

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 493

[CMS–3326–P]

RIN 0938–AT47

### Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

**AGENCY:** Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would update the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarify the CLIA fee regulations. This proposed rule includes a proposal to provide sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees. We are proposing to incorporate limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates. We are also proposing to distribute the administrative overhead costs of test complexity determination for waived tests and test systems with a nominal increase in Certificate of Waiver (CoW) fees. In addition, we are proposing to clarify the methodology used to determine program compliance fees. This proposed rule would ensure the continuing quality and safety of laboratory testing for the public. This proposed rule would also amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes. In addition, this proposed rule would amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) to allow for the imposition of such sanctions on CoW laboratories.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 25, 2022.

**ADDRESSES:** In commenting, please refer to file code CMS–3326–P.

Comments, including mass comment submissions, must be submitted in one

of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3326–P, 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–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Weaver, CMS, (410) 786–3531, and Jessica Wright, CMS, (410) 786–3838, for general information on CLIA fees.

Jeffrey Pleines, CMS, (410) 786–0684, for the budget and financial impact on CLIA fees.

Sarah Bennett or Cindy Flacks, CMS, (410) 786–3531, for personnel issues.

Penny Keller, CMS, (410) 786–3531, or Jelani Sanaa, CMS, (410) 786–1139, for histocompatibility issues.

Sarah Bennett, CMS, (410) 786–3531, for alternative sanctions for CoW laboratories issues.

Nancy Anderson, CDC, (404) 498–2741, for personnel and histocompatibility issues.

#### **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: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable

comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

#### **I. Background**

##### *A. Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees*

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), which replaced in its entirety section 353 of the Public Health Service Act (PHSA). 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 and must be sufficient to cover the general costs of administering the CLIA program, including evaluating and monitoring approved proficiency testing (PT) programs and accrediting bodies and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of nonaccredited laboratories and for the cost of evaluating accredited laboratories to determine overall if an accreditation organization’s standards and inspection process are equivalent to the CLIA program. These evaluations are referred to as validation inspections. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections. Certificate and additional fees vary by group or classification of laboratory, based on such considerations as the Secretary determines relevant, which may include the total test volume and scope of the testing being performed by the laboratories, and only a nominal fee may be required for the issuance and renewal of Certificates of Waiver (CoWs).

In January 2018, we published the “Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988” (83 FR 1004). As part of the general solicitation for comments related to the CLIA fees, more than a few commenters noted that the CLIA compliance and additional fees have not been updated since 1997 and supported increasing the fees. Some of these commenters suggested that the CLIA fees be reviewed annually and updated as needed to cover the program costs of performing biennial surveys.

Based on stakeholder comments from the Request for Information (RFI), in the December 31, 2018 **Federal Register**, we

issued a notice with comment period (83 FR 67723 through 67728) (hereinafter referred to as the December 31, 2018 notice). The December 31, 2018 notice increased fees for laboratories certified under CLIA. The December 31, 2018 notice increased CLIA fees by 20 percent to help ensure the CLIA program could continue to be self-sustaining, as required by law. The 2018 increase was intended to give CMS time to propose a process through rulemaking to allow for ongoing changes to the CLIA fees. The changes being proposed in this rule would result in a continuous level of funding that would increase as the obligations to the CLIA program increase and keep the program adequately funded over time.

In September 2020, we released new tools to reduce burdensome paperwork and authorization delays for laboratories seeking CLIA certification. Laboratories now have the option to pay CLIA certification fees on the CMS CLIA program website. Online payments are processed overnight, which is substantially faster than hard-copy checks.<sup>1</sup>

This proposed rule would make changes to the methodology for determining the amount of the CLIA fees as described in the February 28, 1992 final rule with comment period (57 FR 7002) (hereinafter referred to as the February 1992 final rule) and codified in 42 CFR part 493, subpart F—General Administration. The fees for the CoW, Certificate for Provider Performed Microscopy (PPM), and the provisional certificate that we refer to as the Certificate of Registration (CoR) were based on the cost of issuing the certificates. The Certificate of Accreditation (CoA) and Certificate of Compliance (CoC) fees were based on the annual test volume and scope of testing that separated the laboratories into schedules or groups of laboratories. Except where described below, we are generally proposing to continue determining these fees in the same manner as in the February 1992 final rule, with the exception of a change in the amount of the CoW fee.

As one such change, we propose to allocate, directly from the CoW fees, the administrative overhead costs of the Food and Drug Administration (FDA) process to categorize clinical laboratory tests as waived as described in the memorandum of understanding (MOU) between CMS and FDA (IA19–23). We believe this is appropriate because the functions of the FDA under the MOU are to provide administrative support to

the CLIA program, specifically by categorizing tests as waived.

In addition, we propose implementing certificate fees for the issuance of replacement and revised certificates. We receive numerous requests daily for replacements of lost and misplaced certificates and for revised copies of certificates after demographic, laboratory director, and/or specialty/subspecialty changes. As a result, thousands of replacement and revised certificates have been generated and mailed annually. We believe this additional certificate fee will encourage laboratories to better manage their certificates, provide accurate information when applying for or updating a CLIA certificate, and cover the costs of producing duplicate or revised documents.

The February 1992 final rule also stated at § 493.645(b)(1) that laboratories issued a CoA would be assessed a fee to cover the cost of evaluating the individual laboratories to determine whether an accreditation program's standards and inspection policies are equivalent to the Federal program. The February 1992 final rule explained that there would be a random sample of 5 percent of all accredited laboratories inspected by HHS, and the findings compared to the findings of the Accreditation Organizations (AOs). The February 1992 final rule stated that all accredited laboratories would share the cost of this activity and that the fees would be the same as for inspections by nonaccredited laboratories. We propose new § 493.645(a)(1) to clarify that all accredited laboratories share in the validation inspections costs. Under § 493.645(b)(1), the accredited laboratories currently pay a fee even though HHS inspects only 5 percent of them annually. The fee is 5 percent of what the inspection cost of an equivalent nonaccredited CoC laboratory would pay based on the test volume and scope (that is, the schedule or group) of the laboratories.

In the February 1992 final rule, the inspection fees for laboratories holding a CoC were based on estimates of the length of time required to perform a laboratory survey in the different schedules multiplied by the estimated hourly rate of three different entities that perform surveys. As outlined in the February 1992 final rule, we believe this methodology was a starting point intended to allow the methodology to be adjusted as historical data and experience were gained. The three inspection entities mentioned in the February 1992 final rule were the state agency, contracted surveyors, and Federal surveyors. Of these three

entities, an hourly rate was established solely for the state agencies, as any contracted surveyors' salaries are paid by their contractual amount. The Federal surveyors perform their surveys in conjunction with non-survey work plus actual costs for travel to those surveys. Given this diversity of costs, it is not feasible to determine a Federal hourly rate for just the survey activities.

Due to these difficulties, we propose to cease using the hourly rate outlined in current regulations as the basis for determining compliance inspection fees for laboratories holding a CoC and replace it with the methodology proposed in this rule. We propose to keep inspection fees separated by the schedules as previously determined.

The additional fees allowed for in section 353(m) of the PHSA are fees for determining compliance with the CLIA regulations. Some of these fees were previously included in subpart F but were not implemented due to technical limitations. However, a new data system that can implement these requirements is under development, with an expected startup date of October 2022. Therefore, we propose to implement the collection of additional fees as outlined in the February 1992 final rule, to be effective October 2022, as well as the others in this proposed rule, which would be effective 30 days after the publication of the final rule. We believe the collection of these additional fees will help bridge the shortfall between program expenditures and collections as discussed in section I.A.1.b. of this proposed rule.

The February 1992 final rule provisions codified at 42 CFR part 493, subpart F—General Administration was numbered too close together to allow new provisions or the separation of existing provisions, for clarification, to stay in numerical order. Therefore, we propose to redesignate and renumber some provisions so that the flow of this section is easier to follow. For example, we are proposing to redesignate current § 493.645(a) as § 493.649(a) and remove the current regulatory text at § 493.649. In addition, we propose redesignating current § 493.646 as new § 493.655 to maintain thematic order in that § 493.655, which outlines the payment of fees, is better placed after the provisions discussing the different types of fees. Each such change, including this example, is explained in full at its designated provision within section II. of this proposed rule.

Upon the final rule effective date, which would be 30 days following publication, we propose implementing fee increases as described above. We expect the fee increase to be larger than

<sup>1</sup> <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Index>.

subsequent fee increases and include an across-the-board increase of twenty percent and an inflation factor (CPI-U) of 1.047. We utilized the CPI-U factors promulgated by OMB as part of their economic assumptions for budgetary estimates. To calculate the 4.7 percent compound factor for the two-year increase, we multiplied together factors for each of the two years as follows:

Factor Year 1 (Budgeted Rate for Fiscal Year (FY) 2022) = 1.023

Factor Year 2 (Budgeted Rate for FY2023) = 1.023

The compounded factor = 1.023 × 1.023 = 1.047.

The 20 percent across-the-board (ATB) increase was determined as the amount that, including newly charged fees and inflation, is the difference necessary to fund in total annual projected program obligations and allow for the gradual accumulation of 6 months' worth of obligations as an operating margin at the start of the year. We have calculated that the one-time 20

percent across-the-board increase would generate approximately 12.7 million dollars annually while the inflation factor would generate approximately 3.1 million dollars. The other proposed fees would generate approximately 6.7 million dollars for a total of approximately 22.5 million dollars per year. We believe this would stabilize the CLIA program and allow us to use the inflation factor for future biennial increases. The actual across-the-board percentage may change based on any new information that becomes available or updated assumptions. The revised certificate fee found at proposed § 493.639(a); the replacement certificate fee found at proposed § 493.639(b); the follow-up surveys, substantiated complaint surveys, and unsuccessful PT on CoC laboratories found at proposed § 493.643(d)(1) through (4); follow-up surveys on CoA laboratories found at proposed § 493.645(a)(2); and substantiated complaint surveys on CoW, PPM, or CoA laboratories found at

proposed § 493.645(b) would be implemented on the effective date of the final rule. However, the collection of the fees is dependent on the new data system being online.

1. CLIA Budget Process

Table 1 provides a summary of projected user fee collections, program obligations, and carryover balances through the end of FY 2025. Start of year carryover balances plus anticipated collections at current rates, net of sequester, equals budgetary resources available for obligation, or spending, in a given fiscal year. This amount, less projected program obligations, equals end-of-year carryover. The continued decrease in the projected end-of-year carryover shows financial obligations for the CLIA program continue to significantly outpace user fee collections at current rates. This proposed rule would create sustainable funding in a few different ways.

TABLE 1: CMS Projections for CLIA Obligations and Fee Collections

|                                 | FY 2021       | FY 2022       | FY 2023       | FY 2024        | FY 2025        |
|---------------------------------|---------------|---------------|---------------|----------------|----------------|
| Available Carryover (SOY)*      | \$37,971,994  | \$29,503,205  | \$14,362,115  | (\$2,493,627)  | (\$21,103,458) |
| New collections                 | \$69,874,000  | \$63,000,000  | \$63,000,000  | \$63,000,000   | \$63,000,000   |
| Sequester (5.7%)                | (\$3,982,818) | (\$3,591,000) | (\$3,591,000) | (\$3,591,000)  | (\$3,591,000)  |
| Available Budgetary Resources** | \$103,863,176 | \$88,912,205  | \$73,771,115  | \$56,915,373   | \$38,805,542   |
| Obligations                     | \$74,359,971  | \$74,550,090  | \$76,264,742  | \$78,018,831   | \$79,813,264   |
| Carryover (EOY)*                | \$29,503,205  | \$14,362,115  | (\$2,493,627) | (\$21,103,458) | (\$41,507,722) |

\* SOY = Start of Year, EOY = End of Year

\*\* Budgetary resources mean amounts available to be obligated. In this instance it means the sum of available carryover + new user fee collections less projected sequestration.

a. Two-Part Periodic Increase

First, establishing a two-part periodic increase could be easily implemented and would provide an understandable calculation of fee increases. CMS will publish future fee increases in a notice in the **Federal Register**. CMS will not publish a notice in the **Federal Register** if no fee increases are required. Every 2 years, in preparation for the biennial fee increase, we would calculate the inflation adjustment using the Consumer Price Index for all Urban Consumers (CPI-U). At that time, CMS would look back over the previous 2 years and determine if the calculated CPI-U inflation adjustment would be sufficient to cover actual program

obligations. If the total fee amounts, including any increase applied, do not match or exceed actual program obligations based on a review of the obligations of the previous 2 years, CMS will apply an additional across-the-board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations. If CMS determines that the inflation adjustment is not enough to cover the program obligations, an additional across-the-board amount would be added to the adjustment to ensure that the fee increase is spread equally across all fees in a flat percentage amount, which would cover CLIA obligations. The adjusted fees would become part of the

baseline for the next biennial increase. If the level of collections was found to be sufficient to cover program obligations, CMS would not implement a biennial inflation adjustment or an across-the-board fee increase. With any fee increase, the amount of the increase and a summary of CLIA obligations along with the calculations of the increase using the CPI-U and any determined shortfall would be published in a notice in the **Federal Register**.

Table 2 shows a representation of the change in national average laboratory fees if the two-part increase was 4 percent over the current fees.

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**TABLE 2: Examples, Two-part Increase per Certificate Type \***

| National Average CoC compliance fee/CoA Validation Survey fee        |                 |       |                                  |          | CLIA Biennial Certificate fees |       |       |                                  |          |          |
|--|-----------------|-------|----------------------------------|----------|--------------------------------|-------|-------|----------------------------------|----------|----------|
| Laboratory classification (schedule)                                 | Current average |       | Example, Biennial Increase of 4% |          | Current average                |       |       | Example, Biennial Increase of 4% |          |          |
| Certificate of Compliance (CoC) & Certificate of Accreditation (CoA) | CoC             | CoA   | CoC                              | CoA      | CoC/CoA                        | CoW   | PPM   | CoC/CoA                          | CoW      | PPM      |
| LVA**  | \$360           | \$18  | \$374.40                         | \$18.72  | \$180                          | -     | -     | \$187.20                         | -        | -        |
| A  | \$1,192         | \$60  | \$1,239.68                       | \$62.40  | \$180                          | -     | -     | \$187.20                         | -        | -        |
| B  | \$1,591         | \$80  | \$1,654.64                       | \$83.20  | \$180                          | -     | -     | \$187.20                         | -        | -        |
| C  | \$1,988         | \$99  | \$2,067.52                       | \$102.96 | \$516                          | -     | -     | \$536.64                         | -        | -        |
| D  | \$2,336         | \$117 | \$2,429.44                       | \$121.68 | \$528                          | -     | -     | \$549.12                         | -        | -        |
| E  | \$2,684         | \$134 | \$2,791.36                       | \$139.36 | \$780                          | -     | -     | \$811.20                         | -        | -        |
| F  | \$3,032         | \$152 | \$3,153.28                       | \$158.08 | \$1,320                        | -     | -     | \$1,372.80                       | -        | -        |
| G  | \$3,380         | \$169 | \$3,515.20                       | \$175.76 | \$1,860                        | -     | -     | \$1,934.40                       | -        | -        |
| H  | \$3,728         | \$186 | \$3,877.12                       | \$193.44 | \$2,448                        | -     | -     | \$2,545.92                       | -        | -        |
| I  | \$4,076         | \$204 | \$4,239.04                       | \$212.16 | \$7,464                        | -     | -     | \$7,762.56                       | -        | -        |
| J  | \$4,408         | \$220 | \$4,584.32                       | \$228.80 | \$9,528                        | -     | -     | \$9,909.12                       | -        | -        |
| Not applicable   | -               | -     | -                                | -        | -                              | \$180 | \$240 | -                                | \$187.20 | \$249.60 |

\*Note: The Certificate of Registration (CoR) fee would increase from the \$100 to \$104.

\*\*LVA "Schedule A, Low Volume".

## b. Collection of Other Authorized Fees

The CLIA regulations also authorize the collection of other fees; however, the program has historically not exercised its authority in collecting these fees due to technical difficulties. CMS believes this has been a missed opportunity. With the improvement in technology since 1992, we will be enforcing existing regulatory authority in the collection of these fees as well as clarifying circumstances when such fees are applicable. If finalized, this proposed rule would implement collection of these other fees, which are laboratory specific and provide an incentive for laboratories to remain compliant with all provisions of the CLIA regulations.

The fees include:

- A fee for follow-up surveys to determine correction of the deficient practices found in either a CoC survey or a CoA validation survey;
- An addition of a specialties survey fee when it is necessary to determine compliance of testing in one or more additional specialties outside of the CoC survey cycle;
- A substantiated complaint survey fee;
- A fee for a desk review of unsuccessful PT performance;
- A fee for a replacement certificate when a laboratory loses or destroys a CLIA certificate and requests a replacement certificate; and
- A fee for issuing a revised certificate when the laboratory changes the laboratory director or other

information found on a certificate and requests a new certificate to reflect the changes.

Table 3 represents a national average per incident of the amount that would have been collected had these fees been implemented in FY2019. We totaled the number of follow-up surveys, substantiated complaints, and unsuccessful PT events and multiplied them by the national average number of hours recorded by the state survey agencies for these activities and then multiplied that by the national average unit cost, which was \$72.06 in 2019. The amounts for the revised certificates and replacement certificates are the fee amount as discussed in section II.C. of this proposed rule, specifically at § 493.639(a).

**TABLE 3: Projection of other Authorized Fees per Certificate Type**

| Projected National Average Other Authorized fees         |  |                                       |  |                             |                         |
|--|--|---------------------------------------|--|-----------------------------|-------------------------|
| Certificate type   | Follow-up surveys<br>(including those for<br>the addition of<br>specialties) | Substantiated<br>Complaint<br>Surveys | Unsuccessful<br>Proficiency<br>Testing (PT)<br>event | Replacement<br>Certificates | Revised<br>Certificates |
| Certificate of Compliance<br>(CoC)                       | \$329  | \$1,879                               | \$517  | \$75                        | \$150                   |
| Certificate of<br>Accreditation (CoA)                    | \$329  | \$5,011                               | \$517  | \$75                        | \$95                    |
| Certificate of Registration<br>(CoR)                     | \$329  | \$2,802                               | \$517  | \$75                        | \$150                   |
| Certificate of Waiver<br>(CoW)                           | n/a  | \$1,364                               | n/a  | \$75                        | \$95                    |
| Certificate of Provider<br>Performed Microscopy<br>(PPM) | n/a  | \$2,556                               | n/a  | \$75                        | \$150                   |

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## 2. CoW Fee Increase

This proposed rule would authorize a fee increase for the CoW. A CoW laboratory is limited to performing tests categorized by FDA as waived, which are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or the Secretary has determined pose no unreasonable risk of harm to the patient even if performed incorrectly. Some examples of waived tests include tests for blood glucose or cholesterol. As part of our financial obligations to administer the CLIA program, we compensate FDA for its role in determining if tests and test systems meet criteria to be categorized as waived tests/test systems. This

proposed rule would implement a nominal increase for CoW fees which would offset program obligations to FDA for its role under the CMS-FDA MOU (IA19-23) in categorizing tests and test systems as waived. The obligation to CLIA, defined by the MOU and calculated against the number of CoW laboratories, is approximately \$25 per laboratory to cover the FDA obligation. The additional \$25.00 would increase the current \$180.00 biennial CoW fee to \$205.00. Due to the public health emergency for COVID-19 and the number of smaller laboratories that hold a Certificate of Waiver, we are proposing to delay the implementation of the one-time \$25 fee increase until the Secretary terminates the declaration or allows it to expire.

*B. CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories*

CLIA requires any laboratory that examines human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health, of human beings to be certified by the Secretary for the categories of examinations or procedures performed by the laboratory. The implementing regulations at 42 CFR part 493 specify the conditions and standards that must be met to achieve and maintain CLIA certification. These conditions and standards strengthen Federal oversight of clinical laboratories and help ensure the accuracy and reliability of patient test results.

CMS is always looking for ways to improve our programs and better serve

our beneficiaries. Concerning laboratory oversight, HHS endeavors to improve consistency in the application of laboratory standards, coordination, collaboration, and communication in both routine and emergent situations, thereby further improving laboratory oversight and, ultimately, patient care. The regulations related to CLIA histocompatibility and personnel requirements have not been updated since 1992<sup>2</sup> and 2003,<sup>3</sup> and the regulations for CoW laboratory alternative sanctions have not been updated since 1992.<sup>4</sup> HHS believes it is time to update these regulations to reflect the current state of the American health care system and new advances in technology.

HHS sought expert advice to inform our decision-making on the regulatory updates proposed in this rule. We solicited advice on several topics addressed in this rule from the Clinical Laboratory Improvement Advisory Committee (CLIAC), the official Federal advisory committee charged with advising HHS regarding appropriate regulatory standards for ensuring accuracy, reliability, and timeliness of laboratory testing. On January 9, 2018, we also issued a Request for Information<sup>5</sup> (RFI) that solicited input from the public on issues related to CLIA personnel and histocompatibility requirements, and alternative sanctions for CoW laboratories. We received approximately 8,700 total comments in response to the 2018 RFI. The CLIAC recommendations and information received in response to the 2018 RFI helped us determine the policies proposed in this proposed rule.

This proposed rule would amend histocompatibility and personnel regulations to address obsolete regulations and update the regulations to incorporate changes in technology. This proposed rule would also amend § 493.1804(c) to allow alternative

sanctions to be imposed on CoW laboratories.

### 1. Histocompatibility

The CLIA regulations include requirements specific to certain laboratory specialties such as microbiology and subspecialties such as endocrinology. Histocompatibility is a type of laboratory testing performed on the tissue of different individuals to determine if one person can accept cells, tissue, or organs from another person. The CLIA regulatory requirements for the specialty of histocompatibility at § 493.1278, including the crossmatching requirements, address laboratory testing associated with organ transplantation and transfusion and testing on prospective donors and recipients. As of October 2019, 218 CLIA-certified laboratories perform testing in this specialty. The current specialty regulations were published in the 1992 final rule with comment period, and additional changes were made in the 2003 final rule. Specifically, the 2003 final rule changed the regulations to decrease the number of specialty/subspecialty-specific quality control (QC) regulations in instances where general QC requirements would apply. The specialty of histocompatibility has not yet been similarly updated. Many of the changes proposed in this rule would remove histocompatibility-specific requirements from § 493.1278 that we have determined are addressed by the general QC requirements at §§ 493.1230 through 493.1256 and 493.1281 through 493.1299. We believe that removing specific requirements for obsolete methods and practices and eliminating redundant requirements will decrease the burden on laboratories performing histocompatibility testing. We have heard from our stakeholders, particularly the transplantation community, that physical crossmatches are a barrier to modernized decision-making approaches on organ acceptability based on risk assessment.

For the crossmatching regulations that this proposed rule would amend, HHS requested input from CLIAC on the acceptability and application of newer crossmatching techniques in lieu of physical crossmatching. The CLIAC gathered information on the acceptability and application of newer crossmatching techniques for transplantation because there have been advances in the field of transplantation since 1992. These advances have made the physical crossmatch less significant in non-sensitized patients. The CLIAC stated that histocompatibility testing has evolved from cell-based assays to

molecular typing and solid-phase platforms for antibody detection, improving accuracy and sensitivity. Significant changes have occurred in the clinical practice of transplantation (immunosuppression, desensitization practices), and improvements in anti-rejection therapies have led to improved outcomes and mitigation of risk due to human leukocyte antigen (HLA) antibodies. At its November 2014 meeting, CLIAC made the following recommendations<sup>6</sup> for CMS to 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 algorithms, based on CLIAC deliberation of the Virtual Crossmatch Workgroup input, under which virtual crossmatching would be an appropriate substitute for physical crossmatching. The determination of appropriate criteria and decision algorithms should involve a process that includes an open comment period.

