The Connection

January 2018

Inside this issue:

President's Message

I recently reviewed some employee satisfaction survey results from a North Dakota laboratory. While most of what I saw was expected, one result in particular caught my attention (and not in a good way) - that a fair number of employees did not feel what they did on a daily basis made a significant contribution to patient care. My lab heart broke as I thought about this sentiment. We do such an important job, and patient care is impacted by the results we give – so how could my fellow laboratorians feel this way?

In trying to answer this question, I realized that the lab is one of those things in life that people take for granted. I am reminded of a recent power outage, and how I kept trying to turn the lights on out of habit, only to have nothing happen. Each time I flicked the switch and remained in darkness, I found myself realizing just how much I relied on those lights. Isn't that a good analogy for the lab? We are the epitome of the saying "you don't know what you've got til it's gone". It's a catch-22…people won't appreciate us unless we aren't there, and we, being the dedicated lab professionals that we are, would never let the lab not 'be there'.

The idea of the lab not 'being there' does bring up an interesting image, however. What would healthcare look like without the lab? Stop and think about that. Think about the young baby brought to the ER in the middle of the night because she is having difficulty breathing, and how the positive RSV test issued by the lab gives the parents and physicians involved an answer and a course of action. Think about the patient whose heart attack is identified early through diligent lab testing, thus reducing long-term damage and preserving quality of life. Think about the hopeful couple that finds out they are expecting a baby with a positive pregnancy test. Think about the patient whose lab results show they are ready to go home after a lengthy hospital stay, and can be with family again. The list could go on, and on, and on. And the message is the same with each scenario – what we do in the lab **IS** making a difference for patients, even if they don't necessarily realize it.

Accolades for the laboratory likely aren't going to come from the patient, or the physician, because they don't know what it would be like without the lab, and thanks to laboratorians like you, they hopefully never will! But that does mean we must provide our own compliments. We must remind ourselves and our co-workers of our worth on a daily basis. In doing this, we will boost morale (and maybe even increase those employee satisfaction survey results!), which will help ensure that no patient will ever have to appreciate us because we are gone.

Pat Tille - Region V Director

Change Brings Opportunity!

As I reflect on 2017 and look forward to the future for the laboratory profession and 2018, I am struck by the many challenges and tragedies we faced in our country during this past year. Then I look ahead at what we are struggling with in the laboratory profession. We are facing cuts in reimbursement, challenges to become more efficient and do more with less, increasing technology and the need for more training, and a possible CLIA'88 overhaul on the horizon.

Being a laboratory professional has never been the easy way out, in my opinion. I find our professionals in Region V throughout all four states to be some of the most dedicated and resourceful people that I know. We have a strong representation at the National, Regional and Local level for ASCLS and we have dedicated colleagues making sure our medical care remains high quality.

With all of that, I think it is important to look to the future as an opportunity for growth and improvement in the laboratory profession. Often we view change as negative, and after stepping back and looking at the past year, I believe we truly have a unique opportunity to make the rest of the health care profession and the public stand up and take the laboratory profession seriously. With the rapid changes in technology, we may lose a few positions to an automated front line, but we will gain positions for high complexity interpretations of new methodologies and data mining strategies to improve patient care. We may have to centralize microbiology and immunohematology and other procedures in areas where the volume of the test simply does not warrant having it at every facility, but we will gain efficiency and reduce costs in order to fund new projects and advancements in our field.

As the legislative symposium approaches, I hope that many of you consider attending this year. Now more than ever, we have the opportunity to speak up and make our voices heard. Health care is on the front of all the legislative activities and we have the opportunity to move our profession forward.

I challenge each and everyone of you to take a look at the change that is happening around you in your laboratories and health systems and become proactive to make your voice heard. Make sure you are active and at the table in your local, regional and national discussions on reimbursement and the potentially looming overhaul of CLIA'88. It is our time to make others aware of the value of laboratory diagnostics and the essential need for qualified laboratory professionals at the table to make those decisions. Instead of looking back at 2017 with sadness, let's remember the loss and the tragedies by looking for strategies to move forward. I truly believe that the wind of change is our opportunity to tell everyone who we are and why we are important to health care and the patient's well-being. Hope to see some of you in Washington D.C. in March for the Legislative Symposium!

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services 42 CFR

Part 493

[CMS-3326-NC] RIN

0938-ZB40

Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histo-compatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information seeks public comment regarding several items related to Clinical Laboratory Improvement Amendments of 1988 (CLIA) personnel requirements and histocompatibility requirements, which, with minor exception, have not been updated since 1992. We are also seeking public comment regarding the flexibility to impose alternative sanctions for laboratories issued a Certificate of Waiver (CoW) determined to have participated in proficiency testing (PT) referral. In addition, we are seeking public comment related to appropriate sanctions in situations where we determine that a laboratory has referred its PT samples to another laboratory and has reported the other laboratory's result as their own.

