

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3478-P]

RIN 0938-AV89

Clinical Laboratory Improvement Amendments of 1988 (CLIA); Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Qualifications, and Other Changes

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 amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to allow for virtual access under the CLIA certificate of the primary testing laboratory that generated the data, with the exception of the subspecialty of cytology, and the use of digital images for gynecologic cytology proficiency testing. This proposed rule also includes proposed changes to personnel qualification requirements and other proposed changes pertaining to SARS-CoV-2 reporting requirements, certificate requirements, test reporting requirements, enforcement requirements, public consultation requirements, and editorial and technical updates. These proposed updates aim to strengthen the Federal oversight of clinical laboratories and ensure accurate and reliable patient test results while adapting to modern technological capabilities and industry needs, including workforce shortages.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by December 7, 2026.

ADDRESSES: In commenting, please refer to file code CMS-3478-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/docket/CMS-2026-3235>. 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-3478-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-3478-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:

Penny Keller, penny.keller@cms.hhs.gov, (410) 786-2035.

Jake D. Bunn, jbunn@cdc.gov, (404) 498-4493.

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 the comments. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an 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.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at <http://www.regulations.gov>.

I. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578), which amended section 353 of the Public Health Service Act (PHSA) and is codified at 42 U.S.C. 263a. CLIA and implementing regulations at 42 CFR part 493 set forth the conditions and standards that all laboratories must meet to be certified to perform testing on human specimens under CLIA and to maintain that CLIA certification. These

conditions and standards strengthen Federal oversight of clinical laboratories and help to ensure the accuracy and reliability of patient test results.

This proposed rule encompasses four overarching areas: (1) Virtual access provisions that would codify the flexibility provided by prior exercises of enforcement discretion to allow pathologists and laboratory personnel to review digital laboratory data, digital results, live imaging, and digital images remotely under the CLIA certificate of the primary testing laboratory that generated the data, excluding the subspecialty of cytology; (2) Gynecologic cytology proficiency testing (PT) updates that would allow for the use of digital images of glass slides in PT to align with the Food and Drug Administration (FDA)-authorized digital cytology screening systems; (3) Personnel qualification updates that would address concerns regarding the burden associated with the qualification requirements that took effect on December 28, 2024, including removing human-only laboratory science limitations and adding qualifications for histopathology gross tissue examination personnel and Mohs dermatology laboratory directors; and (4) Other changes that would remove SARS-CoV-2 (the virus causing COVID-19) reporting requirements, update certificate requirements, revise regulatory text requiring establishment of the Clinical Laboratory Improvement Advisory Committee (CLIAC), update test report requirements, revise enforcement requirements, and correct editorial and technical errors.

The proposed rule aims to update CLIA regulations to reflect advances in technology, reduce regulatory burdens on laboratories, and address workforce shortages while maintaining laboratory quality and safety standards.

II. Provisions of the Proposed Regulations

This section provides an overview of the proposed amendments to the CLIA regulations to allow for virtual access under the CLIA certificate of the primary testing laboratory that generated the data, with the exception of the subspecialty of cytology, and the use of digital images of glass slides for gynecologic cytology PT. This section also includes an overview of the proposed changes to personnel qualifications requirements, SARS-CoV-2 reporting requirements, certificate requirements, test reporting requirements, enforcement requirements, and public consultation requirements, as well as proposed

editorial and technical changes to the CLIA regulations.

A. Proposed Changes To Allow for Virtual Access

The existing CLIA certification regulations do not account for remote review of digital laboratory data, digital results, or digital images since these technologies were not available when the original regulations were codified. The CLIA certification regulations at §§ 493.35(a), 493.43(a), and 493.55(a)(2) require laboratories to file a separate application for each laboratory location unless they meet a regulatory exception. With respect to the subspecialty of cytology, section 353(f)(4)(B)(vi) of the PHSA and the regulation at § 493.1274(a) state that cytology screening and slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

Recognizing the urgency of the SARS-CoV-2 public health emergency (PHE) and the need to promote innovative uses of technology, increase testing capacity, and avoid exposure risks to health care providers, patients, and the community, CMS previously exercised enforcement discretion to allow pathologists to review digital data, results, and pathology slides/images remotely during the SARS-CoV-2 PHE, provided laboratories met certain criteria.¹ At that time, CMS noted that it would not enforce the separate certificate requirement for laboratories operating at temporary testing sites, provided that the designated primary site or home base had such a certificate (using the address of the primary site) and the work being performed in the temporary testing site fell within the parameters of the primary site's certificate.

Interested parties encouraged CMS to continue this exercise of enforcement discretion post-SARS-CoV-2 PHE. Based on this feedback and indications that remote review of digital data, results, and images did not decrease the accuracy of test results, on May 11, 2023, upon termination of the SARS-CoV-2 PHE,² CMS issued memo QSO-23-15-CLIA, entitled "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance."³ The memo stated that pathologists and other

qualified laboratory personnel would continue to be able to remotely review digital laboratory data, digital results, and digital images. The memo also stated that laboratories that choose to allow staff to remotely review digital laboratory data, digital results, and digital images could do so only if the following criteria are met:

- The primary laboratory has a current, unrevoked, or unsuspended certificate of waiver (CoW), registration certificate (CoR), certificate of compliance (CoC), certificate for Provider Performed Microscopy (PPM) procedures, or certificate of accreditation (CoA) issued by HHS applicable to the category of examinations or procedures performed by the laboratory (§ 493.3(a)(1));
- The primary laboratory complies with other applicable Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA);
- The laboratory director of the primary laboratory's CLIA certificate is responsible for all testing performed under its CLIA certificate, including testing and reporting performed remotely;
- Survey findings would be cited under the primary laboratory's CLIA certificate. Enforcement actions, if taken, would affect the primary laboratory's CLIA certificate;
- The primary laboratory's test reports should indicate the remote site location where the testing is performed. The laboratory may use a coding system rather than the remote site address (for example, personnel residence) on the final report. This coding system should be available upon request;
- The primary laboratory must be certified in the specialties and/or subspecialties of the work performed at the remote site;
- The primary laboratory should provide CMS a list of all staff working remotely upon request;
- The primary laboratory is responsible for retaining all documentation, including testing performed by staff working remotely; and
- The individual performing remote review must be on the primary laboratory's Form CMS-209, Laboratory Personnel Report (CLIA).

Following CMS's announcement that it would exercise enforcement discretion to allow pathologists and other qualified laboratory personnel to remotely review digital data, results, and images during the SARS-CoV-2

PHE⁴ and post-SARS-CoV-2 PHE,⁵ interested parties, such as members of the pathology community, have encouraged CMS to codify this flexibility. CMS reviewed survey citations from March 1, 2023, to July 1, 2024, for citations related to "remote" or "digital" for the year following the issuance of memo QSO-23-15-CLIA. CMS identified no concerning citation trends related to the remote review of digital data, results, or images during that period.

On September 23, 2025, CMS issued revisions to memo QSO-23-15-CLIA-REVISED⁶ that, in part, discontinued the temporary exercise of enforcement discretion that previously allowed remote review of cytology digital images of slides at locations separate from their primary CLIA-certified cytology laboratory as of 6 months from the date of the revised memo, or March 23, 2026, as section 353(f)(4)(B)(vi) of the PHSA and the regulation at § 493.1274(a) require that all cytological screening be performed on the premises of a CLIA-certified laboratory. CMS noted in this revised memo that laboratories reviewing digital cytology slide images remotely must obtain a separate CLIA certificate for that location to continue reviewing cytology slide images at the remote location as of March 23, 2026.

Recognizing the need for regulatory modernization and to reduce burden and costs for laboratories, CMS and the CDC now propose to codify this flexibility, allowing pathologists and other qualified laboratory personnel to remotely review digital data, results, and images through formal regulatory changes. We propose to add a definition of "virtual access" and update the regulatory language throughout 42 CFR part 493, to include digital laboratory data, digital results, live imaging, and digital images for CoR, CoC, and CoA certificates, facility and retention requirements, and in the general laboratory, analytic, and postanalytic systems sections to ensure testing conducted by means of virtual access maintains the same quality standards as on-site testing, as discussed in more detail below. The definition of virtual access would provide an additional option to the current regulatory

¹ <https://www.cms.gov/files/document/qso-20-21-clia-original-release-date-2020-03-26.pdf>. <https://www.cms.gov/files/document/qso-20-21-clia.pdf>.

² U.S. Dept of Health and Human Services (HHS), <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html#:~:text=February%209%2C%202023,last%20reviewed%20December%2015%2C%202023>.

³ QSO-23-15-CLIA, <https://www.cms.gov/files/document/qso-23-15-clia.pdf>.

⁴ QSO-20-21-CLIA, <https://www.cms.gov/files/document/qso-20-21-clia.pdf>.

⁵ QSO-23-15-CLIA; <https://www.cms.gov/files/document/qso-23-15-clia-original-release-date-2023-05-11.pdf>.

⁶ QSO-23-15-CLIA-REVISED, <https://www.cms.gov/files/document/qso-23-15-clia-revised-2025-09-23.pdf>.

multiple-site exceptions.⁷ Under this proposal, virtual access would not be permitted for the subspecialty of cytology. Individuals who perform cytology slide, digital image or digital data examinations at a location other than the primary CLIA-certified laboratory must continue to obtain a separate CLIA certificate with the subspecialty of cytology for that location, as noted in memo QSO–23–15–CLIA–REVISED.

1. Definitions (§ 493.2)

a. Virtual Access

We propose to revise § 493.2 to add a definition of “virtual access” as follows: Virtual access means review of digital laboratory data, digital results, live imaging, and digital images performed under the CLIA certificate of the primary testing laboratory that generated the data when not physically on the premises of the primary testing laboratory. Such review must be conducted via a secure connection to the primary testing laboratory’s software systems, laboratory information system (LIS), instruments, electronic health records (EHR), or encrypted communications. Virtual access is not permitted in the subspecialty of cytology.

Examples of digital laboratory data, digital results, live imaging, and digital images include but are not limited to quality control data, quality assurance data, data plots or graphics, real-time, simultaneous viewing of microscope slides such as in hematology and histopathology, test results and reporting, and images from slides such as in pathology, hematology, and clinical cytogenetics.

In the memo QSO–23–15–CLIA–REVISED, CMS previously used terminology tied to the review of digital data, results, and images at a remote location. However, CMS and the CDC are now proposing to define this activity as “virtual access” to better reflect the technological capabilities and utilization of modern review methods. Specifically, this proposed terminology change would acknowledge that using secure virtual connections to access laboratory systems can be performed from any secure location with appropriate internet connectivity, rather than being restricted to a specific location. The proposed shift to the “virtual access” terminology would more accurately capture the location-independent nature of these review

capabilities. Utilization of virtual access beyond the physical premises of the primary testing laboratory would be regarded as an activity conducted under the CLIA certificate of the primary testing laboratory.

b. Test Systems

Section 493.2 currently defines “test system” as the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results. We propose to revise the definition of “test system” at § 493.2 by adding “live imaging, digital images” to the list of systems to address new technology and align with our proposal related to virtual access. We also propose to add the words “accurate and reliable” prior to the reference to “test results” in this definition to align with the statutory requirement to assure consistent performance by laboratories of accurate and reliable laboratory examinations and procedures.⁸

2. Certificate Requirements

(§§ 493.43(a)(1) and 493.55(a)(1))

Section 493.43(a) pertains to the filing of an application for a CoR, PPM, and CoC certificate and currently provides that except as specified in § 493.43(b), all laboratories performing nonwaived testing must file a separate application for each laboratory location. We propose to add § 493.43(a)(1), to explain that virtual access would be considered to be conducted at the primary testing laboratory regardless of the physical location of the laboratory personnel and, therefore, would be under the CLIA certificate of the primary testing laboratory that generated the data, and that this would not apply to provider-performed microscopy (PPM) procedure certificates. CMS proposes that virtual access would not apply to the PPM certificate since PPM procedures are performed during the patient’s visit.

Section 493.55(a) pertains to the filing of an application for a CoR and CoA certificate and currently provides that a laboratory may be issued a CoA in lieu of the applicable certificate specified in subpart B or subpart C of the CLIA regulations. A separate application for each location must be filed, except as specified in § 493.55(b). We propose to add a regulation at § 493.55(a)(3), which would state virtual access is considered to be conducted at the primary testing laboratory regardless of the physical location of the laboratory personnel and, therefore, is under the CLIA certificate

of the primary testing laboratory that generated the data.

Under this proposal, if a laboratory employee works out of their home or at another remote location, performing duties such as data analysis or interpretation associated with their primary testing laboratory, those activities would be covered under the CLIA certificate of the primary testing laboratory. A primary testing laboratory’s CLIA certificate would include qualified laboratory personnel who perform data analysis and interpret digital information when using a secure virtual connection to the primary testing laboratory.

We propose to add regulations at §§ 493.43(a)(1)(i) and 493.55(a)(3)(i) that would hold the primary testing laboratory’s laboratory director responsible for all testing performed under the primary testing laboratory’s CLIA certificate, including testing utilizing virtual access. Currently, the laboratory director listed on the primary testing laboratory’s CLIA certificate is responsible for all testing performed under that certificate. We propose to add language to explicitly include testing and reporting performed remotely, utilizing virtual access as well.

We propose to add regulations at §§ 493.43(a)(1)(ii) and 493.55(a)(3)(ii) that would require all testing to be performed by qualified laboratory personnel under the CLIA-certified laboratory. The primary testing laboratory would also be required to provide CMS with a list of all staff utilizing virtual access upon request. For example, staff utilizing virtual access would need to be indicated on Form CMS–209. We are proposing these additions because the laboratory should be aware of who is performing the testing and how it is being conducted for the purpose of investigating complaints (§ 493.1233) or quality issues (§§ 493.1239, 493.1289, and 493.1299).

3. Facility and Retention Requirements (§§ 493.1101(e) and 493.1105(a), (a)(3), (a)(7), and (b))

Due to technological advancements that now enable the scanning of microscope slides and the creation of digital images of these slides, we propose expanding the current retention requirements to include the retention of digital images.

Section 493.1101(e) currently requires that records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. Section 493.1105(a) currently provides that a laboratory

⁷ These exceptions are codified at 42 CFR 493.35(b), 493.43(b), and 493.55(b); <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#part-493>.

⁸ 42 U.S.C. 263a(f)(1)(E); <https://www.govinfo.gov/content/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf>.

must retain its records, and, as applicable, slides, blocks, and tissues. Section 493.1105(b) currently provides that if a laboratory ceases operation, the laboratory must make provisions to ensure that all records, and, as applicable, slides, blocks, and tissues are retained and available for the specified time frames. Section 493.1105(a)(3) currently provides that a laboratory must retain quality control and patient test records for all analytic system activities specified in §§ 493.1252 through 493.1289 for at least 2 years. Finally, section 493.1105(a)(7) currently provides that cytology slide preparations are retained for at least 5 years from the date of examination, and histopathology slides are retained for at least 10 years from the date of examination.

We propose to revise the following regulations pertaining to facility storage and record retention: §§ 493.1101(e) for facilities storage, 493.1105(a), (a)(3), and (b) for retention, 493.1105(a)(7)(i)(A) for cytology retention, and 493.1105(a)(7)(i)(B) for histopathology retention. Specifically, we propose to add “digital images, digital data” to the list of items that laboratories must maintain and store under conditions that ensure proper preservation at § 493.1101(e). We also propose to add “digital images, digital data,” to the lists of items laboratories must retain at § 493.1105(a) and (b). We propose to add “digital images, and digital data,” to the list of items laboratories must retain at § 493.1105(a)(3).

We propose to add “and digital images” to the list of items laboratories must retain for cytology and histopathology at § 493.1105(a)(7)(i)(A) and (B). This proposal would require laboratories to retain both the slide and, if applicable, the digital slide image, as both the slide and the digital image may be required to identify an error for the purpose of investigating complaints (§ 493.1233) or quality issues (§§ 493.1239, 493.1289, and 493.1299).

4. General Laboratory Systems Requirements (§§ 493.1231(a) and 493.1251(b)(2))

Section 493.1231 currently provides that the laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. We propose to add a regulation at § 493.1231(a) that would require the laboratory to have policies that ensure virtual access is performed in a confidential environment on a secure network connection. This proposed addition would ensure laboratories maintain confidentiality of patient

information when utilizing virtual access and networks. If laboratories choose to implement virtual access capabilities, they need to ensure these systems operate within secure environments and networks in order to maintain the confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control (§ 493.1231). This means laboratories should have policies to prevent virtual access from occurring in nonsecure locations or on public networks such as coffee shops, public spaces, or other environments that could compromise data privacy and security. Ultimately, if laboratories elect to use virtual access technologies, they would be held accountable for maintaining the confidentiality of all patient information accessed through these virtual systems.

Section 493.1251(b)(2) currently provides that a procedure manual must include information on microscopic examination, including the detection of inadequately prepared slides, when applicable to the test procedure. We propose to revise § 493.1251(b)(2) to add a reference to digital images. Under this proposal, laboratories would be required to have procedures for digital imaging, if applicable, and for detecting inadequately prepared slides or digital images as they are part of the test procedure.

5. Analytic System Requirements (§ 493.1256(a))

Section 493.1256(a) currently provides that, for each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. We propose to revise the regulation at § 493.1256(a) to add “including testing performed via virtual access.” The proposed revision would clarify that control procedures should include any test process performed via virtual access to ensure the quality and accuracy of patient test results.

6. Postanalytic System Requirements (§§ 493.1283(a)(5) and 493.1291(a)(2))

Section 493.1283(a) currently requires that the laboratory must maintain positive identification of the specimen, the date and time of specimen receipt into the laboratory, the condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability, and the records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

We propose to add a regulation at § 493.1283(a)(5) that would require the laboratory to maintain records of virtual

access, including the identity of the personnel who performed the test(s), the software version (as applicable), and the electronic device used. We propose this addition to ensure a laboratory has records detailing who performed testing via virtual access and what device was used, as a laboratory should be aware of who is performing the testing and how it is being conducted for the purpose of investigating complaints (§ 493.1233) or quality issues (§§ 493.1239, 493.1289, and 493.1299).

Section 493.1291(a)(2) currently provides that the laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the final report destination, in a timely manner, including results and patient-specific data electronically reported to network or interfaced systems. We propose to revise § 493.1291(a)(2) to add a reference to results and patient-specific data electronically reported using virtual access. We propose this addition as the current regulations do not address reporting via virtual access.

We solicit comments on these proposals related to virtual access.

B. Proposed Changes to Gynecologic Cytology PT Requirements (§§ 493.855 and 493.945)

The gynecologic cytology PT regulation at § 493.855(b) currently requires that the laboratory ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Section 493.945(a)(1) in turn specifies that to be approved for PT for gynecologic examinations in cytology, a program must provide test sets composed of 10- and 20-glass slides. CMS and the CDC propose to revise the CLIA regulations at §§ 493.855 and 493.945 to allow gynecological cytology PT for digital images of glass slides.

This proposed change would reflect technological advancements in the field, as the FDA authorized the first digital cytology screening system in 2024, which creates digital images of glass slides for examination.⁹ In addition, PT must be performed using the same methodology as the primary testing method to ensure quality and accurate results (§ 493.801(b)(7)). As laboratories increasingly adopt digital cytology

⁹ FDA's CLIA- Clinical Laboratory Improvement Amendments Database, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

technology for their routine testing methods, CMS and the CDC recognize the importance of ensuring that PT options are available that align with these modern digital methods. This regulatory update would allow laboratories using digital cytology systems to participate in PT programs that utilize digital images, maintaining the integrity and relevance of the PT process while accommodating technological innovation in the field of cytology.

We also propose to revise §§ 493.855(a) and 493.945(a)(2) to add a requirement that PT programs approved by HHS for gynecologic cytology must have a system in place to monitor the integrity of the testing. Currently, with glass slides, the College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP) PT programs require a proctor to monitor the testing to ensure the integrity of the testing event.^{10 11} We propose to add the following requirement for digital images of glass slides to ensure there is a similar mechanism in place: “Proficiency testing programs approved by HHS must have a system in place to monitor the integrity of the testing.” We propose this language to ensure that individual PT results accurately reflect the individual’s performance. Unlike noncytology PT, cytology testing evaluates individuals rather than the laboratory as a whole, creating significantly higher personal stakes for the test participants. When an individual cytotechnologist or pathologist fails the cytology PT, they face the potential loss of their ability to independently screen slides. The proposed heightened monitoring is essential to maintain the credibility of cytology PT and protect public health, given the critical role that cytology plays in cancer detection and prevention programs.

We propose to revise § 493.855(b), including (b)(1) through (3), by adding “or digital images of the test slides” after each reference to a “10-slide test set” or “20-slide test set.” We propose to revise § 493.855(b)(2) and (3) by adding “or digital images of the slides” after each reference to “gynecologic slides” or “reexamination of slides.” In addition, we propose to revise § 493.855(b) to include a reference to

“(b)(1) through (3)” instead of “(b)(1), (b)(2), and (b)(3)” for simplification.

We also propose to revise § 493.945(a)(1) and (b) by adding “or digital images of the test slides” after each reference to “20-glass slides” or “20-slide test sets.” In addition, we propose to revise § 493.945(b) by adding “/digital images” after the word “slides” in the following language “in which the slides have been referenced as specified in paragraph (b)(1) of this section.”

Section 493.945(b)(1) currently states that to determine the accuracy of an individual’s response on a particular challenge (slide), the program must compare the individual’s response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category. For all slide preparations, a 100 percent consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology. We propose to revise § 493.945(b)(1) by adding “/digital image” after the word “slide” in parentheses, adding “or digital images of slide preparations” after “slide preparations” and “or digital image of slide preparation” after “slide preparation.”

Section 493.945(b)(2) currently provides that an individual qualified as a technical supervisor under § 493.1449(b) or (e) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened. We propose to revise § 493.945(b)(2) by adding “or digital images of slide preparations” after “slide preparations.”

Section 493.945(b)(3)(i) currently provides that each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in

cytology qualified under § 493.1449(b) or (e) of this part. We propose to revise § 493.945(b)(3)(i) to read as follows: Each slide set or digital image of the slide set must contain 10 or 20 slides or digital images of the slides with point values established for each slide preparation or digital image of slide preparation based on the significance of the relationship of the interpretation of the slide/digital image to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449(b) or (e) of this part.

Section 493.945(b)(3)(ii)(B) currently states that in accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (– 5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is “high grade squamous intraepithelial lesion” (category “D” on the scoring system chart) and an examinee calls it “normal or negative” (category “B” on the scoring system chart), then the examinee’s point value on that slide is calculated as minus five (– 5). Each slide is scored individually in the same manner. The individual’s score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100. We propose to revise § 493.945(b)(3)(ii)(B) by adding references to “digital image” or “digital image of the slide” in several places. Specifically, we propose to revise § 493.945(b)(3)(ii)(B) to read as follows: In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (– 5) points for an incorrect response on a 10-slide/digital image test set. For example, if the correct response on a slide/digital image of the slide is “high grade squamous intraepithelial lesion” (category “D” on the scoring system chart) and an examinee calls it “normal or negative” (category “B” on the scoring system chart), then the examinee’s point value on that slide/digital image of the slide is calculated as minus five (– 5). Each slide/digital image of the slide is scored individually in the same manner. The individual’s

¹⁰ CAP, https://www.cap.org/wp-content/uploads/documents/PAP-PT-Program-General-Information_112025.pdf.

¹¹ ASCP, https://ascpcontentwebsite.blob.core.windows.net/content/docs/default-source/education/gyn-pt-proctor-user-guide.pdf?sfvrsn=3926201a_1.

score for the testing event is determined by adding the point value achieved for each slide preparation/digital image of the slide, dividing by the total points for the testing event and multiplying by 100.

Section 493.945(b)(3)(ii)(C) through (G) currently provides the criteria for the scoring system. We propose to revise § 493.945(b)(3)(ii)(C) through (G) by adding the words “/digital image” following any references to slides.

We solicit comments on these proposals to allow gynecological cytology PT for digital images of glass slides.

C. Proposed Changes to Personnel Qualification Requirements

On December 28, 2023, the “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories” final rule (88 FR 89976)¹² (2023 CLIA final rule), which updated the requirements in 42 CFR part 493, subpart M related to personnel qualifications and responsibilities, appeared in the **Federal Register**. Since December 28, 2024, the effective date of the updated personnel qualification regulations, CMS has received substantial feedback from interested parties about the revised requirements. While CMS received comments on these proposals in response to the “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories” proposed rule (87 FR 44896),¹³ several of these interested parties later stated that they did not realize the impact the regulatory changes could have on their laboratories until after the rule went into effect. CMS met directly with multiple interested parties to listen to their concerns, most of which were related to the updated laboratory director qualification requirements.

Specifically, interested parties expressed concerns about the requirement at § 493.1405 for physicians to have both 20 hours of continuing education (CE) credit hours in laboratory director responsibilities and 1 year of supervisory laboratory experience to qualify as moderate

complexity laboratory directors,¹⁴ viewing the new requirement as burdensome. Prior to December 28, 2024, physicians for moderate complexity laboratories could qualify as moderate complexity laboratory directors with either 20 CE credit hours in laboratory director responsibilities or 1 year of supervisory laboratory experience, providing more flexibility in meeting the relevant qualification requirements and enabling physicians to open their practices upon graduation. Similarly, dermatology associations raised concerns about the qualification requirements at § 493.1443 for newly graduated and practicing dermatologists to serve as high complexity laboratory directors for laboratories that perform Mohs testing, which now requires both 2 years of supervisory lab experience and 20 CE credit hours in laboratory director responsibilities. Under the previous regulations, dermatologists qualified as high complexity laboratory directors based solely on their residency training, without requiring documentation of prior laboratory supervisory experience or the 20 CE credit hours. Interested parties expressed concerns that more stringent qualification requirements may reduce the number of eligible candidates for laboratory director positions, potentially impacting access to care in rural areas and laboratories that perform Mohs testing.

After consideration of the interested parties’ feedback, CMS published a memo QSO–25–21–CLIA¹⁵ on June 23, 2025, which announced CMS’s exercise of enforcement discretion in limited circumstances with respect to certain regulatory personnel qualification requirements. The enforcement discretion allowed the following:

- Laboratory directors qualifying under § 493.1405(b)(2) could have either at least 1 year of experience directing or supervising nonwaived laboratory testing or 20 CE credit hours in laboratory director responsibilities;
- Additional 20 CE credit hours currently required under §§ 493.1405(b)(3)(ii), 493.1405(b)(4)(iv), 493.1405(b)(5)(iv), 493.1443(b)(2)(iii), and 493.1443(b)(3)(iv) would not be required; and
- Individuals qualified as technical supervisors under § 493.1449(f)(2)(i) could qualify as high complexity laboratory directors for testing in dermatopathology.

CMS noted in this memo its plans to address these changes in future notice-and-comment rulemaking. CMS and the CDC now propose to revise, rescind, or clarify several personnel qualification regulations, as discussed in more detail below.

