying letters are no longer issued and that this had posed challenges for some students. In response to Dora's questions, LFS confirmed that while the qualification letters stopped on October 16, applicants can go directly to their exam providers to determine if they are eligible for that exam.

Jason Pedro suggested that MLT and CLS programs check that the correct contact information uploaded onto the new LFS website, as he recently noted that program contact information for his program had reverted to outdated information.

Legislative Update

Dolapo Afolayan provided the group with an update on AB 658 (Renewal fees for Clinical Laboratories) which was passed and signed by the governor. This bill suspended renewal fees for clinical laboratories for the 2018-2019 renewal years. If your laboratory receives an invoice, they should contact:

Martha Obeso, LFS Examiner II

Personnel Licensing Section, California Department of Public Health

martha.obeso@cdph.ca.gov

Cathy Martin provided the group with an update on AB 387, the bill that would require allied health students to be paid minimum wage during their clinical training. Cathy explained that while the bill was placed on the inactive file in June (making it a 2-year bill), the sponsors continue to work it diligently. Cathy requested HLWI members to keep their eyes and ears open and to share any information or advocacy efforts of which they become aware. She let the group know that this bill could resurface on January 3. Cathy Martin updated the group on a potential MLT scope expansion effort.

Other Business

Cathy Martin called attention to the next scheduled meeting, which will take place in person on March 15, 2018 in Sacramento.

Cathy Martin also reminded the group of the HLWI member survey that was distributed via email and urged individual members to participate.

Adjourn

The meeting adjourned at 10:59 a.m.



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

March 12, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Subject: CMS-3326-NC, Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988; Federal Register (Vol. 83, No. 6), January 9, 2018

Dear Administrator Verma:

On behalf of the California Hospital Association (CHA) and our more than 400 members, we are pleased to offer our comments on the request for information on revisions to personnel regulations, proficiency testing referral, histocompatibility regulations and fee regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CHA appreciates that CMS is considering revisions to regulations under CLIA, many of which have not been updated in over 25 years. We believe the revisions will offer an opportunity to reduce burden and give hospital-based laboratories additional flexibility to address ongoing workforce challenges, improving the quality of care for the patients we serve.

Personnel Regulations

CMS seeks comment on a number of topics — identified in consultation with the Centers for Disease Control and Prevention (CDC), state surveyors and other stakeholders — related to personnel regulations that should be revised to better reflect current knowledge, changes in academic context and advancements in laboratory testing. Specifically, CMS requests information on the appropriate qualification of nursing, physical science and non-traditional degrees, as well as personnel competencies, experience training and skills.

In general, CHA urges CMS to adopt personnel regulations that provide the most flexibility for laboratory directors to make personnel decisions. For example, while we do not support a provision that would consider *any* physical science degree appropriate educational background for CLIA educational requirements, we believe certain coursework and experience could qualify an individual with a physical science or non-traditional degree. **The CLIA regulations should include flexibility to allow the technical consultant and medical director to make personnel requirement decisions that address their workforce needs, based on an individual's experience and educational background.**

In addition, we do not support a revision to the regulations that would consider a bachelor's degree in nursing to be equivalent to a bachelor's degree in biological science, for purposes of the educational requirements for moderate and high complexity testing personnel under CLIA. Nurses play an important

clinical role, particularly in point-of-care testing. However, a nursing degree does not encompass the specialized scientific and technical knowledge of a degree in biological sciences — knowledge that is necessary for oversight roles within the laboratory. **CHA supports the addition of a bachelor's degree in nursing as a separate qualifying degree for moderate complexity testing personnel and technical consultants, as long as they are under the supervision of an individual who meets the qualifications as a laboratory director. We also support the addition of a bachelor's degree in nursing as a separate qualifying degree for high complexity testing personnel, but believe the degree should not qualify for either technical supervisor or laboratory director for any laboratory performing high complexity testing.**

Finally, CHA supports a revision to the regulations that would allow general supervisors with associate's degrees to perform competency assessment for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing. We are also pleased to see that CMS has recognized the staffing challenges that result from contradictory differences in degree requirements for qualifying to assess competency. Current CLIA regulations allow general supervisors with associate's degrees to perform competency assessment on high complexity testing personnel. However, because the personnel requirements for moderate complexity testing do not include the general supervisor category, the same general supervisors cannot perform competency assessment on moderate complexity testing personnel unless they can meet the regulatory qualifications of a technical consultant, which requires a bachelor's degree in chemical, physical or biological science or medical technology.

Proficiency Testing Referral

The Taking Essential Steps for Testing (TEST) Act of 2012 provided the Health and Human Services Secretary with discretion as to which sanctions may be applied to cases of intentional proficiency testing (PT) referral. CMS established three categories of sanctions for PT referral to be applied based on severity and extent, with Category 1 established for the most egregious violations. Category 1 violations encompass cases of repeat PT referral, regardless of circumstances revolving around the violation, and cases where a laboratory reports another laboratory's PT results as its own to the PT program. Sanctions for this category include revoking the laboratory's CLIA certificate for at least one year, banning the owner and operator from owning or operating a CLIA-certified laboratory for at least one year, and imposing a civil money penalty (CMP). CMS seeks comments on applying discretion in situations where it is determined that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's PT results as its own, and under what circumstances the discretion should be applied.