Continued on page 10

NOMINATIONS

ASCLS-ND Nominations 2018-2019

TO NOMINATE SOMEONE PLEASE SEND NAME AND EMAIL ADDRESS TO:

HEATHER WANGLER : heather.wangler@ndus.edu

Job Descriptions:

President Elect: 1 year term, advance to President the following year

Becomes familiar with presidential duties to transition into the position the following year.
Assists the President as needed and serves as CEO in absence of the President.
Develops knowledge of past and present Society activities.
Chairs ASCLS-ND membership development committee, and serves as liaison to LEND Advisory board.
Co-chairs ASCLS-ND delegation at the annual meeting of the ASCLS House of Delegates.
Prepares budget for the following year.
Attends the Region V council meeting, business meetings, and ASCLS annual meeting.

Nominations Committee Chair: 1 year term

Serves as a member of the ASCLS-ND Board of Directors

Solicits nominations for each available elective position via the newsletter or by email to the membership.

Sends out on-line election to constituent society members at least two weeks prior to the meeting.

Prepares a display of the candidates' photographs and biographical information to be exhibited in the Registration area prior to the business meeting.

Conducts the election at the ASCLS-ND annual meeting.

New Professional Delegate (must be a person in the field for < 5 years): 1 year term

Becomes familiar with issues presented to the House of Delegates.

Attends all meetings of the House of Delegates and other meetings as requested by the chair of the ND Delegation.

Submits an article for publication in the winter issue of the ASCLS-ND newsletter.

Board Member at Large: 2 year term

Serves as member of ASCLS-ND Board of Directors.

Serves as committee chair and other leadership roles as requested by the President.

Secretary/Treasurer: 2 year term

Serves as Secretary at all meetings of the Board of Directors and all ASCLS-ND business meetings.

Records and permanently files minutes for all meetings.

Maintains a current list of active ASCLS-ND members.

Receives scholarship applications from CLS/CLT students by February 1 and submits the applications to the Education Committee Chair.

Maintains and opens checking and savings accounts for ASCLS-ND as necessary.

MEMBERSHIP

ASCLS - ND Membership Update

Zac Lunak, President-elect

The national membership committee recently sent membership data comparing member totals in 2016 and 2017. Nationally, ASCLS total membership had dropped approximately 1000 members in 2017 compared to 2016. Below is a table that describes membership totals in ND comparing November 2016 and 2017. In North Dakota, there was a decrease in total membership as well but we actually maintained our professional membership total.

Professional Members-Nov 2016	Total Members-Nov 2016	Professional Members – Nov 2017	Total Members-Nov 2016	Total Member Change 16-17	Professional Member change 16-17
55	91	56	64	-27	1

Our goal this year is to eventually have 100 members. We currently have 78 total members (as of 1/9/18). That number is up from the last update this past Fall, in which we had 62 total members. Thanks to everyone who recruited new members! Having increased membership is more important than ever as we try to have a united voice for very important regulatory and government issues.

Listed below are what I believe ASCLS offers its members. Keep in mind, ASCLS does not restrict its membership to medical laboratorians. Other lab professions, such as phlebotomists, lab assistants, etc. are also welcomed.

Benefits of ASCLS

- Advocacy of profession (government affairs)
- Networking
- Publications
- Continuing Education
- Grassroots activities
- Online Community Resources
- Much more!

Do you know what CRAB stands for when talking about Multiple Myeloma?

Stacy Askvig-ASCLS member

Multiple myeloma patients usually have four clinical signs that happen because of the increase in the abnormal plasma cells. The letters CRAB stand for those four signs:

C stands for increased calcium levels due to the breakdown of bone.

R stands for decreased renal function that happens in multiple myeloma, if left untreated a condition called myeloma kidney can happen and all kidney function may be lost.

A stands for anemia. Multiple Myeloma causes the bone marrow being overtaken by malignant plasma cells and anemia results due to loss of other hematologic precursors. Decrease in red blood cell precursors equals anemia.

B stands for Bone. Multiple Myeloma causes bone lesions due to the malignant plasma cells.