In proposing to revise or rescind certain personnel qualification requirements finalized in the 2023 CLIA final rule (88 FR 89976), CMS has carefully considered whether any serious reliance interests exist that would counsel against proposing these changes. CMS believes that there are no serious reliance interests that would preclude the proposed changes to the personnel qualification requirements set forth in this proposed rule. On June 23, 2025, CMS published QSO–25–21–CLIA, which announced that CMS would exercise enforcement discretion with respect to certain personnel qualification requirements described previously in this proposed rule. Because CMS exercised enforcement discretion related to the personnel qualification requirements, which we are proposing to revise in this proposed rule, laboratories and personnel have not been required to come into full compliance with the more stringent personnel qualification requirements of the 2023 CLIA final rule. As a result, we believe that any reliance interests that might otherwise have arisen from the originally finalized requirements are significantly diminished. Furthermore, the proposed personnel qualification requirement changes in this rule are generally more permissive than the 2023 CLIA final rule requirements; they would restore flexibilities that existed prior to December 28, 2024, and therefore would not impose new burdens on regulated entities. We also recognize that patients and patient advocacy groups may have reliance interests grounded in the regulatory requirements for personnel qualifications of staff who perform testing based on interests relating to test accuracy. CMS and the CDC are committed to oversight of the accuracy and reliability of laboratory testing, consistent with CLIA’s core purpose of protecting patient health and safety. CMS and the CDC have carefully considered whether revisions to the personnel qualification requirements in the 2023 CLIA final rule could give rise to reliance interests grounded in patient safety, and we believe that the proposed requirements maintain appropriate safeguards to ensure the accuracy and reliability of laboratory testing results, while restoring operational flexibilities that do not compromise the quality of

¹² 88 FR 89976; <https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and>.

¹³ 87 FR 44896; <https://www.federalregister.gov/documents/2022/07/26/2022-15300/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and>.

¹⁴ Section 493.1405; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.1405>.

¹⁵ QSO–25–21–CLIA; <https://www.cms.gov/files/document/qso-25-21-clia.pdf>.

care that patients receive. It is important to note that personnel qualifications represent only one element of a broader quality assurance framework. No individual is permitted to perform testing without first completing the required training and demonstrating competency.

We evaluated a couple of potential approaches to address the concerns from interested parties about the new personnel qualification regulations. First, we considered rescinding all of the personnel qualification regulations codified in the 2023 CLIA final rule in their entirety and returning to the prior regulatory requirements; however, this approach would have eliminated the critical flexibility we created for nontraditional degree holders¹⁶ to meet personnel qualification requirements, exacerbating the laboratory workforce shortage. Second, we evaluated the possibility of fully revising the personnel qualification regulations to achieve maximum simplification; however, we determined that the organization of the current regulations is appropriate, as it has been used for 30 years and laboratories are familiar with the structure and the requirements, and we instead selected specific changes based on interested parties' feedback. We believe the proposed approach would be the most effective way to maintain regulatory effectiveness and reduce regulatory burden while providing the clarity laboratories need for their operations at this time. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. As such, these proposed revisions to the CLIA regulations are not expected to compromise testing quality. Beyond initial qualifications, robust safeguards are in place to uphold testing accuracy on an ongoing basis. Each day, laboratories are required to conduct quality control measures to verify that the testing process is being performed

correctly.¹⁷ Additionally, laboratories are required to participate in proficiency testing to validate the accuracy of their results, a process that CMS actively monitors.¹⁸

We do not believe these proposed regulatory changes, if finalized, would impact the accuracy and quality of testing given the safeguards already described. Laboratories would need to carefully review any flexibilities outlined in the proposed rule, if finalized, to determine what best fits their individual needs, as CMS and the CDC aim to provide maximum flexibility while expecting that each laboratory will hire qualified personnel to maintain the accuracy and quality of their specific testing. If CMS were to detect a decrease in quality and accuracy following implementation of the proposed changes, if finalized, as evidenced by its biennial surveys and PT performance monitoring, it would assess whether the regulations need to be revised further through future notice and comment rulemaking to address any identified deficiencies.

CMS and the CDC propose to revise, remove, or clarify several of the personnel qualification requirements that were finalized in the 2023 CLIA final rule. Specifically, we propose to revise the CLIA regulations at §§ 493.2, 493.1273(c), 493.1359(c), 493.1359(d), 493.1405(b), 493.1407(c), 493.1411(b), 493.1417(b), 493.1417(c), 493.1423(b), 493.1443(b), 493.1445(c), 493.1449(c), 493.1449(f), 493.1449(i), 493.1455(a), 493.1455(b), 493.1455(c), 493.1461(c), 493.1461(e), 493.1463(a), 493.1463(b), 493.1463(c), 493.1489(b), 493.1495(b), and 493.1495(c) to address interested parties' concerns about burden and access to care, as discussed in more detail below.

1. Laboratory Director Qualifications

CMS and the CDC propose standardizing moderate and high complexity laboratory director qualification requirements to require at least 1 year of experience directing or supervising laboratory testing or 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities, regardless of educational background. Prior to the 2023 CLIA final rule, physicians seeking to qualify as moderate complexity laboratory directors could meet the qualification requirements at § 493.1405(b)(2) with either 1 year of experience or 20 CE credit hours, and

physicians seeking to qualify as high complexity laboratory directors were required to have 2 years of experience directing or supervising high complexity laboratory testing pursuant to § 493.1443(b)(2). Individuals with a doctoral degree were required to have an HHS-approved board certification and 1 year of experience directing or supervising moderate complexity laboratory testing to be a moderate complexity laboratory director or 2 years of experience directing or supervising high complexity laboratory testing to be a high complexity laboratory director.

We believe the proposed standardized requirements across the different educational backgrounds (that is, medical, doctoral, master's, and bachelor's degrees) are reasonable because the laboratory director's regulatory responsibilities, which center on possessing a thorough understanding of administrative and supervisory duties rather than specialized expertise in each subspecialty, are similar regardless of the laboratory's specialty or complexity. CMS and the CDC also believe this proposed approach is reasonable because each laboratory is required to have a technical consultant or technical supervisor with specific experience in a particular test specialty or subspecialty, complementing the laboratory director's management role. Similarly, we propose that the experience requirements for high complexity laboratory directors would match those for moderate complexity laboratory directors because the core regulatory responsibilities of a laboratory director are similar across both test complexity settings. The key distinction lies in the education requirement for high complexity laboratory directors, which is currently more restrictive and limited to physicians and doctoral degree holders. This proposed approach would ensure appropriate oversight while recognizing that fundamental management responsibilities remain consistent regardless of the laboratory's test complexity level.

CMS and the CDC also propose adding an additional qualification route for physicians that would allow them to qualify as a laboratory director based on at least 1 year of laboratory training during medical residency or fellowship. We are proposing this addition because we agree with interested parties who have asserted that fellowship programs and medical residencies that include 1 year of laboratory experience meet the laboratory experience and training for moderate and high complexity laboratory directors. Table 1 outlines the laboratory director qualification

¹⁶ Sections 493.1405(b)(3)(i)(B), 493.1405(b)(4)(i)(B), 493.1405(b)(4)(i)(C), 493.1405(b)(5)(i)(B), 493.1411(b)(3)(i)(B), 493.1411(b)(4)(i)(B), 493.1423(b)(3), 493.1443(b)(3)(i)(B), 493.1449(c)(3)(i)(B), 493.1449(c)(4)(i)(B), 493.1449(c)(4)(i)(C), 493.1449(c)(5)(i)(B), 493.1449(d)(3)(i)(B), 493.1449(d)(4)(i)(B), 493.1449(d)(5)(i)(B), 493.1449(h)(2)(i), 493.1449(i)(2)(i), and 493.1489(b)(2)(ii); <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#part-493>.

¹⁷ Section 493.1256; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.1256>.

¹⁸ Section 493.801; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.801>.

requirements as they relate to experience, board certification, and CE

credit hours prior to December 28, 2024, under the current regulations finalized

in the 2023 CLIA final rule, and under this proposal.

TABLE 1—LABORATORY DIRECTOR QUALIFICATION REQUIREMENTS PRIOR TO DECEMBER 28, 2024, LABORATORY DIRECTOR QUALIFICATION REQUIREMENTS UNDER CURRENT REGULATIONS, AND PROPOSED LABORATORY DIRECTOR QUALIFICATION REQUIREMENTS *

Degree	Complexity	Qualification requirements prior to December 28, 2024	Current qualification requirements	Proposed qualification requirements
MD/DO (Pathologist) ...	High	Board Certification	Board Certification	No Change.
MD/DO (Pathologist) ...	Moderate	Board Certification	Board Certification	No Change.
MD/DO/DPM (Physicians).	High	• 1-year of laboratory training during residency; or • 2-years supervisory experience	• 2-years of supervisory experience; and • 20 CE credit hours	• 1-year of laboratory training during residency or fellowship; or • 1-year supervisory experience; or • 20 CE credit hours.
MD/DO/DPM (Physicians).	Moderate	• 1-year supervisory experience; or • 20 CE credit hours; or • Residency equivalent to 20 CE credit hours.	• 1-year of supervisory experience; and • 20 CE credit hours	• 1-year of laboratory training during residency or fellowship; or • 1-year supervisory experience; or • 20 CE credit hours.
Doctoral	High	Board Certification	• Board Certification; and • 2-years of supervisory experience; and • 20 CE credit hours	• 1-year of supervisory experience; or • 20 CE credit hours.
Doctoral	Moderate	• Board Certification; or • 1-year supervisory experience	• Board Certification; and • 1-year of supervisory experience; and • 20 CE credit hours	• 1-year of supervisory experience; or • 20 CE credit hours.
Master's	Moderate	• 1-year laboratory experience; and • 1-year supervisory experience	• 1-year laboratory experience; and • 1-year supervisory experience; and • 20 CE credit hours	• 1-year of supervisory experience; or • 20 CE credit hours.
Bachelor's	Moderate	• 2-year laboratory experience; and • 2-year supervisory experience	• 2-year laboratory experience; and • 2-year supervisory experience; and • 20 CE credit hours	• 1-year of supervisory experience; or • 20 CE credit hours.

* Table 1 only addresses laboratory director qualification requirements as they relate to experience, board certification, and CE credit hours. See §§ 493.1405 and 493.1443 for a comprehensive list of the current qualification requirements for laboratory directors.

CMS and the CDC propose to remove the HHS-approved doctoral board certification requirement at §§ 493.1405(b)(3) and 493.1443(b)(3). CMS reviewed the current HHS-approved doctoral board certifications and found that all HHS-approved doctoral board certifications require at least 1 year of supervisory experience. Under this proposal, if finalized, CMS would no longer require the HHS-approved doctoral board certification, in addition to the 1 year of experience directing or supervising high complexity laboratory testing and 20 CE credit hours. However, CMS would continue to accept the current HHS-approved doctoral board certifications, listed in the SOM Appendix C, as documentation of that 1 year of experience directing or supervising high complexity laboratory testing. Individuals with other doctoral board certifications or without a current HHS-approved doctoral board certification would need to provide documentation of 1 year of experience directing or supervising high complexity laboratory testing. Board certification falls within the domain of professional practice and credentialing, which would not be affected by this proposed change.

a. Moderate Complexity Laboratory Director Qualifications (§ 493.1405)

(1) Physicians

Section 493.1405(b)(2)(ii)(A) and (B) currently requires a laboratory director of a laboratory performing moderate complexity testing to have both laboratory training or experience consisting of at least 1 year directing or supervising nonwaived laboratory testing, and at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407. We propose to change the “and” at the end of § 493.1405(b)(2)(ii)(A) to an “or” so that a laboratory director of a laboratory performing moderate complexity testing would no longer need to meet both the requirements at § 493.1405(b)(2)(ii)(A) and (B). We also propose to add a third qualification route at § 493.1405(b)(2)(ii)(C) for at least 1 year of laboratory training during medical residency or fellowship. This proposed revision and addition would allow individuals to qualify as moderate complexity laboratory directors through relevant experience, completion of 20 CE credit hours, or 1 year of laboratory training during medical residency or fellowship.

CMS received feedback from interested parties after the 2023 CLIA

final rule took effect on the increased burden associated with physicians being required to have both 1 year of experience directing or supervising nonwaived laboratory testing and 20 CE credit hours on laboratory director responsibilities. These interested parties noted that in cases of newly graduated physicians, the additional requirement for 1 year of experience directing or supervising nonwaived laboratory testing to start their new medical practices seemed overly burdensome if they had already taken 20 CE credit hours on the responsibilities of a laboratory director. To reduce this burden, CMS and the CDC propose to revert to the regulations in place prior to the 2023 CLIA final rule, which required 1 year of experience directing or supervising nonwaived laboratory testing or 20 CE credit hours on laboratory director responsibilities. We are also proposing this change because we agree with the interested parties who have asserted that fellowship programs and medical residencies that include 1 year of laboratory experience should be deemed to meet the laboratory experience and training for moderate and high complexity laboratory directors, because this would be equivalent to 1 year of directing or supervising non-waived laboratory testing. This proposed approach would

not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which would continue to ensure accurate and quality laboratory testing. The technical consultant or technical supervisor qualification requirements with specific experience in the particular specialty or subspecialty being tested, complementing the director's management role, would also remain unchanged under this proposal.

(2) Doctoral Degree

Section 493.1405(b)(3)(i)(B)(2) currently requires individuals qualifying as a moderate complexity laboratory director with a doctoral degree not in biology/chemistry/medical technology (MT)/clinical laboratory science (CLS)/medical laboratory science (MLS) to have an approved thesis or research project in biology/chemistry/MT/CLS/MLS 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. CMS received feedback from interested parties stating that this regulation was confusing and could be interpreted to mean that only thesis and research projects involving human subjects were acceptable. Interested parties also commented that doctoral research 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 often begins with studies conducted on animal models before consideration for clinical trials involving human participants, often utilizing similar laboratory test procedures and devices. Both CMS and the CDC concur that this requirement could inadvertently exclude those individuals with relevant laboratory experience obtained through work with animal models. Therefore, we propose to revise § 493.1405(b)(3)(i)(B)(2) to remove the language "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."

Section 493.1405(b)(3)(ii) currently requires individuals qualifying as moderate complexity laboratory directors with doctoral degrees to have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities as defined in § 493.1407, be certified and continue to be certified by a board approved by HHS, and to have had at least 1 year of experience directing or supervising

nonwaived laboratory testing. We propose to revise § 493.1405(b)(3)(ii)(A) to rescind the requirement for certification by a board approved by HHS. We propose to redesignate § 493.1405(b)(3)(ii) as § 493.1405(b)(3)(ii)(A) and revise the newly redesignated § 493.1405(b)(3)(ii)(A) to replace the word "and" with "or." If finalized as proposed, individuals with a doctoral degree could qualify as a moderate complexity laboratory director with either 20 CE credit hours or 1 year of experience directing or supervising nonwaived laboratory testing and would no longer require certification by a board approved by HHS. CMS and the CDC aim to reduce burden by aligning all laboratory director qualifications for moderate complexity testing, including doctoral degrees, to have either 1 year of experience or 20 CE credit hours on laboratory director responsibilities. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. The technical consultant or technical supervisor qualification requirements with specific experience in the particular specialty or subspecialty being tested, complementing the laboratory director's management role, would remain unchanged under this proposal.

(3) Master's Degree

We propose to revise § 493.1405(b)(4)(i)(C)(2) to remove the language 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, for individuals qualifying as moderate complexity laboratory directors with a master's degree not in biology/chemistry/MT/CLS/MLS.

We are proposing this amendment because CMS received feedback from interested parties that this regulation was confusing and could be interpreted as only allowing for thesis and research projects involving human subjects. We also agree with interested parties who have asserted that most doctoral research conducted for the diagnosis, prevention, or treatment of disease on human specimens is initially performed on animal models.

Section 493.1405(b)(4)(ii) through (iv) currently requires individuals qualifying as moderate complexity laboratory directors with a master's degree to have at least 1 year of laboratory training or experience, or both, in nonwaived testing, at least 1

year of supervisory laboratory experience in nonwaived testing, and at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407.

We propose to rescind § 493.1405(b)(4)(ii) to remove the requirement for 1 year of additional laboratory training or experience, or both, in nonwaived testing. Furthermore, we propose to redesignate the requirement for 1 year of supervisory laboratory experience in nonwaived testing currently at § 493.1405(b)(4)(iii) to 493.1405(b)(4)(ii)(A) and revise the newly redesignated § 493.1405(b)(4)(ii)(A) to change the word "and" to "or." These proposed revisions aim to reduce burden by aligning all laboratory director qualifications for moderate complexity testing, including master's degrees, to have either 1 year of experience or 20 CE credit hours in laboratory director practice that cover the laboratory director responsibilities. We also propose to redesignate § 493.1405(b)(4)(iv) as § 493.1405(b)(4)(ii)(B). The regulatory requirement at the new proposed § 493.1405(b)(4)(ii)(B) would remain the same. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. The technical consultant or technical supervisor qualification requirements with specific experience in the particular specialty or subspecialty being tested, complementing the director's management role, would also remain unchanged under this proposal.

(4) Bachelor's Degree

Section 493.1405(b)(5)(ii) through (iv) currently requires individuals qualifying as a moderate complexity laboratory director with a bachelor's degree to have at least 2 years of laboratory training or experience, or both, in nonwaived testing, at least 2 years of supervisory laboratory experience in nonwaived testing, and at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407. We propose to rescind § 493.1405(b)(5)(ii) to remove the requirement for 2 years of additional laboratory training or experience, or both, in nonwaived testing to reduce burden.

Furthermore, we propose to redesignate the requirement for 2 years

of supervisory laboratory experience in nonwaived testing currently at § 493.1405(b)(5)(iii) as § 493.1405(b)(5)(ii)(A) and revise the newly redesignated § 493.1405(b)(5)(ii)(A) to change the word “and” to “or” and to also change “2 years” to “1 year” of experience for individuals qualifying as a moderate complexity laboratory director with a bachelor’s degree. We also propose to redesignate § 493.1405(b)(5)(iv) as § 493.1405(b)(5)(ii)(B) and revise the newly redesignated § 493.1405(b)(5)(ii)(B) to include the word “or.” CMS and the CDC are proposing to align all laboratory director qualifications for moderate complexity testing, including bachelor’s degrees, to have either 1 year of supervisory experience or 20 CE credit hours on laboratory director practice that cover the director’s responsibilities.

Section 493.1405(b)(6) currently permits individuals who were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024, to be considered qualified as a laboratory director of moderate complexity testing. We propose to revise § 493.1405(b)(6) to expand the scope from “moderate complexity testing” to “moderate or high complexity testing.” This amendment would allow individuals who qualified as laboratory directors for either moderate or high complexity testing prior to December 28, 2024, to continue to qualify and serve as laboratory directors of moderate complexity testing in a CLIA-certified laboratory under this provision. This revision would provide clarification in response to questions CMS has received from high complexity laboratory directors who were qualified and continued to be qualified to direct high complexity laboratories under § 493.1443(b)(4) as to whether they would be permitted to direct moderate complexity laboratories. Since high complexity laboratory director qualification requirements are more stringent than those for moderate complexity, individuals who meet the qualifications for high complexity laboratory director positions would automatically qualify as moderate complexity laboratory directors. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. The technical

consultant or technical supervisor qualification requirements with specific experience in the particular specialty or subspecialty being tested, complementing the director’s management role, would also remain unchanged under this proposal.

b. High Complexity Laboratory Director Qualifications (§ 493.1443)

(1) Physicians

Section 493.1443(b)(2)(ii) and (iii) currently require individuals qualifying as high complexity laboratory directors with a medical degree to have at least 2 years of experience directing or supervising high complexity testing and at least 20 CE credit hours in laboratory practice that cover the director’s responsibilities defined in § 493.1445. We propose to redesignate § 493.1443(b)(2)(ii) as 493.1443(b)(2)(ii)(A) and revise the regulation to require 1 year rather than 2 years of experience directing or supervising high complexity testing based on the rationale provided above at § 493.1405. We also propose to revise the word “and” to “or” to be consistent with the other high complexity laboratory director qualifications regulations. We also propose to redesignate § 493.1443(b)(2)(iii) as § 493.1443(b)(2)(ii)(B). The regulatory requirement at the newly proposed § 493.1443(b)(2)(ii)(B) would remain the same as before redesignation.

We propose to add a regulation at § 493.1443(b)(2)(ii)(C) to allow a physician to qualify as a high complexity laboratory director with at least 1 year of laboratory training during medical residency or fellowship. CMS received feedback from interested parties regarding the increased burden for physicians to have both 2 years of experience directing or supervising nonwaived laboratory testing and 20 CE credit hours in laboratory practice that cover the director’s responsibilities. Depending on the unique circumstances of their laboratory setting and test menu, the burden was either the experience or the 20 CE credit hours. Interested parties also provided feedback that in cases of newly graduated physicians, the additional requirement of 2 years of experience directing or supervising to start their new medical practices seemed unnecessary and burdensome if they had already taken 20 CE credit hours on the responsibilities of a laboratory director. Interested parties also stated that fellowship programs and medical residencies that include 1 year of laboratory experience should be included to meet the laboratory experience and training for moderate

and high complexity laboratory directors. We are proposing this addition because we agree with interested parties who have asserted that this would be equivalent to 1 year of directing or supervising nonwaived laboratory testing. This proposal would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. The technical consultant or technical supervisor qualification requirements with specific experience in the particular specialty or subspecialty being tested, complementing the director’s management role, would also remain unchanged under this proposal.

(2) Doctoral Degree

Section 493.1443(b)(3)(i)(B)(2) currently requires individuals qualifying as a high complexity laboratory director with a doctoral degree not in biology/chemistry/MT/CLS/MLS to have an approved thesis or research project in biology/chemistry/MT/CLS/MLS 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. We propose to revise § 493.1443(b)(3)(i)(B)(2) to remove the requirement that the approved thesis or research project must be related to laboratory testing involving human specimens. This revision would address interested parties’ comments that animal research models are often the originator for conducting future human research.

Section 493.1443(b)(3)(ii) through (iv) currently requires an individual qualifying as a high complexity laboratory director with a doctoral degree to be certified and continue to be certified by a board approved by HHS, have at least 2 years of laboratory training or experience, or both, laboratory experience directing or supervising high complexity testing, and 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445. We propose to remove § 493.1443(b)(3)(ii), which requires individuals with doctoral degrees to be certified and continue to be certified by a board approved by HHS. This proposed change would make the high complexity qualifications consistent with the moderate complexity qualifications for individuals with a doctoral degree. We propose to redesignate § 493.1443(b)(3)(iii) as 493.1443(b)(3)(ii)(A) and revise the

regulation to only require at least 1 year of experience directing or supervising high complexity testing to be consistent with the other high complexity laboratory director qualifications in response to questions received from interested parties regarding the total years required for laboratory experience and experience directing and supervising high complexity testing.

We propose to rescind § 493.1443(b)(3)(iii)(A) and (B) related to the total number of years of laboratory experience and experience directing and supervising high complexity laboratory testing required for individuals with doctoral degrees qualifying for high complexity laboratory directors. CMS received feedback from interested parties regarding the increased burden for individuals to have both 2 years of experience directing or supervising nonwaived laboratory testing and 20 CE credit hours in laboratory practice that cover the director's responsibilities. We propose to redesignate § 493.1443(b)(3)(iv) as § 493.1443(b)(3)(ii)(B). The regulatory requirement at the newly proposed § 493.1443(b)(3)(ii)(B) would remain the same as before redesignation. The change at § 493.1443(b)(3)(ii)(B) would make the 20 CE credit hours an option for qualification instead of laboratory experience. During the SARS-CoV-2 PHE and after the effective date of the 2023 CLIA final rule, laboratory directors from nontraditional backgrounds had difficulty providing documentation of 2 years of laboratory experience and board certification in a timely manner since their experience was from non-CLIA certified laboratories. The 20 CE credit hours option would allow flexibility for individuals with doctoral degrees without laboratory supervisory experience to qualify as high complexity laboratory directors. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. The technical consultant or technical supervisor qualification requirements with specific experience in the particular specialty or subspecialty being tested, complementing the director's management role, would also remain unchanged under this proposal.

(3) Dermatopathology

Mohs micrographic surgery is a procedure used to treat skin cancer. During Mohs micrographic surgery, the visible tumor and a thin layer of

surrounding skin are removed. The tissue is examined to see if any cancer cells remain at the edges while the patient is still in surgery. If any cancer cells remain, additional skin is removed and examined until no more cancer cells are found at the edges.¹⁹ Mohs micrographic surgery falls under dermatopathology tests and is performed by specially trained dermatologists who have completed extensive training in Mohs surgery.

CMS received many comments from interested parties related to dermatologists performing Mohs micrographic surgery following the effective date of the 2023 CLIA final rule. The commenters noted that dermatologists' specialized training should qualify them to serve as laboratory directors to perform Mohs procedures. This feedback was particularly compelling given the existing shortage of Mohs physicians, especially in rural areas where access to specialized dermatologic care is already limited.²⁰ CMS reviewed provider data and determined that approximately 20 percent of all CoC laboratories are in dermatology offices. In response to these concerns, CMS and the CDC recognized that a targeted approach would likely better serve both the regulatory goals and the practical needs of healthcare delivery in underserved communities.

CMS and the CDC propose adding new regulations for laboratory directors in dermatology office locations performing Mohs micrographic surgery. The proposed regulations for these dermatologists would allow them to qualify as high complexity laboratory directors through dermatology board certification instead of producing documentation from their residency and fellowship to establish experience requirements. We propose to add regulations at § 493.1443(b)(6), (b)(6)(i), (b)(6)(ii), (b)(6)(ii)(A), (b)(6)(ii)(B), and (b)(6)(ii)(C) for high complexity laboratory director qualifications for dermatopathology. The new regulatory requirements would allow individuals to qualify as a high complexity laboratory director for tests in dermatopathology if they meet one of the following requirements: 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 meet one of the following: be certified in anatomic pathology by the American Board of

Pathology or the American Osteopathic Board of Pathology; or be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or certified in dermatology by the American Board of Dermatology, American Osteopathic Board of Dermatology, or American Board of Physician Specialties. We propose to establish regulations for Mohs surgeons that recognize their specialized certification pathway. By recognizing board certification in Dermatology for high complexity laboratory director qualifications for Mohs surgeons, the documentation requirements would be both simplified and standardized.

CMS and the CDC believe that these proposed changes would not affect the laboratory's test quality, accuracy, and reliability, as this change is consistent with the qualification requirements for technical supervisors for tests performed under dermatopathology.

2. Laboratory Director Responsibilities

CMS and the CDC also propose rescinding or revising several regulations that we believe increase the financial, time, and compliance burdens on laboratories without delivering measurable benefits with respect to patient safety and regulatory compliance, including competency for PPM testing personnel and laboratory director on-site visits.

a. PPM Laboratory Director Responsibilities (§ 493.1359)

Section 493.1359(c)(1) through (5) and (d) currently provides that PPM laboratory directors must 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. We propose to rescind the regulations at § 493.1359(c)(1) through (5) and (d), which outline the laboratory director's responsibility to evaluate the competency of all testing personnel and the procedures for doing so as well as the laboratory director's responsibility to evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens and annually thereafter. We propose to rescind these provisions because PPM procedures are performed by a healthcare provider during a patient visit in the context of a physical examination, and because all testing personnel in laboratories with a PPM certificate qualify as PPM laboratory directors. PPM tests are labile and easily deteriorate; any delay in

¹⁹ American Academy of Dermatology (AAD), <https://www.aad.org/public/diseases/skin-cancer/types/common/melanoma/mohs-surgery>.