In the 2018 RFI (83 FR 1005 through 1006, 1008), we requested comments and information related to histocompatibility and crossmatching requirements that may have become outdated and requested suggestions for updating these requirements to align with current laboratory practice. The comments we received in response to the 2018 RFI recommended updating the current histocompatibility and crossmatching requirements to align with current laboratory practices. Both the CLIAC recommendations and the comments on the 2018 RFI informed the changes proposed in this rule.

### 2. Personnel

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity laboratory director (LD) qualifications in the 2003 final rule (68 FR 3713) but otherwise have remained unchanged since we published the 1992 final rule with comment period (57 FR 7002). In the 2018 RFI (83 FR 1005 through 1006, 1008), we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. As we explained in the 2018 RFI, these are areas that the CDC, CMS, stakeholders, and state agency surveyors identified as relevant to our efforts to update the CLIA

<sup>2</sup> See the “Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)” final rule with comment period (57 FR 7002) that published in the February 28, 1992 **Federal Register** (hereinafter referred to as the “1992 final rule with comment period”).

<sup>3</sup> See the “Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications” final rule (68 FR 3640) that published in the January 24, 2003 **Federal Register** (hereinafter referred to as the “2003 final rule”).

<sup>4</sup> See the 1992 final rule with comment period.

<sup>5</sup> See the “Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)” RFI (83 FR 1004) that published in the January 9, 2018 **Federal Register** (hereinafter referred to as the “2018 RFI”).

<sup>6</sup> [https://www.cdc.gov/cliac/docs/summary/cliac1114\\_summary.pdf](https://www.cdc.gov/cliac/docs/summary/cliac1114_summary.pdf).

personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

We received approximately 8,700 comments in response to the 2018 RFI. In response to our questions about nursing degrees, the majority of commenters did not concur that nursing degrees were equivalent to a biological or chemical sciences degree. However, some stakeholders suggested nursing degrees could be used as a separate qualifying degree for nonwaived testing personnel (TP). In response to our questions about physical science degrees as well as non-traditional degrees, stakeholders commented that a physical science degree was hard to define. In considering how to evaluate physical science and other non-traditional degrees, some commenters recommended that we evaluate coursework taken using a semester-hour educational algorithm to qualify individuals for CLIA personnel positions. If an individual has the appropriate coursework without the traditional chemical or biological degree, the individual's educational coursework should be considered when determining whether that individual meets the educational requirements under CLIA. In response to the questions about CA, many commenters stated that individuals with an applicable associate's degree should be permitted to perform CA on moderate complexity TP. Some commenters stated that required training should depend on the complexity of the testing to be performed and that all nonwaived testing should require training related to the individual's laboratory responsibilities. Several commenters also stated that any required training and experience should be in a CLIA-certified laboratory. Many commenters agreed that all training and experience should be documented; many noted that documentation from a former employer should be acceptable, assuming it provided specific details about the individual's job, training, and CA.

In addition to the 2018 RFI, we requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M—Personnel for Nonwaived Testing, §§ 493.1351 through 493.1495. In response, CLIAC established a workgroup that included laboratory experts, representatives from accreditation organizations (AOs), and government. The CLIAC Personnel Regulations Workgroup provided information and data to CLIAC for their deliberation in recommending to HHS

to updating the personnel regulations.<sup>7</sup> CLIAC made 12 recommendations at the April 2019 meeting to improve CLIA personnel regulations, including: (1) making biological science degrees acceptable for laboratory personnel and considering candidates with other degree backgrounds based on coursework; (2) removing the degree in physical science from the CLIA regulations due to its broadness; and (3) requiring personnel to have training and experience in their areas of responsibility.

After the April 2019 CLIAC meeting, CMS and the Centers for Disease Control and Prevention (CDC) met to review and consider the recommendations along with the information provided in response to the 2018 RFI. The following CLIAC recommendations support proposals included in this proposed rule:

- Coursework should be considered in meeting CLIA personnel requirements;
- Degree in physical science should be removed from CLIA regulations;
- All personnel should have appropriate training and experience;
- Remove the statement “possess qualification that are equivalent to those required for such certification”, as applicable;
- Laboratory experience should be clinical in nature;
- 20 credit hours should be required for all LDs except those certified by the American Board of Pathology, American Board of Osteopathic Pathology, and American Board of Dermatology;
- Laboratory directors should make at least two reasonably spaced onsite visits to the laboratories they direct annually. These visits should be documented;
- Modify CLIA requirements for technical consultants (TC) to include an associate degree and training and experience; and
- Modify the definition of mid-level practitioner to include registered nurse anesthetists and clinical nurse specialists.

Following this, CMS and CDC collaborated to develop a list of personnel regulation updates proposed in this rule.

### 3. Alternative Sanctions for CoW Laboratories

In section III.C. of this proposed rule, we are proposing to amend § 493.1804(c)(1) to allow CMS to impose alternative sanctions on CoW laboratories, as appropriate. CoW laboratories are laboratories that only

perform waived tests, that is, simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. For example, a urine dipstick pregnancy test is a waived test. The current regulations state that we do not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements (§ 493.1804(c)(1)). However, while not subject to the biennial routine surveys, CoW laboratories are surveyed as a result of a complaint, and based on the complaint survey, may be found to be out of compliance with a condition-level requirement. In the absence of alternative sanctions, our only recourse in cases of compliance issues found at CoW laboratories is to apply principal sanctions (that is, revocation, suspension, or limitation of the CLIA certificate). We believe the ability to levy alternative sanctions (that is, civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) on CoW laboratories helps CMS ensure appropriate sanctions are applied to CoW laboratories, as in the case of other certificate types (certificate of PPM, CoR, CoC, CoA).

In addition, we believe that this proposed change, if finalized, would reduce burden on CoW laboratories. The ability to impose alternative sanctions would be particularly useful in instances in which we find PT referral violations. PT is the testing of unknown samples sent to a laboratory by an HHS-approved PT program to check the laboratory's ability to determine the correct testing results. This proposed rule would amend the CoW regulations at § 493.1804(c)(1) to allow for the application of alternative sanctions where warranted, in addition to or in lieu of principal sanctions.

We note that while the regulatory text at § 493.1804(c)(1) currently specifies that CMS will not impose alternative sanctions on laboratories that have CoWs because those laboratories are not inspected for compliance with condition-level requirements aligns with the statute, this distinction is not required by the applicable statute at 42 U.S.C. 263a(h). Therefore, in section III.C. of this proposed rule, we are proposing to remove the parenthetical “(CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)” from § 483.1804(c).

In responses received from the 2018 RFI, commenters noted that alternative

<sup>7</sup> [https://www.cdc.gov/cliac/docs/summary/cliac0419\\_summary.pdf](https://www.cdc.gov/cliac/docs/summary/cliac0419_summary.pdf).

sanctions instead of principal sanctions should be an option to create parity for all certificate types, especially in cases of PT referral. Further, commenters also stated that CoW laboratories should be held to the same standards and level of compliance as those that perform moderate complexity and/or high complexity testing.

## II. Provisions of the Proposed Regulations for CLIA Fees

This section provides an overview of the proposed revisions to the CLIA fee requirements established by the February 1992 final rule.

### A. Proposed Definitions of “Replacement Certificate” and “Revised Certificate” (§ 493.2)

At § 493.2, we are proposing to add definitions for “Replacement certificates” and “Revised certificates.” After several years of experience and data analysis, it has been determined that the number of reissued certificates continues to be remarkable. Reissued certificates fall into two different categories: revised and replacement certificates. For further discussion please refer to section II.C. of this proposed rule. We are proposing that these definitions be added to § 493.2 with the other definitions listed to allow clarity in the regulations where fees for replacement and revised certificates are being proposed.

### B. Proposed Changes to Certificate Fees (§ 493.638)

At § 493.638(a), we are proposing to amend the regulatory language to clarify when a laboratory is required to pay a certificate fee and when the certificate is issued. We removed the listing of the individual certificates in the first paragraph of this section as all certificates go through the same process. The current regulation text specifies when a certificate fee is required, but we wish to clarify with more specific wording. The certificate fee is currently incurred when the original certificate is issued; when the certificate is subsequently renewed; if there is a change in certificate type requiring a new certificate to be issued; or if a lapsed certificate is reactivated with a gap in service and therefore reissued. The intent of the regulation is not changing. We believe adding this clarification would improve transparency concerning the requirement to pay certificate fees.

Specifically, at § 493.638(a)(1) for registration certificates, we are proposing to remove the reference to the CoC because we believe the flat fee charged for a CoR and the temporary

nature of the certificate require a separate section. We are proposing to redesignate the fees associated with a CoC to a new provision at § 493.638(a)(5) to keep fee information relevant to the different certificate types separate, rather than referencing the certificate types together.

At § 493.638(a)(2) for CoW, we are proposing to add the costs incurred by FDA to determine whether a test system meets the criteria for waived status, as specified at § 493.15(d). A CMS representative reviews an application for a CoW to determine whether the applicant has requested a CLIA certificate that covers the testing they have listed on the application that they will be performing. The cost of such a review is already part of the CoW fee. However, FDA must expend resources reviewing tests, procedures, and examinations to determine whether a test meets the criteria to be designated as waived. This expense is not currently captured in the fee for a CoW, and we propose that it should be. HHS had delegated the responsibility to FDA for the review of test systems and assignment of complexity, including what is required by § 493.15(d). CMS compensates FDA out of the CLIA funds for this determination under the CMS–FDA MOU (IA19–23). CoW laboratories are restricted to using waived tests. We believe that the regulatory restrictions of test systems for the CoW laboratories and the CMS requirement to determine what tests can be performed in a CoW laboratory under § 493.15(d) require us to place this fee on the CoW laboratories alone. We believe the predicted increase in CoW laboratories will offset expected increases in the obligation to FDA for the continued process of review and categorization of tests as waived.

We are proposing to make editorial changes to clarify the current provision § 493.638(b) that describes certificate fee amounts. We are separating this section into four shorter paragraphs designated as § 493.638(b)(1) through (4). Proposed § 493.638(b)(1) states that CMS will publish a notice in the **Federal Register** when assessed fees are adjusted in accordance with § 493.680. This section also includes a brief discussion of the basis for certificate fees as set forth in § 493.638(c). Proposed § 493.638(b)(2) states that certificate fees would be collected at least biennially. Certificate fees may be assessed more frequently than every 2 years if the laboratory changes its certificate type. Proposed § 493.638(b)(3) states how fees would be determined and proposed § 493.638(b)(4) states that CMS would notify the laboratories when the fees are due and the fee amount. This currently

takes place in the form of a fee coupon sent through U.S. Mail by the Billing and Certificate Issuance contractor.

We are also proposing to move the regulatory text currently found at § 493.643(c)(1) through (3) to a new provision at § 493.638(c) to align the provisions more closely for laboratory schedules and specialties with the related provisions concerning certificate fees. Our intent is to refer back to this provision when the compliance fees are discussed. In addition to redesignating this regulatory text, we propose making minor changes to clarify the regulatory text related to specialties of service before those specialties are explained at § 493.643(c)(3).

At the proposed new § 493.638(c)(3), we are proposing to redesignate the regulatory text currently at § 493.643(c)(1) with changes. We believe that the separation of Schedule A into two parts at § 493.643(c)(1)(i)(A) and (B) was confusing, and we propose listing them as separate schedules. The proposed text in the new provision § 493.638(c)(3) now includes § 493.638(c)(3)(i) through (xi). At § 493.638(c)(3)(i), we propose describing the low volume schedule as Schedule V to differentiate it from Schedule A, now proposed at § 493.638(c)(3)(ii). Current data processing system requirements have been built to refer to the low volume A schedule laboratories as Schedule V and will continue with the new data system.

### C. Proposed Changes to Fees for Revised and Replacement Certificates (§ 493.639)

At § 493.639, we are proposing to revise the current section heading (“Fee for revised certificate”) to read as “Fee for revised and replacement certificates” to match the contents of the section as amended to include both revised certificates and replacement certificates. We are proposing to define and explain revised and replacement certificates in section II.A. of this proposed rule. In this proposed provision at § 493.639 we would further explain the fees associated with each type.

At § 493.639(a), we are proposing to remove the reference to registration certificates as the section applies to all CLIA certificate types under the statutes. We are also proposing to amend the circumstances in which a laboratory may request a revised certificate to include changes to laboratory name and location, laboratory director, or services offered (specialties and subspecialties). We are proposing the fee be based on the national average cost to issue the revised certificate. However, due to differing amounts of



work required per certificate type, the fee is not a single amount. Please see Table 4.

We determined the time and resources required to enter changes to laboratory demographics, review of specialties and subspecialties, and review of laboratory director qualifications using an average of the state survey agencies' calculated unit hourly cost. The state unit hourly cost is determined by the CLIA budget office and is based on a formula of total state costs divided by the total staff years. The total state costs are reported to CMS by the state survey agencies and include staff salaries as determined by each state's civil service pay scale, fringe benefits, travel costs, and other costs such as office supplies, computers containing software required to perform and report a CLIA survey, etc. The total staff year hours are determined by multiplying the number of full-time

employees (FTE) by 1600 hours, representing the productive work year.

The time and resources for state agencies to enter demographic changes are less than those where the qualifications of the laboratory director or services need to be reviewed to ensure CLIA personnel requirements are met. Review of laboratory director qualifications applies to laboratories holding a CoC, a certificate of PPM, or CoR.

AOs are responsible for reviewing CoA laboratory director qualifications, and the AO is also responsible for reviewing the addition of specialties and subspecialties for the CoA laboratory. As such, state agency staff are not responsible for reviewing laboratory director qualifications or changes in specialties/subspecialties for laboratories with a CoA; however, they are responsible for processing the other demographic change requests for CoA laboratories. Therefore, a revised

certificate for a CoA laboratory does not include the cost to review the qualifications of laboratory directors, nor does it include the adding or deleting of specialties or subspecialties.

For a CoC, a change in services (adding or deleting a specialty or subspecialty) does not include review to determine compliance with the regulations for services added; however, the entry or deletion of specialty or subspecialty changes requires state agency personnel time and resources.

CLIA personnel requirements are not required for laboratories with a CoW, nor are there specialty or subspecialty requirements. Therefore, the time and resources required to enter requested demographic changes for CoW laboratories are less than for other certificate types. Please see the section below for the calculations used to determine these fee amounts.

We are proposing the following fees for issuing revised certificates:

**TABLE 4: CMS Proposed Fee for Issuance of Revised Certificate**

| Certificate Type | Fee      |
|------------------|----------|
| CoW              | \$95.00  |
| CoA              | \$95.00  |
| CoR              | \$150.00 |
| CoC              | \$150.00 |
| PPM              | \$150.00 |

The revised certificate fee would be paid prior to the issuance of the revised certificate. Nonpayment of this fee would not result in the revocation of the laboratory's certificate; however, a revised certificate would not be issued.

At § 493.639(a)(1), we are proposing a new provision explaining that the addition of services (that is, specialties/subspecialties) for laboratories with a CoC may result in an additional fee for purposes of determination of compliance if added services require an inspection. That addition of the specialties inspection fee is described in a new provision at § 493.643(d)(2).

We are proposing to delete the current provisions at § 493.639(b)(1) and (2), which provide information on fees for issuing a revised certificate and scenarios that describe changes that may require a change in certificate. We propose to replace them with a new provision at § 493.639(b) that outlines fees for issuing a replacement certificate. We believe the current provisions are confusing as written and where the provisions are located in the regulations.

At the new provision § 493.639(b), we are proposing a fee for issuance of replacement certificates as discussed in section II.A. of this proposed rule. This proposed requirement must account for the time and resources required to issue a replacement certificate when requested. Historically, replacement certificates have been issued without additional fees when a laboratory loses or destroys its current certificate. We have determined that the actual cost of issuing a replacement certificate is \$75.00. A replacement certificate is one where no changes are being requested. The fee would be paid prior to the issuance of the replacement certificate. Nonpayment of this fee would not result in the revocation of the laboratory's certificate; however, a replacement certificate would not be issued.

The calculations used to determine the proposed fee amounts for replacement certificates, and revised certificates were based on the time, and the average state unit costs for 2019 when these fees were set. When these calculations were made, the national average unit hourly cost in 2019 was \$72.06. It was determined that it took

state agency personnel approximately 45 minutes to receive, review, and enter a request for a replacement certificate and another 15 minutes to print and mail the certificate. The cost of the replacement certificate is calculated to cost the CLIA program \$75.00. This cost is rounded up (\$72.06 to \$75.00) to adjust for the time period needed to finalize the rule.

Furthermore, CMS determined that additional state agency resources are expended when issuing revised certificates as follows:

- An additional 20 minutes to review and enter requested demographic changes or \$20.00 for revised CoWs and CoAs.
- An additional 45 minutes to review and enter requested laboratory director changes or specialty changes for \$55.00 for revised CoRs and CoCs.

These additional costs are therefore reflected in the proposed fees for issuing revised certificates. (See Table 4)

*D. Proposed Changes to Fees Applicable to Laboratories Issued a CoC (§ 493.643)*

At § 493.643, we are proposing to rename the section heading "Fee for

determination of program compliance” to “Additional fees applicable to laboratories issued a certificate of compliance” for clarification.

We are proposing to add language at § 493.643(b) to describe the costs included in the fee for routine inspections to increase transparency. We are proposing to delete the second sentence of § 493.643(b) in consideration of a two-part biennial fee increase as discussed under section II.H. (§ 493.680) of this proposed rule. For clarity, we are proposing to redesignate the third sentence of the current provision at § 493.643(b) as § 493.643(c).

At the new provision § 493.643(c)(1), we are proposing that the inspection fee will be based on the schedules of the laboratories as defined in the new provision under § 493.638(c)(3). The fee amounts assigned to the schedules in the February 1992 final rule were based on an estimated number of hours to perform a survey of a laboratory with the scope and volume associated with each schedule multiplied by an estimated 1992 hourly rate for a surveyor of \$35.00. The established hourly rate of \$35.00 was intended to be used as a baseline and then revised after actual data were collected and experience gained (57 FR 7193). In 1992 it was anticipated that the universe of regulated laboratories would be much greater than those regulated prior to the implementation of CLIA ‘88.

The hourly rate for performing laboratory surveys is recalculated by CMS for each state annually to determine the CLIA obligation to support the state survey agencies but

has not been used to increase CLIA fees on an ongoing basis. The national average hourly rate in 2019 was \$72.06. A description of the national average hourly rate calculation is provided in section II.C. of this proposed rule.

Extensive data collected over time now enables us to better estimate the number of hours it takes for a surveyor to perform an inspection of a laboratory within each schedule. Such estimates are primarily driven by the scope and volume of tests run by the laboratory and the laboratory’s compliance with the CLIA regulations. A laboratory with a high-test volume and multiple specialties may have processes and practices that allow it to meet and exceed CLIA regulations as they operate with a high degree of quality and efficiency while ensuring reported results are accurate and timely to provide optimum patient care. The surveyor will likely spend less time on inspecting that laboratory. In contrast, if a laboratory with a small test volume and few specialties does not have processes and practices that allow it to operate with the same high degree of quality and efficiency, such a laboratory is likely not to meet the CLIA requirements. Such laboratories may be reporting test results that may not be accurate and reliable. While the test volume may be low, the surveyor will likely spend additional time surveying such laboratories due to the less-than-optimal operations and processes.

Conversely, the number of hours needed to survey a large laboratory with poor compliance history could be quite large. The surveyor would spend more

time in this laboratory, given the size and poor compliance history, the surveyor would review the prior survey deficiencies to ensure the laboratory’s monitors put into place have corrected the deficiency. In contrast, a surveyor may not need to spend as many hours to survey a laboratory with lower test volume and specialties but a favorable compliance history. Taking each scenario into account, we believe the average number of hours a surveyor spends in each laboratory reflects the universe of laboratories within each schedule. Thus, we will not be changing the differences between the amounts of the fees within the compliance fee schedules relative to each other. They will remain in their relative amounts and be increased across the board by the same percentage in the proposed two-part fee increase (section II.H. (§ 493.680) of this proposed rule).

Table 5 illustrates the different scenarios mentioned previously in this proposed rule and how the number of hours spent on the survey vary based on both the size (the schedule) of the laboratory and poor compliance with the CLIA regulations. Poor compliance is being defined for this illustration as a laboratory with at least one condition-level deficiency cited during a survey. For information about condition-level deficiencies, please see the CLIA website for the Interpretive Guidelines for Laboratories, Appendix C: Interpretive Guidelines.<sup>8</sup>

<sup>8</sup> [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap\\_c\\_lab.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf).

**TABLE 5: Survey Hours with Condition Level Deficiencies Cited vs. Not Cited by Schedule Code**

|   | Condition Level Deficiencies not cited |  | Condition Level Deficiencies cited |   |
|---|--|--|------------------------------------|---|
| Schedule code of laboratories that were surveyed* | Number of laboratories**               | Range of hours required to perform the individual surveys and the average (avg) number hours** | Number of laboratories**           | Range of hours required to perform the individual surveys and the average (avg) number of hours** |
| V-A   | 3,446                                  | 4 – 69 (avg: 12)   | 661                                | 5 – 143 (avg: 18)   |
| B-C   | 1,328                                  | 4 – 69 (avg: 13)   | 320                                | 7 – 123 (avg: 19)   |
| D-E   | 972                                    | 4 – 79 (avg: 15)   | 261                                | 6 – 201 (avg: 23)   |
| F-G   | 727                                    | 5 – 165 (avg: 18)  | 192                                | 6 – 378 (avg: 30)   |
| H-I   | 935                                    | 5 – 284 (avg: 21)  | 279                                | 7 – 497 (avg: 41)   |
| J   | 110                                    | 8 – 213 (avg: 32)  | 23                                 | 8 – 378 (avg: 75)   |

\*For a description of the schedules see the section of this document with the proposed amendments to 42 CFR chapter IV, specifically provision § 493.638(c). The schedules have been grouped as two schedules together to keep the size of the table to a minimum. We are not proposing to change the schedules this way.

\*\*The data comes from the SAS Viya system for surveys completed between 10-01-2017 and 09-30-2019 with condition level deficiencies not cited versus condition level deficiencies cited and separated by schedule codes.

For example, a large laboratory with good compliance in the column titled Condition Level Deficiencies not cited and row J. Additionally, for a medium-sized laboratory (schedules D–E) with no condition level deficiencies cited is 15 hours and ranging to 79 hours. In contrast, the average number of hours spent on survey in small (schedules V–A) laboratories with condition level deficiencies was 18 and ranged to a high of 143 hours. In the largest (schedule J) laboratories, survey hours differed from an average of 32 hours spent in laboratories without condition level deficiencies compared to 75 hours in those laboratories that had condition level deficiencies cited.

The February 1992 final rule did not consider other costs involved in the inspection process, such as continuous training of the state surveyors and monitoring of the state agency program processes by the CMS Locations (Regional Offices). The CLIA program has created and continuously updates periodic training for surveyors through online training modules, onsite meetings, and conference calls.

The surveyors are individually monitored with a Federal Monitoring Survey (FMS) process where CMS location (Regional Office) Federal surveyors observe the individual state surveyor on a survey or perform a survey of the same laboratory after the state surveyor has completed their survey to confirm that the state surveyor is competent and following the prescribed survey process. The CMS locations (Regional Offices) also perform an annual State Agency Performance Review (SAPR) for each state survey agency, including a review of the state

survey agency's training processes and monitoring processes for their state surveyors. This includes a review of the deficiency reports state surveyors have sent to laboratories to determine that the surveyor is following the program's principles of documentation and the proper survey process.