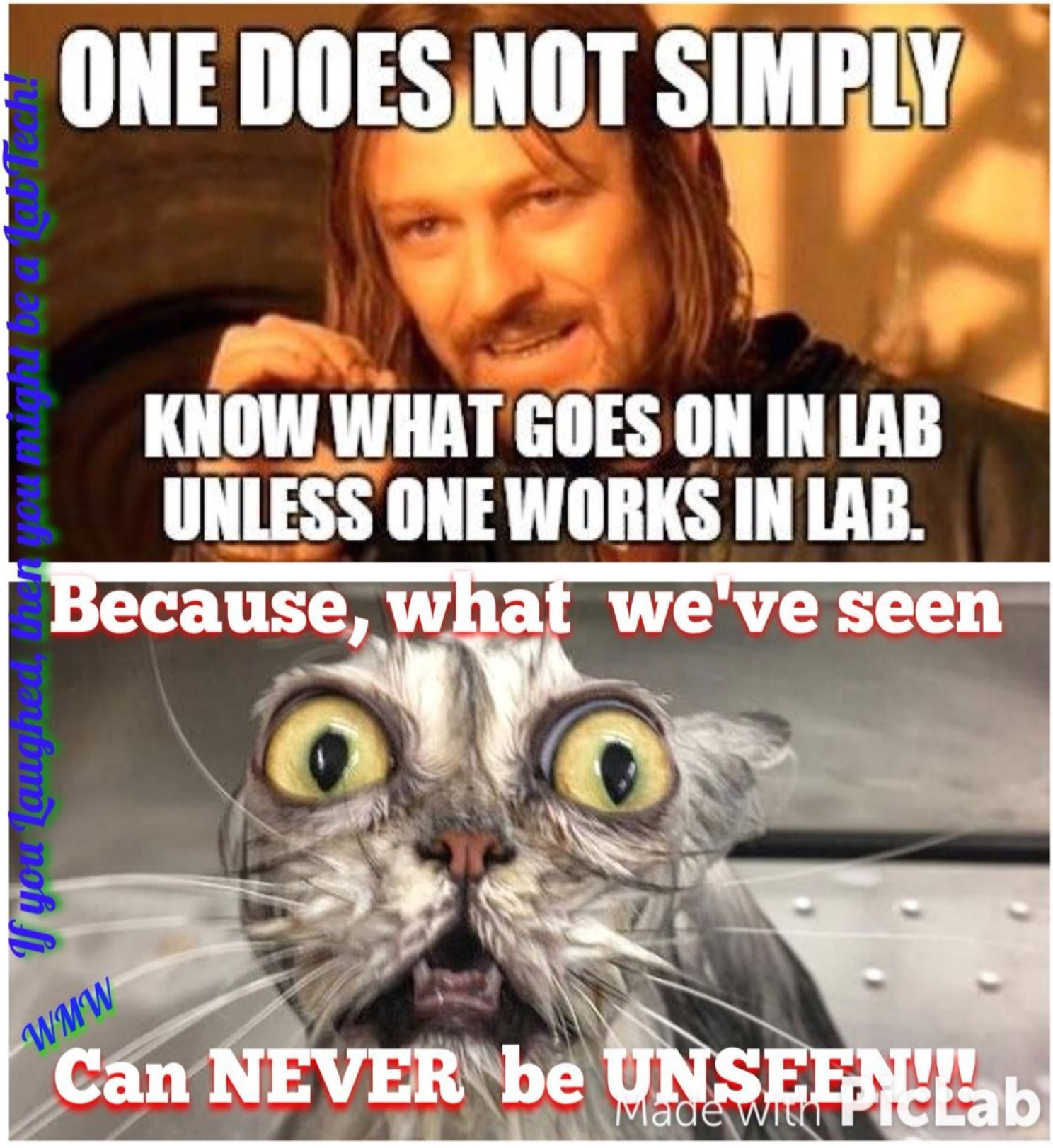
Now you know what CRAB stands for other than a great meal!

STUDENT REP UPDATE

Ali Hassan-Student Rep

I contacted UND at the end of the Fall Semester and they asked me to check back in the spring to schedule a time with the MLS club or students that are taking intro to MLS. I will reach out to them again to set up a date for me to visit the students and share scholarship information as well as my experience with ASCLS so far.

For this year, I have share my experience with our MLS Students at Sanford Health focusing mainly on my experience of the National Meeting at San Diego. I also told them I will be back with scholarship information for them and thoughts on the legislative symposium.


If you Laughed, then you might be a LabTech!
ONE DOES NOT SIMPLY
KNOW WHAT GOES ON IN LAB
UNLESS ONE WORKS IN LAB.
Because, what we've seen
WWW
Can NEVER be UNSEEN!!!
Made with PicLab