²⁰ NIH National Library of Medicine, <https://www.ncbi.nlm.nih.gov/books/NBK606085/#>.

performing the test could compromise the test result's accuracy.²¹ Therefore, PPM tests are conducted by healthcare providers during patient visits, but directly observing these tests to assess competency can disrupt patient care. This situation could create tension between meeting regulatory requirements and providing the best possible treatment environment for patients. In addition, the current standards do not reflect the practical challenges of today's healthcare system, especially in rural areas where resources may already be very limited. In rural physician offices, for example, there may be only one practitioner scheduled at a time, leaving no capacity to step away from patient care to complete paperwork relating to competency requirements. The resulting documentation burden may divert time away from patients who may have to travel significant distances and have few alternative care options. CMS and the CDC believe that these proposed changes would not affect the laboratory's test quality, accuracy, and reliability, as applicable regulations in subpart K would remain unchanged under this proposal.

b. Moderate Complexity Laboratory Director Responsibilities (§ 493.1407)

Section 493.1407(c) currently requires the laboratory director to be on-site 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 provide documentation of these visits, including evidence of performing activities that are part of the laboratory director's responsibilities. We propose to revise § 493.1407(c) to state that laboratory directors must be accessible to the laboratory as needed, which would revert the regulation to the language in place prior to the 2023 CLIA final rule. We also propose to rescind § 493.1407(c)(1) and (2). This revision would address interested parties' concerns that the on-site requirement for laboratory directors, at least once every 6 months, with a minimum of 4 months between the two on-site visits, is burdensome.

Following the implementation of the 2023 CLIA final rule, laboratory director citations remain among the top ten condition-level deficiencies cited by laboratory surveyors, despite laboratory

directors being required to be onsite at the laboratory at least every 6 months. Based on this data, we believe the burden of on-site visits does not outweigh the perceived benefits outlined in the 2023 CLIA final rule.

c. High Complexity Laboratory Director Responsibilities (§ 493.1445)

Section 493.1445(c) currently requires the high complexity laboratory director to be on-site 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 provide documentation of these visits, including evidence of performing activities that are part of the laboratory director's responsibilities. We propose to revise § 493.1445(c) to state that the laboratory director must be accessible to the laboratory as needed. We also propose to rescind § 493.1445 (c)(1) and (2). These proposed revisions and rescissions would address interested parties' concerns that the on-site requirement for laboratory directors is burdensome.

Following the implementation of the 2023 CLIA final rule, laboratory director citations remain among the top ten condition-level deficiencies cited by laboratory surveyors, despite laboratory directors being required to be onsite at the laboratory at least every 6 months. Based on this data, we believe the burden of on-site visits does not outweigh the perceived benefits outlined in the 2023 CLIA final rule.

3. Personnel Qualifications, General

Thirty years ago, a clinical laboratory science degree provided the foundational knowledge and skills necessary for most clinical laboratory work, as testing procedures were more standardized, and the scope of available tests was relatively limited. However, the modern clinical laboratory has undergone a remarkable expansion in its test menu and technological sophistication, fundamentally changing the educational requirements for laboratory professionals.

Today's clinical laboratories offer an increasingly diverse array of specialized testing services that demand expertise far beyond traditional clinical laboratory training. The emergence of molecular diagnostics has revolutionized how laboratories detect genetic disorders, infectious diseases, and cancer markers, requiring professionals with deep knowledge of deoxyribonucleic acid (DNA) sequencing, polymerase chain

reaction (PCR) techniques, and bioinformatics. This type of testing requires professionals with specialized training in complex data interpretation that extends well beyond the scope of traditional clinical laboratory education. Current CLIA personnel regulations may not allow individuals with this specialized training to qualify.

CLIA laboratories encompass a diverse range of facilities with varying staffing models. While some laboratories operate with traditional laboratory medicine professionals (clinical laboratory scientists, medical technologists, pathologists, etc.), others employ individuals from different backgrounds (nonclinical scientists, physicians, public health professionals, etc.). We believe the ongoing workforce shortage in laboratory medicine would benefit significantly from allowing more flexible staffing and operational approaches. Individual facilities and accreditation organizations may choose to maintain more stringent personnel requirements based on their specific operational needs. The CLIA program oversees approximately 300,000 laboratories²² throughout the United States, each presenting unique testing capabilities, hiring challenges, and required skill sets. Given this vast and diverse landscape of laboratory operations, CMS and the CDC must consider the comprehensive scope of all laboratories when establishing personnel requirements that are both practical and effective across the entire regulated community.

CMS reviewed interested parties' feedback suggesting that the regulations and definitions for experience, qualifications, doctoral degrees, and thesis requirements adopted in the 2023 CLIA final rule were restrictive. Multiple interested parties have urged CMS to expand and standardize the current interpretations of biological, chemical, and clinical and medical laboratory science degrees. They stated that most clinical laboratory research is conducted using animal models rather than human subjects, making the experience requirements restrictive and potentially exacerbating existing workforce shortages in the field. Additionally, interested parties argued that the doctoral degree definition codified in the 2023 CLIA final rule lacked necessary flexibility to accommodate nontraditional but relevant educational backgrounds, such as veterinary degrees. CMS and the CDC believe that interested parties raised compelling concerns about the practical

²¹ Provider Performed Microscopy Procedures: A Focus on Quality Practices; Provider Performed Microscopy Procedures—508c—April 2026.

²² Data from Quality, Certification and Oversight Reports (QCOR) as of August 4, 2025.

implications of the new definitions and personnel requirements in the 2023 CLIA final rule.

CMS has also received comments from reproductive medicine laboratory professionals regarding the need to formally recognize the specialized qualifications of professionals with animal science backgrounds in the context of reproductive laboratory testing. Commenters representing the reproductive medicine community have articulated that individuals credentialed in animal science may possess distinct expertise and advanced technical proficiencies that may be directly applicable to critical reproductive testing procedures, including those integral to in vitro fertilization (IVF) treatments. These professionals have often demonstrated established competency in managing complex biological processes and performing laboratory techniques that are foundational to the safe and effective delivery of reproductive medicine services.

Several commenters have expressed concern that the current CLIA regulatory framework, in certain circumstances, requires facilities to engage additional specialized personnel to perform basic laboratory procedures, even when such procedures fall within the demonstrated scope of practice and documented competency of the animal science professionals already employed at those facilities. CMS and the CDC acknowledge that for patients and families pursuing IVF and other assisted reproductive technologies, any operational or staffing barriers that affect the availability or continuity of care may carry significant personal and clinical implications.

We have also heard from numerous histology professional associations that histotechnician/histotechnologist/pathologist assistant (HT/HTL/PA) professionals may not currently qualify as high complexity testing personnel under § 493.1489 despite having specialized training in gross tissue examination and histotechnology procedures. This is primarily because HT/HTL/PA degrees have not historically been recognized under the CLIA regulations as laboratory science degrees, even though these professionals possess specialized laboratory science training specifically focused on histopathology techniques. This creates a scenario in which qualified professionals with specialized histopathology training may be prevented from performing certain tasks due to their degree classification rather than actual competency in the field.

Interested parties from the veterinary and research communities are supportive of expanding the previous interpretation of the definition of experience and training in laboratory science to allow for additional qualified laboratory personnel. Section 353(f)(1)(C) and (2) of the PHS Act gives the Secretary the authority to recognize qualifications of nonhuman laboratory science, as appropriate, for laboratory personnel. CMS and the CDC believe it is appropriate to expand the definitions and language that limit background, education, experience, and training to human-only laboratory science to expand the qualified workforce and reduce the burden, particularly in rural areas, to find qualified laboratory personnel.

After considering the input from interested parties and based on experiences during the SARS-CoV-2 PHE and current workforce shortages, CMS and the CDC propose revising certain definitions and language in the CLIA regulations that limit background, education, experience, and training to human-only laboratory science. During the SARS-CoV-2 PHE, individuals who possessed nontraditional science degrees and laboratory backgrounds played a key role in conducting SARS-CoV-2 testing. This significantly expanded access to testing, particularly in rural areas where traditional medical laboratories could not manage the substantial increase in test volume. A review of our survey data from this period indicates that these facilities performed SARS-CoV-2 tests accurately, with no notable issues. Before the 2023 CLIA final rule, laboratories had broadly interpreted qualification requirements. CMS previously considered a veterinary medicine degree an acceptable doctoral degree for high complexity laboratory director qualifications.²³ In a Government Accountability Office (GAO) study²⁴ released in 2025, one expert noted that during the SARS-CoV-2 PHE, there was confusion regarding the amount of professional training and education required for deployment of tests outside of the clinical laboratory setting.

Even with the contributions from individuals with nontraditional backgrounds assisting with testing efforts, the laboratory professional

vacancy rates remained high throughout the SARS-CoV-2 PHE. A survey published in the March 2023 American Journal of Clinical Pathology (AJCP) found that the average overall vacancy rate for the traditional laboratory professionals in medical laboratories jumped from 8.35 percent in 2020 to 13.82 percent in 2022.²⁵ The individuals from nontraditional backgrounds who temporarily supported testing operations during the SARS-CoV-2 PHE have since returned to their regular roles. The most recent survey findings from the ASCP 2024 Vacancy Survey indicate that although vacancy rates have declined compared with 2022, they remain elevated relative to those observed before the SARS-CoV-2 PHE.²⁶ Results of the ASCP 2024 Vacancy Survey show an increase in overall vacancy rates for the traditional medical laboratory positions in the anatomic pathology, flow cytometry, histology, laboratory information systems, quality assurance/performance improvement, and point-of-care testing departments compared with 2022. Interested parties have expressed concern that the 2023 CLIA final rule may exacerbate workforce shortages and could present significant challenges should another PHE occur. Based on interested party feedback, our experience during the SARS-CoV-2 PHE, and the current workforce shortage, CMS and the CDC propose revising the personnel requirements as outlined below.

a. Biological, Chemical, Clinical or Medical Laboratory Science or Medical Technology Degrees (§ 493.2)

CMS and the CDC propose to introduce a definition for biological, chemical, clinical or medical laboratory science or medical technology degrees to standardize the qualification process and provide clarity to interested parties. CMS received feedback from various interested parties that the qualification regulations have been inconsistently applied, making it challenging for laboratories to ensure they employ staff who meet the requirements of CLIA and its implementing regulations. When determining which degrees should qualify as biological, chemical, clinical or medical laboratory science or medical technology degrees, CMS and the CDC explored several approaches before settling on this proposal.

CMS and the CDC evaluated allowing all science degrees but determined this would be too broad and subject to

²³ State Operation Manual, Appendix C, Rev. 166, Issued: February 03, 17, Effective: March 03, 17, Implementation: March 03, 17, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R166SOMA.pdf>.

²⁴ Government Accountability Office (GAO), <https://www.gao.gov/products/gao-25-106980>.

²⁵ AJCP, <https://academic.oup.com/ajcp/article/161/3/289/7344701?login=true>.

²⁶ AJCP, <https://doi.org/10.1093/ajcp/aqad101>.

varying interpretations, as the term “science” encompasses a wide range of disciplines. CMS and the CDC also considered limiting acceptable degrees to human and animal sciences but found this criterion similarly open to interpretation and potentially problematic. Limiting acceptable degrees to human and animal sciences may seem more specific, but it remains problematic because these fields encompass a broad and diverse range of disciplines. For example, “human sciences” can include psychology, sociology, nutrition, and public health, while “animal sciences” can cover veterinary medicine, zoology, and animal behavior, making it difficult to clearly define which degrees or programs would meet the criteria without ambiguity. Academic programs and degree titles also vary widely between institutions and regions, further complicating consistent interpretation and potentially leading to disputes over eligibility and difficulties in maintaining standardized qualifications. When used in qualification criteria without further specificity, this approach would fail to provide clear, measurable standards for surveyors to assess compliance, leave room for inconsistent interpretation across different surveyors and interested parties, and would not align with the need for objective, verifiable criteria in regulatory enforcement. Similarly, using course labels such as BIO (Biology) or CHEM (Chemistry) as qualification markers presents its own challenges, as the same course content may carry different prefixes depending on the institution or degree program; for example, a biochemistry course might be labeled differently for a nursing

student versus a general science student, potentially creating differences in how qualifications are evaluated for individuals with different educational backgrounds.

For the proposal, CMS and the CDC settled on a practical framework for defining qualifying degrees, with universal recognition, federal backing, and existing institutional reporting processes. We propose to use the 2020 version (most current version) of the U.S. Department of Education’s National Center for Education Statistics (NCES) Classification of Instructional Programs (CIP) categories to define biological, chemical, clinical or medical laboratory science or medical technology degrees. The CIP system was developed by the U.S. Department of Education to bring order to the thousands of similar academic programs that exist under different names and descriptions across institutions. Its primary purpose is to facilitate the organization, collection, and reporting of fields of study and program completions. As the accepted Federal government standard for instructional program classifications, Federal and State agencies, national associations, academic institutions, and employment counseling services widely use CIP codes to collect, report, and analyze educational program data. For example, the CIP is used to provide a standardized taxonomy for tracking student enrollment, and degree completion, ensuring consistent data analysis across colleges. Universities use CIP codes for mandatory federal reporting to the Integrated Postsecondary Education Data System (IPEDS).²⁷ The Department of Homeland Security (DHS) uses CIP codes to determine if a degree qualifies for the

24-month STEM Optional Practical Training (OPT) extension.²⁸ Every post-secondary institution that receives Federal student financial aid must use CIP codes when reporting program data to the government, making this system both comprehensive and mandatory across higher education.²⁹

Specifically, we propose to use category 26 (Biological and Biomedical Sciences) for biological degrees, category 40.05 (Chemistry) for chemical degrees, and category 51.10 (Clinical/Medical Laboratory Science/Allied Professions), with the exception of 51.1006, 51.1009, 51.1011, 51.1012, for clinical or medical laboratory science or medical technology degrees.³⁰ We are proposing to exclude categories 51.1006, 51.1009, 51.1011, and 51.1012 because they are considered allied health professions whose responsibilities and training do not involve clinical laboratory testing. After reviewing these classifications, CMS and the CDC also propose adding to the biological degree definition categories 01.0901, 01.0902, 01.0903, 01.80, and 01.81 within Agriculture, Agriculture Operations, and Related Sciences, which specifically cover General Animal Sciences, Agricultural Animal Breeding, Animal Health, Veterinary Medicine, and Veterinary Biomedical and Clinical Sciences. Based on feedback that CMS has received from interested parties, individuals who have completed these educational courses also possess laboratory training, practical experience, and have undertaken relevant health-related science coursework. We also propose adding category 51.0811 (Pathology/Pathologist Assistant) for the clinical or medical laboratory science or medical technology degrees.

TABLE 2—PROPOSED CATEGORIES FOR BIOLOGICAL, CHEMICAL, CLINICAL OR MEDICAL LABORATORY SCIENCE OR MEDICAL TECHNOLOGY DEGREES FROM THE CIP

Proposed category	Title
01.0901	Animal Sciences, General.
01.0902	Agricultural Animal Breeding.
01.0903	Animal Health.
01.80	Veterinary Medicine.
01.8001	Veterinary Medicine.
01.81	Veterinary Biomedical and Clinical Sciences.
01.8101	Veterinary Biomedical and Clinical Sciences.
01.8102	Comparative and Laboratory Animal Medicine.
01.8103	Large Animal/Food Animal and Equine Surgery and Medicine.
01.8104	Small/Companion Animal Surgery and Medicine.
01.8105	Veterinary Anatomy.
01.8106	Veterinary Infectious Diseases.
01.8107	Veterinary Microbiology and Immunobiology.

²⁷ National Standards for Educational Statistics, IPEDS, [https://nces.ed.gov/ipeds/about-ipeds#:~:text=Degrees%20and%20Certificates%20Conferred%20\(Completo...](https://nces.ed.gov/ipeds/about-ipeds#:~:text=Degrees%20and%20Certificates%20Conferred%20(Completo...)

²⁸ Eligible CIP Codes for the STEM OPT Extension, U.S. Department of Homeland Security,

<https://studyinthestates.dhs.gov/stem-opt-hub/additional-resources/eligible-cip-codes-for-the-stem-opt-extension>.

²⁹ National Standards for Educational Statistics, CIP, FAQs, <https://nces.ed.gov/ipeds/cipcode/FAQ.aspx?y=56#:~:text=11,ifap.ed.gov/>.

³⁰ U.S. Department of Education’s National Center for Education Statistics (NCES), <https://nces.ed.gov/ipeds/cipcode/Default.aspx?y=56>.

TABLE 2—PROPOSED CATEGORIES FOR BIOLOGICAL, CHEMICAL, CLINICAL OR MEDICAL LABORATORY SCIENCE OR MEDICAL TECHNOLOGY DEGREES FROM THE CIP—Continued

Proposed category	Title
01.8108	Veterinary Pathology and Pathobiology.
01.8109	Veterinary Physiology.
01.8110	Veterinary Preventive Medicine, Epidemiology, and Public Health.
01.8111	Veterinary Toxicology and Pharmacology.
01.8199	Veterinary Biomedical and Clinical Sciences, Other.
26.01	Biology, General.
26.0101	Biology/Biological Sciences, General.
26.0102	Biomedical Sciences, General.
26.02	Biochemistry, Biophysics and Molecular Biology.
26.0202	Biochemistry.
26.0203	Biophysics.
26.0204	Molecular Biology.
26.0205	Molecular Biochemistry.
26.0206	Molecular Biophysics.
26.0207	Structural Biology.
26.0208	Photobiology.
26.0209	Radiation Biology/Radiobiology.
26.0210	Biochemistry and Molecular Biology.
26.0299	Biochemistry, Biophysics and Molecular Biology, Other.
26.03	Botany/Plant Biology.
26.0301	Botany/Plant Biology.
26.0305	Plant Pathology/Phytopathology.
26.0307	Plant Physiology.
26.0308	Plant Molecular Biology.
26.0399	Botany/Plant Biology, Other.
26.04	Cell/Cellular Biology and Anatomical Sciences.
26.0401	Cell/Cellular Biology and Histology.
26.0403	Anatomy.
26.0404	Developmental Biology and Embryology.
26.0406	Cell/Cellular and Molecular Biology.
26.0407	Cell Biology and Anatomy.
26.0499	Cell/Cellular Biology and Anatomical Sciences, Other.
26.05	Microbiological Sciences and Immunology.
26.0502	Microbiology, General.
26.0503	Medical Microbiology and Bacteriology.
26.0504	Virology.
26.0505	Parasitology.
26.0506	Mycology.
26.0507	Immunology.
26.0508	Microbiology and Immunology.
26.0509	Infectious Disease and Global Health.
26.0599	Microbiological Sciences and Immunology, Other.
26.07	Zoology/Animal Biology.
26.0701	Zoology/Animal Biology.
26.0702	Entomology.
26.0707	Animal Physiology.
26.0708	Animal Behavior and Ethology.
26.0709	Wildlife Biology.
26.0799	Zoology/Animal Biology, Other.
26.08	Genetics.
26.0801	Genetics, General.
26.0802	Molecular Genetics.
26.0803	Microbial and Eukaryotic Genetics.
26.0804	Animal Genetics.
26.0805	Plant Genetics.
26.0806	Human/Medical Genetics.
26.0807	Genome Sciences/Genomics.
26.0899	Genetics, Other.
26.09	Physiology, Pathology and Related Sciences.
26.0901	Physiology, General.
26.0902	Molecular Physiology.
26.0903	Cell Physiology.
26.0904	Endocrinology.
26.0905	Reproductive Biology.
26.0907	Cardiovascular Science.
26.0908	Exercise Physiology and Kinesiology.
26.0909	Vision Science/Physiological Optics.
26.0910	Pathology/Experimental Pathology.
26.0911	Oncology and Cancer Biology.
26.0912	Aerospace Physiology and Medicine.
26.0913	Biomechanics.

TABLE 2—PROPOSED CATEGORIES FOR BIOLOGICAL, CHEMICAL, CLINICAL OR MEDICAL LABORATORY SCIENCE OR MEDICAL TECHNOLOGY DEGREES FROM THE CIP—Continued

Proposed category	Title
26.0999	Physiology, Pathology, and Related Sciences, Other.
26.10	Pharmacology and Toxicology.
26.1001	Pharmacology.
26.1002	Molecular Pharmacology.
26.1003	Neuropharmacology.
26.1004	Toxicology.
26.1005	Molecular Toxicology.
26.1006	Environmental Toxicology.
26.1007	Pharmacology and Toxicology.
26.1099	Pharmacology and Toxicology, Other.
26.11	Biomathematics, Bioinformatics, and Computational Biology.
26.1101	Biometry/Biometrics.
26.1102	Biostatistics.
26.1103	Bioinformatics.
26.1104	Computational Biology.
26.1199	Biomathematics, Bioinformatics, and Computational Biology, Other.
26.12	Biotechnology.
26.1201	Biotechnology.
26.13	Ecology, Evolution, Systematics, and Population Biology.
26.1301	Ecology.
26.1302	Marine Biology and Biological Oceanography.
26.1303	Evolutionary Biology.
26.1304	Aquatic Biology/Limnology.
26.1305	Environmental Biology.
26.1306	Population Biology.
26.1307	Conservation Biology.
26.1308	Systematic Biology/Biological Systematics.
26.1309	Epidemiology.
26.1310	Ecology and Evolutionary Biology.
26.1311	Epidemiology and Biostatistics.
26.1399	Ecology, Evolution, Systematics and Population Biology, Other.
26.14	Molecular Medicine.
26.1401	Molecular Medicine.
26.15	Neurobiology and Neurosciences.
26.1501	Neuroscience.
26.1502	Neuroanatomy.
26.1503	Neurobiology and Anatomy.
26.1504	Neurobiology and Behavior.
26.1599	Neurobiology and Neurosciences, Other.
26.99	Biological and Biomedical Sciences, Other.
26.9999	Biological and Biomedical Sciences, Other.
40.05	Chemistry.
40.0501	Chemistry, General.
40.0502	Analytical Chemistry.
40.0503	Inorganic Chemistry.
40.0504	Organic Chemistry.
40.0506	Physical Chemistry.
40.0507	Polymer Chemistry.
40.0508	Chemical Physics.
40.0509	Environmental Chemistry.
40.0510	Forensic Chemistry.
40.0511	Theoretical Chemistry.
40.0512	Cheminformatics/Chemistry Informatics.
40.0599	Chemistry, Other.
51.0811	Pathology/Pathologist Assistant.
51.1001	Blood Bank Technology Specialist.
51.1002	Cytotechnology/Cytotechnologist.
51.1003	Hematology Technology/Technician.
51.1004	Clinical/Medical Laboratory Technician.
51.1005	Clinical Laboratory Science/Medical Technology/Technologist.
51.1007	Histologic Technology/Histotechnologist
51.1008	Histologic Technician.
51.1010	Cytogenetics/Genetics/Clinical Genetics Technology/Technologist.

CMS regulates approximately 33,000 nonwaived laboratories³¹ across the United States, spanning an extraordinarily diverse range of testing environments from large hospital systems to highly specialized reproductive medicine labs, dermatopathology practices, histology labs, and research institutions. A one-size-fits-all definition of qualifying educational backgrounds fails to reflect the reality of what makes someone the best-qualified person for a specific laboratory setting. We propose these changes to remove barriers that would otherwise prevent laboratories from selecting the most qualified and suitable candidate for employment, thereby preserving each laboratory's discretion to make personnel decisions consistent with its operational requirements.

This CIP-based approach offers several advantages, including expanding the number of qualifying degrees to include candidates with science backgrounds while creating a standardized, objective list for evaluating biological, chemical, clinical or medical laboratory science and medical technology degrees for personnel qualifications. We propose to accept the CIP codes for the courses listed in Table 2, Proposed Categories for Biological, Chemical, Clinical or Medical Laboratory Science or Medical Technology Degrees for purposes of defining biological, chemical, clinical or medical laboratory science or medical technology degrees. If this proposal is finalized as proposed and there is a change to the CIP codes in the future, CMS would propose corresponding changes to these categories through notice-and-comment rulemaking.

(1) Biological Degree (§ 493.2)

We propose to revise § 493.2 to add the following definition of a biological degree: Biological degree means an academic program classified in the 2020 version of the U.S. Department of Education's NCES CIP under category 26 Biological and Biomedical Sciences, category 01.0901 General Animal Sciences, category 01.0902 Agricultural Animal Breeding, category 01.0903 Animal Health, category 01.80 Veterinary Medicine, and category 01.81 Veterinary Biomedical and Clinical Sciences.

(2) Chemical Degree (§ 493.2)

We propose to revise § 493.2 to add the following definition of a chemical degree: Chemical degree means an academic program classified under

category 40.05 Chemistry in the 2020 version of the U.S. Department of Education's NCES CIP.

(3) Clinical or Medical Laboratory Science or Medical Technology Degree (§ 493.2)

We propose to revise § 493.2 to add the following definition of a clinical or medical laboratory science or medical technology degree: Clinical or Medical Laboratory Science or Medical Technology degree means an academic program classified in the 2020 version of the U.S. Department of Education's NCES CIP under category 51.0811 Pathology/Pathologist Assistant, category 51.1001 Blood Bank Technology Specialist, category 51.1002 Cytotechnology/Cytotechnologist, category 51.1003 Hematology Technology/Technician, category 51.1004 Clinical/Medical Laboratory Technician, category 51.1005 Clinical Laboratory Science/Medical Technology/Technologist, category 51.1007 Histologic Technology/Histotechnologist, category 51.1008 Histologic Technician, and category 51.1010 Cytogenetics/Genetics/Clinical Genetics Technology/Technologist.

CMS and the CDC received feedback from laboratory professionals in histopathology that individuals with HT/HTL/PA degrees receive specialized training in histopathology laboratory science and should be recognized as qualifying laboratory science degrees. We believe that these proposed revisions to the personnel qualification requirements would not adversely affect the quality, accuracy or reliability of laboratory testing. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which will continue to ensure accurate and quality laboratory testing. We believe the proposed revisions to the CLIA regulations are not expected to compromise testing quality. It is important to note that personnel qualifications represent only one element of a broader quality assurance framework. No individual is permitted to perform testing without first completing the required training and demonstrating competency.

Beyond initial personnel qualifications, robust safeguards are in place to uphold testing accuracy on an ongoing basis. Each day, laboratories are required to conduct quality control measures to verify that the testing process is being performed correctly. Additionally, laboratories are required to participate in proficiency testing to

validate the accuracy of their results, a process that CMS actively monitors.

We do not believe these proposed regulatory changes, if finalized, would impact the accuracy and quality of testing given the safeguards already described. Laboratories would need to carefully review any flexibilities outlined in the proposed rule, if finalized, to determine what best fits their individual needs, as CMS and the CDC aim to provide maximum flexibility while expecting that each lab will hire qualified personnel to maintain the accuracy and quality of their specific testing. If CMS were to detect a decrease in quality and accuracy following implementation of the proposed changes, if finalized, as evidenced by its biennial surveys and PT performance monitoring, it would assess whether the regulations need to be revised further through future notice and comment rulemaking to address any identified deficiencies.

b. Doctoral Degree (§ 493.2)

Section 493.2 currently defines "doctoral degree" as 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, medical laboratory science, or medical technology. The current regulation also states that for purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatric medicine (DPM), doctors of veterinary medicine (DVM) degrees, or honorary degrees.

Interested party feedback has indicated that this definition of "doctoral degree" has been confusing and that it limits doctoral degrees to those that only include research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology. In addition, several interested parties had questions about what qualified as at least 3 years of graduate level study and what type of research was considered related to clinical laboratory testing. Prior to the 2023 CLIA final rule, the CLIA regulations did not include a definition of "doctoral degree." CMS had accepted doctoral degrees as defined by the relevant academic institution's doctoral program. Since the implementation of the 2023 CLIA final rule and codification of a definition of "doctoral degree", CMS has received more questions about what qualifies as a doctoral degree than had arisen under the previous practice. Therefore, CMS and the CDC propose to revise § 493.2

³¹ Data from Quality, Certification and Oversight Reports (QCOR) as of August 4, 2025.

to add the following definition of a doctoral degree: Doctoral degree means an earned doctoral degree as defined by the academic institution's doctoral program. This definition is being proposed to reduce ambiguity, address questions surrounding whether master's degree holders meet the criteria for doctoral level qualification and provide the greatest flexibility in its application.