There are also costs to the program to maintain a computerized system for entering inspection findings and compliance monitoring, including proficiency testing. The computer system also allows the CMS locations to run reports to monitor the inspections entered by the state surveyors.

The compliance fees have historically been based on the costs to the CLIA program for the State agencies. These aforementioned activities are obligations outside of the state survey agency annual budgets. We are therefore proposing that the determination of inspection fees for laboratories in each schedule and state will no longer be determined solely by the estimated hours spent on a survey of a laboratory within each schedule nor by the surveyor hourly rate of \$35.00 established in 1992.

We believe that the compliance fees currently set within the schedules should continue to be used but that additional fees, as previously described, should be added to the regulatory scheme. All fees would be increased biennially following the biennial two-part fee increase as proposed in this rule in § 493.680.

We believe we are authorized to base these fees per laboratory schedule (or group) even though the fees will no longer be determined solely by the estimated hours spent on a survey of a

laboratory within each schedule nor by the 1992 surveyor hourly rate of \$35.00 based on section 353(m)(3)(C) of the PHSA, which states that, fees shall 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. We believe our proposals are within the bounds of our authority under the PHSA.

At § 493.643(c)(2), we are proposing to redesignate language from the current § 493.643(b) which states the fees are assessed and payable biennially. We believe this will support the two-part fee increase proposed in this rule and described in § 493.680.

At the new provision § 493.643(c)(3), we are proposing that the fee amount would be the amount applicable to a given laboratory increase listed in the most recent published CLIA fee increase notice in the **Federal Register**.

We are proposing to redesignate current § 493.643(d)(1) and (2) where additional fees for CoC laboratories are discussed at § 493.643(d)(2) and (3) and redesignate the fourth and fifth sentences of current provision § 493.643(b) where an additional fee for a follow-up survey on a CoC laboratory is discussed as a new provision at § 493.643(d)(1). We believe the discussion of additional fees for CoC laboratories should be grouped together.

We are proposing to move the current regulatory text at § 493.643(d)(2) to § 493.643(d)(3) with no changes. Current regulation allows additional fees to be assessed for substantiated complaints; however, this has not been implemented. This proposed rule would

implement fees for substantiated complaints, meaning those complaints where the allegations against the laboratory were found to be true by CMS. We believe implementing the fee for substantiated complaints would cover the costs required to perform such a survey, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and review of the laboratory's plan of correction and monitoring their correction. The fee is proposed to be limited to the cost of the actual time and resources required for these activities.

At new provision § 493.643(d)(4), we are proposing to establish an additional fee for certificates of compliance that are found to have unsuccessful PT through a PT desk review. Current policy requires the review of PT performance every 30–45 days for each laboratory with a CoC that performs testing and is enrolled in PT for an analyte or test included in subpart I. Cases of unsuccessful PT performance require a PT desk review to confirm. Upon confirmation, the laboratory is notified of its regulatory requirement to investigate and correct the unsuccessful PT performance. Currently, such PT desk reviews do not generate an additional fee; however, conducting the desk review requires surveyor time and resources. We believe this new fee would cover the costs of the desk review, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and reviewing the laboratory's plan of correction and monitoring their correction. The fee is proposed to be limited to the cost of the actual time and resources required for these activities. As with the other fees listed in this section, only laboratories with unsuccessful PT performance would be impacted if this rule is finalized. The fees in this section must be paid, or HHS will revoke the laboratory's CoC.

*E. Proposed Changes to Additional Fees Applicable to Laboratories Issued a CoA, CoW, or Certificate for PPM Procedures (§ 493.645)*

At § 493.645, we are proposing to change the current section heading (“Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures”) to clarify the contents of the section as amended. The proposed title would be “Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.”

We are proposing to move in its entirety the regulatory text regarding fees for CLIA-exempt laboratory fees by state laboratory programs in § 493.645(a)(1) through (3) to § 493.649(a)(1) through (3). We believe the fees for approved state laboratory programs should be listed separately from the other CLIA-certified laboratories in the regulations. A state laboratory program is a laboratory program that HHS approves as exempt due to the state requirements being equal to or more stringent than the CLIA requirements. Under such programs, the state provides regulatory oversight of its laboratories in lieu of such laboratories regulated by HHS. HHS approves and monitors such state laboratory programs to ensure standards of the state laboratory programs are and remain at least as stringent as the CLIA regulations. HHS does not issue fees to laboratories covered by these programs but charges a fee to the program as described in the new provision at § 493.646.

We are also proposing to make editorial corrections to the references of §§ 493.645(a) and 493.646 noted in §§ 493.557(b)(4) and 493.575(i) and replacing those references with §§ 493.649(a) and 493.655(b). The requirements previously included at §§ 493.645(a) and 493.646(b) governing applicable fees are proposed to be redesignated as § 493.649(a) and new § 493.655(b).

We are further proposing to redesignate current § 493.645(b)(1) and (2) regarding the payment of inspection fees as new § 493.645(a)(1) and (2). We are proposing new § 493.645(a)(1) to clarify the amount accredited laboratories pay for their inspection (validation survey) fees by removing the last sentence of the current regulatory text, which reads that these costs are the same as those that are incurred when inspecting nonaccredited laboratories. We believe this does not fully explain how the fee is determined. This fee is based on fees that CoC laboratories pay for compliance inspections; however, an accredited laboratory is only assessed 5 percent of the fee a CoC laboratory pays because only 5 percent of CoA laboratories are inspected (undergo a validation survey) annually. For example, a CoC laboratory classified as “schedule D” pays an average biennial compliance fee of \$2,336.00. The accredited laboratory classified as “schedule D” would pay an average biennial inspection (validation survey) fee of \$117.00.

At new § 493.645(a)(2), we are proposing to redesignate the provision from current § 493.645(b)(2), with no

changes. This provision established an additional fee if a laboratory issued a CoA were to be inspected and follow-up visits were necessary because of identified deficiencies. Historically this fee had not been implemented due to technical difficulties described previously in this rule. We are proposing that it be implemented through this proposed rule. As stated in the current regulatory text, the additional fee to cover the cost of these follow-up visits would be based on the actual resources and time necessary to perform the follow-up visits. Also, as stated in the regulatory text, HHS would revoke the laboratory's CoA for failure to pay the fee.

At new § 493.645(b), we are proposing to redesignate the provision from current § 493.645(c). This provision established a fee for substantiated complaint surveys, those in which the allegations against the laboratory were found to be true, on CoA, CoW, or certificate for PPM procedures laboratories. Historically, this fee has not been implemented. We believe implementing the fee for substantiated complaints would cover the costs required to perform such a survey, including documenting the deficiencies found to be violated, preparing a report for the laboratory, and review of the laboratory's plan of correction and monitoring their correction. The fee is limited to the actual time and resources required for these activities.

*F. Proposed Changes to Additional Fees Applicable to Approved State Laboratory Programs (§ 493.649)*

At § 493.649, we are proposing to delete the current language in its entirety and replace it with language from § 493.645(a)(1) through (3). The current provision at § 493.649 would no longer be needed as the methodology for determining inspection fees in this proposed rule is no longer based on a surveyor hourly rate. At new § 493.649, we are proposing to revise the current section heading (“Methodology for determining fee amount”) to give a clear meaning of the contents of the section as amended. The proposed title is “Additional fees applicable to approved State laboratory programs.” We are proposing to replace the current language with current provisions § 493.645(a)(1) through (3) with minor changes (removing “costs of” from current 493.469(a)(3)). The provisions at § 493.645(a)(1) through (3) outline the fees applicable to approved state laboratory programs and have been comingled with the provision that outlines the fees for accredited PPM and CoW laboratories. We believe separating

this provision from the other laboratory certificate types will allow for improved readability and understanding.

*G. Proposed Changes to Payment of Fees (§§ 493.646 and 493.655)*

At § 493.646, we are proposing to redesignate the current provision with minor changes corresponding to the validation survey cost as new § 493.655 and including a reference to § 493.563 that contains the validation inspection information. We believe this provision which outlines the payment of fees, is better placed after discussions of the different types of fees.

We are proposing to redesignate § 493.646(a) and (b) where the payment of fees is discussed to new provisions at § 493.655(a) and (b) with a minor change referencing approved state laboratory programs instead of state-exempt laboratories. The state program pays CMS, not the individual laboratories.

*H. Proposed Methodology for Determining the Biennial Fee Increase (§ 493.680)*

At new provision § 493.680, we are proposing the biennial two-part fee increase, which would be calculated as described in section I.B. of this proposed rule and published as a notice with a comment period at least biennially. Should the off-year of the biennial increase result in unexpected program obligations, CMS may need to calculate an interim fee increase based on either the CPI-U or difference in obligations and total collected fees or a combination of both. All fees, existing and proposed, mentioned in this proposed rule would also be subject to the biennial two-part fee increase.

**III. Provisions of the Proposed Regulations for CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories**

This section provides an overview of the proposed revisions to the CLIA requirements for histocompatibility and personnel and application of alternative sanctions for CoW laboratories originally established by the 1992 final rule with comment period (57 FR 7002), subsequently modified in 1995<sup>9</sup> and 2003,<sup>10</sup> and currently specified in subpart A—General Provisions, subpart K—Quality System for Nonwaived Testing, subpart M—Personnel for

Nonwaived Testing, and subpart R—Enforcement Procedures.

*A. Proposed Changes to Histocompatibility Requirements*

**1. General, Human Leukocyte Antigen (HLA) Typing, Disease-Associated Studies, and Antibody Screening and Identification (§ 493.1278(a) Through (d))**

At § 493.1278(a)(1), we are proposing to amend the requirement by changing “an audible alarms system” to “a continuous monitoring and alert system” because this allows the laboratories more flexibility in determining the best way to monitor refrigerator temperatures. It is very important to monitor temperatures continuously, so that recipient and donor specimens and reagents are stored at the appropriate temperature to ensure accurate and reliable testing.

At § 493.1278(a)(2), we are proposing to modify the requirement by expanding the regulatory language to include that the laboratory must establish and follow written policies and procedures for the storage and retention of patient specimens based on the specific type of specimen because the type and duration of specimen storage are equally important as ease of retrieval. We are retaining the requirement that stored specimens must be easily retrievable.

At § 493.1278(a)(3), we are proposing to delete the labeling requirement for in-house prepared typing sera reagent requirement. If a laboratory is performing histocompatibility testing, this requirement under the general reagent labeling requirements for all test systems must be met under § 493.1252(c) and, therefore, is duplicative.

At § 493.1278(a)(4), we are proposing to revise this requirement by removing the examples (that is, antibodies, antibody-coated particles, or complement) to clarify that these technologies, as well as current and future technologies, are allowed for the isolation of lymphocytes or lymphocyte subsets. We are also proposing to clarify the requirement by adding “identification” of lymphocytes, or lymphocyte subsets. In this type of testing, lymphocytes can be isolated, but the subsets (B-cells and T-cells) are identified rather than isolated. Due to these proposed changes, § 493.1278(a)(4) would be under the proposed revision at § 493.1278(a)(3).

The current requirement at § 493.1278(a)(5) would be redesignated as § 493.1278(a)(4). This requirement remains unchanged. At § 493.1278(b)(1) through (3), we are proposing to delete

these requirements pertaining to establishing HLA typing procedures. The requirement that the laboratory must establish and have written procedures that ensure quality test results are already addressed by the general requirements for all test systems under current § 493.1445(e)(1) and (e)(3)(i) and proposed change at § 493.1278(f), respectively, and therefore, are duplicative.

At § 493.1278(b), we are proposing to redesignate the provisions at paragraph (b)(4) to paragraph (b)(1). At newly redesignated paragraph (b)(1), we are proposing to delete the language that states potential new antigens not yet approved by this committee must have a designation that cannot be confused with WHO terminology because new alleles are approved monthly, which makes this requirement obsolete.

At § 493.1278(b)(5)(i) through (iv), we are proposing to delete the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.

At § 493.1278(b)(5)(v), we are proposing to modify the requirement to add “allele” and delete the “re” prefix in the word “retyping” in this paragraph. We propose inserting “allele” because the regulation only has antigen typing, but there is typing done at the allele level. We are removing redundancy by deleting the “re” prefix since CLIA already requires the laboratory to define frequency and criteria for performing typing under the proposed revision at § 493.1278(b)(2).

At § 493.1278(b)(6)(i) through (iii), we are proposing to delete requirements procedures for HLA typing control materials procedures as they are addressed by the general requirements regarding quality control materials and procedures for all test systems under § 493.1256(a) through (d) and (f) through (h), and therefore, are duplicative.

At § 493.1278(c), we are proposing to delete this requirement for control procedures and materials regarding disease related studies because this is addressed by the general requirements for all test systems under §§ 493.1256(d) and 493.1451(b)(4), and therefore, is duplicative.

At § 493.1278(d), we are proposing to change the name of this section from “Antibody Screening” to “Antibody Screening and Identification” for clarification as both processes apply to histocompatibility testing. The

<sup>9</sup> 60 FR 20047, April 24, 1995 (<https://www.govinfo.gov/content/pkg/FR-1995-04-24/pdf/95-9953.pdf#page=13>).

<sup>10</sup> 68 FR 3640, January 24, 2003 (<https://www.govinfo.gov/content/pkg/FR-2003-01-24/pdf/03-1230.pdf>).

provisions covered under this section apply to both screening and identification. The proposed change at § 493.1278(a)(4) would be under our proposed § 493.1278(c).

At § 493.1278(d)(1) through (3) and (5) through (7), we are proposing to delete these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

## 2. Crossmatching and Transplantation (§ 493.1278(e) and (f))

At § 493.1278(e)(1) through (3), we are proposing to remove these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the provisions to be removed are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative.

Since 1992, there have been important advances in the field of transplantation and histocompatibility. Based on comments received in response to the 2018 RFI and stakeholder and CLIAC input, we understand the current regulations at § 493.1278 do not reflect the standard practice for laboratories performing testing in the specialty of histocompatibility and are viewed by the transplantation community as a barrier to modernized decision making approaches for organ acceptability. Additionally, we understand that the use of risk assessment and alternative immunologic assessment procedures are currently the standard practice for laboratories performing testing in the specialty of histocompatibility. Therefore, we are proposing to add the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:

- Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
- Defining the criteria necessary to assess a recipient's alloantibody status;
- Assessing recipient antibody presence or absence on an ongoing basis;
- Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
- Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;

- Making available all applicable and donor and recipient test results to transplant team;

- Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);

- Defining time limits between recipient testing and the performance of crossmatch; and

- Requiring that the test report must specify what type of crossmatch was performed.

At § 493.1278(f), we are proposing to change the words “transfusion” and “transfused” to “infusion” and “infused”, respectively. The relevance of HLA testing and the decisions of the extent of testing in both a transplant and transfusion setting are critical to both organ and cell acceptance in the host recipient. The use of the word “transfusion” is inappropriate given that the product itself is the transfusion but the action of introducing the product is the process of infusion. Transfusion is more specific to immunohematology. There are specific transfusion regulations in the immunohematology section at § 493.1271 that should not be confused with histocompatibility requirements. Since histocompatibility addresses materials that are not always blood products, we believe the term “infusion” would be more appropriate. This proposed change at § 493.1278(f) would be under the proposed revision at § 493.1278(e).

At § 493.1278(f)(1), we are proposing to revise this requirement to state that laboratories performing histocompatibility testing must establish and have written policies and procedures specifying the types of histocompatibility testing under the proposed regulation at § 493.1278(e). In addition, we are proposing to add “identification” after “antibody screening” under our proposed revision at § 493.1278(c), as identification is an important part of the process for crossmatching. Finally, we are proposing to remove “compatibility testing” at § 493.1278(f)(1) because this activity is specific to immunohematology, and crossmatching is a more appropriate description of what we understand is the current histocompatibility procedure used by laboratories. The proposed change at § 493.1278(f)(1) would be under our proposed § 493.1278(e).

At § 493.1278(f)(1), we are further proposing to modify the current general requirement to specify that the laboratory must establish and follow written policies and procedures that address the transplant type (organ,

tissue, cell) donor type (living, deceased, or paired) and recipient type (high risk vs. non-sensitized). The following terminologies were also updated to reflect current practices: “cadaver donor” is replaced by “deceased donor,” “transfused” is replaced by “infused,” and “combined” is replaced by “paired.” In addition, we believe that clarifying the current regulatory language allows the laboratories to make decisions based on existing technologies and practices for determining what testing is applicable for those transplant programs they serve. The proposed changes at § 493.1278(f)(1) would be under the proposed revision at § 493.1278(e)(1).

At § 493.1278(f)(2) through (3), we are proposing to remove these requirements for renal and nonrenal transplantation crossmatch procedures which are perceived as obstacles to current practices by the transplant community and would allow for alternative immunologic assessment procedures to be used in the designated specialty of histocompatibility. The requirement that the laboratory must establish and follow written policies and procedures test procedures are already addressed in the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1256(c) through (h), and 493.1451(b)(4) and therefore, are duplicative. In addition, we are adding a new requirement for pre-transplant recipient specimens under the proposed § 493.1278(e)(3). Under this new proposed requirement, the laboratory must have written policies and procedures to obtain a recipient specimen for a crossmatch, or to document its efforts to obtain a recipient specimen, collected on the day of transplant. We recognize that the laboratory may not be able to obtain a recipient specimen collected on the day of a transplant since this collection process depends upon the physician obtaining the specimen and submitting it to the laboratory.

At § 493.1278(f)(1)(ii), we are proposing to modify this requirement for laboratory policies and procedures as it would be included in the amended protocol requirements under the proposed regulation at § 493.1278(e)(1)(i) and (iii), and therefore, would be duplicative. The proposed revised requirement reflects current practices in the histocompatibility community.

At § 493.1278(f)(1)(iii), we are proposing to replace “the level of” with “type and frequency” to clarify this revised requirement refers to the type and frequency of testing practice to support the clinical transplant

protocols. We are also proposing to remove the examples of antigen and allele level in the regulation as these examples may not be all-inclusive and generally are reflected in guidance rather than regulatory text. The proposed change at § 493.1278(f)(1)(iii) would be under our proposed § 493.1278(e)(2).

The requirement at § 493.1278(g) would be redesignated as § 493.1278(f). This requirement remains unchanged.

#### *B. Proposed Changes to Personnel Requirements*

CMS recognizes that the COVID-19 public health emergency (PHE) requires flexibility, and we are committed to taking critical steps to ensure America's clinical laboratories can respond during a PHE to provide reliable testing while ensuring patient health and safety. As such, we request that the public provide comments regarding how the CLIA personnel requirements have affected the health system's response to the COVID-19 PHE and any potential opportunities for improvement to such requirements. We welcome suggestions regarding potential improvements that may be specific to a pandemic or public health emergency context, as well as broader recommendations.

#### 1. Definitions (§ 493.2)

##### a. Midlevel Practitioner

At § 493.2, we are proposing to amend the definition of midlevel practitioner by adding a nurse anesthetist and clinical nurse specialist to the definition. CLIA currently defines a midlevel practitioner as a nurse midwife, nurse practitioner, or physician assistant. We agree with CLIA's recommendation to include nurse anesthetists and clinical nurse specialists in the definition of midlevel practitioner. We believe including nurse anesthetists and clinical nurse specialists in the definition will be inclusive of current types of mid-level practitioners. For example, the American Association of Nurse Anesthetists (<https://www.aana.com/>) scope of practice states that the practice may include performing point-of-care testing. If the regulations are too specific, some individuals may not qualify when they would have prior to the proposed change.

##### b. Continuing Education (CE) Credit Hours

At § 493.2, we are also proposing to add a definition for "Continuing education (CE) credit hours" to state that it means either continuing medical education (CME) or continuing education (CE) units. Generally, CME

refers to continuing education credits earned by physicians (by which we mean doctors of medicine, osteopathy, or podiatric medicine). We propose that CE would be a broader term used for individuals seeking to qualify as laboratory directors who are not physicians. In the current CLIA regulations at § 493.1405(b)(2)(i), CME is considered as acceptable training or experience for individuals to qualify as a LD overseeing moderate complexity testing.

As we are proposing in section III.B. of this proposed rule to require all individuals seeking to qualify as LD for both moderate and high complexity testing to have 20 CE credit hours, we believe we need to establish a more general term for purposes of the proposed requirement. As described below, the CE credit hours would cover all of the LD responsibilities defined in the applicable regulations and must be obtained prior to qualifying as a LD. For example, under proposed § 493.1405(b)(2)(ii)(B), the 20 CE credit hours would be required to cover all of the LD responsibilities defined in § 493.1407 (moderate complexity testing).

The term CME was originally used because it was only required at § 493.1405(b)(2)(i), which is a provision specifically related to doctors of medicine, osteopathy, or podiatry. We believe that including a definition for CE credit hours in the CLIA regulations will respect that historic use, afford a means of referring to a broader range of professionals, and alleviate confusion between the terms.

##### c. Doctoral Degree

At § 493.2, we are proposing to add a definition for "doctoral degree" to state that it means an earned post-baccalaureate degree with at least 3 years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. Originally, degrees were given in medical technology; however, the naming convention for medical technology degrees has changed since the regulations were first published in the 1992 final rule with comment period. The degree is now referred to as clinical laboratory science. A clinical laboratory science degree is synonymous with a medical technology degree. For purposes of 42 CFR part 493, doctoral degrees would not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM), or honorary degrees.

We are proposing this modification to CLIA regulations to clarify what we mean by the term "doctoral degree." It seems this general term has created confusion as various stakeholders have asked us the following questions.

- Are doctors of medicine degrees considered to be a type of doctoral degree?
- Does a doctoral degree include traditional (for example, Doctor of Philosophy (Ph.D.), doctorate in science (DSc)) and professional (for example, Doctorate in Clinical Laboratory Science (DCLS)) degrees or does doctoral degree only mean a Ph.D.?

The CLIA regulations for personnel qualifications separate doctors of medicine, osteopathy, and podiatry from other non-medical doctoral degrees by including specific qualification requirements for these three types of degrees. MD and DO degrees pertain to post-graduate level education, specifically in medicine, and are associated with treating illnesses and medical conditions. In contrast, doctoral degrees can be obtained in various fields like biology and chemistry. Historically, we intended a doctoral degree to mean a Ph.D. in a science field related to laboratory work. However, we have come to understand that our doctoral degrees could be interpreted more broadly to include both traditional and professional doctoral degrees. Doctoral degree is a general term used to describe post-graduate level education for various non-medical specific degrees and includes both traditional (for example, Ph.D., DSc) and professional (for example, DCLS) degrees. A traditional earned doctoral degree is generally focused on research and may include academic coursework and professional development. In contrast, a professional earned doctoral degree emphasizes specific skills and knowledge for success in a particular profession without a concentrated focus on research. For example, the DCLS is an advanced professional doctorate designed for practicing clinical laboratory scientists (CLSs) or medical technologists (MTs) who have at least a bachelor's degree and wish to further their level of clinical expertise and develop leadership and management skills. Individuals with a DCLS are experts in clinical laboratory testing. Individuals must have a bachelor's degree in medical technology or clinical laboratory science and the requisite experience in order to be admitted to a DCLS graduate program. The DCLS contributes to increasing laboratory efficiency and improves timely access to accurate and appropriate laboratory information. A graduate of a DCLS

program will be able to: provide appropriate test selection and interpretation of test results; monitor laboratory data and testing processes; improve the quality, efficiency, and safety of the overall diagnostic testing process; and direct laboratory operations to comply with all state and Federal laws and regulations. We would consider a DCLS an acceptable doctoral degree.