SAVE the

ASCLS-ND 2018 State Meeting

Step UP, Speak UP, Stand UP

Why: Because you have **U**nlimited **P**otential

April 16-18, 2018

Ramada Inn, Fargo, ND

Sessions begin ***Monday, April 16 at 12:30pm***

Vendor Evening Social event ***Tuesday, April 17 from 5:30-8:30pm***

Closing Keynote ***Wednesday, April 18 at 12:30pm***

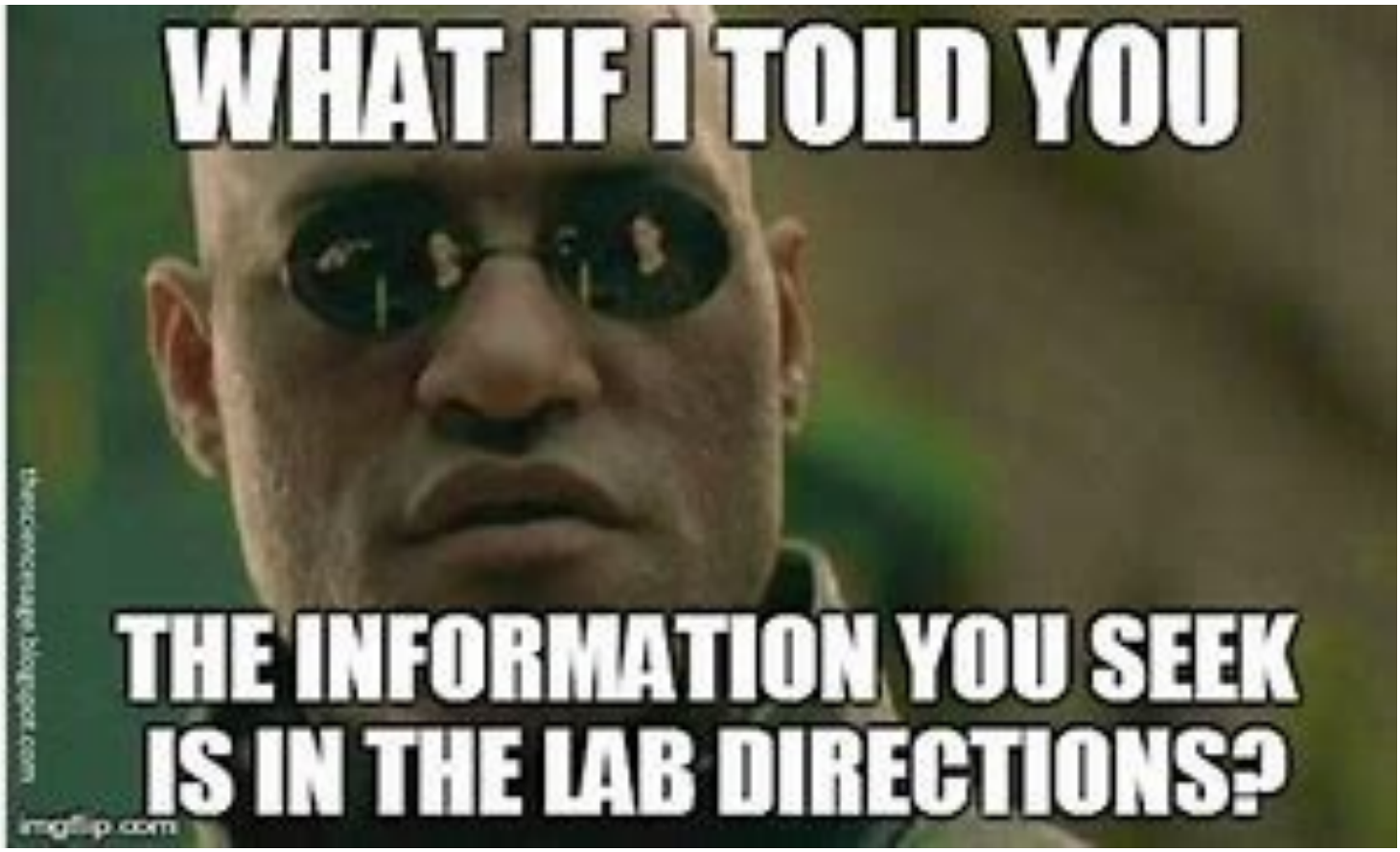
Un-Paralleled Speakers and Education

Un-Paralleled Vendors and New Products

Un-Paralleled Networking with other Professionals

Continued from page 3

This request for information also seeks public comment regarding the updating of fees for determination of program compliance and additional fees for laboratories established under the CLIA regulations. We are also seeking public comment regarding the collection of other fees we are authorized to collect such as fees for revised certificates, post survey follow-up visits, complaint investigations, and activities related to imposition of sanctions.



We intend to consider public comments (including information such as evidence, research, and trends) received in response to this request for information when we draft proposals, in consultation, as appropriate, with the Centers for Disease Control and Prevention (CDC), to update the existing CLIA regulations through future rulemaking. We are also soliciting public comment on other areas of CLIA which should be reviewed and potentially updated.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[**insert date 60 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, refer to file code CMS-3326-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:
3.

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention:

CMS-3326-NC,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and

Human Services,

Attention: CMS-3326-NC,

Mail Stop C4-26-05, 7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services, Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

For general questions, please contact Caecilia Blondiaux, 410-786-2190. For personnel requirements, please contact Sarah Bennett, 410-786-3354. For proficiency testing referral, please contact Sarah Bennett, 410-786-3354. For histocompatibility, please contact Penelope Meyers, 410-786-3366.

For CLIA fees, please contact Cindy Flacks, 410-786-6520.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments.