CMS and the CDC believe that these proposed revisions to the personnel qualification requirements would not adversely affect the quality, accuracy or reliability of laboratory testing. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. We believe the proposed revisions to the CLIA regulations would not compromise testing quality. It is important to note that personnel qualifications represent only one element of a broader quality assurance framework. No individual is permitted to perform testing without first completing the required training and demonstrating competency.

Beyond initial personnel qualifications, robust safeguards are in place to uphold testing accuracy on an ongoing basis. Each day, laboratories are required to conduct quality control measures to verify that the testing process is being performed correctly. Additionally, laboratories are required to participate in proficiency testing to validate the accuracy of their results, a process that CMS actively monitors.

We do not believe these proposed regulatory changes, if finalized, would impact the accuracy and quality of testing given the safeguards already described. Laboratories would continue to have to carefully review any flexibilities outlined in the proposed rule, if finalized, to determine what best fits their individual needs, as CMS and the CDC aim to provide maximum flexibility while expecting that each lab will hire qualified personnel to maintain the accuracy and quality of their specific testing. If CMS were to detect a decrease in quality and accuracy following implementation of the proposed changes, if finalized, as evidenced by its biennial surveys and PT performance monitoring, it would assess whether the regulations need to be revised further through future notice and comment rulemaking to address any identified deficiencies.

c. Experience Directing or Supervising and Laboratory Training or Experience (§ 493.2)

Section 493.2 defines "laboratory training or experience" as training or experience obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted under § 493.3(b). We propose to revise § 493.2 to rescind the definition of "experience directing or supervising" and "laboratory training or experience." CMS added these definitions to the 2023 CLIA final rule in response to comments on the 2018 RFI (83 FR1004)³² and CLIAC recommendations³³ that laboratory training and experience should be clinical in nature. We propose this rescission because the 2023 CLIA final rule narrowed the definition of directing or supervising experience to apply only within CLIA-certified laboratories. Post implementation of the 2023 CLIA final rule, interested parties have argued that testing conducted in non-traditional settings may include the same instrumentation used in CLIA-certified laboratories. For example, during the SARS-CoV-2 PHE, both university and veterinary laboratories already had the molecular instrumentation to provide SARS-CoV-2 testing. Before the implementation of the 2023 CLIA final rule, the regulations did not specify a definition of "experience directing or supervising" allowing for flexibility during the SARS-CoV-2 PHE.

CMS and the CDC believe that these proposed revisions to the personnel qualification requirements would not adversely affect the quality, accuracy or reliability of laboratory testing. This proposed approach does not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing. We believe the proposed revisions to the CLIA regulations will not compromise testing quality. It is important to note that personnel qualifications represent only one element of a broader quality assurance framework. No individual is permitted to perform testing without first completing the required training and demonstrating competency.

Beyond initial personnel qualifications, robust safeguards are in place to uphold testing accuracy on an

ongoing basis. Each day, laboratories are required to conduct quality control measures to verify that the testing process is being performed correctly. Additionally, laboratories are required to participate in proficiency testing to validate the accuracy of their results, a process that CMS actively monitors.

We do not believe these proposed regulatory changes, if finalized, would impact accuracy and quality of testing given the safeguards already described. Laboratories would need to carefully review any flexibilities outlined in the proposed rule, if finalized, to determine what best fits their individual needs, as CMS and the CDC aim to provide maximum flexibility while expecting that each lab will hire qualified personnel to maintain the accuracy and quality of their specific testing. If CMS were to detect a decrease in quality and accuracy following implementation of the proposed changes, if finalized, as evidenced by its biennial surveys and PT performance monitoring, it would assess whether the regulations need to be revised further through future notice and comment rulemaking to address any identified deficiencies.

d. Gross Tissue Examination (§§ 493.1489(b)(7) and 493.1273(c))

CMS and the CDC propose to codify in regulations at § 493.1489(b)(7) guidance that was previously provided in the State Operations Manual (SOM) Appendix C³⁴ as interpretive guidance for § 493.1273(c) explaining that histopathology technical supervisors may delegate certain responsibilities to individuals who qualify as high complexity testing personnel under § 493.1489, including physical examination and description of tissue samples (documenting color, weight, measurements, and other characteristics) and mechanical procedures with specific written protocols. Testing in histopathology includes both gross tissue examination (macroscopic) and the microscopic evaluation of the stained slide(s). Gross tissue examination means the manipulation, orientation, and selection of the desired representative pieces of excised tissue from the total specimen received. This includes the physical examination and description, color, weight, measurements, and other characteristics of the tissue. Selected portions of the tissue are placed into a tissue cassette, subjected to a fixative, processed and infiltrated with paraffin wax, placed onto a slide(s), and stained before being reviewed and evaluated by

³² 83 FR1004; <https://www.federalregister.gov/documents/2018/01/09/2017-27887/request-for-information-revisions-to-personnel-regulations-proficiency-testing-referral>.

³³ CDC CLIAC Meetings website; <https://www.cdc.gov/cliac/php/meetings/index.html>.

³⁴ State Operations Manual Appendix C; <https://www.cms.gov/files/document/som-appendix.pdf>.

a technical supervisor. Gross tissue examination is a critical part of the tissue analysis process to ensure subsequent pathology tests are accurate and reliable.

Section 493.1489(b)(7) currently requires individuals who perform tissue examinations for histopathology to meet the qualifications at § 493.1449(b) or (f). We propose to add a regulation at § 493.1489(b)(7)(ii) that would allow gross tissue examination to be performed by individuals who meet the qualifications at § 493.1489(b)(1) through (5). This proposal would codify interpretive guidance, which is currently found in SOM Appendix C, into formal regulation. Microscopic tissue examinations would still need to be performed by individuals who meet the qualifications at § 493.1449(b) or (f).

We propose to revise § 493.1273(c) to require that gross tissue examination results must be reviewed by the technical supervisor before the final test report is issued. Based on feedback from laboratory professionals in histopathology, we propose to codify this interpretive guidance, which is currently found in SOM Appendix C, into formal regulation. This requirement is currently included in the SOM Appendix C interpretive guidance for §§ 493.1489(b)(7) and 493.1461(e), which states that gross tissue examinations may be performed by individuals qualified under § 493.1489 as delegated by the technical supervisor. The current guidance states that it should be reviewed within 24 hours by the technical supervisor. We propose extending the review timeframe from 24 hours to requiring the review to be completed prior to the finalization of the patient report, to allow more flexibility for laboratories. The existing 24-hour window was established in the guidelines primarily to safeguard specimen stability and to ensure that any additional testing deemed necessary would not be delayed. However, CMS recognizes that this timeframe may not be practical or achievable across all laboratory settings, and the proposed change is intended to accommodate the varying operational realities that different laboratories face.

The gross tissue examination evaluates the physical characteristics of tissue specimens, including tumor size, shape, and location, which provides context for interpreting the cellular abnormalities later observed under microscopic examination. This correlation between gross tissue examination and microscopic findings is fundamental to producing comprehensive and accurate pathology reports, as any discrepancies between

these two levels of analysis can signal potential errors in specimen processing or microscopic evaluation that must be resolved to ensure diagnostic accuracy. The gross tissue examination, when combined with detailed microscopic findings, directly informs critical treatment decisions, including the need for surgical interventions, chemotherapy protocols, or radiation therapy approaches. When individuals other than the pathologist perform the gross tissue examination, the pathologist reviews the gross tissue examination in conjunction with the microscopic findings. CMS and the CDC believe that these proposed revisions to personnel requirements would not adversely affect the quality, accuracy or reliability of laboratory testing as the technical supervisor is still responsible for reviewing the gross tissue examination. This proposed approach would not change CLIA regulatory requirements related to personnel training, annual competency assessment, quality systems, PT, and biennial on-site surveys, which continue to ensure accurate and quality laboratory testing.

4. Other Proposed Personnel Qualification Requirement Changes

a. Moderate Complexity Technical Consultant (§ 493.1411)

Section 493.1411(b)(6)(i) currently allows individuals to qualify as a technical consultant for blood gas analysis if they meet the qualifications at § 493.1411(b)(1), (2), (3), or (4). We propose to revise § 493.1411(b)(6)(i) to include a cross-reference to § 493.1411(b)(5) as well. This would allow individuals with applicable associate degrees to qualify as technical consultants for blood gas analysis. The proposed amendment would address an inadvertent omission of this cross-reference, which was identified subsequent to the implementation of the 2023 CLIA final rule.

b. Moderate Complexity Clinical Consultant (§ 493.1417)

CMS received interested parties' inquiries after the implementation of the 2023 CLIA final rule, requesting clarification on whether clinical consultants who qualified prior to the final rule's effective date of December 28, 2024, continued to qualify. The 2023 CLIA final rule did not include a provision that would permit individuals who previously met the qualifications for the clinical consultant under prior standards to continue to be recognized as qualified under this rule. We propose to add this provision at § 493.1417(c) for clinical consultant moderate complexity

qualifications to address this inadvertent omission in the 2023 CLIA final rule. The proposed provision for clinical consultants would be consistent with the standards applicable to all other personnel positions, namely laboratory director (§ 493.1405(b)(6)), technical consultant (§ 493.1411(b)(7)), and testing personnel (§ 493.1423(b)(8)). In addition, we propose to replace the period at the end of § 493.1417(b) with “; or” to accommodate the proposed addition of § 493.1417(c).

c. Moderate Complexity Testing Personnel (§ 493.1423)

Section 493.1423(b)(7)(ii) currently allows individuals to qualify as moderate complexity testing personnel for blood gas analysis if they have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution and have at least 1 year of laboratory training or experience, or both, in blood gas analysis. Section 493.1423(b)(7)(iii) currently allows individuals to qualify as moderate complexity testing personnel for blood gas analysis if they have earned an associate degree related to pulmonary function from an accredited institution and have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

We propose to redesignate § 493.1423(b)(7)(ii)(A) as § 493.1423(b)(7)(ii) and § 493.1423(b)(7)(iii)(A) as § 493.1423(b)(7)(iii), and revise newly redesignated § 493.1423(b)(7)(ii) and (b)(7)(iii) to replace the word “and” with “or.” We also propose to rescind § 493.1423(b)(7)(ii)(B) and (b)(7)(iii)(B) for moderate complexity testing personnel to be consistent with the requirement for high complexity testing personnel for blood gas analysis, which does not contain an experience requirement. These proposed changes are intended to address an inadvertent error discovered following the implementation of the 2023 CLIA final rule. We believe this error resulted from duplicating the regulation for high complexity blood gas testing personnel at § 493.1489. We believe that less complex testing does not require greater experience requirements in the CLIA regulations.

d. High Complexity Technical Supervisor Qualifications (§ 493.1449)

Section 493.1449(c)(4)(i)(C)(2) currently requires individuals qualifying as a high complexity technical supervisor with a bachelor's degree of equivalency to have at least 16 semester hours in a combination of

graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science and an approved 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. CMS received feedback from interested parties stating that this regulation was confusing and could be interpreted as providing that only thesis and research projects on human subjects were acceptable. Interested parties further pointed out that most doctoral research conducted for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings is initially performed on animal models before it is considered or used in clinical trials with patients. We propose to revise § 493.1449(c)(4)(i)(C)(2) to state that the individual must have at least 16 semester hours in a combination of graduate level coursework and an approved thesis or research project in biology, chemistry, medical technology, or clinical or medical laboratory science.

Section 493.1449(f)(2)(i)(B)(3) currently requires individuals functioning as technical supervisors in the subspecialty of histopathology to be certified in dermatology by the American Board of Dermatology for tests in dermatopathology. We propose to revise § 493.1449(f)(2)(i)(B)(3) to add the American Osteopathic Board of Dermatology, or American Board of Physician Specialties. We propose this revision to codify recognition of the American Osteopathic Board of Dermatology³⁵ and the American Board of Physician Specialties³⁶ for qualification in the regulations rather than in State Operations Manual Appendix C and Admin Info: 26–01–CLIA.

In addition, we propose to redesignate the current § 493.1273(c), which states that individuals who successfully complete a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology, to be included in the high complexity technical supervisor qualifications section. When this regulation was introduced in the 2003 CLIA final rule (68 FR 3640), it was included in subpart

K, Quality System, as part of the updates to quality systems requirements. We intended for these individuals to qualify as technical supervisors; however, a change was made to § 493.1273 rather than subpart M, Personnel for Nonwaived Testing, as outlined in the 2003 CLIA final rule.³⁷ In addition, this revision was inadvertently omitted in the 2023 CLIA final rule, as subpart K was not included. We propose to redesignate § 493.1273(c) from subpart K, to § 493.1449(f)(4) in subpart M. In addition, we propose to revise the regulation to require that individuals must 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 have successfully completed an American Academy of Neurology Committee for Neuromuscular Pathology Training Program or the United Council for Neurologic Subspecialties training program. An individual qualified under § 493.1449 paragraph (b) or (f)(4)(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)(4)(i)(B) of this section, the responsibility for examination and interpretation of neuromuscular pathology specimens.

Section 493.1449(i)(2)(ii) currently requires individuals qualifying as a high complexity technical supervisor in clinical cytogenetics with a doctoral degree to have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. We propose to revise § 493.1449(i)(2)(ii) to add the word “or” at the end of the regulation for consistency with the high complexity technical supervisor qualification requirements at § 493.1449(i).

e. High Complexity Clinical Consultant (§ 493.1455)

Section 493.1455(a) currently requires clinical consultants to be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3) or, for the subspecialty of oral pathology, § 493.1443(b)(5). We propose to revise § 493.1455(a) to add cross-references to the high complexity laboratory director qualifications at § 493.1443(b)(4) and (b)(6) and add the word “or” at the end of the regulation that was inadvertently omitted in the 2023 CLIA final rule. This change would allow individuals who qualify as high complexity laboratory directors under

§ 493.1443(b)(4) and under the proposed new regulation for dermatopathology at § 493.1443(b)(6) to serve as a high complexity clinical consultant. This change would align with the proposed addition of dermatopathology under the high complexity laboratory director qualification requirements.

The 2023 CLIA final rule did not include a provision that would permit individuals who previously met the qualifications for the clinical consultant under prior standards to continue to be recognized as qualified under this rule. We propose to add this provision at § 493.1455(c) for clinical consultant high complexity qualifications, which was inadvertently omitted in the 2023 CLIA final rule. CMS received interested parties’ inquiries after the implementation of the 2023 CLIA final rule requesting clarification on whether clinical consultants who qualified prior to the final rule’s effective date of December 28, 2024, continued to qualify. The proposed regulation would also be consistent with the provisions applicable to all other personnel positions, *i.e.*, laboratory director (§ 493.1443(b)(4)), technical supervisor (§ 493.1449(j)), general supervisor (§ 493.1461(c)(4)), and testing personnel (§ 493.1489(b)(5)). In addition, we propose to replace the period at the end of § 493.1455(b) with “; or” to accommodate the proposed addition of § 493.1455(c).

f. High Complexity General Supervisor (§ 493.1461)

Section 493.1461(c)(3) through (4) currently permits individuals to qualify as high complexity general supervisors if they satisfy the requirements at §§ 493.1443(b)(3), 493.1449(c)(4) or (5), or 493.1461(c)(4). We propose to rescind § 493.1461(c)(3) as this requirement is duplicative of those under § 493.1461(b)(1) and (2). We also propose to redesignate § 493.1461(c)(4) as § 493.1461(c)(3) in light of the proposed rescission of current § 493.1461(c)(3). Section 493.1461(e) currently states that the general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology, because all tests and examinations must be performed by an individual who qualifies as the technical supervisor under the relevant subspecialty. We propose to revise the regulation to state that an individual providing general supervision in histopathology, oral pathology, dermatopathology, and ophthalmic pathology must be qualified as a technical supervisor since we are proposing to allow grossing to be

³⁵ State Operations Manual-Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf.

³⁶ Admin Info: 26–01–CLIA, <https://www.cms.gov/files/document/admin-info-26-01-clia.pdf>.

³⁷ 68 FR 3641; <https://www.govinfo.gov/content/pkg/FR-2003-01-24/pdf/FR-2003-01-24.pdf>.

performed by high complexity laboratory testing personnel. This proposed regulation would align with the proposed addition at § 493.1489(b)(7), which would allow high complexity laboratory testing personnel to perform the gross tissue examination which is a test under histopathology. Gross tissue examination includes the physical examination/description, including color, weight, measurement and other characteristics of the tissue, or other mechanical procedures. These individuals would not qualify as a general supervisor even though they are performing tests and examinations in histopathology.

g. High Complexity General Supervisor Responsibilities (§ 493.1463)

Sections 493.1463(a)(3) and (c) currently provide for additional supervision by the general supervisor for testing personnel who qualify under § 493.1489(b)(5). We propose to rescind both § 493.1463(a)(3) and (c). The 2023 CLIA final rule removed qualifications requiring additional supervision but inadvertently failed to rescind these two particular requirements. The 2023 CLIA final rule removed the qualifications for high school degree high complexity testing personnel. On-site supervision or 24-hour review by the general supervisor is no longer necessary, as there is no longer a qualification provision for individuals with high school degrees for high complexity testing. Section 493.1463(b)(4) currently allows the director or technical supervisor to delegate to the general supervisor the responsibility of evaluating and documenting the competency of all testing personnel. We propose to revise § 493.1463(b)(4) to include “both moderate and high complexity” testing personnel since high complexity laboratories may perform both moderate and high complexity testing.

h. High Complexity Testing Personnel Qualifications (§ 493.1489)

Section 493.1489(b)(2)(i) currently allows an individual qualifying as high complexity testing personnel to have an earned doctoral, master’s, or bachelor’s degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution. We propose to revise § 493.1489(b)(2)(i) to add the word “or” at the end of the paragraph to clarify that individuals may qualify as high complexity testing personnel under § 493.1443(b)(2)(i) or under the proposed revised regulation at § 493.1443(b)(2)(ii).

Section 493.1489(b)(2)(ii) currently requires individuals qualifying for high complexity testing personnel without a doctoral, master’s, or bachelor’s degree in biology/chemistry/MT/CLS/MLS to be qualified under the requirements of §§ 493.1443(b)(3) or 493.1449(c)(4) or (5). We propose to revise § 493.1489(b)(2)(ii) to include cross-references to §§ 493.1443(b)(3)(i)(A), 493.1443(b)(3)(i)(B)(1) or (2), 493.1449(c)(4)(i)(A), 493.1449(c)(4)(i)(B)(1) and (2), 493.1449(c)(4)(i)(C)(1) and (2), 493.1449(c)(5)(i)(A), or 493.1449(c)(5)(i)(B)(1) or (2)(i) through (iii). The newly proposed cross-references include alternative ways in which individuals could qualify as high complexity testing personnel via education only. The experience/training requirements would not apply to this regulation, and individuals would not need to meet the experience/training requirements in the regulations cited to qualify as high complexity testing personnel.

Section 493.1489(b)(3)(i) currently allows an individual to qualify as high complexity testing personnel by possessing an associate degree in laboratory science or medical laboratory technology from an accredited institution. CMS and the CDC are proposing to revise § 493.1489(b)(3)(i) to codify longstanding interpretive guidance. Specifically, we propose to codify in regulatory text that, for purposes of § 493.1489(b)(3)(i), an individual may qualify as high complexity testing personnel by possessing an associate degree in chemical, biological, clinical or laboratory science, or medical technology from an accredited institution.

This proposed codification reflects guidance previously issued in the 2017 SOM Appendix C. We believe codifying this interpretation in regulation would promote clarity, consistency, and transparency for laboratories, accreditation organizations, and other interested parties by ensuring that this qualification standard is expressly stated in the applicable regulatory text.

Section 493.1489(b)(3)(ii) currently requires individuals without an associate degree in laboratory science or medical laboratory technology to have education and training equivalent to that specified in paragraph (b)(2)(i) of this section. We propose to revise § 493.1489(b)(3)(ii) to include the correct cross-reference to

§ 493.1489(b)(3)(i). The cross-reference was incorrectly stated in the 2023 CLIA final rule. Section 493.1489(b)(2)(i) allows qualification with a doctoral,

master’s, or bachelor’s degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution. Section 493.1489(b)(3)(i) allows qualification via an associate’s degree in a laboratory science or medical laboratory technology from an accredited institution. Section 493.1489(b)(3)(ii) outlines an equivalent pathway to an associate’s degree, not a doctoral, master’s or bachelor’s degree.

Section 493.1495(b)(7) and (c) currently require individuals performing high complexity testing qualified under § 493.1489(b)(5) to have on-site, direct supervision or review of testing within 24 hours by the general supervisor. We propose to rescind both § 493.1495(b)(7) and (c). These regulations are now obsolete, as the 2023 CLIA final rule removed qualification pathways for individuals with high school diplomas to perform high complexity testing. With the removal of § 493.1495(b)(7) and (c), we propose to revise § 493.1495(b)(5) by adding the word “and” after the semicolon. In addition, we propose to revise § 493.1495(b)(6) by removing the semicolon and the word “and”, and replacing both with a period.

We solicit comments on these proposals related to personnel qualification requirements.

D. Other Changes

The other proposed changes in this proposed rule fall into the following categories: changes to SARS-CoV-2 reporting requirements, certificate requirements, test report requirements, enforcement requirements, public consultation requirements, and editorial and technical changes.

1. SARS-CoV-2 Reporting Requirements (§§ 493.2, 493.41, 493.555(c)(6), 493.1100(a), 493.1100(b), and 493.1834(d)(2)(iii))

Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act required that “Every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary’s Public Health Emergency declaration with respect to COVID-19 or any extension of such declaration.”³⁸

³⁸ 85 FR 54820, <https://www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient>.

Pursuant to section 18115 of the CARES Act, CMS codified reporting requirements related to SARS-CoV-2 test results at §§ 493.2, 493.41, 493.555(c)(6), 493.1100(a), 493.1100(b), and 493.1834(d)(2)(iii).³⁹ Per section 18115 of the CARES Act, CMS only had the authority to require reporting of SARS-CoV-2 test results until the end of the Federal Public Health Emergency (PHE) declaration. As a result, these regulatory reporting requirements expired with the termination of the SARS-CoV-2 PHE on May 11, 2023.⁴⁰

Consequently, we propose to rescind the CLIA regulations at §§ 493.41, 493.555(c)(6), 493.1100(a), 493.1100(b), and 493.1834(d)(2)(iii) regarding SARS-CoV-2 reporting requirements and revise the regulation at § 493.2, to reflect these proposed rescissions as detailed below.

Section 493.2 currently defines “Condition level requirements” as any of the requirements identified as “conditions” in § 493.41 and subparts G through Q of this part. We propose to revise § 493.2 to remove the reference to § 493.41 from the definition of “Condition level requirements,” as we propose to rescind § 493.41 on the reporting of SARS-CoV-2 test results in its entirety.

Section 493.41 currently states that during the Public Health Emergency, as defined in § 400.200 of chapter IV of Title 42 of the CFR, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We propose to rescind § 493.41 in its entirety.

Section 493.555(c)(6) currently requires an accreditation organization or state licensure program to notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a). We propose to rescind § 493.555(c)(6), as §§ 493.41 and 493.1100(a) are in reference to the reporting of SARS-CoV-2 test results, and we are proposing to rescind these regulations.

Section 493.1100(a) and (b) requires that during the Public Health Emergency, as defined in § 400.200 of chapter IV of Title 42 of the CFR, each laboratory that performs a test that is

intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We propose to rescind § 493.1100(a) regarding the reporting of SARS-CoV-2 test results. We also propose to rescind § 493.1100(b) as “reserved” as we propose to rescind § 493.1100(a).

Section 493.1834(d)(2)(iii) currently provides that for a condition level deficiency under §§ 493.41 or 493.1100(a), the civil money penalty amount is \$1,000 for the first day of noncompliance and \$500 for each additional day of noncompliance. We propose to rescind § 493.1834(d)(2)(iii) since §§ 493.41 and 493.1100(a) are in reference to the reporting of SARS-CoV-2 test results and we are proposing to rescind these regulations.

We solicit comments on these proposals related to SARS-CoV-2 reporting requirements.

2. Certificate Requirements
(§§ 493.35(b)(3), 493.39(b), 493.43(b)(3), 493.45(b)(2), 493.51(a), 493.53(b), 493.55(b)(3), 493.57(a)(2), and 493.63(a))

We propose to revise the CLIA regulations at §§ 493.35(b)(3), 493.43(b)(3), and 493.55(b)(3) to clarify the multiple-site exception and propose to include all types of laboratories instead of hospital laboratories only.

Sections 493.35(b)(3), 493.43(b)(3), and 493.55(b)(3) currently provide, for all certificate types, that laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address. We propose to revise §§ 493.35(b)(3), 493.43(b)(3), and 493.55(b)(3) to clarify the multiple site exception option regarding “contiguous building” and “common direction” by removing the language “within a hospital”, “at contiguous building”, “common direction”, and “for the laboratory sites within the same physical location or street address”, and instead stating that laboratories that are located on the same campus and under the same laboratory director may file a single application or multiple applications. We have received many inquiries regarding the guidance in the SOM Appendix C regarding the multiple-site exception and the meaning of “contiguous,” and we propose these amendments for greater clarity.

In addition, we propose to define “campus” at § 493.2 as the physical area immediately adjacent to the laboratory’s main building, other areas and structures that are not strictly contiguous to the main building, but are located within 250 yards of the main building, and any other area CMS determines on an individual case basis, to be part of the campus of the primary CLIA-certified laboratory. This proposed definition would be consistent with the current provider-based status definition of “campus” at 42 CFR 413.65(a)(2).

The regulations at §§ 493.39(b), 493.45(b)(2), 493.51(a), 493.53(b), 493.57(a)(2), and 493.63(a) contain the notification requirements for each type of CLIA certificate. These regulations currently require laboratories to notify HHS or its designee within 30 days of any change in ownership, name, location, or laboratory director. Additionally, for high complexity laboratories with a CoR or CoC certificate, the relevant regulations require notification of changes in technical supervisors (§§ 493.45(b)(2), 493.51(a)(5)).

Laboratories provide their demographic and contact information on the CMS Form 116 when they apply for CLIA certification. Laboratories currently have no regulatory obligation to notify HHS or its designee of email address changes. We propose revisions to the CLIA regulations at §§ 493.39(b), 493.45(b)(2), 493.51(a), 493.53(b), 493.57(a)(2), and 493.63(a) that would require laboratories to notify HHS or its designee if their email address has changed within 30 days to ensure CMS has the most up-to-date contact information for the laboratory and electronic communications, forms, etc., are sent to the correct email address.

Section 493.39(b) currently requires laboratories with a certificate of waiver to notify HHS or its designee within 30 days of any change(s) in ownership, name, location, or director. We propose to add a regulation at § 493.39(b)(5) that would require laboratories to notify HHS or its designee within 30 days of any change(s) in their email address. We also propose to revise § 493.39(b)(3) to remove the word “or” after location and add “or” after director in § 493.39(b)(4) to accommodate the new proposed regulation at § 493.39(b)(5).

Section 493.45(b)(2) currently requires laboratories with a registration certificate to agree to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only). We propose revisions to § 493.45(b)(2) that would require

³⁹ 85 FR 54820, <https://www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient>.