For the purposes of qualifying under the CLIA personnel regulations, we do not consider a MD or DO to be the same as a non-medical doctoral degree. Therefore, these individuals must continue to qualify under the applicable CLIA personnel regulations, that is, MDs and DOs must qualify under doctors of medicine or osteopathy requirements. Those individuals with non-medical doctoral degrees as outline above must qualify under the doctoral degree requirements. If finalized, the State Operations Manual (SOM)<sup>11</sup> will be updated accordingly.

The CLIA regulations aim to ensure accurate and reliable testing on specimens derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of human beings. Therefore, we believe that DVM should be removed from the qualifying doctoral degrees as it is not relevant to testing on specimens derived from the human body. We understand many of the methodologies may be the same; however, testing on human specimens is clearly specified in the statutory language and regulatory definition of a laboratory under CLIA. Therefore, testing of animal specimens does not meet the intent of the CLIA regulations. Of the nine boards approved by HHS for qualification of applicants with doctoral degrees, only one allows individuals with DVMs to sit

for board certification. Since 1965, American Board of Medical Microbiology has granted certification to four individuals. Individuals who have previously qualified under a provision requiring a doctoral degree will continue to qualify under the new rule, if finalized. If finalized, we would remove the reference to DVMs in the SOM, Chapter 6 (that is, Interpretive Guidelines) under § 493.1443(b)(3) (page 353).

Finally, as discussed above, we are proposing that a doctoral degree must be an earned post-baccalaureate degree with at least three years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. As such, honorary degrees do not meet the intent of a qualifying doctoral degree as an individual has not completed the necessary course and laboratory work required for the post-baccalaureate degree or necessary to ensure quality testing, for example, accurate and reliable results. We believe that qualifying individuals who hold only honorary degrees is not consistent with the public health purposes of the CLIA statute. Furthermore, we believe that this would impede CMS' ability to ensure health and safety of the public and individuals served by CLIA-certified laboratories.

#### d. Training and Experience

At § 493.2, we are proposing to add a definition for "Laboratory training or experience" to state that it means that the training or experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted from CLIA under § 493.3(b). Laboratory subject to CLIA would mean the laboratory meets the definition of a "laboratory" under § 493.2. Training and experience

obtained in a research laboratory that only reports aggregate results or a forensic laboratory does not meet this definition. These types of facilities are exempt from CLIA under § 493.3(b), and as such, training and experience acquired in these facilities is not applicable to CLIA laboratories.

In all situations, an individual is required to meet training and/or experience requirements in addition to the educational requirements to competently perform their regulatory responsibilities. Because the CLIA personnel requirements for nonwaived testing are based on the complexity of testing performed (moderate versus high), we conclude that appropriate training and experience is necessary. Comments from the 2018 RFI support this proposal. Comments received from the 2018 RFI include the following:

- Training and or experience should be in a CLIA certified laboratory.
- Research experience is not equivalent to clinical experience.
- Dependent on complexity level of testing, minimum standards should increase as the complexity level increases.

Further, commenters stated that documentation from a former employer would be acceptable, provided it included specific details of the individual's job description, training and CA for areas of testing performed. This documentation could be from an LD, manager or supervisor.

We concur with the CLIAC recommendation that all personnel should have training and experience in their areas of responsibility as listed in CLIA for the appropriate test complexity as shown in Table 6. which shows the specific personnel categories that have a provision requiring training or experience, or both, or require experience directing or supervising, or both.

**TABLE 6: Personnel Requirements by Test Complexity for Proposed Personnel Changes that Require Training or Experience, or Both**

| CLIA Section  | Role                 | Complexity |
|---------------|----------------------|------------|
| § 493.1407(e) | Laboratory director  | Moderate   |
| § 493.1413(b) | Technical consultant | Moderate   |
| § 493.1425(b) | Testing personnel    | Moderate   |
| § 493.1445(e) | Laboratory director  | High       |
| § 493.1451(b) | Technical supervisor | High       |
| § 493.1495(b) | Testing personnel    | High       |

<sup>11</sup> <https://www.cms.gov/regulations-and-guidance/manuals/downloads/som107c06pdf.pdf>.



This means personnel should have training or experience examining and performing tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring an individual's condition.

Each individual must have documentation of training or experience applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he or she has the skills required for proper performance of pre-analytic, analytic, and post-analytic phases of testing. For example, if the individual performs blood gas testing on a nonwaived point-of-care device, demonstration of skills should include, but is not limited to, the following:

- Proper specimen collection, handling and labelling;
- Proper test performance according to the laboratory's policies and manufacturer's instructions;
- Verification of performance specifications;
- Calibration and preventive maintenance;
- Proficiency testing; and
- Proper reporting of patient test results.

Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field;
- On-site or off-site instrument trainings given by a manufacturer;
- Technical training sessions, workshops, or conferences given by a professional laboratory organization; or
- A formal laboratory training program.

Documentation may consist of, but is not limited to:

- Letters from training programs or employers.
- Attestation statements of an individual's training and experience by the LD.
- Log sheet(s) initialed by the attendees indicating attendance at a training session or in-service.
- Certificates from organizations providing the training session, workshop, conference, specialty course.

We expect all documentation supporting an individual's education, training and experience to be independently generated, that is, not authored by the individual who is trying to meet CLIA personnel qualification requirements. For example, a curriculum vitae (CV) is not acceptable verification, in and of itself, to document an individual's education, training or experience. Letters on letterhead from previous employment, competency assessment, and comprehensive list of job

responsibilities may be examples of acceptable documentation.

Laboratory testing of non-human specimens is not acceptable experience, for example, environmental, animal testing, as it is not used for the purpose of providing information used in the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Many comments received on the 2018 RFI stated that experience from a research laboratory should not be accepted. Depending on the circumstances, research testing can be either exempt from CLIA or subject to CLIA. Specifically, research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients are excepted from the CLIA regulations at § 493.3(b)(2). In accordance with that regulation, only those facilities performing research testing on human specimens that do not report patient-specific results may qualify to be exempt from CLIA certification.<sup>12</sup> An example of a nonpatient-specific result would be "10 out of 30 participants were positive for gene X." The result in this example is a summary of the group data, and is not indicative of an individual's health. An example of a patient-specific result would be "participant A was positive for gene X" in which the result is specific to participant A. In cases where patient-specific test results are maintained by a statistical research center for possible use by investigators in which the results are not reported out as patient-specific and could not be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," CLIA would not apply.

Research testing where patient-specific results are reported from the laboratory, and those results will be or could be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are subject to CLIA. Therefore, we would consider research experience related to reporting patient-specific results as applicable experience to meet the CLIA personnel requirements; however, if the research experience only includes aggregate reporting of results, we would not consider this acceptable experience to meet CLIA personnel requirements as

this type of research testing is exempt from CLIA (§ 493.3(b)(2)).

CLIA regulations at § 493.3(b)(1) specifically exempt facilities or components of facilities that only perform testing for forensic purposes are not subject to CLIA requirements. This was addressed in a Survey and Certification policy memo (S&C-08-35) published on September 5, 2008 (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>). (See the preamble to the 1992 final rule with comment period for an important discussion concerning this subject (57 FR 7014).)

In summary, laboratory results generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body may be relevant to legal proceedings. However, there is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment. The determining factor is not the test itself, but the purpose for which the test is conducted.

In addition, based on the CLIA law and its legislative history, forensic testing is excluded under CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose for providing diagnosis, treatment or assessment of health.

Therefore, we do not consider forensic testing to be acceptable experience or training as a means to meet CLIA personnel requirements as this type of testing is exempt from CLIA (§ 493.3(b)(3)).

#### e. Experience Directing or Supervising

At § 493.2, we are proposing to add a definition for "Experience directing or supervising" to state that it means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted under § 493.3(b). Experience directing or supervising a research laboratory that tests human specimens but does not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients would not meet this definition (for example, reporting of aggregate results). Experience directing or supervising any facility or component of a facility that only performs testing for forensic purposes also would not meet this definition. The ordering of tests and interpreting and applying the results of

<sup>12</sup> <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf>.

these tests in diagnosing and treating an individual's illness would not meet this definition because it is not related to the performance of clinical laboratory testing. Ordering of tests and interpreting and applying of results falls under the practice of medicine and are not related to the performance of clinical laboratory testing. Teaching experience directly related to a medical technology or clinical laboratory sciences program, or a clinical laboratory section of a residency program, would be considered acceptable experience because we understand that such experience from teaching related to a medical technology or clinical laboratory sciences program would include all aspects of the entire testing process (pre-analytic, analytic and post-analytic), as well as quality control and quality assessment. These are critical responsibilities of a laboratory director as defined by CLIA. See discussion on proposed definition of "Laboratory training or experience" for more information on proposed treatment of research laboratories and forensic testing experience.

## 2. PPM Laboratory Director Responsibilities (§ 493.1359)

At § 493.1359, we are proposing to clarify the CA requirements for PPM laboratories in the Standard for PPM LD responsibilities, as this testing is moderate complexity per § 493.19(b)(2) and subject to CA. Based on the fact the regulations do not have a requirement for a TC for PPM laboratories, we believe that it is currently unclear in the regulation how CA applies to these types of laboratories. The SOM, Appendix C (that is, Interpretive Guidelines) on page 151 ([https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap\\_c\\_lab.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf)) discusses CA for PPM laboratories. Therefore, we are proposing to clarify, via modifications to this LD responsibilities section of the regulations, the CA requirement for PPM laboratories. We are proposing that the competency of all TP would be evaluated to ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. This would include the following:

- Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;
- Monitoring the recording and reporting of test results;
- Review of test results or worksheets;

- Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
- Assessment of problem solving skills.

Generally, these requirements mirror the CA provisions for moderate and high complexity testing at §§ 493.1413(b)(8) (TC responsibilities) and 493.1451(b)(8) (TS responsibilities). We are not proposing to include "Direct observation of performance of instrument maintenance and function checks" as the only equipment required for PPM testing is limited to bright-field and phase-contrast microscopy. Typically, TP do not perform these activities for PPM testing; rather, they are performed by third-party entities.

In addition, we are proposing at § 493.1359(d) the same CA intervals as in §§ 493.1413(b)(8) and 493.1451(b)(8) apply to mid-level practitioners for consistency. That is, evaluating and documenting the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually.

## 3. Laboratory Director Qualifications (§ 493.1405)

At §§ 493.1405(b)(1)(ii), 493.1411(b)(1)(ii), 493.1443(b)(1)(ii), and 493.1449, we are proposing to remove "or possess qualifications that are equivalent to those required for such certification." In making this proposal, we acknowledge that there are limited timeframes for an individual to sit for the boards, however, by allowing any such "eligible" individual to qualify under our regulations, we have found that some individuals may never sit for exams, or may even fail the exams. Such individuals were not who we intended to be eligible under these provisions. Further, even if we were to ban such individuals by carving them out of those we considered to hold "qualifications that are equivalent to those required for certification," it would be difficult to identify those individuals and remove them from their LD roles. In making this proposal, we acknowledge having historically accepted letters from individuals that have documented proof from the American Board of Pathology or American Board of Osteopathic Pathology that they are eligible to sit for the boards based on SOM guidance ([https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap\\_c\\_lab.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf), page 351, D6078). In addition, we propose to eliminate the equivalency standard, as we do not have a means to evaluate

equivalency to other boards for equivalency to American Board of Pathology or American Board of Osteopathic Pathology as it would be up to the Board to make a determination of equivalency, and we do not believe in retrospect it would be appropriate to expect those entities to conduct such analyses. Furthermore, we had requested that CLIAC consider what "possessing qualifications that are equivalent to board certification" should mean. CLIAC recommended that this verbiage be removed from relevant sections of subpart M because it was confusing, and we have no mechanism to determine when qualifications are "equivalent to board certification." We concur with the CLIAC recommendation. Further, we believe that individuals who historically may have qualified under this provision would still qualify through alternative routes, thus not disadvantaging individuals seeking to qualify as LDs. If finalized, we further propose that an individual who qualified under the predecessor regulations and is currently employed as a LD may continue to serve in that capacity so long as there is no break in service. For example, an individual who is serving as the LD of a CLIA-certified laboratory at the date of the publication of the final rule, and continues to serve as a LD of CLIA-certified laboratory that performs nonwaived testing, would continue to qualify. However, an individual who does not continue as LD of a CLIA-certified laboratory after the date of implementation of the final rule would need to requalify under the new provisions.

At § 493.1405(b)(2)(ii)(A), we are proposing to change the "or" to an "and" to include directing or supervising nonwaived laboratory testing in the provision. In addition, we are proposing to remove "Beginning September 1, 1993" from § 493.1405(b)(2)(ii)(B) and continue to retain the provision for 20 hours of CE credit hours for moderate complexity LDs who are seeking to qualify without certification by the American Board of Pathology and the American Board of Osteopathic Pathology. We believe by requiring the 20 CE credit hours, the LDs would have a better understanding of their responsibilities in the overall management and direction of laboratories, which would result in improved overall compliance. Historically, LD citations are among the top 10 condition-level deficiencies cited by surveyors. We believe that this would also improve the ability of laboratories to report accurate and

reliable test results, thus helping to protect the health and safety of the public.

At §§ 493.1405(b)(2)(ii)(C) and 493.1443(b)(2)(i), we are proposing to remove the residency provision for the following reasons. First, the residency requirement causes confusion with board certification for doctoral degrees (for example, American Board of Internal Medicine). It is also challenging for these individuals to qualify under this provision as the medical residencies as generally do not include the type of laboratory training or require the 1 year of laboratory training that we would expect to see related to laboratory administration and operation for which the LD is responsible. We would expect the residency program to provide the director the knowledge in principles and theories of laboratory practice, including: quality control and quality assessment; proficiency testing; the phases of the total process (that is, pre-analytic, analytic, and post-analytic), as well as general laboratory systems; facility administration; and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing. However, a typical residency does not include performing laboratory training for a year (defined in interpretive guidelines as 2,080 hours of laboratory training) nor does it include knowledge in principles and theories of laboratory practice. We have observed, and AOs have noted to us, that very few individuals qualify through the medical residency route. The onus for providing the documentation related to clinical laboratory experience during residency is on the applicant (that is, it must be documentation of the individual's clinical laboratory experience during residency).

CLIA recommended that we clarify the residency requirements by emphasizing the requisite laboratory training must be "clinical laboratory training," meaning "have at least one year of clinical laboratory training during medical residency or fellowship." However, we believe that 1 year of laboratory training is vague. We also believe that after removing the residency requirement, there would be several alternative routes for individuals to qualify as LDs. Individuals seeking to qualify as a moderate complexity LD may still qualify under § 493.1405(b)(3) through (5) without a medical residency. We would continue to accept residency experience as counting toward the requirement of 2 years of laboratory experience directing or supervising high complexity testing for

doctors of medicine, doctors of osteopathy, or doctors of podiatry. We would also accept experience directing or supervising high complexity testing from a medical fellowship program toward the requirements outlined in the regulations. Generally, a fellowship program follows a residency program and is for those individuals who choose to pursue additional training in their specialty. Section 493.1443(b)(2)(ii) is the current requirement that allows individuals with at least 2 years of experience directing or supervising high complexity testing to qualify under paragraph (b)(2).

At § 493.1405(b)(3), we are proposing to revise paragraph (b)(3)(ii) to include an educational option that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology (see section I.D.1.a of this proposed rule). We are also proposing to add paragraph (b)(3)(iii) to include the addition of 20 CE credit hours for doctoral degrees, as well as the current paragraphs (b)(3)(i) through (ii). This would include the requirement to be certified by an applicable board and continue to be certified and have at least 1 year of experience directing or supervising nonwaived testing.

The current CLIA regulations at §§ 493.1405, 493.1411, 493.1423, 493.1441, 493.1449, 494.1461, and 493.1489 indicate acceptable degrees for personnel as those in a chemical, physical, biological, or clinical laboratory science or medical technology. Degree names and types have changed since the CLIA regulations were first published in 1992. As a result, in some cases, there are degrees for which the area of study may not be clear based on the name of the degree given. This makes it challenging for CMS, state agencies, Exempt States (ES), and AOs to determine what types of degrees are considered acceptable degrees in order to qualify CLIA personnel. At the time the CLIA regulations were published, individuals typically received a degree in the areas of biology, chemistry, medical technology, or clinical laboratory science. Today, we often must perform an evaluation of transcripts to determine if the individuals meet CLIA personnel requirements.

We believe it is important that individuals lacking a traditional degree in chemical, biological, or clinical laboratory science or medical technology should be considered if they have completed the coursework that is equivalent to the aforementioned traditional degrees and acquired

documentation of the equivalent educational coursework. In addition to the educational requirements discussed in this section, CLIA also has experience and training requirements (see our proposed updates to §§ 493.1405, 493.1411, and 493.1423), but they will not be addressed in this educational discussion.

We believe degrees should be in a science that deals in the kind of clinical laboratory testing, that is, that which is related to testing of human specimens as the definition of a "laboratory," which is defined in terms of the examination of materials from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings (see § 493.2). In some cases, it is clear that a degree would meet these standards. For example, degrees in microbiology, genetics, molecular biology, biochemistry, and organic chemistry would be considered appropriate degrees. In other instances, it is not apparent whether the degree would meet such requirements. Environmental sciences, biotechnology, and marine biology are examples of degrees that would not appear in keeping with the scope of the CLIA program. At face value, we do not believe these types of degrees should qualify an individual under the requirements in subpart M because they are not related to clinical laboratory testing. Environmental science degrees may cover such areas as ecosystem management, the impact of industrialization on the environment, and natural resource management. Biotechnology degrees focus on developing technologies and products related to medical, environmental, and industrial areas. Marine biology focuses on studying marine organisms, their behaviors, and interactions with the environment. We would not consider these to be appropriate degrees under the CLIA program because these degrees do not generally appear to be focused on clinical laboratory testing or focused on the testing of human specimens, which is the scope of the CLIA regulations. However, in this proposed rule, we are proposing an option for an educational algorithm based on semester hours as an alternative qualification mechanism. Individuals with degrees that are not clearly biological or chemical in nature may be evaluated using this algorithm if finalized and may qualify for CLIA personnel positions in subpart M.

In developing the proposed algorithm, we explored the required courses for bachelor's, master's, and doctoral degrees in the major studies of biology,

chemistry, and medical technology. For purposes of this discussion, only degrees in biology and chemistry will be addressed, as degrees in medical technology and clinical laboratory science do not need to be evaluated for equivalency. Multiple sections of the CLIA regulations specify that educational degrees in “chemical, physical or biological science or medical laboratory technology from an accredited institution” constitute appropriate education to qualify for

laboratory roles in the noted complexity and laboratory specialty areas. In all situations, the educational requirement is based on the laboratory individual having a sufficient educational background (coursework) to be qualified to gain the subsequent training and experience to competently perform their roles.

Three levels (small, medium, and large) of both public and private accredited universities and colleges were reviewed. For purposes of this

research, small institutions were defined as less than 5,000 students, medium as 5,000 to 15,000 students, and large as greater than 15,000 students. Seven colleges and universities were evaluated for all three defined types. Table 7 describes the number of semester hours (SH) required across all three sizes of colleges and universities for both a bachelor's in Biology and a bachelor's in Chemistry.

**TABLE 7: Average Required Semester Hours (SH)\* for Bachelor's Degrees in Biology and Chemistry**

| Semester Hours (SH)                | Bachelor's Biology | Bachelor's Chemistry |
|------------------------------------|--------------------|----------------------|
| Biology SH                         | 20-49              | ≥8**                 |
| Chemistry SH                       | 8-20               | 25-56                |
| Other (Includes biology/chemistry) | 7-28               | 11-42                |

\* Quarter hours may be converted to semester hours by multiplying the semester hours by 1.5. For example, 3 semester hours is equivalent to 4.5 quarter hours.

\*\*The majority of colleges and universities did not break out the biology SH, but instead grouped them in “Other”.

In general, accredited colleges and universities require general biology, molecular biology or genetics, general chemistry, organic chemistry, and biochemistry. We are proposing a specific coursework algorithm to qualify candidates, in lieu of a qualifying degree, for all testing levels. At present, only § 493.1489(b)(2)(ii) specifies specific coursework required. This is for an associate degree individual to perform high complexity testing. Specifying coursework requirements will allow CMS, state agencies, AOs, and ES to consistently evaluate educational qualifications.

For both the doctoral degree and master's degree curricula, there were no consistent coursework thesis or research requirements for Biology and Chemistry majors of study. For example, evaluation of the master's degree requirements revealed three tracks that included:

- Coursework;
- Coursework and thesis; and
- Coursework, thesis, and research.

For doctoral degrees, we will propose the following educational algorithm for those individuals who have a doctoral degree that is not clearly in a chemical or biological science. We would expect those individuals to:

- Meet master's degree equivalency; and
- At least 16 SH of additional doctoral-level coursework in biology, chemistry, medical technology, or clinical laboratory science; and

- A thesis or research project in biology, chemistry, medical technology, or clinical laboratory science related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of or the assessment of the health of human beings.

CLIAAC recommended that other degrees (such as those in the humanities, physical sciences, and others) may not have the requisite science coursework, and candidates for positions should be considered based on a minimum number of hours of courses with laboratory components with relevance to clinical laboratory testing (which could also come from post-degree curricular work). We concur with CLIAAC's recommendation that relevant science and laboratory coursework should be considered when evaluating an individual's education qualifications.

The educational algorithm may allow individuals without a traditional chemical or biological degree to meet the CLIA personnel education requirements based on their coursework. Individuals who may have the appropriate coursework would not be disadvantaged by having a degree that is not considered chemical or biological in nature. Please note that the requirements for the applicable laboratory training or experience, or both, found in subpart M (and discussed previously), are required in addition to the educational requirement.

At § 493.1405(b)(4), we are proposing to redesignate current paragraphs

(b)(4)(ii) and (iii) as paragraphs (b)(4)(iv) and (v), respectively. We are proposing new paragraphs (b)(4)(ii) and (iii) as additional educational options that include a qualification algorithm for an individual that does not have a master's degree in a chemical, biological, or clinical laboratory science or medical technology (see section I.D.1.c. of this proposed rule). We are proposing to add a new requirement at paragraph (b)(4)(vi) to include the addition of 20 CE credit hours.

As a result of the above discussion, we are proposing that individuals meet either of the following two options for use as educational algorithms:

• Option 1

++ Meet bachelor's degree equivalency; and

++ At least 16 SH of additional graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

• Option 2

++ Meet bachelor's degree equivalency; and

++ At least 16 SH, which may include a combination of graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

At § 493.1405(b)(5), we propose to redesignate current paragraphs (b)(5)(ii) and (iii) to paragraphs (b)(5)(iii) and (iv), respectively. In addition, we are proposing a new paragraph (b)(5)(ii) with an educational option that includes a qualification algorithm for an individual that does not have a bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology (see section I.D.1.c. of this proposed rule). We are also proposing to add a new requirement at paragraph (b)(5)(v) to include the addition of 20 CE credit hours.

In general, an associate degree requires the completion of 60 semesters, and a bachelor's degree requires the completion of 120 semester hours. In the case of bachelor's degrees, for this reason, we are proposing that the equivalent educational requirements for associate degrees at § 493.1489(b)(2)(ii) should be doubled. That is, an individual must have at least 120 SH, or equivalent, from an accredited institution that, at a minimum, include either 48 SH of medical laboratory technology or clinical laboratory science courses; or 48 SH of science courses that include: 12 SH of chemistry, which must include general chemistry and biochemistry or organic chemistry; 12 SH of biology, which must include general biology and molecular biology, cell biology or genetics; and 24 SH of chemistry, biology, or medical laboratory technology or clinical laboratory science in any combination. *Note:* We are not proposing to amend the education SH requirements at § 493.1489(b)(2)(ii) in this proposed rule, as there is no need to amend.