I. Background

A. Personnel Requirements

Generally, the Clinical Laboratory Improvement Amendments of 1988 **(**CLIA) regulations related to personnel re-

quirements have not been updated since 1992, with the exception of minor changes to doctoral high complexity laboratory director qualifications in 2003 (see 68 FR 3713). We are soliciting public comments (including information such as evidence, research, and trends) and intend to draft proposals, to update the existing CLIA personnel regulations through future rulemaking. The topics listed in this request for information are areas that the Centers for Disease Control and Prevention (CDC), CMS, stakeholders and State Agency surveyors identified as concepts that should be relevant to our efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context and advancements in laboratory testing. Therefore, prior to starting the rulemaking process, we are seeking public comments (including information such as evidence, research, and trends), including stakeholder and surveyor feedback, specific to the topics discussed in this request for information. We intend to consider any such comments when we draft proposals to update the existing CLIA personnel regulations to better protect public health and safety and reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

1. Nursing Degrees

As noted in Survey & Certification Letter 16-18-CLIA[1], we currently 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

1 Survey & Certification Letter 16-18-CLIA

SC 16-18-CLIA, S&C website: http://www.cms.gov/Medicare/Provider-Enrollment-and- Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

under CLIA. We are considering drafting proposals to amend 42 CFR §§493.1411 (moderate complexity technical consultant), 493.1423 (moderate complexity testing personnel), and 493.1489 (high complexity testing personnel) to expressly reflect that policy. We are also considering whether a nursing degree should be considered as a separate qualifying degree, as opposed to the equivalent of a biological science degree, for purposes of meeting the educational requirements for moderate and high complexity testing personnel and technical consultants. As such, we are also considering proposing to amend §§493.1411, 493.1423, and 493.1489 to add a nursing degree as a separate qualifying degree to the current list of qualifying degrees for the moderate and high complexity testing personnel and technical consultants.

We are seeking public comments (including information such as evidence, research, and trends) related to whether, for purposes of meeting the educational requirements for moderate complexity technical consultants and testing personnel and high complexity testing personnel,

§§493.1411, 493.1423, and 493.1489 should be amended: (1) to expressly reflect that a nursing degree is equivalent to a biological science degree; or (2) to add nursing degrees as a separate qualifying degree (as opposed to the equivalent of a biological science degree) to the current list of qualifying degrees.

2. Physical Science Degrees

Due to variation in usage and the absence of universally accepted definitions, a "physical science degree" is difficult to define for regulatory purposes. We note, however, that physical science is a broad discipline often described as the study of non-living systems, such as astronomy, physics, and earth sciences. Generally, these types of degrees are not related to clinical laboratory testing. We note that in some instances, individuals with these types of degrees have been able to qualify as high complexity testing personnel under §493.1489.

We are seeking public comments (including information such as evidence, research, and trends) on what is considered a physical science degree and whether any physical science degree(s) should be considered as educational background(s) appropriate for qualifying to meet the CLIA educational requirements at §§493.1405, 493.1411, 493.1423, 493.1443, 493.1449,

493.1461, and 493.1489.

3. Personnel Competencies

We recognize that the personnel qualifications for general supervisors may be less stringent than those of technical consultants. However, the current CLIA regulations allow general supervisors with associate's degrees (§493.1461) to perform competency assessment on high complexity testing personnel (see §§493.1461(c)(2), 493.1489 (b)(2)(i)), but 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 (§493.1411). Technical consultants, at a minimum, are required to have a bachelor's degree in chemical, physical, or biological science or medical technology. We recognize that high complexity testing is inherently more involved than moderate complexity testing. We have received feedback from laboratories and other stakeholders that the difference in degree requirements to qualify to assess competency presents staffing challenges in laboratories. We are seeking public comments (including information such as evidence, research, and trends) regarding whether general supervisors, with associate's degrees, should be allowed to perform competency assessment for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing.

4. Personnel Experience, Training and Skills

Currently, when we refer to laboratory training, experience and/or skills[2], we mean that the individual qualifying has the training in and the experience with non-waived clinical laboratory testing or in the specialties and subspecialties in which the individual is performing testing. Generally, the type of training and experience required under the current CLIA personnel regulation at part 493, subpart M, is clinical in nature. This means examination and test performance on human specimens for purposes of obtaining or providing information for the diagnosis, treatment, and monitoring of patients.

We are seeking public comments (including information such as evidence, research, and trends) on what should be considered appropriate laboratory training, experience and skills when determining the qualifications necessary for all[3] personnel to meet CLIA requirements, and what comprises appropriate documentation to verify the training, experience and skills for all personnel positions in part 493, subpart M.

5. Non-Traditional Degrees

Several current CLIA personnel requirements allow a position to be filled by an individual with a degree in a "chemical, physical, biological or clinical laboratory science, or medical technology."[4] We recognize there are non-traditional degrees (for example, Regents Bachelor of Arts) that may include job experience in lieu of coursework and that typically do not include a major concentration of study (for example, biology or chemistry), but are instead classified as general education degrees.