⁴⁰ QSO-23-15-CLIA; <https://www.cms.gov/files/document/qso-23-15-clia-original-release-date-2023-05-11.pdf>.

laboratories to notify HHS or its designee within 30 days of any change(s) in their email address.

Section 493.51(a) currently requires a laboratory with a certificate of compliance to notify HHS or its designee within 30 days of any change in ownership, name, location, director, or technical supervisor (laboratories performing high complexity only). We propose adding a new regulation at § 493.51(a)(5) that would require laboratories to notify HHS or its designee within 30 days of any change(s) in their email address. We also propose to revise § 493.51(a)(4) to remove the word “or” after director and renumber § 493.51(a)(5) as § 493.51(a)(6) to accommodate the new proposed regulation at § 493.51(a)(5).

Section 493.53(b) currently requires a laboratory with a certificate for PPM procedures to notify HHS or its designee within 30 days of any change in ownership, name, location, or director. We propose adding a new regulation at § 493.53(b)(5) that would require laboratories to notify HHS or its designee if their email address changes. We also propose to revise § 493.53(b)(3) to remove the word “or” after location and add the “or” after director in § 493.53(b)(4) to accommodate the newly proposed regulation at § 493.53(b)(5).

Section 493.57(a)(2) currently requires a laboratory with a registration certificate to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only). We propose revisions to § 493.57(a)(2) that would require laboratories to notify HHS or its designee within 30 days of any change(s) in their email address.

Section 493.63(a) currently requires a laboratory with a certificate of accreditation to provide notification within 30 days of any change in ownership, name, location, or director. We propose to add a regulation at § 493.63(a)(5) that would require laboratories to notify HHS or its designee if their email addresses change. We also propose to revise § 493.63(a)(3) to remove the word “or” after Location and add “or” after director in § 493.63(a)(4) to accommodate the newly proposed regulation at § 493.63(a)(5).

We solicit comments on these proposals related to certificate requirements.

3. Test Report Requirements (§ 493.1291(c)(2))

The regulation at § 493.1291(c)(2) currently provides that the test report

must include the name and address of the laboratory location where the test was performed. We propose revisions to this provision that would require the laboratory’s CLIA number and the name of the laboratory as it appears on the CLIA certificate to also be included in the test report.

Laboratories may use commercial names on the test report that do not match the name on the CLIA certificate. Additionally, multiple laboratories may operate at the same address, as permitted by QSO–18–20–CLIA.⁴¹ Specifically, this proposed change would establish clear traceability and accountability for laboratory testing and reporting by creating a direct link between test results and the specific laboratory facility that performed the analysis. Currently, some laboratories operate under multiple “doing business as” (DBA) names while functioning as a single entity, which can mislead healthcare providers, patients, and other interested parties about the true source of laboratory services. Requiring the inclusion in the test reports of the laboratory name, as it appears on the CLIA certificate, and the CLIA number would eliminate confusion caused by using multiple business names and ensure that all parties can accurately identify and verify the credentials of the laboratory performing the tests. This transparency would enable better oversight by regulatory bodies and provide healthcare providers and patients with the information necessary to make informed decisions about laboratory services. CMS received a record number of complaints during the SARS–CoV–2 PHE and struggled to identify the responsible laboratory because test reports often lacked the laboratory’s CLIA number or displayed a name different from the name that appears on the laboratory’s CLIA certificate. Therefore, we propose to require this information to be included in the test report.

We solicit comments on this proposal related to test report requirements.

4. Enforcement Requirements (§§ 493.807(a) and (b), 493.1810(d)(2), 493.1826(a)(2), 493.1832(c)(2), 493.1834(b), 493.1834(f)(2)(iii), 493.1834(e)(1)(ii)(D), and 493.1836(c)(3))

CMS proposes several modifications to the enforcement procedures to reduce burden and maintain safety standards. CMS proposes rescinding the mandatory

6-month reinstatement waiting period requirement that currently prevents laboratories from resuming testing even after achieving compliance following PT failures. Interested parties have argued that this waiting period creates access to care issues, particularly in rural communities where alternative testing options may be limited. CMS also proposes that the duration of alternative sanctions, including requirements for patient notification, would continue until a laboratory’s CLIA certificate is revoked, rather than, if earlier, at the time of suspension or limitation. Suspension or limitation of a CLIA certificate is typically not effective until after an administrative hearing decision, except in immediate jeopardy situations where suspension or limitation takes effect immediately. This proposed change is particularly important in cases of immediate jeopardy, where patient notification is critical. Under the current regulations, in situations where a suspension or limitation becomes effective immediately, laboratories may not be required to provide patient notification, potentially leaving patients unaware of life-threatening errors in their test results.

We propose to revise the CLIA regulations at §§ 493.807(a) and (b), 493.1810(d)(2), 493.1826(a)(2), 493.1832(c)(2), 493.1834(b), 493.1834(f)(2)(iii), 493.1834(e)(1)(ii)(D), and 493.1836(c)(3) to reduce burden, ensure patient care, and fix minor spelling, cross-references, and technical errors.

We propose to revise § 493.807(a) to delete the following language “one of which may be on site.” Section 493.807(a) currently provides that if a laboratory’s certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in PT for one or more specialties, subspecialties, analytes, or tests, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive PT events, one of which may be on site, before CMS would consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte, or test. Section 493.807(a) outlines how a laboratory’s certificate can be reinstated after it fails to participate successfully in PT for one or more specialties, subspecialties, analytes, or tests. We propose removing the language “one of which may be on site,” as interested parties have found it

⁴¹ QSO–18–20–CLIA; <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/qso18-20-clia>.

confusing. Laboratories would be able to use PT that is already on-site at the laboratory or order off-cycle PT to fulfill these reinstatement events.

We propose to rescind the existing § 493.807(b) that establishes mandatory waiting periods for laboratories seeking to resume testing after cancellation, limitation or suspension of their CLIA certificate. Section 493.807(b) currently provides that the cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than 6 months from the date of cancellation, limitation or suspension of the CLIA certificate. Under the current regulation, when a laboratory fails PT resulting in its cancellation of Medicare and Medicaid approval, suspension of Medicare or Medicaid payments, or suspension or limitation of its CLIA certificate for a specific specialty, subspecialty, analyte, or test, the laboratory cannot be reinstated prior to 6 months from the date of the adverse action.

In 1992, CMS initially determined that a 6-month suspension period was necessary following PT failures. This position was explained in the 1992 CLIA final rule with comment period that appeared in the February 28, 1992 **Federal Register** (57 FR 7002).⁴² The 1992 CLIA final rule addressed numerous public comments received regarding the proposed waiting period. Many commenters argued that a 6-month waiting period from the date of termination of Medicare approval or CLIA certification was excessively long and requested an expedited reinstatement process. Others suggested that fewer than three PT events should be required for reinstatement, on the grounds that laboratories cannot improve their performance when they are prohibited from testing. Additionally, some suggested that rather than imposing a termination period, laboratories should be reinstated once they demonstrate that the problems leading to the failure have been corrected and they have achieved success in two PT events.

In response to these comments, CMS maintained that after a laboratory voluntarily withdraws from offering services or faces termination, it is essential for the laboratory to demonstrate that problems have been corrected before services can resume.

CMS acknowledged that, while a 6-month period may seem excessive to some, the agency had previously provided a failing laboratory with at least this amount of time to correct its performance problems, yet the laboratory was unable to do so. CMS determined that reinstatement criteria should include two consecutive PT testing events to demonstrate that problems have been corrected, which would take a minimum of 6 months.

Based on more than 30 years of experience, CMS now seeks to remove the mandatory 6-month waiting period to reduce the burden on laboratories and maintain access to testing for patients, particularly in rural areas. CMS has determined that the 6-month waiting period has proven to be more punitive than motivational in achieving compliance, which is the primary purpose of enforcement actions. Most laboratories are able to demonstrate compliance prior to 6 months.

Compliance includes a successful demonstration on two consecutive PT testing events, which ensures patient safety and reliability of testing results. Interested parties have consistently argued that laboratories should be permitted to restart testing as soon as they demonstrate compliance with requirements, rather than being forced to wait through a 6-month time period. This concern has been particularly emphasized as an access to care issue, especially affecting rural communities where alternative testing options may be limited or unavailable. For instance, a small rural hospital that receives a limitation on its immunohematology testing capabilities would be required to send life-saving transfusion testing to reference laboratories, potentially causing delays in critical patient treatment. Recognizing these practical challenges, CMS has historically exercised flexibility in enforcing this regulation due to legitimate access to care concerns. Additionally, accreditation organizations have expressed significant difficulties with the underlying logic and practical application of this regulatory requirement, further supporting the need for its rescission. Removing § 493.807(b) would eliminate the timing restriction on reinstatement after enforcement actions, provided the laboratory meets § 493.807(a) and CMS verifies compliance.

Section 493.1810(d)(1) and (2) currently provides that an alternative sanction continues until the earlier of the following occurs: (1) The laboratory corrects all condition level deficiencies; or (2) CMS's suspension, limitation, or revocation of the laboratory's CLIA

certificate becomes effective. Section 493.1844(d)(2)(i) states that as a general rule, if a laboratory appeals a suspension, limitation, or revocation of a CLIA certificate, the suspension, limitation or revocation is not effective until after a hearing decision by an administrative law judge (ALJ). Section 493.1844(d)(2)(ii)(A) provides an exception to this general rule where CMS determines that conditions at the laboratory pose immediate jeopardy. In that case, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

Currently, if CMS determines that the conditions at the laboratory pose immediate jeopardy such that the suspension or limitation of the CLIA certificate is effective immediately, it results in the discontinuation of any additionally imposed alternative sanctions, including but not limited to the Directed Portion of a Plan of Correction (DPPOC) at § 493.1832(b)(2), pursuant to §§ 493.1810(d)(2), 493.1832(c)(2), and 493.1844(d). If the alternative sanctions are discontinued under § 493.1832(b)(2), laboratories are not required to provide CMS a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by CMS for notification purposes, thus leaving affected patients potentially unnotified. In cases of immediate jeopardy, patient notification is paramount as life-threatening errors in results may exist, and time is of the essence. Allowing the discontinuation of the DPPOC after the effective date of the suspension or limitation in immediate jeopardy situations may have a direct effect on patient care. Additionally, CMS does not impose alternative sanctions like the Directed Plan of Correction (DPOC) at § 493.1832(b)(1), which aids laboratories in their corrective actions when immediate jeopardy is found, and laboratories are in the most need of guidance. CMS cannot suspend or limit the CLIA certificate to prevent unsafe conditions while assisting the laboratory with a DPOC. CMS must choose between immediate suspension or limitation of the CLIA certificate without a DPOC or allowing the laboratory to continue testing. Therefore, at § 493.1810(d)(2), we propose to revise the regulation to remove the words “suspension, limitation, or” in order to extend CMS's ability to oversee corrective actions of

⁴² 57 FR 7002 (February 28, 1992); <https://title.loc.gov/storage-services/service/11/fedreg/fr057/fr057040/fr057040.pdf>.

laboratories and ensure patient safety. CMS is aware that there are instances in which suspension, limitation, or revocation should result in the discontinuation of an alternative sanction, such as the sanction of a civil money penalty. Therefore, we are not proposing to add or change the alternative sanction of a civil money penalty which is governed by § 493.1834. Section 493.1834(f)(2)(iii) provides that the civil money penalty will continue to accrue until CMS suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures. Based on more than 30 years of experience, CMS has identified, and now seeks to fill, a gap in the sanction regulations that it believes would assist laboratories in achieving and maintaining compliance with CLIA requirements. For example, in immediate jeopardy cases, a DPOC may aid the laboratory in achieving compliance more effectively than just suspending or limiting testing, and a DPOC helps aid the laboratories in their corrective actions and ensures that patients are notified under the DPPOC of issues that may have occurred and could affect the accuracy and reliability of their tests.

Accordingly, CMS proposes to update §§ 493.1832 and 493.1836 to reflect the change described above and remove "suspension" or "limitation." Currently, § 493.1832(c)(2) provides that the directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate. We propose to revise § 493.1832(c)(2) to remove "day suspension, limitation, or" and add "is effective" for clarity at the end of the sentence. Currently, § 493.1836(c)(3) provides that if the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's CoR, CoC, CoA, or PPM certificate is effective for state on-site monitoring. We also propose to revise § 493.1836(c)(3) to remove "suspension, limitation, or" to align with the proposed changes at § 493.1810(d)(2).

Section 493.1826(a)(2) currently contains a spelling error. We propose to revise § 493.1826(a)(2) to correct the spelling of "specialties."

We propose to revise § 493.1834(b) and (f)(2)(iii) to add "certificate of waiver" to the scope of laboratories that may have civil money penalties imposed. Section 493.1834(b) currently provides the procedures that CMS follows to impose a civil money penalty

in lieu of, or in addition to, suspending, limiting, or revoking the CoR, CoC, CoA, or PPM certificate of a laboratory that is found to have condition level deficiencies. Section 493.1834(f)(2)(iii) currently provides that the duration of the civil money penalty continues until CMS suspends, limits, or revokes the laboratory's CoR, CoC, CoA, or PPM certificate or compliance is achieved, whichever is earlier. The 2023 CLIA final rule updated 42 CFR part 493, subpart R to allow CMS to impose alternative sanctions on certificates of waivers by removing the phrase at § 493.1804(c)(1) that explicitly prohibited it. Upon review, these two additional regulatory paragraphs at § 493.1834(b) and (f)(2)(iii) require updates to reflect that change at § 493.1804(c)(1).

Section 493.1834(e)(1)(ii)(D) currently provides that CMS's written notice of its intent to impose a civil monetary penalty must include, among other information, the opportunity for the laboratory to respond to the notice in accordance with § 493.1810(c). We also propose to revise § 493.1834(e)(1)(ii)(D) to correct the cross-reference from § 493.1810(c) "notice of imposition" to § 493.1810(b) "opportunity to respond" for accuracy.

We solicit comments on these proposals related to enforcement requirements.

5. Public Consultation Requirements (§ 493.2001(a))

Section 353(q) of the PHSA requires that the Secretary shall consult with appropriate private organizations and public agencies in carrying out the provisions of CLIA. The regulation at § 493.2001(a) states that "HHS will establish a Clinical Laboratory Improvement Advisory Committee [CLIA] to advise and make recommendations on technical and scientific aspects of the provisions of this part 493." Consistent with Executive Order 14217⁴³ entitled "Commencing the Reduction of the Federal Bureaucracy," CLIA was declared terminated by the Secretary on March 31, 2025.⁴⁴

We propose to revise § 493.2001(a) to change the word "will" to "may," thereby making the establishment of CLIA permissive and not required. This proposed change would align the regulation with the current statutory authority at section 353(q) of the PHSA,

which requires public consultation but does not specifically require the establishment of CLIA, with the termination of CLIA by the Secretary on March 31, 2025, and would reflect the proposed discretionary nature of future advisory consultations. While CMS and the CDC would continue public consultation, as required by the statute, maintaining this regulation would allow for the future establishment and use of CLIA should the need arise.

We solicit comments on this proposal related to public consultation requirements.

6. Editorial and Technical Changes (§§ 493.17(a), (b) and (c), 493.35(b)(2), 493.801(b), 493.901(a), 493.931, and 493.933)

We propose to revise the CLIA regulations at §§ 493.17(a), (b) and (c), 493.35(b)(2), 493.801(b), 493.901(a), 493.931, and 493.933 to correct errors in cross-references and to ensure consistency and clarity. Specifically:

The proposed revisions to § 493.17(a), (b) and (c) are administrative and conforming in nature. They would reflect the current FDA categorization process and responsibilities, and would not alter the criteria used to categorize laboratory tests, the scoring methodology, or the complexity thresholds established under § 493.17(a).

Sections 493.17(a), (c)(4) and (c)(5) currently provide that notices of the test categorization will be published in the **Federal Register** which includes each specific test system, assay, and examination categorized by complexity. We propose to revise these provisions by replacing "**Federal Register**" with "FDA's CLIA—Clinical Laboratory Improvement Amendments Database" or "CLIA—Clinical Laboratory Improvement Amendments Database" which would reflect FDA's current process for test categorization notices.

Section 493.17(b) currently states that CLIA will conduct categorization reviews upon HHS's request and recommend revisions to the criteria for categorizing tests. We propose to replace the word "will" with "may." This proposed change would reflect the termination of CLIA by the Secretary on March 31, 2025, and the proposed discretionary nature of future advisory consultations as discussed in section II.D.5. of this proposed rule, and would align the regulatory text with how the categorization review process currently operates in practice. This revision would simply clarify that such reviews by CLIA are not mandatory but available upon HHS' request.

⁴³ Executive Order 14217, <https://www.federalregister.gov/documents/2025/02/25/2025-03133/commencing-the-reduction-of-the-federal-bureaucracy>.

⁴⁴ CDC's CLIA website, <https://www.cdc.gov/cliia/php/about/index.html>.

Section 493.17(c)(1)(i) currently provides that when a manufacturer submits a 510(k) or PMA application to FDA for a new commercial test system, assay, or examination, it must include supporting data specifically for device/test categorization. FDA will determine the test's complexity category, notify the manufacturer directly, and simultaneously inform both CMS and CDC of the assigned category. FDA is required to consult with CDC in three specific situations: when categorizing a brand-new technology that hasn't been categorized before, when FDA determines consultation is necessary for a requested change to an existing categorization, and when a manufacturer formally requests FDA review of a categorization decision under 21 CFR 10.75. We propose to remove the now-obsolete requirements at § 493.17(c)(1)(i) regarding CDC consultation, the three enumerated consultation situations and simultaneous notification to CMS. Specifically, we propose to remove the language "FDA will consult with CDC concerning test categorization in the following three situations." from § 493.17(c)(1)(i). We also propose to revise § 493.17(c)(1)(i) to include "De Novo request" in addition to the current 510(k) and PMAs for the device categorization and remove the term "simultaneously" regarding notification to CMS. In addition, we propose to combine the proposed provision at § 493.17(c)(1)(i) with the current provision at § 493.17(c)(1)(ii), merging them into a single provision at § 493.17(c)(1). As part of this change, we propose to redesignate § 493.17(c)(1)(i) and (c)(1)(ii) as the newly combined § 493.17(c)(1). We propose to remove the current obsolete requirements related to the consultation situations with the CDC at § 493.17(c)(1)(i)(A) through (C), to align the regulations with the current FDA process. These proposed changes at § 493.17(c)(1) would align the regulations with the current FDA process for CLIA test categorization.

Section 493.17(c)(2) currently provides that for test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to the Public Health Service (PHS). It also states that these requests will be forwarded to CDC for evaluation, and that CDC will determine complexity category and notify the applicant, CMS, and FDA of the categorization decision. Furthermore, in the case of a request for a change of category or for previously uncategorized

new technology, the current regulation states that PHS will receive the request application and forward it to CDC for categorization. We propose to remove the language "These requests will be forwarded to the CDC for evaluation;" and "In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization." from § 493.17(c)(2), as the request is now submitted directly to the FDA. In addition, we propose to add the language "or recategorization" to the first sentence of § 493.17(c)(2) following "categorization." These proposed changes at § 493.17(c)(2) reflect the fact that in 2003, the Secretary delegated authority to implement the CLIA test complexity categorizations to the FDA and would align with the current FDA process.⁴⁵

Section 493.35(b)(2) currently provides an exception to the application for a CoW requirements, providing that not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application. We propose to revise § 493.35(b)(2) to remove the reference to the combination of moderately complex tests, since this regulation only refers to CoW applications, which are not approved to perform moderate complexity tests as outlined in § 493.37(g).

Section 493.801(b) currently requires that the laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the PT sample as it would a patient specimen, up until the point at which it would refer a patient specimen to a second laboratory for any form of further testing. We propose to revise the cross-reference in § 493.801(b) from paragraph (b)(4) to paragraph (b)(5). The regulation at § 493.801(b)(4) refers to inter-laboratory communication and not reflex testing as stated in § 493.801(b)(5).

Section 493.901(a) currently requires that, for a PT program to be approved by HHS, it must have a "minimum of 10

laboratory participants" for each specialty, subspecialty, and analyte or test for which the PT program is seeking reapproval. This requirement was established to ensure that PT programs have a sufficient number of participants to generate statistically valid data for grading, preventing laboratories from being burdened with ungradable PT events due to small peer groups. The CLIA regulatory framework for PT approval exists to serve and evaluate CLIA-regulated entities. Therefore, to align with our historical interpretation of the term "laboratory participants," and to continue to ensure the integrity of PT as a quality assurance tool for clinical laboratories, we are proposing to clarify that the term refers to CLIA-certified laboratory participants and revise § 493.901(a) to replace the phrase "minimum of 10 laboratory participants" with "minimum of 10 CLIA-certified laboratory participants."

We propose to remove from the specialty of Endocrinology at § 493.933, "Table 1 to Paragraph (b)—Analyte or Test," the following analytes: cancer antigen (CA) 125, carcinoembryonic antigen (CEA), serum folate, and vitamin B12. We also propose to remove from the specialty of Endocrinology at § 493.933, "Table 2 to Paragraph (c)(2)—Criteria for Acceptable Performance," the following analytes: cancer antigen (CA) 125, carcinoembryonic antigen (CEA), serum folate, and vitamin B12. We propose moving these analytes to the correct specialty of Routine Chemistry at § 493.931, which would align with the FDA categorization.⁴⁶

In § 493.931, Table 1 currently provides the analytes that require PT for routine chemistry. We propose to revise the table for Routine Chemistry analytes at § 493.931, "Table 1: Table 1 to Paragraph (b) Analyte or Test Procedure," to add the following analytes: cancer antigen (CA) 125, carcinoembryonic antigen (CEA), serum folate, and vitamin B12. We also propose to revise the table for Routine Chemistry analytes for acceptable performance at § 493.931, "Table 2 to Paragraph (c)(2)—Criteria for Acceptable Performance," to add the following: cancer antigen (CA) 125—target value ± 20 percent, carcinoembryonic antigen (CEA)—target value ± 15 percent or ± 1 ng/mL (greater), serum folate—target value ± 30 percent or ± 1 ng/mL (greater), and vitamin B12—target value ± 25 percent or ± 30 pg/mL (greater). We propose these changes because CA 125, CEA, serum folate, and vitamin B12 are

⁴⁵ 68 FR 64350; <https://www.federalregister.gov/documents/2003/11/13/03-28435/delegation-of-authority>.

⁴⁶ FDA's CLIA Categorizations website; <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations>.

categorized by the FDA as General Chemistry (Routine Chemistry).⁴⁷

III. Severability

To the extent a court may enjoin any part of this proposed rule, if finalized, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of the rule as finalized held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

This proposed rule outlines proposed changes to the CLIA regulations which encompasses four overarching areas: (1) Virtual access provisions that would codify the flexibility provided by prior exercises of enforcement discretion to allow pathologists and laboratory personnel to review digital laboratory data, digital results, live imaging, and digital images remotely under the CLIA certificate of the primary testing laboratory that generated the data, excluding the subspecialty of cytology; (2) Gynecologic cytology PT updates that would allow for the use of digital images of glass slides in PT to align with the FDA-authorized digital cytology screening systems; (3) Personnel qualification updates that would address concerns regarding any burden associated with the qualification requirements that took effect on December 28, 2024, including removing human-only laboratory science limitations and adding qualifications for histopathology gross tissue examination personnel and Mohs dermatology laboratory directors; and (4) Other changes that would remove SARS-CoV-2 reporting requirements, update certificate requirements, revise regulatory text requiring establishment of CLIA, test report requirements, enforcement requirements, and correct editorial and technical errors.

We believe that the proposed provisions in this rule, if finalized, are generally capable of functioning on an independent basis.

We seek comments on the severability of these provisions in the proposed rule.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide 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, 44 U.S.C. 3506(c)(2)(A) 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 estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Laboratory Costs To Update Policies and Procedures

1. ICRs Regarding Virtual Access

CMS and the CDC propose to codify this virtual access flexibility through formal regulatory changes. The proposed virtual access provisions would codify the flexibility provided by enforcement discretion, allowing laboratory personnel to review digital laboratory data, digital results, live imaging, and digital images remotely under the CLIA certificate of the primary testing laboratory that generated the data, excluding the subspecialty of cytology. We propose to add a definition of “virtual access” (§ 493.2) and update the regulatory language throughout 42 CFR part 493, to include digital laboratory data, digital results, live imaging, and digital images for CoR, CoC, and CoA certificates (§§ 493.43(a)(1) and 493.55(a)(1)), facility and retention requirements (§§ 493.1101(e) for facilities storage, 493.1105(a), (a)(3), (a)(7), and (b) for retention, 493.1105(a)(7)(i)(A) for cytology retention, and 493.1105(a)(7)(i)(B) for histopathology retention), and in the general laboratory (§§ 493.1231(a) and 493.1251(b)(2)), analytic (§ 493.1256(a)) and postanalytical systems (§§ 493.1283(a)(5) and 493.1291(a)(2)) sections to ensure testing performed via virtual access maintains the same

quality standards as on-site testing, as discussed in more detail below.

If the proposals related to virtual access are finalized as proposed, we expect approximately 33,955 CLIA-certified laboratories to be affected (CoC laboratories = 16,960; CoA laboratories = 16,995 (Data from Quality, Certification and Oversight Reports (QCOR) as of August 4, 2025). We expect that approximately 40 percent of the 33,955 CoC and CoA laboratories would utilize virtual access (hospital, independent, industrial, public health, and pharmacy laboratories) and incur costs for the time needed to review the revised regulations and update their policies and procedures to be in compliance. This is 13,582 laboratories. The total one-time burden per laboratory to review and update affected policies and procedures is estimated to be 4 to 6 hours. A management level employee (11–9111) would perform this task at an hourly median wage of \$56.71 per hour as published by the 2024 Bureau of Labor Statistics.⁴⁸ The wage rate would be \$113.42 to include overhead and fringe benefits. The burden hours are estimated to range from 54,328 hours to 81,492 hours (13,582 laboratories × 4 or 6 hours). The total cost would range from \$6,161,882 to \$9,242,823 (54,328 or 81,492 hours × \$113.42).

There is an ongoing burden for quality control and record keeping requirements for the approximate 13,582 CLIA-certified laboratories at §§ 493.43(a)(1)(i), 493.55(a)(3)(ii), 493.1256, and 493.1283(a)(5). We estimate this burden to be 3 hours per year. The total burden hours are estimated to be 40,746 (13,582 laboratories × 3 hours). Total cost would be approximately \$4,621,411 (40,746 hours × \$113.42). The revised information collection request will be submitted to OMB for approval under the OMB Control numbers of 0938–0151 and 0938–0612.

2. ICRs Regarding Gynecologic Cytology PT Requirements

CMS and the CDC propose to revise the CLIA regulations for gynecological cytology PT (§§ 493.855(a), 493.855(b), 493.945(a)(1), 493.945(b)(1), 493.945(b)(2), 493.945(b)(3)(i), 493.945(b)(3)(ii)(B), and 493.945(b)(3)(ii)(C) through (G)) to allow digital images of glass slides to align with FDA-authorized digital cytology screening systems.

⁴⁸ U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics (OEWS) Profiles, <https://data.bls.gov/oes/profile/>.

⁴⁷ FDA's CLIA-Clinical Laboratory Improvement Amendments Database, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/search.cfm>.