CHA believes that laboratories should not be punished for following their standard operating procedures, which may result in the unintentional referral of a PT sample to another laboratory. PT is a tool to ensure laboratory test results are reliable and accurate. Laboratories are required to test PT samples in the same manner as patient specimens, except that they may not refer these samples to another laboratory for testing for any reason. However, it is common standard operating procedure for patient specimens to be referred other laboratories within a system for reflex, confirmatory or distributive testing. This PT referral requirement is contradictory and confusing, creating burden for laboratories to test PT samples in a manner different than they would test a patient sample.

CHA supports giving CMS greater level of discretion in applying sanctions where it is determined that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's PT results as its own. Hospitals and health systems may have several laboratories operating under multiple

CLIA certificates, although they act in concert as a laboratory “system.” In these circumstances — if a PT referral violation occurred due to referral of samples for additional, confirmatory, or reflex testing to provide a result — CLIA certification would be jeopardized for all laboratories that followed their standard procedure for patient samples. Impacting an entire health system in such a situation poses severe risk to patient safety and quality of care. **CMS should apply discretion in these circumstances in which imposing an ownership ban across an entire health system would endanger the public health.**

Alternative Sanctions for PT Referral for Certificate of Waiver (CoW) Labs

Currently, PT is optional for waived testing. However, CMS does not have the authority to impose alternative sanctions on CoW labs that choose to participate in PT, because those laboratories are not inspected for compliance with condition-level requirements. Therefore, the only recourse in cases of PT referral found at CoW laboratories are principal sanctions (revocation, suspension or limitation). CMS’s ability to exercise discretion in sanctions would encourage more CoW laboratories to participate in PT, which would help ensure improved laboratory testing quality and reduce regulatory burden on CoW laboratories. **CHA supports revisions to the CLIA regulations that would allow more discretion in issuing sanctions against CoW laboratories.**

Histocompatibility

CMS notes that since the CLIA specialty requirements for histocompatibility testing were initially finalized in 1992, there have been many advancements in laboratory testing. The Clinical Laboratory Improvement Amendments Advisory Committee (CLIAC) Virtual Crossmatch Workgroup was convened to gather information on the acceptability and application of virtual crossmatching in lieu of serologic crossmatching for transplantation. The CLIAC workgroup found that advances in the field have made the physical crossmatching less significant and, in some cases, obsolete. As such, it made a number of recommendations, including regulatory changes or guidance that would allow virtual crossmatching to replace physical crossmatching as a prerequisite for organ transplant. **CHA supports these recommendations.**

CHA appreciates the opportunity to respond to this request for information. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688 or Megan Howard, senior policy analyst, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs

Legislative Update: Workforce Bills – 2018

AB 2018 (Maienschein)	<p><u>Mental Health Provider Loan Repayment:</u> Amends current statute for state loan repayment programs to allow psychiatry trainees that meet necessary criteria to be eligible for loan repayment during their training. Currently, the state’s primary loan incentive program aimed at enticing students to work in community psychiatry has only been used to commence loan repayment <i>after</i> a student has completed residency training and is employed in a community mental health setting. It does not apply, for example, to trainees in two innovative fellowship programs run by UC San Diego and UC San Francisco that teach specialized psychiatric competencies for practice in community mental health programs. These fellowship programs attract capable residents who train in underserved communities. The students provide mental health services and train with a commitment to be employed in these settings after they finish training, but they are not deemed eligible for loan repayment because they are trainees even though they are providing billable psychiatric services.</p> <p>CHA Position: Support</p>	<p>Introduced: 2/05/18</p> <p>Amended and Referred to Health Committee: 2/21/18</p>
AB 2143 (Caballero)	<p><u>Registered Nurse and Physician Assistance Loan Forgiveness for Mental Health Specialties:</u> Existing law authorizes a licensed mental health service provider, as defined, including, among others, a psychologist and a marriage and family therapist, who provides direct patient care in a publicly funded facility or a mental health professional shortage area to apply for grants under the Mental Health Practitioner Education Fund in the State Treasury and provides that moneys in that fund are available, upon appropriation, for expenditure by the Office of Statewide Health Planning and Development for purposes of the program. This bill would add physician assistants who specialize in mental health services and psychiatric-mental health nurse practitioners to those licensed mental health service providers eligible for grants under the program.</p> <p>CHA Position: Follow, Hot</p>	<p>Introduced: 2/12/18</p> <p>Referred to B&P: 03/01/18</p>
AB 2202 (Gray)	<p><u>University of California, Merced, Medical School:</u> This bill would appropriate an unspecified sum of moneys from the General Fund to the Regents of the University of California each fiscal year, commencing with the 2018–19 fiscal year, for the creation, construction, and establishment of the University of California, Merced School of Medicine.</p> <p>CHA Position: Follow</p>	<p>Introduced: 2/12/18</p> <p>Referred to H.Ed: 03/01/18</p>
AB 2281 (Irwin)	<p><u>Medical Laboratory Workforce Modernization:</u> Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law requires a medical laboratory technician to be licensed by the department, sets forth the duties that a licensed medical laboratory technician is authorized to perform, and prohibits a licensed medical laboratory technician from performing microscopic analysis or immunohematology procedures. This bill would exempt from that prohibition blood smear reviews, microscopic urinalysis, and blood typing of moderate complexity.</p> <p>CHA Position: Support</p>	<p>Introduced: 2/13/18</p> <p>Referred to B&P: 03/01/18</p>