We are seeking public comments (including information such as evidence, research, and trends) related to such non-traditional degrees, specifically whether these types of degrees should

2 See §§493.1405, 493.1406, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, 493.1489, 493.1491.
3 See §§493.1405, 493.1406, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, 493.1489, 493.1491.
4 See §§493.1405, 493.1411, 493.1423, 493.1449(c) through (j) and (n) through (q), 493.1461, 493.1489.

be considered to meet the requirements for a chemical, physical, biological or clinical laboratory science, and/or medical technology degrees.[5]

B. Proficiency Testing Referral

The Taking Essential Steps for Testing Act ("TEST Act") (Pub. L. 112-202, enacted on December 4, 2012) amended section 353 of the Public Health Service Act (PHSA) to provide the Secretary with discretion as to which sanctions may be applied to cases of intentional PT referral. Such discretion may in some circumstances replace the automatic revocation of the laboratory's CLIA certificate and subsequent imposition of the 2-year ban on the laboratory's owner or operator, which would prevent them from owning or operating a CLIA-certified laboratory for 2 years.

1. Discretion for Category 1 PT Referral

The final rule entitled, "Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral", published in the May 2, 2014 **Federal Register** (79 FR 25463 through 25467 and 25480 through 25481), amended the regulations to implement the TEST Act and provide the prescriptive framework for the application of sanctions in PT referral cases (see also 79 FR 27106). These regulations allow for a more appropriate enforcement action based upon the nature and extent of an intentional PT referral violation and the penalties that are imposed. These regulations include three categories of sanctions for a PT referral to be applied under certain specified conditions, based on the severity and extent of the violation. These categories reserve revocation and the resulting laboratory director/owner/operator prohibition for the most

5 See §§493.1405, 493.1411, 493.1423, 493.1449(c) through (j) and (n) through (q), 493.1461, 493.1489.


THE DOCTOR CALLED AND SAID
TO TELL YOU
YOUR LABS ARE IN


ALL FOOD MUST GO
TO THE LAB FOR TESTING

egregious violations while permitting less serious sanctions in cases where circumstances warrant.

"Category 1", found at §493.1840(b)(1), is for the most egregious violations, encompassing 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. This category includes the revocation of the laboratory's CLIA certificate for at least 1 year, bans the owner and operator from owning or operating a CLIA-certified laboratory for at least 1 year, and may include the imposition of a civil money penalty (CMP). The application of the owner exemption from the ban is determined on a case-by-case basis (see

§493.1840(b)(1)(ii)).

We are seeking public comment related to applying discretion in situations where we determine 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.

2. Alternative Sanctions for PT Referral by CoW Laboratories

Section 353(d)(2)(C) of the PHSA states that laboratories issued a CoW are only exempt from subsections (f) and (g) of the statute. All other subsections apply, including the prohibition against PT referral in subsection (i), which refers to "any laboratory" that the Secretary determines has intentionally referred its PT samples. Therefore, CoW laboratories that participate in PT are not exempt from the ban against PT referral. Per §493.1775(b), CoW laboratories may be inspected to determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health, evaluate a complaint, determine whether the laboratory is performing tests beyond the scope of its

certificate, or to collect information regarding the appropriateness of tests specified as waived tests. In addition, §493.1775(c) requires the laboratory to comply with the basic inspection requirements of §493.1773. However, the CLIA regulations at §493.1804(c)(1) state that we do not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements. Therefore, our only recourse in cases of PT referral found at CoW laboratories are principal sanctions (that is, revocation, suspension, or limitation).

We are seeking public comments (including information such as evidence, research, and trends) to determine if alternative sanctions instead of principal sanctions should be an option in these cases in order to create parity for all certificate types for laboratories determined to have participated in PT referral.

C. Histocompatibility

Generally, the CLIA regulations related to histocompatibility have not been updated since 1992, with the exception of certain changes in 2003 (see 68 FR 3640). We are soliciting public comment and intend to draft proposals, to update the existing CLIA histocompatibility regulations through future rulemaking. The topics listed in this request for information are areas that CDC, CMS, the Clinical Laboratory Improvement Amendments Advisory Committee (CLIAC), and stakeholders identified as concepts that should be relevant to our efforts to update the CLIA histocompatibility requirements to better reflect current knowledge, changes in transplant medicine, and advancements in laboratory testing. We intend to consider any such information when we draft proposals to update the existing CLIA histocompatibility requirements to better protect the public health and safety and reflect current knowledge, changes in transplant medicine, and advancements in laboratory testing.

1. Crossmatching

As a result of changes in histocompatibility testing technology and practices, as well as advances in organ transplantation since 1992, we believe that some of the requirements found at

§493.1278 have become outdated and may preclude the use of current transplantation practices. For example, in some cases, performing a "virtual crossmatch" has replaced the use of a "physical crossmatch" to determine compatibility between the donor and recipient.