If this proposal is finalized as proposed, we expect approximately 3,229 CLIA-certified laboratories performing testing in the subspecialty of cytology to be affected. We are unable to determine how many laboratories have adopted digital images for screening as the primary method of patient testing. We estimate the number of laboratories to be about 25 percent of 3,229 laboratories, which is 807 laboratories. We estimate it would take 1 to 1.5 hours for a laboratory to fill in this information on the PT submission form and update policy and procedures. A management-level employee (11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. The burden hours are estimated to range from 807 to 1,211 (807 × 1 or 1.5 hours). The total cost would range from \$91,530 to \$137,352 (807 or 1,211 hours × \$113.42). The revised information collection request will be submitted to OMB for approval under the OMB Control number of 0938–0612.

3. ICRs Regarding Personnel Qualification Requirements

We propose to revise the following CLIA personnel regulations: PPM laboratory director responsibilities (§ 493.1359); moderate complexity laboratory director qualifications (§ 493.1405); moderate complexity laboratory director responsibilities (§ 493.1407); moderate complexity technical consultant qualifications (§ 493.1411); moderate complexity clinical consultant qualifications (§ 493.1417); moderate complexity testing personnel qualifications (§ 493.1423); high complexity laboratory director qualifications (§ 493.1443); high complexity laboratory director responsibilities (§ 493.1445); high complexity technical supervisor qualifications (§ 493.1449); high complexity clinical consultant qualifications (§ 493.1455); high complexity general supervisor qualification (§ 493.1461); high complexity general supervisor responsibilities (§ 493.1463); and high complexity testing personnel qualifications (§ 493.1489).

We propose to revise these personnel regulations to address concerns regarding the burden associated with qualification requirements that took effect December 28, 2024, including removing human-only laboratory science limitations and adding qualifications for histopathology gross

tissue examination personnel and Mohs dermatology laboratory directors.

If this proposal is finalized as proposed, we expect 24,441 PPM laboratories to incur costs to review the finalized regulations and update their affected policies and procedures to be in compliance. The total one-time burden per laboratory is estimated to be 0.25 to 0.5 hours. The burden hours are estimated to be 6,110 to 12,221 (24,441 PPM laboratories × 0.25 to 0.5 hours). A management level employee (11–9111) would perform this task at an hourly median wage of \$56.71 per hour. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost for laboratories would range from \$692,996 to \$1,386,106 (6,110 or 12,221 hours × \$113.42).

If this proposal is finalized as proposed, we expect approximately 33,955 CLIA-certified laboratories to be affected (CoC laboratories = 16,960; CoA laboratories = 16,995) (Data from Quality, Certification and Oversight Reports (QCOR) as of August 4, 2025). We expect 33,955 CoC and CoA laboratories to incur costs for the time needed to review the revised 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 estimated to be 2.25 to 4.5 hours. The burden hours are estimated to be 76,399 and 152,798 (33,955 × 2.25 or 4.5 hours). The total cost would range from \$8,665,175 to \$17,330,349 (76,399 or 152,798 hours × \$113.42). The revised information collection request will be submitted to OMB for approval under the OMB Control number of 0938–0612.

4. ICRs Regarding Other Changes

We also propose changes to the following regulatory requirements: SARS–CoV–2 reporting requirements (§§ 493.2, 493.41, 493.555(c)(6), 493.1100(a), 493.1100(b), and 493.1834(d)(2)(iii)); certificate requirements for electronic delivery (§§ 493.35(b)(3), 493.39(b), 493.43(b)(3), 493.45(b)(2), 493.51(a), 493.53(b), 493.55(b)(3), 493.57(a)(2), and 493.63(a)); test reporting requirements (§ 493.1291); enforcement requirements (§§ 493.807(a), 493.807(b), 493.1810(d)(2), 493.1826(a)(2), 493.1832(c)(2), 493.1834(f)(2)(iii), 493.1834(e)(1)(ii)(D), and 493.1836(c)(3)); and public consultation requirements (§ 493.2001(a)).

These proposals, if finalized as proposed, would impact approximately 307,038 CLIA-certified laboratories (CoW laboratories = 248,642; CoC laboratories = 16,960; CoA laboratories

= 16,995; and PPM laboratories = 24,441 (Data from Quality, Certification and Oversight Reports (QCOR)) as of August 4, 2025).

We expect that the 33,955 CoC, CoA laboratories would incur costs for the time needed to review the revised 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 estimated to be 0.5 to 1 hour. The burden hours are estimated to be 16,978 and 33,955 (33,955 CoCs × 0.5 or 1 hour). A management-level employee (11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42, including overhead and fringe benefits. The total cost would range from \$1,925,645 to \$3,851,176 (16,978 or 33,955 hours × \$113.42).

We expect 248,642 CoW laboratories to incur costs to review regulations and update their affected policies and procedures. The total one-time burden per laboratory is estimated to be 0.25 to 0.5 hours. The burden hours are estimated to be 62,161 to 124,321 (248,642 CoW laboratories × 0.25 or 0.5 hours). The total cost for laboratories would range from \$7,050,301 to \$14,100,488 (62,161 or 124,321 hours × \$113.42).

We also expect 24,441 PPM laboratories to incur costs to review regulations and update their affected policies and procedures. The total one-time burden per laboratory is estimated to be 0.25 to 0.5 hours. The total hours are estimated to be 6,110 to 12,221 (24,441 PPMs × 0.25 or 0.5 hours). A management-level employee (11–9111) would perform this task at an hourly median wage of \$56.71 per hour. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost for laboratories would range from \$692,996 to \$1,386,106 (6,110 or 12,221 hours × \$113.42). The revised information collection request will be submitted to OMB for approval under the OMB Control number of 0938–0612 and 0938–0581.

5. Accreditation Organization (AO) and Exempt State (ES) Costs To Update Policies and Procedures

If the proposed changes are finalized as proposed, seven approved AOs and two ESs would have to review their policies and procedures, provide updates, and submit the changes to CMS for approval. We assume an estimated one-time burden of 30 to 729 hours to identify the applicable legal obligations and to develop the policies and

procedures needed to implement the proposed changes. The burden hours are estimated to be 270 to 6,561 (9 AOs/ESs × 30 or 729 hours). A management-level employee (11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost would range from \$30,623 to \$744,149 (270 or 6,561 hours × \$113.42). The revised information collection

request will be submitted to OMB for approval under the OMB Control number of 0938–0686.

6. PT Programs

There are no collection of information requirements associated with the addition of digital images of glass slides to gynecologic PT proposal because the documentation is already being collected and maintained by the PT program as normal course of business and is a usual and customary practice in

accordance with implementing regulations of the PRA at 5 CFR 1320.3(b)(2). The burden to add digital images to the cytology PT program and update the software for the change in analyte specialty is discussed in the Regulatory Impact Analysis (RIA) section below.

Table 3 reflects the total burden and associated costs for the provisions included in this proposed rule for laboratories.

TABLE 3—SUMMARY OF COSTS FOR COLLECTION OF INFORMATION IN THIS PROPOSED RULE FOR LABORATORIES

Information collection requests	Estimated burden hours one-time (total burden hours)	Estimated burden hours ongoing (total ongoing hours)	Cost one-time	Cost ongoing, per year	Total cost, one-time + ongoing	OMB document No.
Virtual Access	4–6 (54,328 to 81,492)	3 (40,746)	\$6,161,882–\$9,242,823	\$4,621,411	\$10,783,293–\$13,864,234	0938–0151 and 0938–0612.
Gynecological Cytology PT Requirements.	1–1.5 (807–1,211)	N/A	91,530–137,352	N/A	91,530–137,352	0938–0612.
Personnel Qualifications (PPM).	0.25–0.5 (6,110–12,221)	N/A	692,996–1,386,106	N/A	692,996–1,386,106	0938–0612.
Personnel Qualifications, (CoC and CoA).	2.25 to 4.5 (76,399–152,798)	N/A	8,665,175–17,330,349	N/A	8,665,175–17,330,349	0938–0612.
Other Changes (CoW)	0.25–0.5 (62,161–124,321)	N/A	7,050,301–14,100,488	N/A	7,050,301–14,100,488	0938–0612 and 0938–0581.
Other Changes (PPM)	0.25–0.5 (6,110–12,221)	N/A	692,996–1,386,106	N/A	692,996–1,386,106	0938–0612 and 0938–0581.
Other Changes (CoC and CoA).	0.5–1.0 (16,978–33,955)	N/A	1,925,645–3,851,176	N/A	1,925,645–3,851,176	0938–0612 and 0938–0581.
AO and ES	30–729 (270–6,561)	N/A	30,623–744,149	N/A	30,623–744,149	0938–0686.
Totals	38.5–743.5 (223,163–424,780)	3 (40,746)	25,311,148–48,178,549	4,621,411	29,932,559–52,799,960	N/A.

If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this rule.

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. Virtual Access

As discussed in section II.A of this proposed rule, on May 11, 2023, CMS issued memo QSO–23–15–CLIA–REVISED, entitled “Clinical Laboratory Improvement Amendments of 1988

(CLIA) Post-Public Health Emergency (PHE) Guidance” informing interested parties that pathologists and other qualified laboratory personnel would continue to be able to remotely review digital data, results, and images, but locations that review physical slides and use microscopes must have their own CLIA certificate. The memo also stated that laboratories that choose to allow staff to remotely review digital data, results, and images could do so if specific criteria were met, as outlined in section II.A of this proposed rule. Considering this exercise of enforcement discretion, we assume virtual access testing models are likely already in place in some laboratories. The intent of the CLIA program is to ensure that test results provided to individuals and their healthcare providers are accurate, timely, and reliable. As discussed in section II.A of this proposed rule, we propose to add a definition for virtual access and update pertinent regulatory language to include the use of virtual access throughout 42 CFR part 493. We also propose to update the regulatory language throughout 42 CFR part 493, for all certificate types, facility and retention requirements, and in the

general laboratory, analytic, and postanalytic systems sections to ensure virtual access maintains the same quality standards as on-site testing. Virtual access would not include the subspecialty of cytology, as section 353(f)(4)(B)(vi) of the PHSA and the regulation at § 493.1274(a) state that cytology screening and slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

2. Gynecologic Cytology PT

Laboratory instrumentation’s technological capabilities are evolving to meet the modern needs of the industry. As discussed in section II.B of this proposed rule, in 2024, the FDA authorized for marketing the first digital cytology screening system, which creates digital images of glass slides. Current gynecologic cytology PT requirements at § 493.855(a) and (b) require that “each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event would be conducted on-site in each laboratory at least once each year, and each individual participates in an annual

testing event that involves the examination of a 10-slide test set as described in § 493.945.” We are proposing to revise the regulations at §§ 493.855(a) and 493.945(b) based on the recent authorization of the first digital cytology screening system and the necessity for more stringent PT requirements to ensure that PT is performed in the same manner as the primary testing method.

3. Personnel Qualification Requirements

The proposed personnel qualification updates, as discussed in section II.C. of this proposed rule, relate to laboratory director qualifications and responsibilities, blood gas testing personnel and competency assessor qualifications, gross tissue examination personnel qualifications, and include proposed changes to the gross tissue examination technical supervisor review process. The 2023 CLIA final rule updated the requirements under 42 CFR part 493, subpart M, pertaining to laboratory director qualifications and responsibilities, specifically addressing personnel qualifications and duties. As discussed in section II.C of this proposed rule, since the effective date of the updated personnel regulations, CMS has received substantial feedback from interested parties about the revised personnel qualification requirements.

CMS met directly with multiple interested parties to hear their concerns, which mainly focused on laboratory director qualifications. Interested parties expressed concerns about the requirement for physicians to have both 20 hours of CE in laboratory director responsibilities and 1 year of supervisory laboratory experience to qualify as moderate complexity laboratory directors, viewing this as burdensome. Prior to December 28, 2024, physicians for moderate complexity laboratories could qualify as moderate complexity laboratory directors with either 20 CE in laboratory director responsibilities or 1 year of supervisory laboratory experience, providing more flexibility in meeting qualification requirements and enabling physicians to open their practices upon graduation. Similarly, dermatology associations raised concerns about the qualification requirements for newly graduated and practicing dermatologists to serve as high complexity laboratory directors for laboratories that perform Mohs testing, which now require 2 years of supervisory laboratory experience and 20 CE in laboratory director responsibilities. Under previous regulations, dermatologists could qualify as laboratory directors based solely on their residency training,

without requiring documentation of prior laboratory supervisory experience or the 20 CE. Interested parties noted that more stringent qualification requirements may reduce the number of eligible candidates for laboratory director positions, potentially impacting access to care in rural areas and laboratories that perform Mohs testing.

As discussed in section II.C of this proposed rule, after carefully reviewing the new personnel regulations, CMS and the CDC have determined that several personnel regulations should be revised, removed, or clarified.

CMS and the CDC propose removing definitions and language that limit background, education, experience, and training to human-only laboratory science. Interested parties from the veterinary and research communities are supportive of expanding the previous interpretation of the definition of experience and training in laboratory science to allow for additional qualified laboratory personnel. Section 353(f)(1)(C) and (2) of the PHS Act gives the Secretary the authority to recognize qualifications of nonhuman laboratory science, as appropriate, for laboratory personnel. CMS and the CDC believe it is appropriate to expand the definitions and language that limit background, education, experience, and training to human-only laboratory science to expand the qualified workforce and reduce the burden, particularly on rural areas, to find qualified laboratory personnel. We also propose rescinding or revising several regulations that we believe increase the financial, time, and compliance burdens on laboratory directors without delivering measurable benefits with respect to patient safety and regulatory compliance, including competency for PPM testing personnel, laboratory director on-site visits, and additional requirements of experience and courses specifically in CLIA laboratory director’s responsibilities.

Based on interested parties’ feedback, CMS and the CDC propose to add regulations for testing personnel that may perform histopathology gross tissue examination and Mohs dermatology laboratory directors who perform testing in dermatopathology. The regulations for histology testing personnel allow individuals who may not have previously qualified to now meet the qualifications to perform histopathology gross tissue examination, expanding the number of individuals qualified to perform this test. Mohs dermatology laboratory directors can now qualify through their dermatology board certification instead of producing documentation from their residency and fellowship to establish experience

requirements. These additional regulations would result in a less burdensome qualification process and address workforce shortages.

Current CLIA regulations may impose undue burdens to meet testing personnel qualifications for moderate complexity blood gas testing. This may lead to increased costs for obtaining and maintaining those qualifications and may lead to a lack of qualified testing personnel. Also, CLIA regulations restrict who can perform competency assessments for moderate complexity blood gas testing, which may lead to a lack of qualified personnel who can perform competency assessments. CMS and the CDC propose to add regulations that would allow flexibility for blood gas personnel requirements.

Current CLIA regulations do not include personnel qualifications for gross tissue examinations. To address this gap, this proposed rule includes educational requirements for high complexity testing personnel qualifications, including recognizing histotechnicians, histotechnologists, and pathologist assistants as high complexity testing personnel.

Current CLIA interpretive guidance, which is found in SOM Appendix C, recommends that in the case of gross tissue examinations, all physical examinations/descriptions of tissue including color, weight, measurement, and other characteristics of the tissue; or other mechanical procedures, performed in the absence of the technical supervisor by individuals qualified under § 493.1489 should be reviewed within 24 hours by the technical supervisor. The proposed rule would codify this interpretive guidance at § 493.1273(c), with a modification to provide that results must be reviewed by the technical supervisor before the final test report is issued, instead of within 24 hours.

4. Other Changes

This proposed rule also includes proposals related to removing the obsolete requirement for SARS-CoV-2 results reporting, as the SARS-CoV-2 PHE has ended, updating the requirement that laboratories must notify HHS or its designee if their email addresses change, adding the CLIA number and laboratory name to test reports, modifying enforcement requirements, and revising regulatory text requiring the establishment of CLIAC for public consultation. Other editorial and technical changes to fix cross-references and ensure consistency and clarity are also included.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13132, “Federalism”; Executive Order 13563, “Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1)

have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

An RIA must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the OMB Office of Information and Regulatory Affairs (OIRA) has determined this proposed rule is significant per section 3(f)(1) of E.O. 12866, see Table 4 (Summary of All Estimated Costs and Cost Savings). We have prepared this RIA to the best of our abilities, 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. We estimate that this proposed rule would impose initial costs ranging from a low estimate of \$19,352,721 to a high estimate of \$40,654,504 during year one of implementation. At the same time, this proposed rule would generate recurring annual cost savings beginning the first year of implementation, with these savings continuing annually. Estimated annual cost savings range from a low estimate of \$2,809,311 and a high estimate of \$149,751,325. Table 5 (Annual and Present Value Estimates of Costs, Cost Savings, and Total Anticipated Impact (3 Percent and 7 Percent Discount Rates) presents estimates of year one and ongoing annualized costs, cost savings, and total anticipated impact over a 5-year time period (2028–2032) using 3 percent and 7 percent discount rates, consistent with OMB Circular A–4.

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

TABLE 4—SUMMARY OF ALL ESTIMATED COSTS AND COST SAVINGS

Estimated costs and benefits	Initial/implementation (Year 1)		Ongoing annually/maintenance (Year 2–5)	
	Low estimate	High estimate	Low estimate	High estimate
Costs:				
Laboratory Costs to Update Policies and Procedures for all Personnel Qualifications and Other Changes	(\$19,033,833)	(\$38,067,665)	\$0	\$0
Accreditation Organization and Exempt State Costs for All Updates	(30,623)	(744,149)	0	0
(Voluntary) Implementation Costs of Virtual Access (estimate for one laboratory)	(102,143)	(1,601,616)	0	0
(Voluntary) Maintenance and Compliance Costs of Virtual Access (estimate for one laboratory)	0	0	(113)	(340)
PT Programs to Update Software Costs for Gynecologic Cytology PT	(94,592)	(103,779)	0	0
Gynecologic Cytology PT Quantifiable Costs for Laboratories	(91,530)	(137,295)	0	0
Total Estimated Costs	– (19,352,721)	(40,654,504)	(113)	(340)
Cost Savings:				
Laboratory Director Qualifications (Boards including CE estimate for renewal)	+3,846,856	+117,927,825	+1,525,056	+90,431,700
Laboratory Director Qualifications (CE hours estimate)	+2,716,400	+33,955,000	0	0
Laboratory Director Responsibilities (Annual on-site travel and lodging)	+644,431	+1,723,282	+644,431	+1,723,282
Laboratory Director Responsibilities (Annual PPM competency assessment)	+639,937	+57,596,683	+639,937	+57,596,683
Total Estimated Cost Savings	+7,847,624	+211,202,790	+2,809,424	+149,751,665
Total Anticipated Impact (Total Cost Savings – Total Cost)	– (11,505,097)	+170,548,286	+2,809,311	+149,751,325

TABLE 5—YEAR-SPECIFIC UNDISCOUNTED AND PRESENT VALUE ESTIMATES OF COSTS, COST SAVINGS, AND TOTAL ANTICIPATED IMPACT

[3 Percent and 7 percent discount rates]

	Undiscounted value (low estimate–high estimate)	Year-specific present value ^a	
		3% Discount rate (low estimate–high estimate)	7% Discount rate (low estimate–high estimate)
Total Estimated Costs:			
Year 1 (2028)	\$19,352,721–\$40,654,504	\$19,352,721–\$40,654,504	\$19,352,721–\$40,654,504
Year 2 (2029)	113–340	110–330	106–318
Year 3 (2030)	113–340	107–320	99–297
Year 4 (2031)	113–340	103–311	92–278
Year 5 (2032)	113–340	100–302	86–260
Total Estimated Cost Savings:			

TABLE 5—YEAR-SPECIFIC UNDISCOUNTED AND PRESENT VALUE ESTIMATES OF COSTS, COST SAVINGS, AND TOTAL ANTICIPATED IMPACT—Continued
[3 Percent and 7 percent discount rates]

	Undiscounted value (low estimate–high estimate)	Year-specific present value ^a	
		3% Discount rate (low estimate– high estimate)	7% Discount rate (low estimate– high estimate)
Year 1 (2028)	7,847,624–211,202,790	7,847,624–211,202,790	7,847,624–211,202,790
Year 2 (2029)	2,809,424–149,751,665	2,727,596–145,394,722	2,625,631–139,956,696
Year 3 (2030)	2,809,424–149,751,665	2,648,152–141,163,808	2,454,795–130,809,997
Year 4 (2031)	2,809,424–149,751,665	2,571,022–137,056,124	2,296,068–122,351,399
Year 5 (2032)	2,809,424–149,751,665	2,496,138–133,067,931	2,145,859–114,846,391
Total Anticipated Impact (Total Cost Savings – Total Cost):			
Year 1 (2028)	– (11,505,097)–170,548,286	– (11,505,097)–170,548,286	– (11,505,097)–170,548,286
Year 2 (2029)	2,809,311–149,751,325	2,727,486–145,394,392	2,625,524–139,956,378
Year 3 (2030)	2,809,311–149,751,325	2,648,045–141,163,487	2,454,695–130,809,700
Year 4 (2031)	2,809,311–149,751,325	2,570,919–137,055,813	2,295,975–122,351,121
Year 5 (2032)	2,809,311–149,751,325	2,496,038–133,067,628	2,145,771–114,846,130

^a Present values were calculated by multiplying the annual estimate by the applicable OMB Circular A–4 discount factor. Discount factors equal 1.0000 (2028), 0.9709 (2029), 0.9426 (2030), 0.9151 (2031), and 0.8885 (2032) for the 3 percent discount rate, and 1.0000 (2028), 0.9346 (2029), 0.8734 (2030), 0.8163 (2031), and 0.7629 (2032) for the 7 percent discount rate.

C. Detailed Economic Analysis

1. Benefits

a. Virtual Access

We have determined there would be several non-quantifiable benefits for laboratories currently using or deciding to implement a virtual access testing model. Clinical laboratories across the country are currently experiencing a critical shortage of qualified laboratory personnel (Diane C. Halstead, Robert L. Sautter, *A Literature Review on How We Can Address Medical Laboratory Scientist Staffing Shortages, Laboratory Medicine*, Volume 54, Issue 1, January 2023, Pages e31–e36, <https://doi.org/10.1093/labmed/lmac090>). Workforce recruitment and retention is another challenge faced by many clinical laboratories across the country, but particularly in rural areas where positions are staying vacant longer (Leber AL, Peterson E, Dien Bard J, Personnel Standards and Workforce Subcommittee, American Society for Microbiology. *The Hidden Crisis in the Times of COVID–19: Critical Shortages of Medical Laboratory Professionals in Clinical Microbiology*. J. Clin. Microbiol. 2022 Aug. 17; 60(8) <https://pmc.ncbi.nlm.nih.gov/articles/PMC9383190/>). We believe virtual access can enhance job opportunities and flexibilities in clinical laboratories by enabling qualified personnel to review, digital laboratory data, digital results, live imaging, and digital images via a secure connection to the laboratory software systems, LIS, instruments, or EHR. If this proposal is finalized as proposed, virtual access would allow for travel cost savings and a lessened

burden for personnel who normally would commute to the primary testing laboratory for job duties that are applicable. We believe there would be an additional benefit for laboratories using virtual access as outlined in this proposed rule, because no additional CLIA certificate or fees outside of the primary testing laboratory where the digital laboratory data, images, and results are transmitted from and back to would be required. However, any location using a microscope to examine physical slides would require its own CLIA certificate. Laboratories would also benefit from virtual access because it would allow for the use of new technologies as the industry evolves to meet modern laboratory testing needs. Virtual access provides several public health benefits, as noted in the CMS issued memo QSO–23–15–CLIA–REVISED titled “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance.” This exercise of enforcement discretion allowed laboratories to increase their testing capacity and accessibility in locations or in situations where on-site reviews were not feasible. We believe codifying this flexibility to allow for virtual access would continue to allow for an increase in testing capacity and accessibility across the country. However, data is not currently being collected on the number of laboratories that have relied on the enforcement discretion or the extent to which it has affected testing capacity and accessibility. Therefore, at this time, the benefits of codifying virtual access allowances cannot be reliably quantified.

b. Personnel Qualifications

(1) Laboratory Director Qualifications and Responsibilities

We have identified quantifiable and non-quantifiable benefits associated with several of the proposed changes to the personnel qualification requirements. We believe that by making these changes, there would be an increased availability of qualified laboratory directors. The changes described in this proposed rule would permit laboratory experience outside a CLIA-certified laboratory, including a medical residency or fellowship, and animal research projects as pathways to gain the necessary laboratory experience and education to qualify as a laboratory director. Laboratory directors who oversee high complexity or moderate complexity testing may qualify as laboratory directors by obtaining 20 CE credits in laboratory director responsibilities or laboratory experience, providing more qualification opportunities. Also, removing the board certification requirement for laboratory directors who oversee moderate complexity testing would reduce burden and cost continuously, as boards require CE credit hours to maintain certification.

CMS and the CDC propose new regulations for laboratory director qualifications for dermatopathology high complexity testing. Based on feedback from multiple dermatology boards, we propose that dermatologists’ specialized training should qualify them as laboratory directors for testing Mohs procedures. According to research, in 2014, there were 2,240 Mohs surgeons in the U.S., and 1,118 of them were

members of the American College of Mohs Surgery (ACMS) (H Feng, D Belkin, and RG Geronemus. *Dermatologic Surgery* 45(1): p. 160–163, January 2019). Members of ACMS and the American Society for Mohs Surgery (ASMS) boards must be trained as part of a fellowship training program for one to 2 years after dermatology residency to be certified. By allowing dermatologists to be qualified as laboratory directors, it

would increase the pool of qualified members to oversee dermatopathology laboratories. Other proposed changes allow for cost savings in addition to lessening the burden. Removing the requirement for laboratory directors to be on-site at least twice a year would reduce costs. Additionally, removing the requirement for PPM competency assessments would further reduce costs.

As presented in Table 6 (Laboratory Director Qualifications and Responsibilities Cost Savings), we estimated quantifiable benefits for laboratories related to laboratory director qualifications and responsibilities. A breakdown of the cost savings is provided in the RIA Section 2, Costs.

TABLE 6—LABORATORY DIRECTOR QUALIFICATIONS AND RESPONSIBILITIES COST SAVINGS

Change	Affected CLIA certificate or complexity type(s)	Initial/implementation (year 1)		Ongoing annually/maintenance	
		Low estimate	High estimate	Low estimate	High estimate
Laboratory Director Qualifications (Boards with CE 1st year estimate).	Moderate Complexity Laboratory Directors.	\$3,846,856	\$117,927,825	\$1,525,056	\$90,431,700
Laboratory Director Qualifications (CE credits).	CoC/CoA	2,716,400	33,955,000	0	0
Laboratory Director Responsibilities (Annual on-site travel and lodging).	CoC/CoA	644,431	1,723,282	644,431	1,723,282
Laboratory Director Responsibilities (Annual PPM competency assessment).	PPM	639,937	57,596,683	639,937	57,596,683
Total Cost Savings		7,847,624	211,202,790	2,809,424	149,751,665

(2) Blood Gas Testing Personnel and Competency Assessor Qualifications

CMS and the CDC propose to add qualifiers for moderate complexity blood gas testing personnel to allow those with the applicable associate degrees to qualify as technical consultants for blood gas analysis. We also propose to rescind the regulations requiring that for moderate complexity blood gas testing, the personnel should have a year of experience. These proposed changes are intended to address an inadvertent error discovered following the implementation of the 2023 CLIA final rule. We believe this error resulted from duplicating the regulation for high complexity blood gas testing personnel at § 493.1489. We believe that less complex testing does not require greater experience requirements in the CLIA regulations. These proposed changes offer more flexibility by allowing more opportunities to qualify as moderate complexity blood gas testing personnel and to provide competency assessments while maintaining the laboratory’s ability to produce accurate and reliable testing.