Revised: March 8, 2018

AB 2539 (Mathis)	<p><u>Steve Thompson Loan Repayment Program:</u> Existing law establishes the Steven M. Thompson Physician Corps Loan Repayment Program (program) in the California Physician Corps Program within the Health Professions Education Foundation, which provides financial incentives, including repayment of educational loans, to a physician and surgeon who practices in a medically underserved area, as defined. This bill would reduce until January 1, 2021, and only for program participants who enroll in the program on or after January 1, 2019, and before January 1, 2021, that the clinic or the physician owned and operated medical practice setting have at least 30% of patients (instead of 50%), if the area is a rural area, as defined, or at least 50% of patients, if the area is not a rural area, who are from the above-described populations. The bill would require the foundation to prepare a study to determine the effect that the revised definition has on funding for loan repayment granted under the program during the calendar years 2019 and 2020.</p> <p>CHA Position: Support</p>	<p>Introduced: 2/14/18</p> <p>Referred to Health: 03/05/17</p>
AB 2759 (Santiago)	<p><u>Baccalaureate versus Associate Degree Nursing training and employment:</u> Would prohibit clinics and health facilities that receive public funds from excluding students enrolled in an approved public community college associate degree pre-licensure nursing program from clinical placement. Would also prohibit clinics and health facilities from discriminating against a person (in employment, compensation or other means) because he or she has an associate degree in nursing instead of a baccalaureate degree.</p> <p>CHA Position: Oppose</p>	<p>Introduced: 2/16/18</p>
SB 906 (Beall and Anderson)	<p><u>Peer Specialist Certification:</u> This bill would require the State Department of Health Care Services to establish, no later than July 1, 2019, a statewide peer, parent, transition-age, and family support specialist certification program, as a part of the state's comprehensive mental health and substance use disorder delivery system and the Medi-Cal program. The bill would include 4 certification categories: adult peer support specialists, transition-age youth peer support specialists, family peer support specialists, and parent peer support specialists.</p> <p>CHA Position: Follow, Hot</p>	<p>Introduced: 1/17/18</p> <p>Set for Hearing in Senate Health: 03/14/18</p>
SB 1348 (Pan)	<p><u>Diversity and demographic reporting for allied health students:</u> This bill would require, beginning in 2019 and in each year thereafter, the chancellor to include in the annual report, for each community college program that offers certificates or degrees related to allied health professionals that require clinical training, specified information relating to clinical training for those certificates or degrees. For example, The name and address of the clinical placement sites, including, but not limited to, the licensed hospital, clinic, or other medical facilities that contracts with the community college for each clinical rotation, as applicable. The length and types of clinical rotations, as applicable. Supervision ratios at each site. The numbers of students participating in clinical training, including demographic data related to race, ethnicity, gender, and proficiency in languages other than English. Employment retention at each clinical placement site, as applicable.</p> <p>CHA Position: Follow, Hot</p>	<p>Introduced: 2/16/18</p> <p>Set for Hearing in Senate Ed: 04/04/18</p>

Revised: March 8, 2018

SB 1373 (Stone)	<p>Pharmacist Ratios: This bill would require a general acute care hospital licensed by the department to employ, at a minimum, one full-time pharmacist for every 100 licensed beds, and for additional licensed beds, employ additional pharmacists on a pro rata basis. The bill would require a general acute care hospital that is licensed for less than 100 beds to employ one pharmacist on at least a part-time basis.</p> <p>CHA Position: Oppose</p>	<p>Introduced: 2/16/18</p>
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Health Laboratory Workforce Initiative Advisory Group

2018 Meeting Dates

Thursday, March 15, 2018

10:00 am - 2:00 pm

IN PERSON MEETING

California Hospital Association
1215 K Street, 8th Floor Board Room
Sacramento, CA 95814
1-800-882-3610
Passcode: 6506506#

Thursday, May 24, 2018

10 - 11 am

VIA CONFERENCE CALL

1-800-882-3610
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Thursday, September 20, 2018

10 am - 2 pm

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