In addition to the degrees discussed above, we are proposing a new framework for evaluating non-traditional degrees, a part of the educational algorithm described previously. One example of a non-traditional degree may be a Regents Bachelor of Arts (RBA), which is a baccalaureate degree program designed for adult students. The basic principle of an RBA is that credit is awarded for what students know regardless of how that knowledge was obtained. In other words, students may earn college-equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a Board of Regents. It is a general education degree without the designation of a major. Many of

these individuals have an associate degree in medical laboratory technology (MLT), but not an appropriate bachelor's degree that would make them eligible to qualify under the provisions in CLIA personnel requirements that require minimum of a bachelor's degree. This becomes problematic because there is no designation of a major, and CLIA qualifies individuals with the highest academic degree applicable to CLIA. Generally, in these cases, we have seen that these individuals have an associate degree (AA) degree in MLT and have many years of clinical laboratory experience. Currently, these individuals cannot meet CLIA personnel qualifications in subpart M that require a minimum of a bachelor's degree. We believe that their education and experience should qualify them to be TCs as long as their AA is in medical laboratory technology or laboratory science. Public feedback from the 2018 RFI supported that a non-traditional degree should be considered as a means to meet CLIA requirements for the TC and TP for moderate complexity testing, providing a minimum number of semester hours were obtained in chemistry, biology, and laboratory sciences. We believe a non-traditional degree can be a means to qualify as TC and TP, providing an adequate number of biology, chemistry or medical laboratory, or clinical laboratory science courses is part of the curriculum in addition to meeting the training or experience requirements.

At § 493.1405(b)(6) through (7), we are proposing to remove the "grandfather" provisions as these requirements had to have been met by February 28, 1992. Individuals can no longer qualify under these provisions. A grandfather is a provision in which a previous rule would continue to apply to individuals already qualified and employed in the given personnel capacity upon implementing a new rule. The new rule will apply to all individuals seeking to qualify after the implementation of said rule. We propose to revise paragraph (b)(6) with a new grandfather provision for all individuals who qualified under this provision, as well as § 493.1406 prior to the date of the final rule. We intend to allow individuals already qualified and employed in the given personnel capacity as of the date of the final rule to continue to be qualified under the new provisions (that is, grandfathered). However, we intend to require all individuals becoming employed by a laboratory or changing assignments within a laboratory after the final rule's effective date to qualify under the new provisions. This includes

those individuals who may have been previously employed in a given position prior to the effective date but took a break or a leave of absence and came back after the date of the final rule.

#### 4. Laboratory Director Qualifications on or Before February 28, 1992 (§ 493.1406)

At § 493.1406, we are proposing to remove the grandfather provision for these requirements as they had to have been met by February 28, 1992. Individuals can no longer qualify under these provisions. We plan to grandfather all individuals qualified under this provision prior to the date of the final rule under § 493.1405(6). All individuals qualifying after the date of the final rule will be required to qualify under the new provisions.

#### 5. Laboratory Director Responsibilities (§ 493.1407)

At §§ 493.1407(c) and 493.1445(c), we are proposing to revise the requirements so that the LD must be on-site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on-site visits. However, laboratory directors may elect to be on-site more frequently. The laboratory must provide documentation of these visits, including evidence of performing activities that are part of the LD responsibilities. We concur with CLIA's recommendation that LDs should make at least two (reasonably spaced) on-site visits to each laboratory they direct per year. We would expect the on-site visits to be once every 6 months with an interval of at least 4 months between the two on-site visits. We will continue to require that the LD is accessible to the laboratory to provide telephone or electronic consultation as needed. Based on a review of information provided by state agencies, AOs, and ESs, onsite LD on-site visits are required as follows:

- 18 percent (n=9 of 49) of states require on-site visits and one territory;
- 71 percent (n=3 of 7) AOs; and
- 100 percent (n=1 of 2) ES.

CLIA statistics show that LD citations are consistently among the top 10 condition-level deficiencies cited by surveyors.<sup>13</sup> Feedback from the states, AOs, and ES indicated that the number of deficiencies cited at the time of the survey was less when the LD was on-site full-time or made regular on-site visits. Based on anecdotal information from the state agencies, ES, and AOs, the laboratories that did not have a LD who made regular visits to the

<sup>13</sup> <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAopten.pdf>.

laboratory tended to have an increased number of citations related to overall noncompliance with laboratory requirements. Some states currently require on-site laboratory directors to visit their laboratory at prescribed intervals, while others do not (see Table 8 for a complete list of states and territories). Feedback from states and AOs that did not have such a

requirement for on-site visits, generally supported the addition a requirement for on-site visits. Further, on-site visits are meant to supplement regular interactions between off-site directors and the lab (for example, by telephone or other telepresence). We concur with CLIAC's recommendations that clear documentation of LD on-site visits should demonstrate the laboratory is in

continuous compliance with current laws and regulations, including but not limited to the assessment of the physical environment for safe laboratory testing. The on-site LD visits cannot be delegated. We believe adding the on-site requirement supports increased compliance for laboratories.

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**TABLE 8: State and Territorial Requirements for On-site Laboratory Directors Every 6 Months**

| <b>Requirement for On-site Laboratory Directors<br/>Every 6 Months</b>   | <b>Do not Require On-site Laboratory Directors<br/>Once Every 6 Months</b>  |
|--|---|
| Georgia<br>Hawaii<br>Maine<br>Maryland<br>Nevada<br>New York<br>Oklahoma<br>Pennsylvania<br>Rhode Island<br>Tennessee<br>Puerto Rico (territory) | Alabama<br>Alaska<br>American Samoa (territory)<br>Arkansas<br>Arizona<br>California<br>Colorado<br>Connecticut<br>Delaware<br>District of Columbia<br>Florida<br>Guam (territory)<br>Idaho<br>Illinois<br>Indiana<br>Iowa<br>Kansas<br>Kentucky<br>Louisiana<br>Massachusetts<br>Michigan<br>Minnesota<br>Mississippi<br>Missouri<br>Montana<br>North Carolina<br>North Dakota<br>Nebraska<br>New Hampshire<br>New Jersey<br>New Mexico<br>Ohio<br>Oregon<br>Saipan (territory)<br>South Carolina<br>South Dakota<br>Texas<br>Utah<br>Vermont<br>Virginia<br>Virgin Islands (territory)<br>Washington<br>West Virginia<br>Wisconsin<br>Wyoming |
| N=10 states + 1 US territory   | N=40 states, 4 US territories, + District of Columbia   |

**BILLING CODE 4120-01-C****6. Technical Consultant Qualifications  
(§ 493.1411)**

As discussed in section II.B.3. of this proposed rule, we are proposing to amend § 493.1411(b)(1)(ii) by removing “or possess qualifications that are

equivalent to those required for such certification.”

As discussed in section II.B.16. of this proposed rule, we are proposing to amend § 493.1411(b)(3)(i) by removing an earned doctoral, master’s, or bachelor’s degree in “physical science” as a means to qualify. We further

propose to redesignate current paragraph (b)(3)(ii) as paragraph (b)(3)(iii). Then, we propose to revise paragraph (b)(3)(i) by changing the “and” to an “or” and to add a requirement at new paragraph (b)(3)(ii) to meet either § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii) to allow individuals

who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TC using the educational algorithm.

As discussed in section II.B.16. of this proposed rule, we are proposing to revise § 493.1411(b)(4)(i) by removing a doctoral, master's, or bachelor's degree in "physical science" as a means to qualify, and adding an earned doctoral, master's, or bachelor's degree in "clinical laboratory science" as a means to qualify. At § 493.1411(b)(4), we are proposing to change the "and" to an "or" in paragraph (b)(4)(i). We are also proposing to redesignate current paragraph (b)(4)(ii) as paragraph (b)(4)(iii) and to add new paragraph (b)(4)(ii) to state that the individual must meet the criteria in § 493.1405(b)(5)(ii) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TC using the educational algorithm. We would also redesignate current paragraph (b)(5)(ii) as paragraph (b)(5)(iii) with the addition of "or."

At § 493.1411(b), we are proposing to add a requirement at paragraph (b)(5) to allow individuals with an associate degree in medical laboratory technology or clinical laboratory science and at least 4 years of laboratory training or experience, or both, in nonwaived testing and the designated specialty or subspecialty areas of service for which the TC is responsible for qualifying as TCs. As discussed in section I.B. of this proposed rule, CLIA recommended that we modify CLIA requirements to add the option for individuals with an associate degree to qualify as TCs. We concur with the CLIA recommendation. In general, this will allow individuals who may have an applicable associate degree in addition to required training or experience, or both, to qualify as TCs. We recognize that the current personnel qualifications for general supervisors (GS) for high complexity testing may be less stringent than those of TCs for moderate complexity testing. The current CLIA regulations allow an individual with an associate degree (§ 493.1461) to perform CA on high complexity TP (see §§ 493.1461(c)(2), 493.1489(b)(2)(i)). The regulations under moderate complexity state that the TC is responsible for CA and does not allow delegation of this responsibility to any individual. The high complexity regulations allow the LD or TS to delegate the CA to the GS. However, the same individual cannot perform CA on TP for moderate complexity testing unless they can qualify as a TC. Therefore, if a

laboratory performs both moderate and high complexity testing, a GS can only perform CA on moderate complexity TP if they can meet the regulatory requirements of a TC. This proposed change would allow individuals with applicable associate degrees to assess competency in laboratories that perform both moderate and high complexity testing and bring parity to who performs CA for all nonwaived laboratories while maintaining the laboratory's ability to produce accurate and reliable testing.

At § 493.1411(b), we are proposing to add a requirement at paragraph (b)(6) to allow individuals who are qualified under § 493.1411(b)(1), (2), (3), or (4) or have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution and have at least 2 years of laboratory training or experience, or both, in blood gas analysis to qualify as TC for blood gas testing only. Most blood gas testing was categorized as high complexity when the original regulations were finalized in the 1992 final rule with comment period. Due to improved technology, most routine blood gas testing is now categorized as moderate complexity. We are proposing this change because we believe that it would provide adequate oversight of moderate complexity blood gas testing. Adding this provision specific to TCs in the area of blood gas testing would allow individuals to qualify as a TC in this specific area of expertise. Please note that we will still not consider a degree in respiratory therapy or cardiovascular technology to be equivalent to a biological or chemical science degree. An individual with these qualifications should be able to oversee the testing and CA of personnel performing blood gas testing.

At § 493.1411(b)(7), we are proposing to add a grandfather provision to include those already qualified prior to the date of the final rule, including nurses.

#### 7. Testing Personnel Qualifications (§ 493.1423)

We are proposing to redesignate § 493.1423(b)(2), (3), and (4) as § 493.1423(b)(4), (5), (6), respectively.

We are also proposing to separate current paragraph (b)(1) into two separate provisions. Revised paragraph (b)(1) would include the current requirement of a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located. New paragraph (b)(2) would include the requirement of an earned doctoral, master's, or bachelor's degree in a chemical, biological, or clinical

laboratory science or medical technology from an accredited institution. As discussed in section II.B.16. of this proposed rule, we are proposing to remove an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify. In addition, we are proposing to add an earned doctoral, master's, or bachelor's degree in nursing as a means to qualify. In Survey and Certification memo 16-18-CLIA,<sup>14</sup> we stated that "a bachelor's in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity TP" and that "an associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity TP." We appreciate all comments received in response to the 2018 RFI and agree that a nursing degree is not equivalent to a biological or chemical science degree. We also concur with some commenters' recommendation that nursing degrees be used as a separate qualifying degree for TP. As testing practices and technologies have evolved, point of care testing has become a standard of practice in many health care systems, allowing laboratory results to be delivered to the treating health care provider as rapidly as possible. We recognize that in many health care systems, nurses perform the majority of the point of care testing in many different scenarios (for example, bedside, surgery centers, end-stage renal disease facilities). We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency.

We are proposing to add new paragraph (b)(3) to include the requirement that the individual must meet the criteria in § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii) or (b)(5)(ii) to allow individuals who do not have a chemical, biological, or clinical laboratory science or medical technology degree to be eligible to qualify as a TP using the educational algorithm. See discussion in section II.B.3. of this proposed rule.

In addition, we are proposing to add at paragraph (b)(7) a requirement to allow individuals for blood gas testing to be qualified under § 493.1423(b)(1) through (4) or have earned a bachelor's degree in RT or cardiovascular

<sup>14</sup> <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-16-18.html?DLPage=1&DLEntries=10&DLFilter=16-18&DLSort=3&DLSortDir=descending>.



technology from an accredited institution or have an AA related to pulmonary function and have at least 2 years training or experience or both in blood gas analysis. We are proposing this addition so that parity can exist with high complexity TP requirements for blood gas testing at § 493.1489(b)(6). See previous discussion at § 493.1411(b).

#### 8. Laboratory Director Qualifications (§ 493.1443)

As discussed in section II.B.3. of this proposed rule, we are proposing to amend § 493.1443(b)(1)(ii) by removing “or possess qualifications that are equivalent to those required for such certification.” As discussed in the above section of this proposed rule, we are proposing to amend § 493.1443(b)(2) by removing the residency requirement at paragraph (b)(2)(i) as a means to qualify and redesignating paragraph (b)(2)(ii) (which requires the individual to have at least 2 years of experience directing or supervising high complexity testing) as paragraph (b)(2)(i). As discussed in section II.B.3. of this proposed rule, we are also proposing to add new paragraph (b)(2)(ii) to require 20 CE credit hours.

We are also proposing to redesignate current paragraph (b)(3)(i) as new paragraph (b)(3)(iii) and to redesignate the provisions of paragraphs (b)(2)(ii)(A) and (B) as new paragraph (b)(3)(iv).

As discussed in section II.B.16. of this proposed rule, we are proposing to redesignate the introductory text of paragraph (b)(3) as new paragraph (b)(3)(i) to revise this paragraph by removing an earned doctoral, master's, or bachelor's degree in “physical science” as a means to qualify. As discussed in section II.B.3. of this proposed rule, we would revise newly redesignated paragraph (b)(3)(i) by adding an earned doctoral, master's, or bachelor's degree in “medical technology” as a means to qualify.

As discussed in section I.D.1.c. of this proposed rule, we are proposing to add an educational requirement at new paragraph (b)(3)(ii) that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology.

At paragraphs (b)(3)(ii) and (b)(4) and (5), we are proposing to delete these paragraphs to remove the grandfather provisions as these requirements had to have been met by February 24, 2003, March 14, 1990, and February 28, 1992, respectively, and individuals can no longer qualify under these provisions. We are proposing to add new paragraph (b)(4) to specify the new grandfather

provision. We are also proposing to redesignate paragraph (b)(6) as new paragraph (b)(5).

Finally, as discussed in section II.B.3. of this proposed rule, we are proposing to add a 20 CE credit hour requirement at new paragraph (b)(3)(v).

#### 9. Laboratory Director Responsibilities (§ 493.1445)

For proposals related to § 493.1445, please see the discussion at II.B.5. of this proposed rule.

#### 10. Technical Supervisor Qualifications (§ 493.1449)

At § 493.1449, we are proposing to combine the provisions of paragraphs (c) through (g) into new paragraph (c) and combine paragraphs (h) through (j), (n), and (q) into new paragraph (d). We are also proposing to redesignate paragraphs (k), (l), (m), (o), and (p) as paragraphs (e), (f), (g), (h), and (i), respectively. We propose to make these changes to simplify the regulations by reducing confusion and grouping identical TS requirements into a combined provision. We are also proposing to insert the education algorithm at paragraph (c)(4)(i)(B).

At newly redesignated paragraph (e)(1)(ii)(B) (formerly paragraph (k)(1)(ii)(B)), we are proposing to remove and reserve this paragraph since the American Society of Cytology has not provided certification for cytology since 1998; certification is provided by American Board of Pathology and American Board of Osteopathic Pathology.

At newly redesignated paragraph (d) (formerly paragraph (q)), we are proposing to amend the immunohematology requirement for the TS requirement to align with other TS qualifications and allow individuals with doctoral, master's, and bachelor's degrees with appropriate training and experience to qualify as a TS for immunohematology. This provision will be included in § 493.1449(d). The current regulation requires that the TS for immunohematology be a doctor of medicine or osteopathy. Fulfilling the CA requirements (for example, direct observation) can be challenging in rural facilities as the TS may not be onsite as the individual(s) may cover a large geographic area. Often a MT/CLS with a SBB (Specialist in Blood Bank) from ASCP (American Society for Clinical Pathology)<sup>15</sup> is on-site to oversee the day-to-day operations of the blood bank. By allowing qualified individuals with

doctoral, master's, or bachelor's degrees, to qualify as TSs, the personnel responsibilities will align with the current practices in laboratories without affecting the ability of the laboratory to provide accurate and reliable results. Further, this proposed change may help alleviate a shortage of physicians in rural areas and does not constitute a risk to public health or the individuals served by the laboratory.

As discussed in section II. B.16. of this proposed rule, we are proposing at § 493.1449 to remove an earned doctoral, master's, or bachelor's degree in “physical science” as a means to qualify.

#### 11. General Supervisor Qualifications (§ 493.1461)

As discussed in section II. B.16. of this proposed rule, we are proposing at § 493.1461(c)(1)(i) to remove an earned doctoral, master's, or bachelor's degree in “physical science” as a means to qualify. At § 493.1461(c)(3) through (5), we are proposing to delete the grandfather provisions as these requirements had to have been met by February 28, 1992, April 24, 1995, and September 1, 1992, respectively, and individuals can no longer qualify under these provisions. We plan to grandfather all individuals qualified under this provision. We are also proposing to add new paragraph (c)(3) to specify a new grandfather provision for those individuals who had qualified prior to the publication of the final rule.

#### 12. General Supervisor Qualifications on or Before February 28, 1992 (§ 493.1462)

At § 493.1462, we are proposing to remove the grandfather provision as this requirement must have been met by February 28, 1992. These individuals would be included in the grandfather provision for § 493.1461(c)(3) through (5).

#### 13. General Supervisor Responsibilities (§ 493.1463)

At § 493.1463(b)(4), we are proposing to revise the language stating the need to annually evaluate and document the performance of all testing personnel to now require the evaluation and documentation of the competency of all testing personnel. Historically, CLIA has allowed the TS to delegate all CA to the GS. However, the current regulations only speak to the ability of the GS to perform annual CA. We are clarifying that the GS may be delegated both the semi-annual and the annual CA.

<sup>15</sup> <https://www.ascp.org/content/docs/default-source/boc-pdfs/exam-content-outlines/ascp-boc-us-procedures-book-web.pdf>.

#### 14. Cytotechnologist Qualifications (§ 493.1483)

At §§ 493.1483(b)(2) and 493.1489(b)(2)(ii)(B)(1), we are proposing to replace “CAHEA” with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and to remove, “or other organization approved by HHS.” In October 1992, the American Medical Association (AMA) announced its intent to support the establishment of a new and independent agency to assume the accreditation responsibilities of the Commission on Allied Health Education Accreditation (CAHEA), which is CAAHEP. HHS has no approval process for programs not approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or CAAHEP.

At § 493.1483(b)(3) through (5), we are proposing to remove the grandfather provisions as these requirements had to have been met by September 1, 1992, or September 1, 1994, as individuals can no longer qualify under these provisions. We plan to grandfather all individuals qualified under this provision prior to the date of the final rule. These individuals would be included in the new grandfather provision at § 493.1483(b)(3).

#### 15. Testing Personnel Qualifications (§ 493.1489)

We are proposing to remove paragraph (b)(3) as the February 28, 1992 grandfather provision must have been met by February 28, 1992. We are also proposing to redesignate paragraphs (b)(2)(i) and (ii) to paragraphs (b)(3)(i) and (ii), respectively. As noted, at § 493.1489(b)(2)(ii)(B)(1), we are proposing to replace “CAHEA” with “CAAHEP” and to remove “or other organization approved by HHS.”

In addition, we are proposing to revise paragraph (b)(1) to separate the provisions into two paragraphs (that is, paragraph (b)(1) and new paragraph (b)(2)(i)). New paragraph (b)(1) would include the current requirement of a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located. New paragraph (b)(2)(i) would include an earned doctoral, master’s, or bachelor’s degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution. As discussed in section II.B.16. of this proposed rule, we are proposing to remove an earned doctoral, master’s, or bachelor’s degree in “physical science” as a means to qualify. We are also proposing to add an

earned doctoral, master’s, or bachelor’s degree in nursing as a means to qualify (see discussion at § 493.142 in section II.B.7. of this proposed rule). In addition, we are proposing to add new paragraph (b)(2)(ii) to state who may be qualified under § 493.1443(b)(3) or § 493.1449(c)(4) or (5) to allow individuals who do not have a chemical, biological, or clinical science or medical technology or clinical laboratory science degree to be eligible to qualify as a TC using the educational algorithm.

At § 493.1489(b)(4), we are proposing to amend this requirement by moving the military provision out of the April 24, 1995, grandfather provision and make it a mechanism that individuals will be able to qualify to be equivalent to the already existing provision in moderate complexity testing (§ 493.1423(b)(3)). We believe these individuals have the requisite educational background to meet the requirements to perform laboratory testing under CLIA. In addition, we are proposing to remove paragraph (b)(4) introductory text and paragraph (b)(4)(i) [the text that currently states “On or before” through “graduated from a [ML] or [CL] training program approved or accredited by ABHES, CAHEA, or other organizations approved by HHS”] per the discussion under § 493.1483(b)(2). As a result, the current military requirement at paragraph (b)(4)(ii) would be redesignated as paragraph (b)(4).

#### 16. Technologist Qualifications on or Before February 28, 1992 (§ 493.1491)

The current language at § 493.1491(b)(6) is being included in the grandfather at § 493.1489(b)(5). We are proposing to remove § 493.1491 as individuals can no longer qualify under this provision.

#### 17. Proposed Removal of Earned Degree in Physical Science as an Educational Requirement

At §§ 493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489, we are proposing to remove “physical science” and add a new educational requirement for the ability to qualify based on semester hours. We concur with CLIA’s recommendation that a degree in physical science should be removed from the CLIA regulations as it is too broad and may not include relevant laboratory science coursework. It is a broad discipline often described as the study of nonliving systems, such as astronomy, physics, and earth sciences. Generally, these types of degrees are not related to clinical laboratory testing. Due to variation in

usage and the absence of universally accepted definitions, a “physical science degree” is difficult to define for regulatory purposes. We believe that the proposed semester algorithm will allow individuals to qualify in the absence of a traditional chemical, biological, or clinical laboratory science or medical technology degree. An individual graduating with a physical science degree may or may not have sufficient course experience to meet the educational requirement, so the degree alone should not be listed among those that satisfy the educational requirement. We note that in some instances, individuals with these types of degrees have been able to qualify as high complexity TP under § 493.1489 and GSs under § 493.1461(b)(2) as long as they have the applicable training or experience (see section I.D.1.c. of this proposed rule).

#### 18. Clinical Laboratory Science and Medical Technology

At §§ 493.1405(b)(3) and (b)(5)(i), 493.1411(b)(4) and (6), 493.1443(b)(3)(i), and 493.1449(c)(3)(i), (c)(5)(i), (d)(3)(i), (d)(5)(i), (h)(2)(i), and (i)(2)(i), we are proposing to remove any text referring to “medical technology” degrees and replace such text with references to degrees in “clinical laboratory science and medical technology” so that the latter phrase appears consistently throughout subpart M. Originally, degrees were given in medical technology, however; the naming convention for medical technology degrees has changed since the regulations were first published in the 1992 final rule with comment period. The degree is now referred to as clinical laboratory science. A clinical laboratory science degree is synonymous with a medical technology degree.