(3) Gross Tissue Examination Personnel Qualifications

The proposed changes to the personnel qualifications that permit histotechnicians, histotechnologists, and pathologist assistants to qualify as high complexity testing personnel may close a regulatory gap and address

workforce shortages by increasing the availability of testing personnel who can perform gross tissue examination.

(4) Gross Tissue Examination Technical Supervisor Review

The proposed changes to the gross tissue examination technical supervisor review process would provide a benefit of less restrictive guidance. It would permit laboratories to perform the review before the final test report is issued, instead of within 24 hours, which should allow for more flexibility in the gross tissue examination process while maintaining the laboratory’s ability to produce accurate and reliable testing.

c. Gynecologic Cytology PT

We believe there would be several non-quantifiable benefits for cytology laboratories associated with finalization of our proposal related to gynecologic cytology PT. As a result of the FDA authorization of new technologies in this area, cytology laboratories may decide to perform gynecologic cytology testing using digital images. If a laboratory performs gynecologic cytology testing using digital images, it must comply with gynecologic cytology PT requirements at § 493.855(a) and (b). The requirement for PT programs that offer gynecologic cytology PT specimens to include a system to monitor the integrity of testing, if offering a digital image option, would benefit laboratories using digital cytology systems by

allowing them to participate in PT programs that utilize digital images while maintaining the integrity and relevance of the PT process.

d. Other Changes

(1) Certificate Requirements

One of the benefits of this proposed rule is that it would modernize CLIA by leveraging a digital-first approach, promoting sustainability, and allowing for faster communication between CMS and laboratories.

(2) Proposed Addition of CLIA Number and Laboratory Name to Test Reports

CMS is aware that laboratories sometimes use commercial names that are not identical to names on the CLIA certificate, and the current regulations do not address this situation. Specifically, this proposed change would establish clear traceability and accountability for laboratory testing and reporting by creating a direct link between test results and the specific laboratory facility that performed the analysis. Currently, some laboratories operate under multiple DBA names while functioning as a single entity, which can mislead healthcare providers, patients, and other interested parties about the true source of laboratory services. Requiring the inclusion of the laboratory name as it appears on the CLIA certificate and CLIA number in test reports would eliminate confusion caused by using multiple business names and ensure that all parties can

accurately identify and verify the credentials of the laboratory performing the tests. This transparency would enable better oversight by regulatory bodies and provide healthcare providers and patients with the information necessary to make informed decisions about laboratory services.

(3) Enforcement Requirements

Modifying enforcement requirements by rescinding the mandatory 6-month reinstatement waiting period, which currently prevents laboratories from resuming testing even after they have returned to compliance following PT failures, and by continuing alternative sanctions, including patient notification requirements, until a laboratory's CLIA certificate is revoked rather than when it is suspended or limited, would reduce burden while maintaining safety standards.

2. Costs

a. Virtual Access

The proposed addition of virtual access into the CLIA regulations for laboratories electing to review digital laboratory data, digital results, live imaging, and digital images performed under the CLIA certificate of the primary testing laboratory that generated the data via a secure connection to the primary testing laboratory software systems, LIS, instruments, EHR, or encrypted communications when not physically on the premises of the primary testing laboratory would have initial and ongoing impact costs for those applicable laboratories. This proposed rule formally outlines the proposed compliance requirements, including the primary testing laboratory's CLIA laboratory director's oversight responsibilities, testing limitations, and facility and retention requirements for laboratories that currently utilize virtual access and laboratories that may voluntarily choose to implement virtual access in the future. The virtual access allowances in this proposed rule provide an additional testing option for laboratories, further increasing testing capabilities and flexibility.

Laboratory business models can vary significantly depending on the types of testing performed, the testing complexities, and the populations or geographic regions served. These variations can influence operational workflows, staffing, and financial decisions that laboratories must consider when determining which tests to offer and implement, including how results would be reviewed, verified, and reported. Considering these factors, it is

difficult to specifically pinpoint how many laboratories currently utilize or in the future would implement virtual access. However, we estimate approximately 40 percent (13,582) of all CoC and CoA laboratories may already have the capability to use or implement virtual access. The 40% estimate was calculated using CLIA enrollment data by identifying the current number of laboratories classified as hospital-based, independent, industrial, public health, or pharmacies. This number was then divided by the total number of laboratories with a CoA or CoC certificate type to calculate the percentage.

When estimating virtual access costs, we considered the total testing process of virtual access to include the test analysis, transmission of results, images, or data via a secure connection, review at a secure location, and transmission back to the primary testing laboratory. To estimate the cost impacts for laboratories voluntarily using or implementing in the future virtual access, we relied on publicly available data for common expense costs for equipment and maintenance, service agreements, digital software and licensing, data storage, digital results and imaging, validation and verification, and administrative compliance. Since virtual access is voluntary, we estimated the cost for one laboratory to implement virtual access with consideration for the lowest and highest estimates for equipment, software, and administrative costs. These cost estimates are outlined in Table 7 (Virtual Access Quantifiable Costs per Laboratory).

(1) Quantifiable Equipment and Software Costs

To estimate the total cost for each CoC and CoA laboratory to acquire digital whole slide instrumentation or other applicable instrumentation capable of analyzing and/or reporting laboratory data, digital results, live images, and/or digital images, we reviewed publicly available data on common expenses for whole slide imaging instrumentation. To determine the equipment cost, we considered the cost for the equipment only, not including any customizations a laboratory may purchase based on their testing workflow. We estimate the cost for a laboratory to acquire equipment would range from \$100,000 to \$1,500,000 (1 Laboratory $\times$ 100,000 or 1,500,000 dollars) (Kumar N, Gupta R, Gupta S. Whole Slide Imaging (WSI) in Pathology: Current Perspectives and Future Directions. *J Digit Imaging*. 2020;33(4):1034–1040, <https://pmc.ncbi.nlm.nih.gov/articles/>

PMC7522141). We assume the cost for equipment would be a one-time cost burden for laboratories purchasing equipment. If the laboratory leases equipment, we assume there would be a decreased cost initially and ongoing, as leasing commonly allows laboratories to acquire equipment without a significant initial investment and with other offset costs for testing materials. We assume the lifespan of the equipment would vary for each laboratory, so additional costs to replace the equipment at the end of life or lease were not included in the initial cost range to acquire the equipment.

Concurrently, laboratories may utilize software during the testing process to facilitate the transfer of laboratory data, digital results, live and/or digital images through a secure private network. Laboratories must also have a system in place to detail who performed the test via virtual access and on what device the test was performed to resolve quality issues and complaints. To estimate the costs of digital software, we reviewed publicly available websites of companies offering and comparing digital software prices. This allowed us to determine an estimated cost range by considering the lowest and highest price for digital software options. The digital software costs ranged from \$1,000 to \$100,000 (1 Laboratory $\times$ 1,000 or 100,000 dollars) based on the software's functionality and features. We assume laboratories that require customizations, multiple instrumentation integrations, and user licenses would have an increased cost, comparable to the upper end of the range. We estimate costs associated with digital software, including licensing costs, would be ongoing for the life of the test, and the cost may vary over time depending on the type of software license purchased (for example, perpetual, annual, or subscription) (<https://www.labx.com/categories/software>, <https://www.itqlick.com/laboratory-connector/pricing>). Maintenance costs that may be associated with the digital software were not included in the initial cost to acquire the software because we assume these costs would vary over time.

(2) Quantifiable Administrative Costs

We estimate that CoC and CoA laboratories would incur labor costs for the time needed to review the revised regulations and update their policies and procedures if they are currently using virtual access. Laboratories voluntarily implementing virtual access would incur labor costs for the time needed to write policies and procedures. The total one-time burden per laboratory to review, update, or

write policies and procedures is estimated to be 4 to 6 hours. Using the most recently published data by the 2024 Bureau of Labor Statistics, a management level employee (Code 11–9111) would perform these tasks at an hourly median wage of \$56.71 per hour. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost would range from \$454 to \$681 [1 Laboratory × (4 hours × \$113.42) or (6 hours × \$113.42)].

Similarly, we estimate that CoC and CoA laboratories would also incur labor costs for the time required for staff to implement virtual access testing and quality assurance processes to monitor the virtual access testing. The total one-time burden per laboratory for these activities is estimated to be 6 to 8 hours. A management level employee (Code 11–9111) would perform these tasks at an hourly median wage of \$56.71 per hour as published by the 2024 Bureau

of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost for each laboratory for these activities would range from \$681 to \$907 [1 Laboratory × (6 hours × \$113.42) or (8 hours × \$113.42)].

We estimate that laboratories currently utilizing or implementing virtual access would have other ongoing administrative costs associated with notifying CMS of virtual access staff and recordkeeping. The ongoing cost burden per laboratory for these activities is 5 to 15 minutes per operating day, once a month. A management level employee (Code 11–9111) would perform these tasks at an hourly median wage of \$56.71 per hour as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost for these activities for each laboratory that chooses to implement

virtual access would range from \$9 to \$28 [1 Laboratory × (0.08 hours × \$113.42) or (0.25 hours × \$113.42)]. These estimated costs would be ongoing for the life of the test.

Laboratories electing to implement virtual access would have ongoing administrative costs associated with the equipment maintenance, personnel training and competency assessments, and semiannual verification studies. A management level employee (Code 11–9111) would perform these tasks at an hourly median wage of \$56.71 per hour as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. The estimated total ongoing burden for each laboratory would range from 1 to 3 hours. The total cost per laboratory would range from \$113 to \$340 [1 Laboratory × (1 hour × \$113.42) or (3 hours × \$113.42)].

TABLE 7—VIRTUAL ACCESS QUANTIFIABLE COSTS PER LABORATORY

	Initial/implementation (Year 1)		Ongoing/maintenance and compliance	
	Low estimate	High estimate	Low estimate	High estimate
Laboratory	1	1	1	1
Equipment Costs	\$100,000	\$1,500,000		
Software Costs	\$1,000	\$100,000		
Administrative Costs	\$1,143	\$1,616	\$113	\$340
Total	\$102,143	\$1,601,616	\$113	\$340

(3) Non-Quantifiable Costs

If this proposal is finalized as proposed, a number of non-quantifiable costs would also result for laboratories utilizing or voluntarily implementing virtual access testing. We are unable to quantify the cost for laboratories for the equipment maintenance, including service agreements because these costs would vary greatly depending on the type of equipment maintenance a laboratory acquires (for example, original equipment manufacturer service, in-house service, or service provided by a third party (<https://www.labmanager.com/the-business-of-science-financial-strategies-every-lab-manager-needs-to-know-34421>)). These costs are variable due to the level of the service contracts negotiated by each laboratory. A laboratory may also choose to outsource the service of the equipment, and we do not have the capability to determine those costs.

As outlined in sections II.A of this proposed rule, for compliance, laboratories utilizing virtual access would be required to follow facility and retention CLIA requirements for

nonwaived testing, including the storage of laboratory data, digital results, live images, and/or digital images. We are not able to quantify the cost to store these files, images, or data because the average cost for storage differs depending on the type of storage used: cloud or local, volume and retention needs, and access and security features. We assume most laboratories would have access to cloud storage options or a local network server where files may be stored at a reduced cost. Also, laboratories utilizing an existing laboratory information system or electronic medical record to report patient results would have capabilities for storing patient results in their existing system (<https://www.ncbi.nlm.nih.gov/books/NBK562702/>).

We are not able to quantify the costs associated with obtaining testing materials that may be required or needed for validation and verification studies. These costs would vary depending on the test complexity, testing requirements determined by the equipment manufacturer, and any

system customizations based on specific testing needs.

b. Personnel Qualifications

(1) Laboratory Director Qualifications and Responsibilities

To estimate the cost savings for removing the requirement for moderate complexity laboratory directors to be board certified, we looked at the websites of each of the nine HHS-approved certification boards for laboratory directors to gather the appropriate information. To determine the cost, we used the application fee, exam fee, and annual fee or maintenance fee.

We assumed that the laboratory directors would not let their certification lapse, and the application fee and the exam fee were only used in the calculation for the first year of cost savings. The application fees ranged from \$225 to \$775, and the exam fees ranged from \$200 to \$1,050 for a single exam. For those requiring a general and a specialty exam, the fees ranged from \$525 to \$2,225. We looked at annual fees/maintenance fees that the boards charged, which ranged from \$112 to

\$500, and the CE course fees were set at a low of \$20 and a high of \$50. There is a large range of fees for CE courses as determined by the type of course and how they are received. For example, when a person registers for a conference, sometimes as many as 60 CE credits are available over the course of the conference, depending on the activities/presentations during the conference. Other courses are taken online at little to no cost. We assumed that courses offering CE usually cost between \$20 and \$50, but we understand that this may be an underestimation. From the boards' websites, we were able to determine how many credits were required annually to retain certification. To

determine the cost savings, we multiplied the lowest number of credits by the lowest CE fee (10 CE Credits $\times$ \$20 CE Fees = \$200) and the highest number of credits by the highest CE fee (50 CE Credits $\times$ \$50 = \$2,500). These numbers were added to the sum of the application fee, exam fee, and annual fee to determine the savings for the first year. We removed the application fee and the exam fee for years 2 and 3 only because some boards retain a three-year cycle for continuing education credits.

To estimate the number of laboratories affected by this proposed change, we used the number of PPM-certified laboratories since PPM testing is considered moderate complexity. To find the low range, we divided the

number of PPM laboratories by five because, according to the CLIA regulations, one director may oversee up to five laboratories. For the high range, we assumed all the laboratories were directed by one person and used the total number of PPM laboratories. We multiplied the lowest number of laboratories by the lowest cost for board certification and the highest number of laboratories by the highest cost for certification to reach the range of \$3,846,856 to \$117,927,825 for the first year and \$1,525,056 to \$90,431,700 for later years. These cost savings estimations are outlined in Table 8 (Laboratory Director Board Certification Cost Savings for Moderate Complexity Laboratories).

TABLE 8—LABORATORY DIRECTOR BOARD CERTIFICATION COST SAVINGS FOR MODERATE COMPLEXITY LABORATORIES

	First year		Years 2 and 3	
	Low estimate	High estimate	Low estimate	High estimate
Total Number of Affected Groups	4,888	24,441	4,888	24,441
Application Fee	\$275	\$775	\$0	\$0
Exam Fee	\$200	\$2,225	\$0	\$0
Maintenance Fee	\$112	\$500	\$112	\$1,200
Continuing Education	\$200	\$2,500	\$200	\$2,500
Total	\$3,846,856	\$117,927,825	\$1,525,056	\$90,431,700

A personnel change proposed in this rule is to remove the requirement to have 20 CE hours in laboratory director responsibilities to qualify as a laboratory director. This proposed change would reduce the burden and cost for all 33,955 CoC and CoA laboratories and their directors. To estimate the CE hour cost savings, we assumed that courses offering CE usually cost between \$20

and \$50, but we understand that this may be an underestimation. To find the low range, we divided the number of CoC and CoA laboratories by five because, according to the CLIA regulations, one director may oversee up to five laboratories. For the high range, we assumed all the laboratories were directed by one person and used the total number of CoC and CoA

laboratories. Based on a low estimate of \$20 and a high estimate of \$50 for each course, we estimate the cost savings range from \$2,716,400 to \$33,955,000 ($6,791 \times \$20 \times 20$ CE hours or $33,955 \times \$50 \times 20$ CE hours). These cost savings estimates are outlined in Table 9 (CE Hours Cost Savings for All CoC and CoA Laboratory Directors).

TABLE 9—CE HOURS COST SAVINGS FOR ALL CoC AND CoA LABORATORY DIRECTORS

	Low estimate		High estimate	
Number of CoC/CoA Laboratories	6,791	33,955	6,791	33,955
CE Course Fees	\$20	\$20	\$50	\$50
CE Credit Hours	20	20	20	20
Total	\$2,716,400	\$13,582,000	\$6,791,000	\$33,955,000

A personnel change proposed in this rule includes removing the requirement for PPM laboratory competency assessments which would reduce costs associated with labor. This proposed change would reduce the burden and the cost to all 24,441 PPM laboratories and their directors. To find the low range we divided the number of PPM laboratories by five because according to the CLIA regulations one director may oversee up to five laboratories. For the high range we assumed all the

laboratories were directed by one person and used the total number of PPM laboratories. The following five procedures are the minimum regulatory requirements for assessing the competency of all personnel performing PPM procedures: directly observe routine patient test performance, including, if applicable, specimen handling, processing, and testing, monitor the recording and reporting of test results, review test results or worksheets, assess test performance

through testing internal blind testing samples or external PT samples, and assess problem-solving skills. Testing under a CLIA Certificate for PPM procedures is restricted to nine specific microscopic examinations using bright-field or phase-contrast microscopy: all direct wet-mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements, all potassium hydroxide (KOH) preparations, pinworm examinations, fern tests, post-coital direct, qualitative

examinations of vaginal or cervical mucous, urine sediment examinations, nasal smears for granulocytes, fecal leukocyte examinations, qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

However, not every PPM laboratory performs all nine of these PPM procedures. Also, PPM laboratories vary in size, and we do not have data on the number of personnel at each location. The cost of PT materials varies because they can be purchased from various vendors or prepared in-house using previously performed patient specimens. Due to this variability in PPM competency assessments, we determined cost savings by estimating

the number of personnel, labor hours, and assuming a physician (Code 29–1210) would perform this task at an hourly median wage of \$130.92 per hour, as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$261.84, including overhead and fringe benefits. We assumed at least two personnel would need to be available to complete the competency assessment. One for performing the testing and one to assess the competency. We did not include cost savings for the PT materials used because we are unable to determine the costs due to the variability of materials used by each laboratory. For the low estimate, we used one PPM test, and for the high

estimate, we used all nine PPM tests. We estimated it would take 15–30 minutes or 0.25 to 0.5 hours to assess someone's competency, including the direct observation for each PPM test. Based on a low estimate of 1 PPM test and a high estimate of 9 PPM tests for each competency assessment, we estimate the cost savings range from \$639,937 to \$57,596,683. Low estimate: (4,888 PPM laboratories × 2 personnel × 1 PPM test) × (0.25 hours × \$261.84). High estimate: (24,441 PPM laboratories × 2 personnel × 9 PPM tests) × (0.5 hours × \$261.84). These cost savings estimations are outlined in Table 10 (Competency Assessment Cost Savings for PPM Laboratories).

TABLE 10—COMPETENCY ASSESSMENT COST SAVINGS FOR PPM LABORATORIES

	Low estimate				High estimate			
Number of Laboratories	4,888	4,888	4,888	4,888	24,441	24,441	24,441	24,441
Number of Personnel ..	2	2	2	2	2	2	2	2
PPM Test(s) Performed	1	1	9	9	1	1	9	9
Labor Hours	0.25	0.5	0.25	0.5	0.25	0.5	0.25	0.5
Wage Rate	\$261.84	\$261.84	\$261.84	\$261.84	\$261.84	\$261.84	\$261.84	\$261.84
Total	\$639,937	\$1,279,874	\$5,759,433	\$11,518,865	\$3,199,816	\$6,399,631	\$28,798,341	\$57,596,683

A personnel change proposed in this rule includes removing the requirement for laboratory directors to be on-site at the laboratories they direct at least twice a year. This change would reduce the burden and the cost to the laboratories. To estimate the cost savings, we referred to Table 21 (Estimated Travel Costs to Meet On-site Laboratory Director Requirement) given in the Regulatory Impact Analysis of the final rule, “CLIA Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Final Rule”, as a starting point using the same assumptions but with current information.

There are 40 states, four territories, and the District of Columbia where the laboratory director is not required to be on-site at least twice per year. Therefore, some of the 24,824 CoC and CoA laboratories (August 08, 2025, Quality, Certification and Oversight Reports (QCOR)) that have incurred travel costs would no longer have that burden. Based on the final rule, we assume that between five percent (1,241) and 20 percent (4,965) of the CoC and CoA laboratories must travel twice a year to meet the requirement. We assumed that this travel would include a combination of two modes of transportation, driving and flying. For the low estimate, we assumed that one percent of the 24,824 or 248 would compensate their directors

for flights, while four percent or 993 would compensate them for their mileage to drive. For the high estimate, we assumed that, at most, two percent of the 24,824 or 496 would compensate their laboratory director for flying and that 18 percent or 4,468 would compensate for driving.

Driving: We believe most laboratory directors would drive fewer than 250 miles round-trip to reach the laboratories they direct. We assume these laboratory directors 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 \$0.70 per mile (<https://www.gsa.gov/travel?gsaredirect=travel-resources>) for a maximum cost of \$175 per trip. This may be an overestimation because we believe not all laboratory directors who drive would travel 250 miles round-trip. Based on the low estimate of 993 laboratories and our high estimate of 4,468 laboratories, our calculated cost savings estimate for driving ranges from \$173,768 to \$781,956. The cost savings estimations are outlined in Table 10 (Cost Savings for Laboratory Director on-site visit requirements).

Flying and Lodging: Our estimates for the cost savings of flying assume that, in these cases, travel to a remote site is necessary. We believe basing it on travel

to a remote site would overestimate the cost savings because in many locations, although the laboratory director may fly to reach their destination, they would not travel to remote locations, and the travel cost savings would be less. However, we do not know the specific circumstances under which flying would be required. Consistent with the airfare assumption used in the 2023 CLIA final rule, we estimated a conservative maximum airfare of \$1,500 to account for travel to remote locations or other circumstances where airfare costs may be higher. We estimated lodging costs to average \$175 per night based on the average of 100 hotel rates throughout the U.S. for 2024 (Business Travel News; https://ik.imgkit.net/3vlqs5axxjf/BTN/uploadedfiles/Microsites/Consumer_Travel_Index/BTN_2024_US_Per%20Diems%20Ranked_CTI.pdf).

We assumed lodging for two nights would be needed. Therefore, the total estimated cost savings for one trip would be \$1,500 flight + \$350 lodging, or \$1,850 per trip. Based on the low estimate of 248 laboratories and our high estimate of 496 laboratories that require flying to on-site visits, the cost savings would be between \$470,663 and \$941,326. Based on these assumptions for both driving and flying, we estimate the total cost savings for laboratories that compensate travel for the laboratory

director range from \$644,431 to \$1,723,282. The cost savings estimations are outlined in Table 11 (Cost Savings for Laboratory Director on-site visit requirements).

TABLE 11—COST SAVINGS FOR LABORATORY DIRECTOR ON-SITE VISIT REQUIREMENTS

Regulation change	Affected group	Total number of affected group				Airfare cost (\$1,500)	Lodging cost (\$175 * 2 nights)	Driving cost (\$0.70/mile * 250 miles)	Total impact for laboratory director on-site regulation changes	
	CoA & CoC Laboratories	Low estimate		High estimate					Low estimate	High estimate
On-Site Laboratory Director	Driving	4%	993	18%	4,468	N/A	N/A	\$175	\$173,768	\$781,956
	Flying	1%	248	2%	496	\$1,500	\$350	N/A	470,663	941,326
		Total	124	Total	4,965	Total Cost Savings			644,431	1,723,282

We anticipate short-term implementation costs to update policies and procedures. As presented in Table 12 (Laboratory Director Qualifications and Responsibilities Policies and Procedures Quantifiable Costs), we estimated quantifiable costs that would be incurred by laboratories to update policies and procedures relating to the proposed changes. We expect 33,955 CoC and CoA laboratories and 24,441 PPM laboratories would have cost

impacts for the time needed to review the revised regulations and update policies and procedures to ensure compliance. We estimate the total one-time cost burden per CoC and CoA laboratory is 1.5 to 3 hours and 0.25 to 0.5 hours per PPM laboratory. Assuming a management-level employee (Code 11–9111) would perform this task at an hourly median wage of \$56.71 per hour as published by the 2024 Bureau of Labor Statistics, the wage rate would be

\$113.42 to include overhead and fringe benefits. For CoC and CoA, the total cost would range from \$5,776,764 to \$11,553,528 [33,955 CoC and CoA laboratories × (1.5 hours × \$113.42) or (3 hours × \$113.42)]. For PPM, the total cost would range from \$693,025 to \$1,386,049 [24,441 PPM laboratories × (0.25 hours × \$113.42) or (0.5 hours × \$113.42)].

TABLE 12—LABORATORY DIRECTOR QUALIFICATIONS AND RESPONSIBILITIES POLICIES AND PROCEDURES QUANTIFIABLE COSTS

Change	Affected CLIA certificate type(s)	Low estimate	High estimate
Laboratory Director Qualifications and Responsibilities Policies and Procedures Updates.	CoC/CoA	\$5,783,569	\$11,567,139
Laboratory Director Qualifications and Responsibilities Policies and Procedures Updates.	PPM	693,025	1,386,049
Total Costs		6,476,594	12,953,188

(2) Blood Gas Testing Personnel and Competency Assessor Qualifications

We anticipate short-term implementation costs to update policies and procedures. As presented in Table 13 (Blood Gas Testing Qualifications Quantifiable Cost), we estimated quantifiable costs that would be

incurred by laboratories to update policies and procedures relating to the proposed changes. We estimate the total one-time cost burden per CoC and CoA laboratory is 0.25 to 0.5 hours. Assuming a management-level employee (Code 11–9111) would perform this task at an hourly median

wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics, the wage rate would be \$113.42 to include overhead and fringe benefits. The total cost would range from \$962,794 to \$1,925,588 [33,955 CoC and CoA laboratories × (0.25 hours × \$113.42) or (0.5 hours × \$113.42)].

TABLE 13—BLOOD GAS TESTING QUALIFICATIONS QUANTIFIABLE COST

Change	Affected CLIA certificate type(s)	Low estimate	High estimate
Blood Gas Testing Personnel and Competency Assessor Qualifications Policies and Procedures Updates.	CoC/CoA	\$962,794	\$1,925,588

(3) Gross Tissue Examination Personnel Qualifications

We anticipate short-term implementation costs to update policies and procedures. As presented in Table 14 (Gross Tissue Examination Personnel Qualifications Quantifiable Cost), we

estimated quantifiable costs that would be incurred by laboratories to update policies and procedures relating to the proposed changes. We estimate the total one-time cost burden per CoC and CoA laboratory is 0.25 to 0.5 hours. Assuming a management-level

employee (Code 11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics, the wage rate would be \$113.42 to include overhead and fringe benefits. The total cost would range from

\$962,794 to \$1,925,588 [33,955 CoC and CoA laboratories × (0.25 hours × \$113.42) or (0.5 hours × \$113.42)].

TABLE 14—GROSS TISSUE EXAMINATION PERSONNEL QUALIFICATIONS QUANTIFIABLE COST

Change	Affected CLIA certificate type(s)	Low estimate	High estimate
Gross Tissue Examination Personnel Qualifications Policies and Procedures Updates	CoC/CoA	\$962,794	\$1,925,588

(4) Gross Tissue Examination Technical Supervisor Review

We anticipate short-term implementation costs to update policies and procedures. As presented in Table 15 (Gross Tissue Examination Technical Supervisor Review Quantifiable Cost), we estimated quantifiable costs that

would be incurred by laboratories to update policies and procedures relating to the proposed changes. We estimate the total one-time cost burden per CoC and CoA laboratory is 0.25 to 0.5 hours. Assuming a management-level employee (Code 11–9111) would perform this task at an hourly median

wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics, the wage rate would be \$113.42 to include overhead and fringe benefits. The total cost would range from \$962,794 to \$1,925,588 [33,955 CoC and CoA laboratories × (0.25 hours × \$113.42) or (0.5 hours × \$113.42)].