The CLIA regulations require a crossmatch to be performed as part of the laboratory testing process (see 42 CFR 493.1278(e)). Although not specified in the regulation, the crossmatching procedures in use in 1992 were physical crossmatches (also referred to as serologic crossmatches), that is, a mixing of specimens from donor and recipient to check for compatibility. We understand that these regulations are viewed by the transplantation community as a barrier to modernized decision-making approaches on organ acceptability based on risk assessment.

Virtual crossmatching generally refers to an assessment of immunologic compatibility based on the patient's alloantibody profile compared to the donor's histocompatibility antigens. In virtual crossmatching, laboratory test results already performed on donors and recipients are compared in order to predict compatibility and determine whether an organ is acceptable for a patient.

The 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 workgroup reported on advances in the field of transplantation since the CLIA regulations were published in 1992. These advances have made the physical crossmatching less significant or even obsolete in some cases. Specifically:

- Histocompatibility testing has evolved from cell based assays to molecular typing and solid phase platforms for antibody detection, leading to improved accuracy, sensitivity, specificity.
- Significant changes have occurred in the clinical practice of transplantation (for example, immunosuppression, desensitization practices), and improvements in anti-rejection therapies have led to improved outcomes and mitigation of risk due to antibodies against human leukocyte antigens (HLA).

These advances have made virtual crossmatching a viable alternative to physical crossmatching. The Virtual Crossmatch Workgroup presented a report called the Acceptability and Application of Virtual Crossmatching in lieu of Serologic Crossmatching for Transplantation,[6] to the full CLIAC at its November 2014 meeting. CLIAC deliberated on the report and recommended that we explore:

- Regulatory changes or guidance(s) that would allow virtual crossmatching to replace physical crossmatching as a pre-requisite for organ transplant.
- Appropriate criteria and decision-making algorithms, based on the Virtual Crossmatch Workgroup input provided to CLIAC, under which virtual crossmatching would be an appropriate substitute for physical crossmatching. The determination of appropriate criteria and decision-making algorithms should involve a process that includes an open comment period.

6 The Acceptability and Application of Virtual Crossmatching in lieu of Serologic Crossmatching for Transplantation (2014) https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac1114/8_BRAY_Virtual_Crossmatch_Workgroup_Report_Nov-2014.pdf.

We are seeking public comments (including information such as evidence, research, and trends) related to these two CLIAC recommendations; that is, whether virtual crossmatching should be an acceptable alternative to physical crossmatching, and under what criteria and decision-making algorithms virtual crossmatching would be an appropriate substitute for physical crossmatching.

2. Updating the Histocompatibility Requirements

Since the CLIA specialty requirements for histocompatibility testing were initially finalized in 1992, there have been many advancements in laboratory testing. We believe that some of the requirements found at §493.1278 other than those related to crossmatching may also be outdated or are redundant with other requirements found in subpart K of the regulations. We are seeking public comments (including information such as evidence, research, and trends) related to any histocompatibility regulations that have become outdated, and suggestions for updating the histocompatibility regulations to align with current laboratory practice.

D. CLIA Fees

With the exception of the certificate fees notice which was published in the August 29, 1997 **Federal Register** (62 FR 45915 through 45821), the CLIA regulations related to fees have not been updated since 1992, and we intend to update the CLIA regulations with regard to fees. These fee updates would include the determination of program compliance fees for laboratories holding a Certificate of Compliance (CoC), additional fees for laboratories holding a Certificate of Accreditation (CoA), fees for revised certificates, follow-up visits, complaint investigations, and activities related to the imposition of sanctions.

Section 353(m) of the PHSA requires the Secretary to impose two separate types of fees: "certificate fees" and "additional fees." Certificate fees are imposed for the issuance and renewal of certificates (except that only a nominal fee may be required for the issuance and renewal of CoWs) and must be sufficient to cover the general costs of administering the CLIA program, including and evaluating and monitoring approved PT programs and accrediting bodies

and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of non-accredited laboratories and for the cost of performing PT on laboratories that do not participate in approved PT programs. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections and PT. Certificate and additional fees must vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories. The regulations provide for a methodology for determining compliance fee amounts (§493.649) and periodic updating of the certificate fee amounts (§493.638(b)).

1. Fees for Revised Certificate

The regulations also allow for collection of fees for revised certificates (§493.639). We are exploring an appropriate methodology for determining a fair and reasonable fee to support these requests. At present, laboratories may request a revised certificate due to a change in name, location, director, services offered (for example, specialty or subspecialty), or certificate type (for example, CoC to Certificate of Provider-performed Microscopy (PPM) Procedures). There is a cost associated with such a request, including staff time to verify and make the edits in the data system, the contractor's time to print the revised certificate, and the supplies required to print the revised certificate. The fee for revised certificate would likely be a standard nominal fee for such requests.