#### C. Proposed Change to CLIA Requirements for Alternative Sanctions for CoW Laboratories

As discussed in section I.C. of this proposed rule, we are proposing to amend § 493.1804(c)(1) by removing the phrase “(CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)”.

#### IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of

Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A) required issues for the following information collection requirements (ICRs).

The requirements and burden will be submitted to OMB under OMB Control Number 0938–0612, which expires January 31, 2024. The information collection will be revised to account for the burden.

#### A. CLIA Fees

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### B. Histocompatibility, Personnel, and Alternative Sanctions

##### 1. Laboratory Costs To Update Policies and Procedures

If this rule is finalized, we expect that the 34,082 CoC and CoA laboratories would incur costs for the time needed to review the revised personnel regulations and update their policies and procedures to be in compliance. The total one-time burden per laboratory to review and update affected policies and procedures is 5 to 7 hours. A management level employee (11–9111) would perform this task at an hourly wage of \$557.61 per hour as published by the 2021 Bureau of Labor Statistics.<sup>16</sup> The wage rate would be \$115.22 to include overhead and fringe benefits. The total cost would range from \$19,634,640 to \$27,488,496 (34,082 laboratories × 5- or 7-hours × \$115.22).

Similarly, we expect that the 31,982 PPM laboratories would incur costs for the time needed to review and update the one change clarifying the requirement for CAs in PPM laboratories. We assume a one-time burden of 0.25 to 0.5 hours per laboratory for this task (31,982 × 0.25 or 0.5 hours). A management level employee (11–9111) would perform this task at an hourly wage of \$57.61 per hour as published by the 2021 Bureau of Labor Statistics.<sup>17</sup> The wage rate would be \$115.22 to include overhead and fringe benefits. The total cost would range from \$921 to \$1,842,483 (31,982 laboratories × 0.25- or 0.5-hours × \$115.22).

If finalized, the changes to the histocompatibility requirements would affect approximately 218 laboratories that perform testing in this specialty.

The laboratories may need to make additional changes to their policies and procedures for the histocompatibility updates. We assume a one-time cost of 1 to 2 hours per laboratory for this task (218 × 1 or 2). A management level employee (11–9111) would perform this task at an hourly wage of \$57.61 per hour as published by the 2021 Bureau of Labor Statistics.<sup>18</sup> The wage rate would be \$115.22 to include overhead and fringe benefits. The total cost would range from \$25,118 to \$50,236 (218 laboratories × 1- or 2-hours × \$115.22).

##### 2. Accreditation Organization and Exempt State Costs To Update Policies and Procedures

If the proposed changes are finalized, seven approved accrediting organizations and two exempt states would have to review their policies and procedures, provide updates and submit the changes to CMS for approval (9 organizations/exempt states × 10 or 15 hours). We assume a one-time cost of 10 to 15 hours to identify the applicable legal obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. A management level employee (11–9111) would perform this task at an hourly wage of \$57.61 per hour as published by the 2021 Bureau of Labor Statistics.<sup>19</sup> The wage rate would be \$115.22 to include overhead and fringe benefits. The total cost would range from \$10,370 to \$17,283 (9 × 10- or 15 hours × \$115.22).

Table 9 reflects the total burden and associated costs for the provisions included in this proposed rule.

**TABLE 9: Summary of All Costs for Collection of Information in this Proposed Rule**

| Information Collection Requests*   | Burden Hours Increase/Decrease (+/-)* | Cost (+/-)*        |
|--|---------------------------------------|--------------------|
| A. Laboratory Costs to Update Policies and Procedures                                  |                                       |                    |
| CoC/CoA  | +7                                    | \$27,488,496       |
| PPM  | +0.5                                  | \$728,185          |
| Histocompatibility   | +2                                    | \$50,236           |
| B. Accreditation Organization and Exempt State Costs to Update Policies and Procedures | +15                                   | \$17,283           |
| <b>TOTAL</b>   | <b>+24.5</b>                          | <b>+28,284,200</b> |

\*All costs reflected in this table are one-time only costs. There are no ongoing costs.

<sup>16</sup> <https://www.bls.gov/oes/tables.htm>.

<sup>17</sup> <https://www.bls.gov/oes/tables.htm>.

<sup>18</sup> <https://www.bls.gov/oes/tables.htm>.

<sup>19</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm).

## V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents; we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## VI. Regulatory Impact Analysis

### A. Statement of Need

#### 1. CLIA Fees

As discussed in section I. of this proposed rule, when CLIA was enacted and its implementing regulations were finalized in 1992, CLIA fees were established based on estimates as to the average time a survey would take, cost of the surveyor salary per hour, as well as the size of the laboratory (schedules A, B, etc.). As discussed in section II. of this proposed rule, we are proposing to increase certain CLIA fees, add new CLIA fees, and institute a biennial fee increase based on our analysis of the overall level of collections relative to the costs of maintaining the CLIA program, which project a shortfall beginning in calendar year 2023.

#### 2. Histocompatibility, Personnel, Alternative Sanctions

This rule also proposes to update the CLIA regulations concerning histocompatibility (§ 493.1278), personnel (§§ 493.1351 through 493.1495), and alternative sanctions for laboratories operating under a CoW (§ 493.1804). With few exceptions, no changes have been made to the requirements listed above since the CLIA regulations were finalized in the 1992 final rule with comment period (57 FR 7002). Many changes have occurred in the practice of laboratory medicine since that time, and other parts of the regulations have since been updated to eliminate redundancies and streamline requirements. HHS assessed the need to update the sections addressed in this proposed rule and solicited public input via the 2018 RFI (83 FR 1004) and advice from the CLIAC ([www.cdc.gov/cliac/past-meetings.html](http://www.cdc.gov/cliac/past-meetings.html)) before making decisions about the changes to propose.

Because the specialty of histocompatibility is an evolving area of the clinical laboratory, several changes were made to update and clarify the histocompatibility requirements finalized in the 2003 final rule (68 FR 3640). Since then, there have continued to be advancements in

histocompatibility testing. As a result, some requirements have become obsolete and may preclude using current, improved methods and practices. As already mentioned, there have been updates to other parts of the CLIA regulations to eliminate redundancy with general quality system requirements. However, changes to eliminate redundancy have not previously been made in the histocompatibility specialty, which we believe would simplify and streamline the regulations. Thus, we propose eliminating redundant histocompatibility specialty regulations in this proposed rule.

Provisions to end a phase-in period, previously included in subpart M, that allowed individuals with an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science to meet the qualification requirements for LD of high complexity testing prior to obtaining board certification, were finalized in the 2003 final rule (68 FR 3640). This rule also revised and expanded the qualifications required for such individuals to direct a laboratory performing high complexity testing. No other changes have been made to clarify or update subpart M since 1992, even though the top 10 laboratory deficiencies have historically continued to include qualification requirements and responsibilities for moderate and high complexity LD. These high numbers of deficiencies may be due, in part, to the redundancy throughout subpart M or to requirements that are unclear, both of which may be an ongoing source of confusion for laboratories and individuals seeking to determine their qualification status. The number of deficiencies may also be due to laboratories whose directors are on-site infrequently or not at all.

The CLIA requirements at § 493.1804 describe general considerations for the imposition of sanctions under the CLIA program. This includes principal or alternative sanctions as described in § 493.1804(c). This section specifies that alternative sanctions are not imposed on laboratories issued a CoW, but discretion is permitted in applying principal or alternative sanctions to laboratories issued other certificate types. Since the CLIA statute at 42 U.S.C. 263a(h) does not make this distinction concerning alternative sanctions, we found that § 493.1804(c) can be updated to reflect CMS' belief that alternative sanctions instead of principal sanctions should be an option to create parity for all certificate types. In some cases, we believe the imposition of principal sanctions on CoW laboratories is not appropriate and

could create an undue burden on these laboratories that do not currently have the option of receiving alternative sanctions, if appropriate, as laboratories with other certificate types.

In summary, we based our decision to update our regulations at § 493.1278 related to histocompatibility on changes in practice, advice from the CLIAC, and responses to the 2018 RFI. We based our decision to update the personnel requirements in subpart M, §§ 493.1351 through 493.1495, and propose changes in this rule to delete obsolete and redundant regulations and to clarify this subpart specifying personnel qualifications and responsibilities on advice from CLIAC, common questions we have received, and responses to the 2018 RFI. We based our decision to update our regulation at § 493.1804(c) to allow for alternative sanctions to be imposed on CoW laboratories on responses received to the 2018 RFI.

### B. Overall Impact

We have examined the potential impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) (having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”)); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the

rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory actions and/or economically significant effects (\$100 million or more in any one year). The regulation is not economically significant within the meaning of section 3(f)(1) of the Executive order since neither the low estimate: \$28,145,841 nor the high estimate: \$57,528,591 exceeds the \$100 million annual threshold.

This proposed rule increases certain CLIA Fee requirements and will affect approximately 265,335 clinical laboratories, resulting in some budget implications. However, since laboratories, accrediting organizations, and exempt states will need to make changes to comply with the Federal regulatory changes, we have provided an assessment of the impact of estimated costs of these changes in Table 14.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of clinical laboratories and AOs are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year). For purposes of the RFA, approximately 82 percent of clinical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 2021 (<https://www.aha.org/>

[statistics/fast-facts-us-hospitals](#)), and 100 percent of the AOs are nonprofit organizations. Individuals and states are not included in the definition of a small entity. While a significant number of clinical laboratories and accrediting agencies are affected by this rule, the impact is not economically significant. It is anticipated that the benefits obtained by ensuring quality laboratory testing will outweigh the costs. See Table 10. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. We are voluntarily preparing a Regulatory Impact Analysis, including both a qualitative and quantitative analysis, and are requesting public comments on the impacts to assist us in making this determination in the final rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital located outside a metropolitan statistical area with fewer than 100 beds. There are approximately 905 small rural hospitals in the U.S. Such hospitals often provide limited laboratory services or may refer all their testing to larger facilities. We are unable to estimate the number of laboratories that support small rural hospitals and do not expect that the rule will have a significant impact on small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess

anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold was approximately \$158 million. We do not anticipate this proposed rule would impose an unfunded mandate on states, tribal governments, and the private sector of more than \$158 million annually. We request comments from states, tribal governments, and the private sector on this assumption.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Two states have exempt status, which means we have determined that the state has enacted laws relating to the laboratory requirements that are equal to or more stringent than CLIA requirements, and the state licensure program has been approved by us. If this rule is finalized, the two states, New York and Washington, would need to update their policies and procedures to maintain their exempt status but would otherwise not incur additional costs. Therefore, this proposed rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication, and there is no change in the distribution of power and responsibilities among the various levels of government.

C. Anticipated Effects

Tables 10 and 11 reflect the estimated impact for the provisions included in this proposed rule.

TABLE 10: Summary of Estimated Impact for Proposed Regulations

| Proposed Change   | Low estimate | High estimate |
|---|--------------|---------------|
| Laboratories updating policies and procedures related to personnel and histocompatibility   | \$20,524,180 | \$29,279,200  |
| Accrediting organizations and exempt states updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit | \$10,370     | 17,283        |
| Travel for site visits-Driving  | \$150,800    | \$678,745     |
| Travel for site visits-Flying   | \$478,400    | \$956,800     |
| Total Increased cost  | \$21,163,750 | \$31,034,043  |

**TABLE 11: Summary of Estimated Impact for Proposed Fee Regulations**

| Proposed Change             | Low estimate       | High estimate       |
|-----------------------------|--------------------|---------------------|
| CLIA Fee Regulations        | \$9,144,894        | \$29,661,467        |
| <b>Total Increased cost</b> | <b>\$9,144,894</b> | <b>\$29,661,467</b> |

## 1. Fees

This proposed rule impacts approximately 265,335 CLIA certified laboratories. Certificate of Waiver (CoW) = 201,767; Certificate of Provider Performed Microscopy (PPM) = 29,988; Certificate of Registration (CoR) = 2,826; Certificate of Compliance (CoC) = 17,799; Certificate of Accreditation (CoA) = 15,781. (Data from Quality, Certification and Oversight Reports (QCOR) as of September 27, 2020)

## a. Two-Part Biennial Survey Fees

## (1) CoC Laboratories Compliance Survey Fees

Table 12 reflects the national average of compliance fees for each classification of laboratories (schedules) that requires inspection. Specifically, Table 12 represents the national average for each schedule for the current Compliance Survey Fees (noted with a “c”) as paid biennially by laboratories

that hold a CoC and the national average for each schedule for the new Compliance Survey Fees (noted with a “n”) that will be paid after the first biennial two-part fee increase (estimating a 5 percent increase as a low estimate and a 20 percent increase as a high estimate) by laboratories that hold a CoC. As discussed in section II. of this proposed rule, Table 12 shows estimated increases for CoC laboratories subject to the biennial fee increase.

**TABLE 12: Two-part fee for CoC Survey Fees \***

| Laboratory classification (schedules) | Current average (c) | New average (n)<br>Low increase = 5% | New average (n)<br>High increase = 20% | Number of Laboratories per schedule* | Number of Laboratories per schedule divided by 2** |
|---------------------------------------|---------------------|--------------------------------------|--|--------------------------------------|--|
| V                                     | \$360               | \$378                                | \$432                                  | 6,462                                | 3231   |
| A                                     | \$1,192             | \$1,251.60                           | \$1,430                                | 4,054                                | 2027   |
| B                                     | \$1,591             | \$1,670.55                           | \$1,909                                | 147                                  | 73.5   |
| C                                     | \$1,988             | \$2,087.40                           | \$2,386                                | 2,032                                | 1,016  |
| D                                     | \$2,336             | \$2,452.80                           | \$2,803                                | 176                                  | 88   |
| E                                     | \$2,684             | \$2,818.20                           | \$3,221                                | 1,427                                | 713.5  |
| F                                     | \$3,032             | \$3,183.60                           | \$3,638                                | 815                                  | 407.5  |
| G                                     | \$3,380             | \$3,549                              | \$4,056                                | 517                                  | 258.5  |
| H                                     | \$3,728             | \$3,914.40                           | \$4,474                                | 1,733                                | 866.5  |
| I                                     | \$4,076             | \$4,279.80                           | \$4,891                                | 195                                  | 97.5   |
| J                                     | \$4,408             | \$4,628.40                           | \$5,290                                | 189                                  | 94.5   |

\*Number of CoC labs by laboratory classification (schedules) (Data from Certification and Survey Provider Enhanced Reporting (CASPER) 0086S CLIA Laboratories Schedule Counts) Includes CoR labs of application type CoC.

\*\*The fees are biennial; therefore, approximately half the CoC laboratories are affected annually.

## (2) CoA Laboratories Validation Survey Fees

Table 13 shows the national average of the Validation Survey Fee for each schedule of accredited laboratory. Specifically, Table 13 represents the national average fees for each schedule

for the current Validation Survey Fee (noted with a “c”) as paid biennially by laboratories that hold a CoA and the national average for the new Validation Survey Fee (noted with an “n”) that will be paid the first biennial two-part fee increase (estimating a 5 percent increase as a low estimate and a 20 percent

increase as a high estimate) by laboratories that hold a CoA. As discussed in section II. of this proposed rule, Table 13 shows estimated increases for CoA laboratories subject to the biennial fee increase.

**TABLE 13: Two-part fee for Certificate of Accreditation (CoA) Validation Survey Fees\***

| Laboratory classification (schedules) | Current average (c) | New average (n) 5% | New average (n) 20% | Number of laboratories per schedule* | Number of Laboratories per schedule divided by 2** |
|---------------------------------------|---------------------|--------------------|---------------------|--------------------------------------|--|
| V                                     | \$18                | \$18.9             | 21.6                | 2,108                                | 1054   |
| A                                     | \$60                | \$63               | 72                  | 2,522                                | 1261   |
| B                                     | \$80                | \$84               | 96                  | 135                                  | 67.5   |
| C                                     | \$99                | \$103.95           | 118.8               | 1,739                                | 869.5  |
| D                                     | \$117               | \$122.85           | 140.4               | 189                                  | 94.5   |
| E                                     | \$134               | \$140.7            | 160.8               | 1,524                                | 762  |
| F                                     | \$152               | \$159.6            | 182.4               | 900                                  | 450  |
| G                                     | \$169               | \$177.45           | 202.8               | 612                                  | 306  |
| H                                     | \$186               | \$195.3            | 223.2               | 3,043                                | 1521.5   |
| I                                     | \$204               | \$214.2            | 244.8               | 1,098                                | 549  |
| J                                     | \$220               | \$231              | 264                 | 1,914                                | 957  |

\*Number of CoA labs by laboratory classification (schedules) (Data from CASPER 0086S CLIA Laboratories Schedule

Counts) Includes CoR labs of application type CoA.

\*\*The fees are biennial; therefore, approximately half the CoA laboratories are affected annually.

(3) Certificate of Waiver (CoW) Waived Test Categorization Certificate Fee

Table 14 shows the additional fee to be added to Certificates of Waiver (CoW) to offset program obligations to FDA for its role in the categorization of tests and

test systems as waived. Specifically, Table 14 represents the certificate fee (noted with a “c”) as paid biennially by laboratories that hold a CoW and the new certificate Fee (noted with an “n”) that will be paid by laboratories that hold a CoW using the current number of

CoW labs for the low estimate and the current number plus 10,000 new CoW for the high estimate. As discussed in section II. of this proposed rule, Table 14 reflects a total increase of \$25 as each laboratory’s part of the Waived test categorization fee.

**TABLE 14: Certificate of Waiver (CoW) Waived Test Categorization Fee\***

| Type of CLIA certificate    | Current Fee (c) | New Fee (n) based on current number of CoW labs |
|-----------------------------|-----------------|---|
| Certificate of Waiver (CoW) | \$180           | \$205   |

\*Total CoW labs as of 9-27-2020 = 201,767 / 2 = 100,883.50 (data from QCOR) for the low estimate. Addition of 10,000 new CoW labs 211,767/2 = 105,883.50 for the high estimate. The fees are biennial; therefore, approximately half the CoW laboratories are affected annually.

(4) Two-Part Biennial Certificate Fees

Table 15 shows the national average of the certificate fee for each schedule for the CoC and CoA laboratories and shows the CoW, PPM, and CoR certificate fees. Specifically, Table 15 represents the national average fees for each schedule for the CoC and CoA

Certificate Fee and the CoW, PPM, and CoR (noted with a “c”) as paid biennially by laboratories that hold a CoC, CoA, CoW, PPM, or CoR and the national average fees for each schedule for the new CoC and CoA Certificate Fee and the CoW, PPM, and CoR (noted with an “n”) that will be paid after the first biennial two-part fee increase

(using 5 percent to arrive at a low estimate and 20 percent to arrive at a high estimate) by laboratories that hold a CoC, CoA, CoW, PPM, or CoR. As discussed in section II. of this proposed rule, Table 15 reflects estimated increases for all laboratory types subject to the biennial fee increase.

**TABLE 15: Two-part Biennial Certificate Fee**

| Type of CLIA Certificate   | Laboratory schedule | Current fee (c) | New fee (n) using 5% for the low estimate | New fee (n) using 20% for the high estimate | Number of laboratories* |            | Number of Laboratories divided by 2** |            |
|--|---------------------|-----------------|---|---|-------------------------|------------|---------------------------------------|------------|
| Certificate of Waiver (CoW)  | Not applicable      | \$205.00        | \$215.25                                  | 246.00                                      | 201,767                 |            | 100,883.5                             |            |
| Certificate of Provider Performed Microscopy (PPM)                     | Not applicable      | \$240.00        | \$252.00                                  | 288.00                                      | 29,988                  |            | 14,994                                |            |
|  |                     |                 |   |   | <b>CoC</b>              | <b>CoA</b> | <b>CoC</b>                            | <b>CoA</b> |
| Certificate of Compliance (CoC) and Certificate of Accreditation (CoA) | V                   | \$180.00        | \$189.00                                  | 216.00                                      | 6,462                   | 2,108      | 3231                                  | 1054       |
| CoC and CoA  | A                   | 180.00          | 189.00                                    | 216.00                                      | 4,054                   | 2,522      | 2027                                  | 1261       |
| CoC and CoA  | B                   | 180.00          | 189.00                                    | 216.00                                      | 147                     | 135        | 73.5                                  | 67.5       |
| CoC and CoA  | C                   | 516.00          | 541.80                                    | 619.20                                      | 2,032                   | 1,739      | 1,016                                 | 869.5      |
| CoC and CoA  | D                   | 528.00          | 554.40                                    | 633.60                                      | 176                     | 189        | 88                                    | 94.5       |
| CoC and CoA  | E                   | 780.00          | 819.00                                    | 936.00                                      | 1,427                   | 1,524      | 713.5                                 | 762        |
| CoC and CoA  | F                   | 1,320.00        | 1,386.00                                  | 1,584.00                                    | 815                     | 900        | 407.5                                 | 450        |
| CoC and CoA  | G                   | 1,860.00        | 1,953.00                                  | 2,232.00                                    | 517                     | 612        | 258.5                                 | 306        |
| CoC and CoA  | H                   | 2,448.00        | 2,570.40                                  | 2,937.60                                    | 1,733                   | 3,043      | 866.5                                 | 1521.5     |
| CoC and CoA  | I                   | 7,464.00        | 7,837.20                                  | 8,956.80                                    | 195                     | 1,098      | 97.5                                  | 549        |
| CoC and CoA  | J                   | 9,528.00        | 10,004.40                                 | 11,433.60                                   | 189                     | 1,914      | 94.5                                  | 957        |
| Certificate of Registration (CoR)                                      | Not applicable      | \$100           | \$105                                     | 120.00                                      | 2,826                   |            | 1,413                                 |            |

\*Number of laboratories from QCOR and CASPER 0086S CLIA Laboratories Schedule Counts.

\*\*The fees are biennial; therefore, approximately half the CoA laboratories are affected annually.

**b. Proposed New Replacement and Revised Fees**

Table 16 shows the cost of the replacement and revised certificate fees

for each certificate type. These fees have not been charged prior to this proposed rule. A low estimate used the current number of laboratories and a high

estimate used the number of labs plus half again that amount.

**TABLE 16: CLIA Replacement and Revised Certificates FY2019\***

| Certificate type | Number of Replacement Certificates issued in FY2019 | Cost of Replacement Certificate | Number of Revised Certificates issued in FY2019 | Cost of Revised Certificate |
|------------------|---|---------------------------------|---|-----------------------------|
| CoC              | 259   | \$75                            | 515   | \$150                       |
| CoW              | 2,824   | \$75                            | 6,985   | \$95                        |
| CoA              | 496   | \$75                            | 505   | \$150                       |
| PPM              | 525   | \$75                            | 984   | \$95                        |
| Total:           | 4104  | \$75                            | 8989  | \$150                       |

\* Number of Replacement and Revised Certificates FY2019 (Data from CASPER 0104D CLIA 116 Activity report).

**c. New Additional Fees**

Table 17 shows the cost of the additional fees added by this proposed

rule. These fees are only paid by laboratories with substantiated complaint surveys, unsuccessful performance of PT, or follow-up surveys

for the determination of correction of deficiencies found on an original survey.