2. Compliance Determination, Additional Fees, and Methodology for Determining Fee Amounts

Laboratories holding a CoC are subject to fees for determination of program compliance according to the regulations at §493.643(b). Laboratories that hold a CoA are subject to additional fees as outlined in §493.645(b). As noted in this request for information, the statute requires certificate and additional fees to vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories. Section 493.643(c) lists the classifications, or schedules, of laboratories based on the laboratory's scope and volume of testing. These schedules are used to determine the fee amount a laboratory is assessed and will not be revised. The compliance determination fees have not been increased since the final rule was published in 1992. The cost of conducting compliance determination activities

(for example, surveys, PT reviews, and evaluating personnel) has increased over the life of the CLIA program.

The regulations allow for us to collect fees for follow-up visits post survey, complaint investigations, and activities associated with imposing sanctions. Such fees for laboratories holding a CoC are outlined in §§493.643(b) and 493.643(d), while laboratories holding a CoA, CoW and a PPM Certificate are subject to §§493.645(b)(2) and 493.645(c), as applicable. We are exploring methodology for assessing a fair fee for these compliance determination activities.

The methodology for determining fee amounts is found in §493.649. The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate for each entity, which includes costs to perform required activities and necessary administration costs. The hourly rate is multiplied by the average number of hours required to perform these activities. We are seeking public comments (including information such as evidence, research, and trends) on an alternate method to calculate the average hourly rate for each entity as outlined in §493.649(b). We are also seeking information on whether the method should be standardized and updated annually or as needed.

We are therefore soliciting public comments (including information such as evidence, research, and trends) on the best method for instituting this regulatory authority to collect CLIA fees.

II. Solicitation of Comments

This is a request for information only. Respondents are encouraged to provide complete but concise responses to the questions listed in the sections outlined below. Please note that a response to every question is not required. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs

incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that we will not respond to questions about the policy issues raised in this RFI. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non- attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become Government property and will not be returned. We may publically post the comments received, or a summary thereof.

We are soliciting public input on the following areas:

A. Clarifications of degree(s)

- We are seeking public comment related to whether a bachelor's degree in nursing should be considered equivalent to a bachelor's degree in biological science or should be considered a qualifying degree to meet the CLIA requirements for moderate and high complexity testing personnel as well as for technical consultants.

- We are seeking public comment on what is considered a physical science degree and if a physical science degrees have the educational backgrounds such that all or some should to be considered a qualifying degree to meet the intent of the CLIA requirements at §§493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489.

- We are seeking public comment related to non-traditional degrees (for example, Regents

Bachelor of Arts) specifically whether any of these types of degrees should be considered to meet the requirements for a chemical, physical, biological or clinical laboratory science, and/or medical laboratory technology degrees.

B. Other Requirements for CLIA Personnel Categories

- We are seeking public comment regarding whether general supervisors should be allowed to perform competency assessment for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing.
- We are seeking public comment on what is appropriate laboratory training, experience and skills when qualifying all personnel to meet CLIA requirements, and what comprises appropriate documentation to verify the training, experience and skills for all personnel positions in part 493, subpart M.

C. Proficiency Testing Referral

- We are seeking public comment regarding the feasibility of applying alternative sanctions in cases of PT referral that involve waived testing.
- We are seeking public comment related to applying discretion in situations where we determine that a laboratory has referred its proficiency testing samples to another laboratory and has reported those results from another laboratory as their own, and under what circumstances should that discretion be applied.

D. Histocompatibility

- Virtual crossmatching: We are seeking public comment on the acceptability and application of virtual crossmatching in lieu of physical crossmatching for transplantation.
- Criteria and decision making algorithms: We are seeking public comment on appropriate criteria and decision algorithms under which virtual crossmatching would be an appropriate substitute for physical crossmatching. We are also seeking public comment on the existence of commonly accepted current guidelines for virtual crossmatching in histocompatibility.

- Updating histocompatibility regulations: We are seeking public comment on histocompatibility regulations that are no longer necessary because they are obsolete or redundant with requirements found in other sections of the CLIA regulations. We are also seeking public comment on any histocompatibility regulations that should be modified to reflect current practices.

E. CLIA Fees

- We are seeking public comments (including information such as evidence, research, and trends) on an alternate method to calculate the average hourly rate for each entity as outlined in §493.649(b). We are also seeking comment on whether the method should be standardized and updated annually or as needed.

- We are seeking public comment on a methodology that would set a fair and reasonable fee for revised certificate requests. We also seek comment as to whether fees should be nominal and, if nominal, whether such fee would cover the costs associated with the task.

- We are seeking public comment to update the fees for determination of program compliance as well as additional fees to accredited laboratories as outlined in §§493.643(b) and 493.645(b) respectively. We are also seeking comment on whether fees collected should be subject to the same ten schedules at §493.643(c), and whether they should change based on any updates to the methodology for determining the average hourly rate.

- We are seeking public comment on exploring an appropriate methodology for assessing a fair fee for other compliance determination activities to include performing follow-up visits, complaint investigations, and activities associated with imposition of sanctions.

We are also soliciting general feedback from stakeholders on what other areas of CLIA they would potentially have recommendations for changing.