TABLE 17: New Additional Fees

| Proposed Fees                         | Affected CLIA Certificate type(s)   | Total Number of Affected Laboratories * | Hourly Cost           | Occupation                    | Hours |        | Range of Cost Estimate for Proposed new fees per incident |               |
|---------------------------------------|---|---|-----------------------|-------------------------------|-------|--------|---|---------------|
|                                       |   |   |                       |                               | Low   | High   | Low Estimate  | High Estimate |
| Substantiated Complaints              | All Laboratory types  | 56                                      | \$150.22 <sub>1</sub> | 13-1041<br>43-1011<br>43-9199 | 5.00  | 184.75 | \$751.10  | \$27,753.15   |
| Unsuccessful Proficiency Testing (PT) | Certificate of Compliance (CoC) laboratories                                      | 1,308                                   | \$150.22              | 13-1041<br>43-1011<br>43-9199 | 1.25  | 32.25  | \$187.78  | \$4,844.60    |
| Follow-up Surveys <sup>2</sup>        | Certificate of Compliance (CoC) & Certificate of Accreditation (CoA) laboratories | 225                                     | \$150.22              | 13-1041<br>43-1011<br>43-9199 | 8.65  | 19.08  | \$1,299.40  | \$2,866.20    |
| Total Estimated Cost                  |   |   |                       |                               |       |        | \$2,238.30  | \$35,463.95   |

\*Total number of affected laboratories is based on actual numbers from FY2019; Data from CASPER reporting system.

<sup>1</sup>\$75.11 hourly rate includes \$27.79 (13-1041: Compliance Officer) + \$28.91 (43-1011: First-Line Supervisors of Office and Administrative Support Workers) + \$18.41 (43-9199: Office and Administrative Support Workers, All Other). The wage rate would be doubled to \$150.22 to include overhead and fringe benefits. Data from the Department of Labor.

<sup>2</sup>Includes Follow-up surveys on CoC and CoA laboratories and for Addition of Specialties.

#### d. Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

This proposed rule, if finalized, could impact all of the 271,399 CLIA-certified laboratories (accessed from the CMS Quality Improvement Evaluation System (QIES) database October 4, 2019) to some extent. The changes to the personnel requirements would impact 34,082 CoC and CoA laboratories, as well as 31,982 PPM Certificate laboratories. The histocompatibility changes would impact 218 CoC and CoA laboratories certified for this specialty; and the allowance for alternative sanctions could impact 201,767 CoW laboratories only if they are found to be out of compliance with CLIA and subject to sanctions. The proposed rule, if finalized, would also impact the seven CLIA-approved AOs and two exempt states. Although complete data are not available to calculate all estimated costs and benefits that would result from the changes proposed in this rule, we are providing an analysis of the potential impact based on available information and certain assumptions. Implementation of these proposed requirements in a final rule would result in changes that are anticipated to have both quantifiable and non-quantifiable

impacts on laboratories, AOs, and exempt states, as specified above. In estimating the quantifiable impacts, we include costs to CoC, CoA, and PPM laboratories that could result from the need to update policies and procedures. We also estimate costs for travel expenses that laboratories may incur to meet the proposed requirement to have an LD on-site at least once every 6 months. For quantifiable impacts on AOs and exempt states, we estimate the costs for updating their policies and procedures to reflect the new requirements, if finalized, for personnel and histocompatibility.

#### 2. Quantifiable Impacts

##### a. Laboratory Costs To Update Policies and Procedures

If this rule is finalized, we expect that the 33,580 CoC and CoA laboratories would incur costs for the time needed to review the revised personnel regulations and update their policies and procedures to be in compliance with them. We assume a one-time burden of 5 to 7 hours per laboratory to review and update affected policies and procedures, and we assume the person performing this task would be a management level employee paid \$115.22 per hour (wages, salary and benefits; [www.bls.gov/news.release/](http://www.bls.gov/news.release/)

[ecec.t02.htm](http://ecec.t02.htm)). Therefore, we estimate the one-time costs for CoC and CoA laboratories to update policies and procedures to comply with the revised personnel requirements would range from \$19,634,640 to \$27,488,496 (see Table 18).

Similarly, we expect that the 29,998 PPM laboratories would incur costs for the time needed to review and update the one change clarifying the requirement for CAs in PPM laboratories. We assume a one-time burden of 0.25 to 0.5 hours per laboratory for this task, also to be performed by a management level employee paid \$115.22 per hour (wages, salary and benefits). Therefore, we estimate the one-time costs for PPM laboratories to update the single revised policy and procedure to comply with the personnel requirements would range from \$864,092 to \$1,728,185 (see Table 18).

If finalized, the changes to the histocompatibility requirements would affect approximately 218 laboratories that perform testing in this specialty (QIES database October 4, 2019). While these laboratories are included in the calculations above, they may need to make additional changes to their policies and procedures for the histocompatibility updates, if the proposed rule is finalized. We assume a

one-time burden of one to two hours per laboratory for this task, as described above. Therefore, the laboratory costs for updating policies and procedures related to histocompatibility would range from \$25,118 to \$50,236 (see Table 18).

**b. Accreditation Organization and Exempt State Costs To Update Policies and Procedures**

If the proposed changes are finalized, seven approved accrediting organizations and two exempt states would have to review their policies and procedures, provide updates and submit the changes to us for approval. We estimate a one-time burden of 10 to 15 hours to identify the applicable legal

obligations and to develop the policies and procedures needed to reflect the new requirements for personnel and histocompatibility. We assume the person performing this review will be a management level employee paid \$115.22 per hour (wages, salary and benefits). Therefore, we estimate the costs for accrediting organizations and exempt states to update their policies and procedures would range from \$10,370 to \$17,283 (see Table 18).

**TABLE 18: Estimated Costs to Update Policies and Procedures**

| Proposed Regulation Change    | Affected Group                              | Total Number of Affected Groups | Hourly Cost | Hours |      | Range of Cost Estimate for Personnel and Histocompatibility Proposed Changes |               |
|-------------------------------|---|---------------------------------|-------------|-------|------|--|---------------|
|                               |   |                                 |             | Low   | High | Low Estimate   | High Estimate |
| Personnel                     | CoC & CoA Laboratories                      | 33,580                          | \$115.22    | 5     | 7    | \$19,634,640   | \$27,488,496  |
|                               | PPM Laboratories                            | 29,988                          | \$115.22    | 0.25  | 0.50 | \$864,092  | \$1,728,185   |
| Histocompatibility            | CoC & CoA Laboratories                      | 218                             | \$115.22    | 1     | 2    | \$25,118   | \$50,236      |
| Personnel, Histocompatibility | Accrediting Organizations and Exempt States | 9                               | \$115.22    | 10    | 15   | \$10,370   | \$17,283      |
| <b>Total Increased Cost</b>   |   |                                 |             |       |      | \$20,534,220   | \$29,284,500  |

**c. Laboratory Costs for On-Site Laboratory Director Requirement**

Estimating the potential travel costs for LD to meet the on-site requirement is complex, due to wide variation in the numbers of individuals who might incur travel costs, variation in the distances traveled and modes of transportation used, and variation among already existing state and accreditation requirements for LD to be on-site at some frequency. In addition, we had limited available data on which to base our assumptions. Therefore, we used an approach in calculating our estimates such that the estimates described below may be higher than actual costs that would be incurred if the proposed change is finalized. We are requesting public comments and data to assist us in estimating this impact in the final rule.

In general, 11 states, one territory, and three out of seven AOs currently have some requirement for on-site visits by LD, although the required frequencies vary. Ten states, including the exempt state of New York, (Supplemental Table) plus the territory of Puerto Rico currently have requirements that are as stringent or more stringent than the

proposed provision that requires a LD to be on-site at least once every 6 months. Therefore, we have not counted CoC laboratories in these 10 states or in Puerto Rico among those that would be impacted if the proposed requirement for on-site LD visits was finalized. One accrediting organization (AABB) now requires on-site LD visits at least once a quarter. However, AABB only accredits 265 laboratories, or approximately 1.6 percent, of all accredited laboratories (QIES database, October 4, 2019). Some of these laboratories are part of a hospital or other health care system that has laboratory specialties accredited for CLIA purposes by one or more of the other accrediting organizations, and therefore, would be impacted by the proposed requirement for on-site LD visits. Since we do not have data to determine the number of such laboratories that are only accredited by AABB and already be meeting this proposed requirement, and the number is likely to be relatively small, we are not adjusting the number of impacted laboratories based on AABB accreditation.

In the 40 states, four territories, and the District of Columbia, where the LD is not required to be on-site at least twice per year, 26,007 CoC and CoA laboratories (QIES, October 4, 2019) may not meet this new requirement, if finalized, and may incur travel costs. We have not adjusted this number where the proposed provision was partially met, since no frequency was specified for CoC laboratories in three additional states, CoA laboratories under two additional accrediting organizations, or laboratories in the exempt State of Washington.

We assume that in most instances, the LD is on-site daily or otherwise more frequently than twice per year. Based on a review of state and AO information, discussed earlier in the preamble for this proposed rule, we assume that between 5 percent (1300) and 20 percent (5201) of the CoC and CoA laboratories would need their LD to travel to the laboratory twice a year to meet this requirement. For our estimate, we assumed this travel would include a combination of two modes of transportation, driving, and flying. For the low estimate, we assumed that 1 percent of the 26,007 laboratories, or

260, would compensate their directors for flights while 4 percent, or 1,040 laboratories, would compensate them for their mileage to drive. For the high estimate, we assumed that, at most, 2 percent of the 26,007 laboratories, or 520, would compensate their LD for flying, and the other 18 percent, or 4,681 laboratories, would compensate for driving.

- **Driving:** We believe most LD would drive fewer than 250 miles round trip to reach the laboratories they direct. We assume these LD would drive to the location, conduct business, and return home the same day. We base our calculations for driving on the maximum estimated distance of 250 miles at \$0.58 cents per mile (Government travel reimbursement rates for mileage (<https://www.gsa.gov/travel-resources>)) for a maximum cost of \$145.00 per trip. This may be an overestimate since we believe not all the

individuals who drive would travel 250 miles round trip. Based on the low estimate of 1,040 laboratories incurring costs for driving and our high estimate of 4,681 laboratories incurring costs for driving, our calculated cost for driving is estimated to range from \$150,800 to \$678,745 (see Table 19).

- **Flying:** Our estimates for the cost of flying assume that travel to a remote site would be necessary in these cases. We believe basing it on travel to a remote site will over-estimate the cost since in many locations, although the LD may fly to reach their destination, they would not travel to remote locations, and the travel costs would be less. However, we do not know the specific circumstances for which flying would be required. We estimated the maximum airfare for this travel to be \$1500 and lodging costs to average \$170.00 per night (based on the average of 100 hotel rates throughout the U.S. in 2019 ([https://](https://www.businesstravelnews.com/uploadedFiles/9_Microsites/Corporate_Travel_Index/Corporate_Travel_Index_2019/US_Diem/4-5_USHotelDetail.pdf)

[www.businesstravelnews.com/uploadedFiles/9\\_Microsites/Corporate\\_Travel\\_Index/Corporate\\_Travel\\_Index\\_2019/US\\_Diem/4-5\\_USHotelDetail.pdf](https://www.businesstravelnews.com/uploadedFiles/9_Microsites/Corporate_Travel_Index/Corporate_Travel_Index_2019/US_Diem/4-5_USHotelDetail.pdf))). We assumed lodging for two nights would be needed. Therefore, the estimated cost for one trip would be \$1500 flight + \$340.00 lodging or \$1840.00 per trip. Based on the low estimate of 260 laboratories incurring costs for remote travel and our high estimate of 520 laboratories incurring costs for remote travel, the range for laboratory costs for flying to on-site visits would be between \$478,400 and \$956,800 (see Table 19).

Based on these assumptions for both driving and flying, if this proposed rule is finalized, we estimate the total cost for laboratories to compensate for LD travel would range from \$629,200 to \$1,635,545.

**TABLE 19: Estimated Travel Costs to Meet On-site Laboratory Director Requirement**

| Proposed Regulation Change  | Affected Group           | Total Number of Affected Group |               | Airfare Cost (\$1,500) | Hotel Cost (\$170/2 nights) | Driving Cost (\$0.58/mile*250 miles) | Total Low Impact for Personnel and Histocompatibility Regulation Changes |               |
|-----------------------------|--------------------------|--------------------------------|---------------|------------------------|-----------------------------|--------------------------------------|--|---------------|
|                             |                          | Low Estimate                   | High Estimate |                        |                             |                                      | Low estimate   | High estimate |
| On-Site Laboratory Director | CoA and CoC Laboratories |                                |               |                        |                             |                                      |  |               |
|                             | Driving                  | 1,040(4%)                      | 4,681(18%)    | NA                     | NA                          | \$145                                | \$150,800  | \$678,745     |
|                             | Flying                   | 260 (1%)                       | 520(2%)       | \$1,500                | \$340                       | N/A                                  | \$478,400  | \$956,800     |
| <b>Total Increased Cost</b> |                          |                                |               |                        |                             |                                      | \$629,200  | \$1,635,545   |

#### d. Results

We estimate that the overall impact of adding requirements for the proposed changes in personnel, histocompatibility, and travel for LD on-site visits will range from \$11,421,708 to \$16,983,208 in the first year (see Tables 18 and 19) if these proposed changes are finalized.

For each of the changes, Table 20 shows the projected range of cost

estimates annually for 5 years starting in 2020. We assume costs for updating policies and procedures will be one-time costs only incurred in 2021. We presume the travel costs will be ongoing and will not change significantly over the 5-year period. The maximum cost estimate of approximately \$16.1 million for the first year based on 2020 costs and approximately \$1.6 million for subsequent years is not considered a

significant economic impact. This proposed rule does not reach the economic threshold and thus is not considered a major rule. We request comments and additional data to assist us in making a more thorough and accurate prediction of impact of the final rule.

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**TABLE 20: Five-Year Projection for Total Estimated Annual Costs for Proposed Histocompatibility and Personnel Regulations**

| Proposed Change   | 2023                |                     | 2024             |                    | 2025             |                    | 2026             |                    | 2027             |                    |
|---|---------------------|---------------------|------------------|--------------------|------------------|--------------------|------------------|--------------------|------------------|--------------------|
|   | Low                 | High                | Low              | High               | Low              | High               | Low              | High               | Low              | High               |
| Laboratories updating policies and procedures related to personnel and histocompatibility   | \$10,787,073        | \$15,339,510        | \$0              | \$0                | \$0              | \$0                | \$0              | \$0                | \$0              | \$0                |
| Accrediting organizations and exempt states updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit | \$5,435             | \$8,153             | \$0              | \$0                | \$0              | \$0                | \$0              | \$0                | \$0              | \$0                |
| Travel-Driving  | \$150,800           | \$678,745           | \$150,800        | \$678,745          | \$150,800        | \$678,745          | \$150,800        | \$678,745          | \$150,800        | \$678,745          |
| Travel-Flying   | \$478,400           | \$956,800           | \$478,400        | \$956,800          | \$478,400        | \$956,800          | \$478,400        | \$956,800          | \$478,400        | \$956,800          |
| <b>Total Increased cost</b>   | <b>\$11,421,708</b> | <b>\$16,983,208</b> | <b>\$629,200</b> | <b>\$1,635,545</b> | <b>\$629,200</b> | <b>\$1,635,545</b> | <b>\$629,200</b> | <b>\$1,635,545</b> | <b>\$629,200</b> | <b>\$1,635,545</b> |

\* Low/high estimates represent the sum of estimates in Table 17 to update policies and Table 18 to estimate travel costs.

## BILLING CODE 4120-01-C

## e. Non-Quantifiable Impacts and Benefits

## (1) CLIA Fees

CMS has limited knowledge of the non-quantifiable impacts and benefits and is seeking public comment on this topic.

## (2) Histocompatibility, Personnel, Alternative Sanctions

If the changes proposed in this rule for histocompatibility, personnel, and alternative sanctions are finalized, several non-quantifiable impacts, most of which are considered benefits, will result for laboratories, accrediting organizations, and exempt states concerning changes in the requirements for personnel, histocompatibility, and alternative sanctions for CoW laboratories. We solicit comments and data to determine quantifiable estimates for these non-quantifiable impacts in the final rule.

Many personnel changes proposed in this rule would decrease the burden and provide greater flexibility for laboratories by increasing the number of eligible candidates for some personnel categories by expanding and clarifying the qualifying degrees. Examples of these proposed changes that would increase the number of qualified candidates for personnel categories include the addition of: clinical nurse specialists and certified registered nurse anesthetists in the definition of midlevel practitioners, a bachelor's degree in respiratory therapy as a possible qualifying degree as a TC and TP for moderate and high complexity blood gas testing, an associate or bachelor of nursing degree as a qualifying degree for moderate complexity TP, and a bachelor of nursing degree as a qualifying degree for high complexity TP. Adding these options as qualifying degrees does not preclude the need for individuals to meet clinical laboratory training and experience requirements. Another proposed personnel change that would decrease burden, increase flexibility for laboratories, and streamline regulations is aligning the technical supervisor qualifications for laboratories performing immunohematology with those of other specialties such as hematology. Instead of limiting those qualified to serve as a technical supervisor in immunohematology to individuals with a doctor of medicine or doctor of osteopathy degree and appropriate certification and experience, if this proposed rule is finalized, individuals may also qualify with a doctoral, master's, or bachelor's degree in a chemical, biological, or

clinical laboratory science or medical technology and 1, 2, or 4 years applicable experience, respectively. All of these proposed changes, if finalized, would streamline the regulations and could increase a laboratory's ability to find qualified personnel, especially in rural areas. As it is not possible to predict the pathway a laboratory would use to qualify individuals when hiring personnel, we cannot quantify the impacts that would result. However, we request comments and data to assist us in estimating these impacts in the final rule.

If the rule is finalized, several other changes being proposed in this rule will impact laboratories and their personnel. However, we do not have data to quantify the impact. One proposed change is the qualification requirement for 20 CE credit hours, as defined, to cover LD responsibilities as defined in the regulations prior to serving as an LD. This requirement would apply to LD for both moderate and high complexity testing except for those doctors of medicine, osteopathy, or podiatry who are certified by the American Board of Pathology, the American Osteopathic Board of Pathology, or other boards approved by HHS. Although there would be costs associated with obtaining these credits, currently employed LD, at the effective date of the final rule, will not be required to obtain the 20 CE credit hours to retain their employment status. In the future, we cannot predict the number of laboratories that would choose to hire a LD through the qualification route that would require the 20 CE credit hours. Another proposed change that could impact laboratories that cannot be quantified is the removal of physical science degrees as qualifying degrees for any personnel categories. As stated above, we cannot predict the number of laboratories that may have otherwise chosen to hire personnel with a physical science degree. Currently, employed laboratory personnel, at the effective date of the final rule, will not be disqualified. We request comments and data to assist us in more accurately estimating these impacts in the final rule.

The changes to the histocompatibility requirements proposed in this rule would impact laboratories, accrediting organizations, and exempt states if finalized. This proposed rule would streamline the histocompatibility requirements and remove those that are no longer relevant based on current testing practices, adding flexibility for laboratories and removing perceived barriers to current practices. It would remove specific requirements that are

redundant with those covered in general under §§ 493.1251, 493.1252, 493.1256, and 493.1445, simplifying the requirements related to procedure manuals; test systems, equipment, instruments, reagents, materials, and supplies; control procedures; and LD responsibilities. We believe these impacts would decrease the burden and positively affect laboratories certified to perform testing in this specialty, as well as health care providers and patients. We request comments and data to assist us in more accurately estimating the impact of these histocompatibility changes in the final rule.

Last, concerning the alternative sanctions provision being proposed in this rule, when finalized, the rule would allow us discretion in imposing alternative sanctions (that is, civil money penalties (CMP), directed plan of correction, directed portion of a plan of correction, and on-site state monitoring), rather than only being able to impose principal sanctions (that is, revocation, suspension, limitation of the CLIA certificate), in CoW laboratories, if appropriate. We believe this change would increase flexibility, decrease potential burden while moving those laboratories toward compliance, and have no added economic impact on CoW laboratories. As previously described, an example of when this proposed regulatory change could decrease the burden would be in the case of sanctions imposed for improper proficiency testing referral. Although we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past, if it occurred in the future, the ability to impose alternative sanctions, if appropriate, would be less punitive and potentially decrease any quantifiable economic impact. At this time, we cannot quantify what that impact would be.

*D. Alternatives Considered*

## 1. CLIA Fees

We considered multiple options prior to this proposed rule, including limiting across-the-board increase to varying percentages and timeframes required to achieve reasonable carryover targets for the CLIA program as a whole. We discussed multiple options in the notice with comment period (NC), including limiting the increase to varying percentages and timeframes across a single fee type, specifically Compliance Fees. When preparing the NPRM, we reviewed the alternatives in the NC to see if they were viable moving forward. The approach proposed here was the best scenario for longevity for

maintaining the fiscal solvency of the user-funded CLIA program. We have determined that 2 quarters worth of obligations were a reasonable carryover target based on program funding requirements and the time to accumulate and make available current year fee collections. We have also decided to build up to the carryover target over a 3-year period to avoid either overcharging or undercharging. For example, we considered the following options:

- Setting various one-time dollar level fee increases for Certificate of Waiver laboratories.
- Setting various percentage increases for the one-time across-the-board increase.

Public comments received from the 2018 notice with comment period (Medicare Program; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees)<sup>20</sup> were considered during rulemaking. We are also seeking public input on additional alternatives to consider.

## 2. Histocompatibility, Personnel, Alternative Sanctions

Several alternatives were considered in developing these proposed changes to the histocompatibility, personnel, and alternative sanctions requirements under CLIA. In all cases, one option would be to leave the regulations as written. However, because many of the changes being proposed for histocompatibility and personnel resulted from public input via the 2018 RFI and recommendations made by CLIAC and would add flexibility, remove redundant or obsolete requirements, clarify and streamline the regulations, and decrease burden while maintaining laboratory quality, we perceived that not making these changes would not be preferable. Also, the proposed change to allow alternative sanctions to be imposed on CoW laboratories aligns the regulations with the CLIA statute; therefore, no other options were considered.

Regarding the histocompatibility requirements, we initially considered only removing the crossmatch regulatory requirement at § 493.1278(f)(2) which was perceived as a barrier to current practice with kidney transplantation. However, we decided to obtain input from stakeholders to identify any concerns regarding crossmatching and other current regulatory requirement under the histocompatibility specialty. Our

purpose for seeking stakeholder input through CLIAC and the 2018 RFI was to obtain information on whether the current histocompatibility requirements, including requirements for crossmatching, needed to be revised from when CLIA was published in 1998 and 2003 to reflect the current practice. Our proposed revision reflects our attempt to address the inputs from the stakeholders and are intended to reflect the current practices as provided to CMS by the stakeholders through the 2018 RFI and CLIAC.

One of the personnel requirements being proposed is to require that LD of moderate and high complexity testing, who are qualified through an educational pathway other than being a certified anatomic or clinical pathologist, have at least 20 CE credit hours related to their LD responsibilities. We considered requiring this of all LD. However, since pathologists obtain this education as part of their education and training, it would be redundant and could increase costs to require this, although we do not have data to estimate what those costs would be since we do not know how many LD would qualify using this pathway. We believe it is appropriate to propose this requirement for other LD qualification routes. This information is critical for fulfilling LD responsibilities and is not always included in education and training for alternative qualification pathways.

Another LD requirement proposed in this rule is on-site visits to the laboratory at least once every 6 months, with at least a 4-month interval between on-site visits. We considered requiring these visits at a different frequency or not adding this requirement. However, surveyors reported that laboratories in which the director is not on-site tend to have more issues and citations when inspected, and ten states, the territory of Puerto Rico, and one of the CLIA-approved AOs already require LD to be on-site at least once every 6 months. As a result, CLIAC recommended that LD make and document at least two reasonably spaced on-site visits per year to supplement other interactions with staff and verify that the laboratory complies with laws and regulations. We agree with the CLIAC recommendation that two on-site visits per year is an appropriate frequency to achieve the intended improvement in laboratory compliance without adding a significant burden to laboratories. We will monitor this impact if the proposal is finalized. Requiring these visits at a greater frequency and keeping all other factors the same would increase total projected costs for each on-site visit added per

year. While requiring on-site visits only once per year would reduce estimated costs, it could delay the potential time it takes to identify laboratory issues that could ultimately result in patient harm. A third personnel requirement proposed in this rule for which we considered various options is the expansion of the definition of midlevel practitioners to include certified registered anesthetists, and clinical nurse specialists as personnel qualified to serve as a LD or TP in PPM laboratories. Currently, this definition is limited to nurse midwives, nurse practitioners, or physician assistants, licensed by the state where the individual practices, if required in the state where the laboratory is located. We considered not expanding this definition or expanding it to include only one of the proposed categories. However, certified registered anesthetists and clinical nurse specialists are both considered advanced practice registered nurses, as are certified nurse midwives and nurse practitioners. All four categories require at least a master's degree in nursing, and all may play a role in providing primary and preventive care services to the public. This may include performing the microscopic examinations required under PPM. As there is no expected cost-increasing impact of adding either of these nursing categories to the midlevel practitioner definition, and the change would increase flexibility and access to PPM testing, we are proposing it in this rule. We are requesting public comments related to alternative changes to be considered to assist us in finalizing this rule.

## E. Conclusion

### 1. CLIA Fees

Although the effect of the changes will increase laboratory costs, implementation of these changes would be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees.

### 2. Histocompatibility, Personnel, Alternative Sanctions

We estimate that the cost to laboratories, accrediting organizations, and exempt states to comply with the changes proposed in this rule would range between \$11,421,708 and \$16,983,208 in 2020 dollars for the first year and between \$629,200 and \$1,635,545 in subsequent years. Although the proposed changes will increase laboratory costs, implementation of these changes, if finalized, streamline and simplify

<sup>20</sup> 83 FR 67723, December 31, 2018 (<https://www.govinfo.gov/content/pkg/FR-2018-12-31/pdf/2018-28359.pdf>).

regulations, add flexibility in laboratory hiring practices, ensure that the LD is on-site at least twice per year, and align histocompatibility testing with current methods and practices. These changes will also allow alternative sanctions to be imposed on CoW laboratories.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 6, 2022.

Rochelle P. Walensky, MD, MPH, Director of the Centers for Disease Control and Prevention, approved this document on July 1, 2022.

#### List of Subjects in 42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

### PART 493—LABORATORY REQUIREMENTS

■ 1. The authority citation for part 493 continues to read as follows:

**Authority:** 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16).

■ 2. Amend § 493.2 by—

■ a. Adding the definitions of “Continuing education (CE) credit hours”, “Doctoral degree”, “Experience directing or supervising”, and “Laboratory training or experience” in alphabetical order;

■ b. Revising the definition of “Midlevel practitioner”; and

■ c. Adding the definitions of “Replacement certificate” and “Revised certificate” in alphabetical order.

The additions and revision read as follows:

#### § 493.2 Definitions.

\* \* \* \* \*

*Continuing education (CE) credit hours* means either continuing medical education (CME) or continuing education units (CEUs). The CE credit hours must cover the applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director.

\* \* \* \* \*

*Doctoral degree* means an earned post-baccalaureate degree with at least three years of graduate level study that

includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM) degrees, or honorary degrees.

\* \* \* \* \*

*Experience directing or supervising* means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

\* \* \* \* \*

*Laboratory training or experience* means that the training or experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

*Midlevel practitioner* means a nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

\* \* \* \* \*

*Replacement certificate* means an active CLIA certificate that is reissued with no changes made.

\* \* \* \* \*

*Revised certificate* means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of this part, revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

\* \* \* \* \*

#### § 493.557 [Amended]

■ 3. Amend § 493.557 in paragraph (b)(4) by removing the reference “§§ 493.645(a) and 493.646(b)” and adding in its place the reference “§§ 493.649(a) and 493.655(b)”.

#### § 493.575 [Amended]

■ 4. Amend § 493.575 in paragraph (i) by removing the reference “§§ 493.645(a) and 493.646(b)” and adding in its place the reference “§§ 493.649(a) and 493.655(b)”.

■ 5. Section 493.638 is revised to read as follows:

#### § 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee that covers the costs incurred for the issuance, renewal, change in

certificate type, or reinstatement of a terminated certificate with a gap in service, and other direct administrative costs, as applicable. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates, the fee is a flat fee that includes the costs for issuing the certificates, collecting the fees, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing allowed for the requested certificate.

(2) For a certificate of waiver, the fee includes the costs for issuing the certificate; collecting the fees; evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate; and determining whether a laboratory test meets the criteria for a waived test.

(3) For a certificate for PPM procedures, the fee includes the costs for issuing the certificate, collecting the fees; and evaluating whether the procedures, tests, or examinations listed on the application meet the criteria for inclusion in the subcategory of PPM procedures.

(4) For a certificate of accreditation, the fee includes the costs for issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and evaluating whether the procedures, tests, or examinations listed on the application fall within the testing appropriate for the requested certificate.

(5) For a certificate of compliance, the fee includes the costs for issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, and evaluating whether the procedures, tests or examinations listed on the application fall within the testing appropriate for the requested certificate.

(b) *Fee amount.* (1) The certificate fee amount is set biennially by HHS. CMS will publish a notice in the **Federal Register** biennially with any adjustments to the fee amounts, including any adjustments due to inflation, in accordance with § 493.680. For certificates of waiver and certificates of PPM, the certificate fee amount is based on the category of test complexity performed by the laboratory. For all other certificate types, the fee amount is based on the category of test complexity performed by the laboratory and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, or proficiency testing purposes) and specialties tested, with

the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in paragraph (c) of this section.

(2) Certificate fees are assessed and payable at least biennially.

(3) The amount of the fee payable by the laboratory is the amount listed in the most recent notice published in the **Federal Register** at the time the application, renewal, change in certificate type, or reinstatement is processed by HHS or its designee.

(4) After processing an application for an issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service, HHS or its designee notifies the laboratory of the applicable fee amount.

(c) *Classification of laboratories for purposes of determining the fee amount for certificate types other than certificates of waiver or certificates of PPM.* (1) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assessment, and proficiency testing are excluded from the laboratory's total annual volume.) Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(2) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

- (A) Bacteriology.
- (B) Mycobacteriology.
- (C) Mycology.
- (D) Parasitology.
- (E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

- (A) Syphilis Serology.
- (B) General immunology.

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

- (A) Routine chemistry.
- (B) Endocrinology.
- (C) Toxicology.
- (D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

- (A) ABO grouping and Rh typing.
- (B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

- (A) Cytology.
- (B) Histopathology.
- (C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Clinical Cytogenetics.

(3) There are 11 schedules of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the 11 schedules in paragraphs (c)(3)(i) through (xi) of this section based on the laboratory's scope and volume of testing:

(i) *Schedule V.* The laboratory performs not more than 2,000 laboratory tests annually.

(ii) *Schedule A.* The laboratory performs tests in no more than three specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(iii) *Schedule B.* The laboratory performs tests in at least four specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iv) *Schedule C.* The laboratory performs tests in no more than three specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule D.* The laboratory performs tests in at least four specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(vi) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vii) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(viii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(ix) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(x) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(xi) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

■ 6. Section 493.639 is revised to read as follows:

**§ 493.639 Fees for revised and replacement certificates.**

(a) If, after a laboratory is issued a certificate, it requests a revised

certificate, the laboratory must pay a fee to cover the cost of issuing a revised certificate. The fee for a revised certificate is based on the cost to issue the revised certificate to the laboratory. The fee must be paid in full before the revised certificate will be issued.

(1) If laboratory services are added to a certificate of compliance, the laboratory must pay an additional fee if required under § 493.643(d)(2).

(2) [Reserved]

(b) If, after a laboratory is issued a certificate, it requests a replacement certificate, the laboratory must pay a fee to cover the cost of issuing a replacement certificate. The fee for a replacement certificate is based on the cost of issuing the replacement certificate to the laboratory. The fee must be paid in full before issuing the replacement certificate.

■ 7. Section 493.643 is revised to read as follows:

**§ 493.643 Additional fees applicable to laboratories issued a certificate of compliance.**

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee.* Included in the fee for determining program compliance are costs for evaluating qualifications of laboratory personnel; monitoring laboratory proficiency testing; and conducting onsite inspections of laboratories including: documenting deficiencies, evaluating laboratories' plans to correct deficiencies, creating training programs, training surveyors, and necessary administrative costs.

(c) *Fee amount.* The amount of the fee for determining program compliance is set biennially by HHS.

(1) The fee is based on the category of test complexity and schedules or ranges of annual laboratory test volume and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of determining program compliance as set forth in § 493.638(c).

(2) The fee is assessed and payable biennially.

(3) The amount of the program compliance fee is the amount applicable to the laboratory listed in the most recent notice published in the **Federal Register** at the time that the fee is generated.



(d) *Additional fees.* (1) If a laboratory issued a certificate of compliance has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed fee.

(2) If, after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(3) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the Government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

(4) Laboratories with a certificate of compliance must pay a fee if the laboratory fails to perform successfully in proficiency testing for one or more specialties, subspecialties, analytes, or tests specified in subpart I of this part, and it is necessary to conduct a desk review of the unsuccessful performance. The additional fee is based on the actual resources and time necessary to perform the desk review. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

■ 8. Amend § 493.645—

- a. By revising the section heading;
- b. By removing paragraph (a);
- c. By redesignating paragraphs (b) and (c) as paragraphs (a) and (b);
- d. By revising newly redesignated paragraph (a); and
- e. In newly redesignated paragraph (b) by adding a paragraph heading.

The revisions and addition read as follows:

**§ 493.645 Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.**

(a) *Accredited laboratories.* (1) A laboratory that is issued a certificate of accreditation is assessed an additional fee to cover the cost of performing validation inspections described at § 493.563. All accredited laboratories share in the cost of these inspections. These costs are five percent of the same costs as those that are incurred when inspecting nonaccredited laboratories of the same schedule (or range) and are paid biennially by each accredited laboratory whether the accredited laboratory has a validation inspection or not. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(2) If a laboratory issued a certificate of accreditation has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laboratory an additional fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(b) *Complaint surveys.* \* \* \*

**§ 493.646 [Removed]**

■ 9. Section 493.646 is removed.

■ 10. Section 493.649 is revised to read as follows:

**§ 493.649 Additional fees applicable to approved State laboratory programs.**

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) The State's pro rata share of general overhead to administer the laboratory certification program under section 353 of the PHS Act.

(b) [Reserved]

■ 11. Section 493.655 is added to read as follows:

**§ 493.655 Payment of fees.**

(a) Except for laboratories covered by approved State laboratory programs, all laboratories are notified in writing by HHS or its designee of the appropriate

fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For approved State laboratory programs, HHS estimates the cost of conducting validation inspections as described at § 493.563 within the State on at least a biennial period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

■ 12. Section 493.680 is added to read as follows:

**§ 493.680 Methodology for determining the biennial fee increase.**

(a) *General rule.* Except for fees assessed to State laboratory programs approved by HHS, the fee amounts described in this subpart are subject to a biennial increase based on a two-part calculation of the Consumer Price Index-Urban (CPI-U) inflation adjustment and, if applicable, an additional increase as follows:

(1) CMS calculates the inflation rate using the compounded CPI-U over 2 years and, provided that the calculated rate is greater than zero, applies an increase to all fee amounts equal to the calculated rate.

(2) If the total fee amounts, including any increase applied under paragraph (a)(1) of this section, do not match or exceed actual program obligations based on a review of the previous 2 years' obligations, CMS applies an additional across the board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations.

(b) *Baseline.* Any increase applied under paragraph (a) of this section is incorporated into the baseline fee amounts for any subsequent biennial increase.

(c) *Publication.* Any increase applied under paragraph (a) of this section, including the calculation thereof, will be published as a notice in the **Federal Register**.

■ 13. Section 493.1278 is amended by—

- a. Revising paragraphs (a)(1) and (2);
- b. Removing paragraph (a)(3);
- c. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(3) and (4), respectively;
- d. Revising newly redesignated paragraph (a)(3);

- e. Removing paragraphs (b)(1), (2), and (3);
  - f. Redesignating paragraphs (b)(4) and (5) as paragraphs (b)(1) and (2), respectively;
  - g. In newly redesignated paragraph (b)(1), removing the phrase “latest report of the” and the second sentence;
  - h. Revising newly redesignated paragraph (b)(2);
  - i. Removing paragraph (b)(6).
  - j. Revising paragraphs (c), (d), (e), and (f); and
  - k. Removing paragraph (g).
- The revisions read as follows:

**§ 493.1278 Standard: Histocompatibility.**

(a) \* \* \*

(1) Use a continuous monitoring system and alert system to monitor the storage temperature of specimens (donor and recipient) and reagents and notify laboratory personnel when temperature limits are exceeded.

(2) Establish and follow written policies and procedures for the storage and retention of specimens based on the specific type of specimen. All specimens must be easily retrievable. The laboratory must have an emergency plan for alternate storage.

(3) If the laboratory uses immunologic reagents to facilitate or enhance the isolation or identification of lymphocytes or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

\* \* \* \* \*

(b) \* \* \*

(2) Have available and follow written criteria for determining when antigen and allele typing are required.

(c) *Antibody screening and identification.* The laboratory must make a reasonable effort to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening, identification, and crossmatch.

(d) *Crossmatching.* For each type of crossmatch that a laboratory performs, the laboratory must do the following, as applicable:

(1) Establish and follow written policies and procedures for performing a crossmatch.

(2) Have available and follow written criteria for the following:

(i) Defining donor and recipient human leukocyte antigen (HLA) antigens, alleles, and antibodies to be tested;

(ii) Defining the criteria necessary to assess a recipient's alloantibody status;

(iii) Assessing recipient antibody presence or absence on an ongoing basis;

(iv) Typing the donor at the serologic level to include those HLA antigens to

which antibodies have been identified in the potential recipient, as applicable;

(v) Describing the circumstances in which pre- and post-transplant confirmation testing of donor and recipient specimens is required;

(vi) Making available all applicable donor and recipient test results to the transplant team;

(vii) Ensuring immunologic assessments are based on test results obtained from a test report from a CLIA-certified laboratory; and

(viii) Defining time limits between recipient testing and the performance of a crossmatch.

(3) The test report must specify the type of crossmatch performed.

(e) *Transplantation.* Laboratories performing histocompatibility testing for infusion and transplantation purposes must establish and follow written policies and procedures specifying the histocompatibility testing (that is, HLA typing, antibody screening and identification, and crossmatching) to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory's policies and procedures must include, as applicable—

(1) Testing protocols that address:

(i) Transplant type (organ, tissue, cell);

(ii) Donor (living, deceased, or paired); and

(iii) Recipient (high risk vs. unsensitized);

(2) Type and frequency of testing required to support clinical transplant protocols; and

(3) Process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant. If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.

(f) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

**■ 14. Amend § 493.1359:**

■ a. In paragraph (a) by removing the word “and”;

■ b. By revising paragraph (b)(2); and

■ c. By adding paragraphs (c) and (d).

The revision and additions read as follows:

**§ 493.1359 Standard: PPM laboratory director responsibilities.**

\* \* \* \* \*

(b) \* \* \*

(2) Is performed in accordance with applicable requirements in this subpart and subparts H, J, and K of this part;

(c) Evaluate the competency of all testing personnel and ensure that the

staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;

(2) Monitoring the recording and reporting of test results;

(3) Review of test results or worksheets;

(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and

(5) Assessment of problem solving skills; and

(d) Evaluating and documenting the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

■ 15. Amend § 493.1405 by revising paragraph (b) to read as follows:

**§ 493.1405 Standard: Laboratory director qualifications.**

\* \* \* \* \*

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least 1 year directing or supervising nonwaived laboratory testing; and

(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or

(3)(i) Hold an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet master's equivalency; and

(B) Have at least 16 semester hours of additional doctoral level coursework in biology, chemistry, medical technology (MT), or clinical laboratory science (CLS); or

(C) A thesis or research project in biology/chemistry/MT/CLS related to

laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and

(A) Be certified and continue to be certified by a board approved by HHS; and

(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or

(4)(i) Have earned a master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours of additional graduate-level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

(iii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours, which may include a combination of graduate-level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iv) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and

(v) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and

(vi) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407; or

(5)(i) Have earned a bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(A) 48 semester hours of medical laboratory technology courses; or

(B) 48 semester hours of science courses that include—

(1) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(2) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(3) 24 semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(iii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and

(iv) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and

(v) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407.

(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

#### § 493.1406 [Removed]

■ 16. Section 493.1406 is removed.

■ 17. Amend § 493.1407 by revising paragraph (c) to read as follows:

#### § 493.1407 Standard; Laboratory director responsibilities.

\* \* \* \* \*

(c) The laboratory director must:

(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

\* \* \* \* \*

■ 18. Amend § 493.1411 by revising paragraph (b) to read as follows:

#### § 493.1411 Standard; Technical consultant qualifications.

\* \* \* \* \*

(b) The technical consultant must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is

responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i) Hold an earned doctoral or master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet either requirements in § 493.1405(b)(3)(ii) or (b)(4)(ii) or (iii); and

(iii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet § 493.1405(b)(5)(ii); and

(iii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(5)(i) Have earned an associate's degree in medical laboratory technology or clinical laboratory science; and

(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

(6) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or

(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

**Note 1 to paragraph (b):** The technical consultant requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service,

excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

■ 19. Amend § 493.1423 by revising paragraph (b) to read as follows:

**§ 493.1423 Standard; Testing personnel qualifications.**

\* \* \* \* \*

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or

(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology, or nursing from an accredited institution; or

(3) Meet the requirements in § 493.1405(b)(3)(ii), (b)(4)(ii) and (iii), or (b)(5)(ii); or

(4) Have earned an associate's degree in a chemical, biological science or medical laboratory technology or nursing from an accredited institution; or

(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(6)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

(7) For blood gas analysis, the individual must—

(i) Be qualified under paragraph (b)(1), (2), (3), or (4) of this section; or

(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or

(C)(1) Have earned an associate's degree related to pulmonary function from an accredited institution; and

(2) Have at least 2 years of training or experience, or both, in blood gas analysis.

■ 20. Amend § 493.1443 by revising paragraph (b) to read as follows:

**§ 493.1443 Standard: Laboratory director qualifications.**

\* \* \* \* \*

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(i) Have at least 2 years of experience directing or supervising high complexity testing; and

(ii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

(3)(i) Hold an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet master's equivalency; and

(B) Have at least 16 semester hours of additional doctoral level coursework in biology, chemistry, medical technology, or clinical laboratory science; or

(C) A thesis or research project in biology, chemistry, medical technology, or clinical laboratory science related to laboratory testing for the diagnosis, prevention, or treatment of any disease

or impairment of, or the assessment of the health of, human beings; and

(iii) Be certified and continue to be certified by a board approved by HHS; and

(iv) Have at least 2 years of:

(A) Laboratory training or experience, or both; and

(B) Laboratory experience directing or supervising high complexity testing; and

(v) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

■ 21. Amend § 493.1445 by revising paragraph (c) to read as follows:

**§ 493.1445 Standard; Laboratory director responsibilities.**

\* \* \* \* \*

(c) The laboratory director must:

(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits.

Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

\* \* \* \* \*

■ 22. Section 493.1449 is revised to read as follows:

**§ 493.1449 Standard; Technical supervisor qualifications.**

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the

State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or

(3)(i) Have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet the requirements in § 493.1443(b)(3)(ii); and

(B) [Reserved]

(iii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(4)(i) Have earned a master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, or clinical laboratory science or medical technology; or

(iii)(A) Meet bachelor's degree equivalency; and

(B) Have at least 16 semester hours, which may include a combination of graduate level coursework in biology, chemistry, medical technology, or clinical laboratory science and a thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(iv) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(5)(i) Have earned a bachelor's degree in a chemical or biological science or clinical laboratory science or medical technology from an accredited institution; or

(ii) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(A) 48 semester hours of medical laboratory technology courses; or

(B) 48 semester hours of science courses that include—

(1) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(2) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(3) 24 semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(iii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or

the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(3)(i) Have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at § 493.1443(b)(3)(ii); and

(iii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or

(4)(i) Have earned a master's degree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at paragraphs (c)(4)(ii) and (iii) of this section; and

(iii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(5)(i) Have earned a bachelor's degree in a chemical or biological science or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at paragraph (c)(5)(ii) of this section; and

(iii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

(e)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(2) An individual qualified under paragraph (b) or (d)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (k)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains

ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) An individual qualified under paragraph (b) or (f)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Meet one of the following requirements:

(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or

(3) Be certified in dermatology by the American Board of Dermatology; or

(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Must meet one of the following requirements:

(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be certified by the American Board of Ophthalmology and have successfully

completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B)(2) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Be certified in oral pathology by the American Board of Oral Pathology; or

(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(h) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(i) Have an earned doctoral degree in a biological or clinical laboratory science or medical technology from an accredited institution; or

(ii) Meet the education requirement at § 493.1443(b)(3)(ii); and

(iii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

**Note 1 to paragraph (h):** The technical supervisor requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

(i) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science or medical technology from an accredited institution;

(ii) Meet the education requirement at § 493.1443(b)(3)(ii); and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

■ 23. Amend § 493.1461 by revising paragraphs (c), (d)(3)(i), and (e)(1) and (4) to read as follows:

**§ 493.1461 Standard: General supervisor qualifications.**

\* \* \* \* \*

(c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical,

biological, or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under § 493.1489(b)(3); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(3) Meet the requirements at § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

(d) \* \* \*

(3)(i) Have earned an associate's degree related to pulmonary function from an accredited institution; and

\* \* \* \* \*

(e) \* \* \*

(1) In histopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (f)(1);

\* \* \* \* \*

(4) In oral pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (g).

#### § 493.1462 [Removed]

■ 24. Section 493.1462 is removed.

■ 25. Amend § 493.1463 by revising paragraph (b)(4) to read as follows:

#### § 493.1463 Standard: General supervisor responsibilities.

\* \* \* \* \*

(b) \* \* \*

(4) Evaluating and documenting the competency of all testing personnel.

\* \* \* \* \*

■ 26. Amend § 493.1483 by revising paragraph (b) to read as follows:

#### § 493.1483 Standard: Cytotechnologist qualifications.

\* \* \* \* \*

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the

Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

■ 27. Amend § 493.1489 by revising paragraph (b) to read as follows:

#### § 493.1489 Standard: Testing personnel qualifications.

\* \* \* \* \*

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or

(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, or clinical laboratory science or medical technology or nursing from an accredited institution;

(ii) Be qualified under the requirements of § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(3)(i) Have earned an associate's degree in a laboratory science or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(1) 24 semester hours of medical laboratory technology courses; or

(2) 24 semester hours of science courses that include—

(i) 6 semester hours of chemistry;

(ii) 6 semester hours of biology; and

(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes:

(1) Completion of a clinical laboratory training program approved or accredited

by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or

(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or

(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of [effective date of the final rule], and have done so continuously since [effective date of the final rule].

(6) For blood gas analysis—

(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section;

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate's degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of § 493.1449(b) or (l) to perform tissue examinations.

#### § 493.1491 [Removed]

■ 28. Section 493.1491 is removed.

■ 29. Amend § 493.1804 by revising paragraph (c)(1) to read as follows:

#### § 493.1804 General considerations.

\* \* \* \* \*

(c) \* \* \*

(1) CMS may impose alternative sanctions in lieu of, or in addition to, principal sanctions.

\* \* \* \* \*

Dated: July 13, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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