TABLE 15—GROSS TISSUE EXAMINATION TECHNICAL SUPERVISOR REVIEW QUANTIFIABLE COST

Change	Affected CLIA certificate type(s)	Low estimate	High estimate
Gross Tissue Examination Technical Supervisor Review Policies and Procedures Updates.	CoC/CoA	\$962,794	\$1,925,588

(5) Personnel Regulations Non-Quantifiable Costs

There are non-quantifiable costs associated with the changes to the personnel regulations. The changes to the blood gas testing personnel and competency assessment qualifications could not be quantified other than by updating the policies and procedures, because the revisions provide flexibility to the laboratory. It is unclear the number of laboratories that would use the new flexibility and how often. The same is true for the new flexibilities for gross tissue examination personnel qualifications and gross tissue examination technical supervisor review.

c. Gynecologic Cytology PT

(1) Costs for Laboratories

As presented in Table 16 (Gynecologic Cytology PT Quantifiable Costs), the implementation of the proposed rule for gynecologic cytology PT would primarily impact cytology laboratories. We estimate approximately 25 percent of all cytology laboratories

(807 cytology laboratories) have adopted digital images for screening as their primary method of patient testing, and would have a cost burden for the time needed to review the revised regulations and update policies and procedures to ensure compliance. We estimate the total one-time cost burden per cytology laboratory is 1 to 1.5 hours. Assuming a management-level employee (Code 11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics, the wage rate would be \$113.42 to include overhead and fringe benefits. The total cost for 807 cytology laboratories would range from \$91,530 to \$137,295 [807 laboratories × (1 hour × \$113.42) or (1.5 hours × \$113.42)].

(2) Costs for PT Programs

Changes to the requirements for gynecologic cytology PT would affect two PT programs currently offering gynecologic cytology PT. We estimate that these PT programs would incur costs to update software to include the review of digital slides with an internal monitoring system, review the updated

regulations, and update their affected policies and procedures. We estimate the total one-time cost burden per PT program is 1 to 1.5 hours to review the updated regulations and update affected policies and procedures. We assume these tasks would be performed by a management-level employee (Code 11–9111) at an hourly median wage of \$56.71 per hour as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. For these activities, the total cost for two PT programs would range from \$227 to \$340 [2 PT programs × (1 hour × \$113.42) or (1.5 hours × \$113.42)].

Concurrently, we estimate the total one-time cost burden per PT program to develop or modify existing software is 416 to 456 hours. Upon request, these estimated hours were provided by the ASCP, one of the two PT programs that currently offer gynecologic cytology PT. The total cost for two PT programs would range from \$94,365 to \$103,439 [2 PT programs × (416 hours × \$113.42) × (456 hours × \$113.42)].

TABLE 16—GYNECOLOGIC CYTOLOGY PT QUANTIFIABLE COSTS

	Cytology laboratories		PT programs	
	Low estimate	High estimate	Low estimate	High estimate
Total Impacted	807	807	2	2
Administrative Costs	\$91,530	\$137,295	\$227	\$340
Software Development or Modifications			\$94,365	\$103,439
Total	\$91,530	\$137,295	\$94,592	\$103,779

d. Other Changes

As presented in Table 17 (Other Changes Quantifiable Costs), we estimated quantifiable costs that would be incurred by laboratories relating to the proposed other changes. We estimate the total one-time cost burden per CoC and CoA laboratory is 0.5 to 1 hour, 0.25 to 0.5 hours per CoW laboratory, and 0.25 to 0.5 hours per PPM laboratory. Assuming a management-level employee (Code 11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics, the wage rate would be \$113.42 to include overhead and fringe benefits. For CoC and CoA, the total cost would range from \$1,925,588 to \$3,851,176 [33,955 CoC and CoA laboratories $\times$ (0.5 hours $\times$ \$113.42) or

(1 hour $\times$ \$113.42)]. For CoW, the total cost would range from \$7,050,244 to \$14,100,488 [248,642 CoW laboratories $\times$ (0.25 hours $\times$ \$113.42) or (0.5 hours $\times$ \$113.42)]. For PPM, the total cost would range from \$693,025 to \$1,386,049 [24,441 PPM laboratories $\times$ (0.25 hours $\times$ \$113.42) or (0.5 hours $\times$ \$113.42)].

A summary of those costs is provided for each category under Other Changes:

1. SARS-CoV-2 Reporting

Requirements: There is no foreseen cost burden as the reporting requirements ended when the SARS-CoV-2 PHE was terminated.

2. *Certificate Requirements:* There is no foreseen cost burden. The laboratory's email address is already required on Form CMS-116.

3. *Addition of CLIA Number and Laboratory Name to Test Reports:* We

anticipate a cost to some laboratories that do not currently have their laboratory name and/or CLIA number on their test reports to update the Laboratory Information Management System (LIMS) or non-LIMS-based test report, such as paper-based processes (for example, PDF and fax). Currently, there is no available data on how many laboratories lack this information on their test reports. There are also expected to be short-term implementation costs to update policies and procedures.

4. *Enforcement Requirements:* There is no foreseen cost burden for the proposed enforcement requirements.

5. *Editorial and Technical Changes:* There is no foreseen cost burden for the proposed editorial and technical changes.

TABLE 17—OTHER CHANGES QUANTIFIABLE COSTS

Change	Affected CLIA certificate type(s)	Low estimate	High estimate
Other Changes Policies and Procedures Updates	CoC/CoA CoW PPM	\$1,925,588 7,050,244 693,025	\$3,851,176 14,100,488 1,386,049
Total Costs		9,668,857	19,337,713

e. Accreditation Organization and Exempt State Costs

If the proposed changes are finalized, seven approved AOs and two ESs would have to identify the applicable legal obligations and develop the policies and procedures needed to reflect the new requirements for virtual access, gynecologic cytology PT, and all personnel updates. We reviewed data from CMS-R-185—December 29, 2023, where each AO and ES provided to CMS

the number of labor hours per year for their organization to accumulate information and develop a comparison between their requirements and survey process and those of CLIA, see Table 18 (Estimation of Accreditation Organizations and Exempt States Labor Hours). Of note, the table does not include data from A2LA. Based on this information, we estimate a one-time cost of 30 to 729 hours to implement the proposed changes. We assume a

management-level employee (Code 11–9111) would perform this task at an hourly median wage of \$56.71 per hour, as published by the 2024 Bureau of Labor Statistics. The wage rate would be \$113.42 to include overhead and fringe benefits. The total cost would range from \$30,623 to \$744,149 [9 $\times$ (30 hours $\times$ \$113.42) or (729 hours $\times$ \$113.42)]. The estimated costs are presented in Table 19 (Accreditation Organization and Exempt State Costs).

TABLE 18—ESTIMATION OF ACCREDITATION ORGANIZATIONS AND EXEMPT STATES LABOR HOURS

Name of accreditation organization/exempt state	AABB	ACHC	ASHI	CAP	COLA	NY	TJC	WA
Number of hours (per year) for organization to accumulate information and develop a crosswalk (comparison between their requirements and survey processes and those of CLIA	160	180	30	150	729	240	550	48

TABLE 19—ACCREDITATION ORGANIZATION AND EXEMPT STATE COSTS

Change	Low estimate	High estimate
Accreditation Organization and Exempt State Labor Costs to Implement Proposed Rule	\$30,623	\$744,149

3. Transfers

The proposed rule does not include any transfers of payments between persons or groups.

4. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique commenters (20,574) on the 2023 CLIA

final rule would be the estimated number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters

reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we assumed that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities that would review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. Therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the 2024 Bureau of Labor Statistics for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$113.42 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is \$226.84 (2 hours × \$113.42). Therefore, we estimate that the total cost of reviewing this regulation is \$4,667,006 (\$226.84 × 20,574).

D. Alternatives Considered

1. Virtual Access

Several alternatives were considered when proposing the changes in this rule. When considering alternatives to formal rulemaking for virtual access, CMS and the CDC evaluated two primary options: codifying the current

enforcement discretion or discontinuing it. These technological developments have fundamentally changed how laboratory services can be delivered, making the original regulatory framework inadequate for current capabilities. Therefore, formal rulemaking emerged as the most viable path forward to provide regulatory clarity while acknowledging modern technological realities.

2. Personnel Qualifications

The changes to the personnel requirements are being proposed in response to interested parties' concerns after the 2023 CLIA final rule regulatory updates to subpart M became effective on December 28, 2024. The qualifications for a laboratory director were changed to add experience and 20 CE credit hours. Interested parties were concerned that additional qualifications could lead to a workforce shortage, especially in rural areas. Other concerns mentioned the increased burden on laboratories from the laboratory directors' on-site visits and workforce shortage due to restrictive qualification requirements. CMS and the CDC evaluated a couple of potential approaches to address the concerns from interested parties about the new personnel qualification regulations. First, we considered rescinding all of the personnel qualification regulations codified in the 2023 CLIA final rule in their entirety and returning to the prior regulatory requirements; however, this approach would have eliminated the critical flexibility we created for nontraditional degree holders⁴⁹ to meet personnel qualification requirements.

Second, we evaluated the possibility of fully revising the personnel qualification regulations to achieve maximum simplification; however, we determined that the organization of the current regulations is appropriate, as it has been used for 30 years, and laboratories are familiar with the structure and the requirements, and selected specific changes based on interested parties' feedback.

3. Gynecology Cytology PT Requirements

No feasible alternatives are apparent for the changes proposed for gynecological cytology PT with digital images due to the FDA authorization of the first digital cytology screening system, which creates digital images of glass slides, in 2024. Laboratories performing gynecological cytology testing using digital images would have to perform PT in the same manner as the primary testing method to ensure quality and accurate results while maintaining regulatory compliance. Therefore, making no changes in this area creates a regulatory gap.

4. Other Changes

No feasible alternatives are apparent for the proposed other changes.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>), we have prepared an accounting statement in Table 20 showing the classification of the impact associated with the provisions of this rule.

TABLE 20—ACCOUNTING STATEMENT

Category	Minimum estimate	Maximum estimate	Source citation (RIA, preamble, etc.)
Benefits:			
Monetized benefits (cost savings), 2028–2032	\$4.0 million (7%) \$3.9 million (3%)	\$162.5 million (7%) \$162.8 million (3%)	
Initial Year 1 (2028)	+\$7,847,624	+\$211,202,790	RIA Section B (Table 4).
Year 2 (2029)	+\$2,809,424	+\$149,751,665	RIA Section B (Table 4).
Year 3 (2030)	+\$2,809,424	+\$149,751,665	RIA Section B (Table 4).
Year 4 (2031)	+\$2,809,424	+\$149,751,665	RIA Section B (Table 4).
Year 5 (2032)	+\$2,809,424	+\$149,751,665	RIA Section B (Table 4).
Costs:			
Annualized monetized costs, 2028–2032	\$4.4 million (7%) \$4.1 million (3%)	\$9.3 million (7%) \$8.6 million (3%)	
Initial Year 1 (2028)	(\$19,352,721)	(\$40,654,504)	RIA Section B (Table 4).
Year 2 (2029)	(113)	(340)	RIA Section B (Table 4).
Year 3 (2030)	(113)	(340)	RIA Section B (Table 4).
Year 4 (2031)	(113)	(340)	RIA Section B (Table 4).
Year 5 (2032)	(113)	(340)	RIA Section B (Table 4).

⁴⁹ Sections 493.1405(b)(3)(i)(B), 493.1405(b)(4)(i)(B), 493.1405(b)(4)(i)(C), 493.1405(b)(5)(i)(B), 493.1411(b)(3)(i)(B), 493.1411(b)(4)(i)(B), 493.1423(b)(3),

493.1443(b)(3)(i)(B), 493.1449(c)(3)(i)(B), 493.1449(c)(4)(i)(B), 493.1449(c)(4)(i)(C), 493.1449(c)(5)(i)(B), 493.1449(d)(3)(i)(B), 493.1449(d)(4)(i)(B), 493.1449(d)(5)(i)(B),

493.1449(h)(2)(i), 493.1449(i)(2)(i), and 493.1489(b)(2)(ii); <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#part-493>.

*F. Regulatory Flexibility Act (RFA)
(Effects on AOs, Clinical Laboratories,
and PT Programs)*

The 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, approximately 76 percent of clinical laboratories are considered small nonprofit organizations as reported in the American Hospital Association (AHA) Fast Fact Sheet, updated February 2026 (<https://www.aha.org/infographics/2026-02-05-fast-facts-us-hospitals-infographics>). Clinical laboratories operate in a variety of organizational settings. Consequently, affected laboratories may be classified under multiple North American Industry Classification System (NAICS) codes depending on the parent organization. We estimate most laboratories are small businesses and fall under the following NAICS categories: 621112 Office of Physicians (except Mental Health Specialists), 621511 Medical Laboratories, and 622110 General Medical and Surgical Hospitals. All CMS-approved accreditation organizations are private nonprofit organizations, as required under § 493.551(a). All approved non-governmental PT programs must be offered by a private nonprofit organization, consistent with § 493.901. Because we lack sufficient data to develop an accurate estimate of the number of laboratories that meet the definition of a small business, we assume, for purposes of this analysis, that all laboratories may fall within that category and could therefore be affected by this rule. We anticipate, however, that this impact would be economically positive rather than negative.

As detailed in Tables 4 and 5, we expect there would be significant cost savings beyond the initial impact of updating policies and procedures for laboratories. The exact savings or costs would depend on the types, scope, and complexity of testing in the laboratory. The adoption of the proposed virtual access flexibility, if finalized, would be voluntary, and many laboratories have already taken advantage of this flexibility under the post-PHE enforcement discretion announced in QSO–23–15–CLIA–REVISED. CMS was urged to codify this flexibility that allowed for virtual access by interested parties and small entities, such as physician-owned laboratories. See Table 7 for estimated per laboratory costs for virtual access. For proposed changes in gynecological cytology PT, we estimate that two PT programs would incur a

one-time cost burden as described in Table 16. The proposed personnel changes in the proposed rule are associated with the majority of cost savings and would vary depending on the type of laboratory and services offered. The proposed flexibilities in personnel qualifications were proposed specifically to address concerns from interested parties and small entities. See Tables 6, 8, 9, 10, and 11 for estimated cost savings, and Tables 12 through 16 for estimated costs. We estimate the one-time cost burden for the other proposed changes contained in this proposed rule in Table 17. Table 19 contains estimated costs for AOs and ESs to implement the policies contained in this proposed rule, if finalized. CMS will seek public comments on the RFA to help improve the estimates for the final rule.

G. Unfunded Mandates Reform Act (UMRA)

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 2026, that threshold is approximately \$193 million. We found that this proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final 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 CMS. With the implementation of the proposed rule, 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.

I. E.O. 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, entitled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2024, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. As outlined in the RIA Section B. Overall Impact, Table 4 (Summary of All Estimated Costs and Cost Savings), we estimate that this proposed rule would generate an average estimate of \$155,800,639 in annualized cost savings at a 7 percent discount rate, discounted relative to year 2028, over a five-year time period.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 5, 2026.

Dr. Erica Schwartz, MD, MPH, JD, RADM, USPHS (ret), Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR), approved this document on October 2, 2026.

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 part 493 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), 1395x(s)(3) and(s)(17).

■ 2. Section 493.2 is amended by—

- a. Adding the definitions of “Biological degree”, “Campus”, “Chemical degree”, and “Clinical or Medical Laboratory Science or Medical Technology” in alphabetical order;
- b. Revising the definition of “Condition level requirements” and “Doctoral degree”;
- c. Removing the definitions of “Experience directing or supervising”, and “Laboratory training or experience”;
- d. Revising the definition of “Test system”; and
- e. Adding the definition of “Virtual access” in alphabetical order.

The additions and revisions read as follows:

§ 493.2 Definitions.

* * * * *

Biological degree means an academic program classified in the 2020 version of the U.S. Department of Education's National Center for Education Statistics (NCES) Classification of Instructional Programs (CIP) under category 26 Biological and Biomedical Sciences, category 01.0901 General Animal Sciences, category 01.0902 Agricultural Animal Breeding, category 01.0903 Animal Health, category 01.80 Veterinary Medicine, and category 01.81 Veterinary Biomedical and Clinical Sciences.

* * * * *

Campus means the physical area immediately adjacent to the laboratory's main building, other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building, and any other area CMS determines on an individual case basis to be part of the campus of the primary CLIA-certified laboratory.

* * * * *

Chemical degree means an academic program classified under category 40.05 Chemistry in the 2020 version of the U.S. Department of Education's National Center for Education Statistics (NCES) Classification of Instructional Programs (CIP).

* * * * *

Clinical or Medical Laboratory Science or Medical Technology degree means an academic program classified in the 2020 version of the U.S. Department of Education's National Center for Education Statistics (NCES) Classification of Instructional Programs (CIP) under category 51.0811 Pathology/Pathologist Assistant, category 51.1001 Blood Bank Technology Specialist, category 51.1002 Cytotechnology/Cytotechnologist, category 51.1003 Hematology Technology/Technician, category 51.1004 Clinical/Medical Laboratory Technician, category 51.1005 Clinical Laboratory Science/Medical Technology/Technologist, category 51.1007 Histologic Technology/Histotechnologist, category 51.1008 Histologic Technician, and category 51.1010 Cytogenetics/Genetics/Clinical Genetics Technology/Technologist.

* * * * *

Condition level requirements means any of the requirements identified as "conditions" in subparts G through Q of this part.

* * * * *

Doctoral degree means an earned doctoral degree as defined by the academic institution's doctoral program.

* * * * *

Test system means the instructions and all of the instrumentation, equipment, reagents, live imaging, digital images, and supplies to perform an assay or examination and generate accurate and reliable test results.

* * * * *

Virtual access means review of digital laboratory data, digital results, live imaging, and digital images performed under the CLIA certificate of the primary testing laboratory that generated the data when not physically on the premises of the primary testing laboratory. Such review must be conducted via a secure connection to the primary testing laboratory's software systems, laboratory information system (LIS), instruments, electronic health records (EHR), or encrypted communications. Virtual access is not permitted in the subspecialty of cytology.

* * * * *

■ 3. Section 493.17 is amended by revising paragraph (a) introductory text, and paragraphs (b) and (c) to read as follows:

§ 493.17 Test Categorization.

(a) *Categorization by criteria.* Notices will be published in the FDA's CLIA—Clinical Laboratory Improvement Amendments Database which lists each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

Note: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

* * * * *

(b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, may conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) *Process for device/test categorization utilizing the scoring system under § 493.17(a).* (1) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k), De Novo request, and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will inform CMS of the device/test category. Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization or recategorization to FDA. FDA will determine the complexity category and notify the applicant and CMS of the categorization decision.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in FDA's CLIA—Clinical Laboratory Improvement Amendments Database, it is considered to be a test of high complexity until FDA, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) FDA will publish revisions periodically to the list of moderate and high complexity tests in the CLIA—Clinical Laboratory Improvement Amendments Database.

■ 4. Section 493.35 is amended by revising paragraphs (b)(2) and (3) to read as follows:

§ 493.35 Application for a certificate of waiver.

* * * * *

(b) * * *

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than 15 waived tests per certificate) public health testing may file a single application.

(3) Laboratories that are located on the same campus and under the same laboratory director may file a single application or multiple applications.

* * * * *

■ 5. Section 493.39 is amended by revising paragraphs (b)(3) through (5) to read as follows:

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

* * * * *

(b) * * *

(3) Location;

(4) Director; or

(5) Email address.

§ 493.41 [Removed]

■ 6. Section 493.41 is removed.

■ 7. Section 493.43 is amended by revising paragraphs (a) and (b)(3) to read as follows:

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing nonwaived testing must file a separate application for each laboratory location.

(1) Virtual access is considered to be conducted at the primary testing laboratory regardless of the physical location of the laboratory personnel and, therefore, is under the CLIA certificate of the primary testing laboratory that generated the data. This does not apply to provider-performed microscopy (PPM) procedure certificates.

(i) The laboratory director is responsible for all testing performed including testing utilizing virtual access.

(ii) All testing must be performed by qualified laboratory personnel under the CLIA-certified laboratory that provides virtual access. The primary testing laboratory must provide CMS with a list of all staff utilizing virtual access upon request.

(2) Reserved

* * * * *

(b) * * *

(3) Laboratories that are located on the same campus and under the same laboratory director may file a single application or multiple applications.

* * * * *

■ 8. Section 493.45 is amended by revising paragraph (b)(2) to read as follows:

§ 493.45 Requirements for a registration certificate.

* * * * *

(b) * * *

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director, email address, or technical supervisor (laboratories performing high complexity testing only);

* * * * *

■ 9. Section 493.51 is amended by—

■ a. Revising paragraph (a)(4);

■ b. Redesignating paragraph (a)(5) as paragraph (a)(6); and

■ c. Adding a new paragraph (a)(5).

The revision and addition read as follows:

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

* * * * *

(a) * * *

(4) Director;

(5) Email address; or

* * * * *

■ 10. Section 493.53 is amended by—

■ a. Revising paragraphs (b)(3) and (4); and

■ b. Adding paragraph (b)(5).

The revisions and addition read as follows:

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

* * * * *

(b) * * *

(3) Location;

(4) Director; or

(5) Email address.

■ 11. Section 493.55 is amended by—

■ a. Adding paragraph (a)(3); and

■ b. Revising paragraph (b)(3).

The addition and revision read as follows:

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) * * *

(3) Virtual access is considered to be conducted at the primary testing laboratory regardless of the physical location of the laboratory personnel and, therefore, is under the CLIA certificate of the primary testing laboratory that generated the data.

(i) The laboratory director is responsible for all testing performed including testing utilizing virtual access.

(ii) All testing must be performed by qualified laboratory personnel under the CLIA-certified laboratory that provides virtual access. The primary testing laboratory must provide CMS with a list of all staff utilizing virtual access upon request.

(b) * * *

(3) Laboratories that are located on the same campus and under the same laboratory director may file a single application or multiple applications.

* * * * *

■ 12. Section 493.57 is amended by revising paragraph (a)(2) to read as follows:

§ 493.57 Requirements for a registration certificate.

* * * * *

(a) * * *

(2) Agrees to notify HHS within 30 days of any changes in ownership,

name, location, director, email address, or technical supervisor (laboratories performing high complexity testing only).

* * * * *

■ 13. Section 493.63 is amended by—

■ a. Revising paragraphs (a)(3) and (4); and

■ b. Adding paragraph (a)(5).

The revision and addition read as follows:

§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.

* * * * *

(a) * * *

(3) Location;

(4) Director; or

(5) Email address.

* * * * *

§ 493.555 [Amended]

■ 14. Section 493.555 is amended by removing paragraph (c)(6).

§ 493.801 [Amended]

■ 15. Section 493.801 is amended in paragraph (b) introductory text by removing the paragraph reference “(b)(4)” and adding in its place the paragraph reference “(b)(5)”.

§ 493.807 [Amended]

■ 16. Section 493.807 is amended in paragraph (a) by removing the following language “one of which may be on site,” and removing paragraph (b).

■ 17. Section 493.855 is amended by revising paragraphs (a) and (b) to read as follows:

§ 493.855 Standard; Cytology: gynecologic examinations.

* * * * *

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section. Proficiency testing programs approved by HHS must

have a system in place to monitor the integrity of the testing.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set or digital images of the test slides as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set or digital images of the test slides as described in paragraphs (b)(1) and (2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set or digital images of the test slides as described in paragraphs (b)(2) and (3) of this section. Individuals are given not more than 2 hours to complete the 10-slide test set or digital images of the test slides and not more than 4 hours to complete the 20-slide test set or digital images of the test slides. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1) through (3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set or digital images of the test slides. For an individual who fails

an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set or digital images of the test slides. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides or digital images of the slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set or digital images of the test slides and scores at least 90 percent. Reexamination of slides or digital images of the slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set or digital images of the test slides. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides or

digital images of the slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set or digital images of the test slides and scores at least 90 percent.

■ 18. Section 493.901(a) is amended by revising Paragraph (a) to read as follows:

§ 493.901 Approval of proficiency testing programs.

(a) Require a minimum of 10 CLIA-certified laboratory participants for each specialty, subspecialty, and analyte or test for which the proficiency testing program is seeking reapproval;

■ 19. Section 493.931 is amended by revising Table 1 to Paragraph (b) and Table 2 to Paragraph (c)(2) to read as follows:

§ 493.931 Routine chemistry.

(b) * * *

Table 1 to Paragraph (b)—Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT).
Albumin.
Alkaline phosphatase.
Amylase.
Aspartate aminotransferase (AST/SGOT).
Bilirubin, total.
Blood gas (pH, pO2, and pCO2).
B-natriuretic peptide (BNP).
proBNP.
Calcium, total.
Cancer antigen (CA) 125.
Carbon dioxide.
Chloride.
Carcinoembryonic antigen (CEA).
Cholesterol, total.
Cholesterol, high density lipoprotein.
Cholesterol, low density lipoprotein, (direct measurement).
Creatine kinase (CK).
CK-MB isoenzymes.
Creatinine.
Ferritin.
Folate, serum.
Gamma glutamyl transferase.
Glucose (Excluding measurements on devices cleared by FDA for home use).
Hemoglobin A1c.
Iron, total.
Lactate dehydrogenase (LDH).
Magnesium.
Phosphorus.
Potassium.
Prostate specific antigen (PSA), total.
Sodium.
Total iron binding capacity (TIBC) (direct measurement).
Total Protein.
Triglycerides.
Troponin I.
Troponin T.

Table 1 to Paragraph (b)—Analyte or Test Procedure—Continued

Urea Nitrogen.
Uric Acid.
Vitamin B12.

* * * * *

(2) * * *

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte or test	Criteria for acceptable performance
The criteria for acceptable performance are—	
Alanine aminotransferase (ALT/SGPT)	Target value $\pm 15\%$ or 6U/L (greater).
Albumin	Target value $\pm 8\%$.
Alkaline phosphatase	Target value $\pm 20\%$.
Amylase	Target value $\pm 20\%$.
Aspartate aminotransferase (AST/SGOT)	Target value $\pm 15\%$ or 6U/L (greater).
Bilirubin, total	Target value $\pm 20\%$ or ± 0.4 mg/dL (greater).
Blood gas pCO ₂	Target value $\pm 8\%$ or ± 5 mm Hg (greater).
Blood gas pO ₂	Target value $\pm 15\%$ or ± 15 mmHg (greater).
Blood gas pH	Target value ± 0.04 .
B-natriuretic peptide (BNP)	Target value $\pm 30\%$.
Pro B-natriuretic peptide (proBNP)	Target value $\pm 30\%$.
Calcium, total	Target value ± 1.0 mg/dL.
Cancer antigen (CA) 125	Target value $\pm 20\%$.
Carbon dioxide	Target value $\pm 20\%$.
Carcinoembryonic antigen (CEA)	Target value $\pm 15\%$ or 1 ng/mL (greater).
Chloride	Target value $\pm 5\%$.
Cholesterol, total	Target value $\pm 10\%$.
Cholesterol, high density lipoprotein (HDL)	Target value $\pm 20\%$ or 6 mg/dL (greater).
Cholesterol, low density lipoprotein (LDL), direct measurement	Target value $\pm 20\%$.
Creatine kinase (CK)	Target value $\pm 20\%$.
CK-MB isoenzymes	Target value $\pm 25\%$ or 3 ng/mL (greater) or MB elevated (presence or absence).
Creatinine	Target value $\pm 10\%$ or 0.2 mg/dL (greater).
Ferritin	Target value $\pm 20\%$.
Folate, serum	Target value $\pm 30\%$ or ± 1 ng/mL (greater).
Gamma glutamyl transferase	Target value $\pm 15\%$ or 5 U/L (greater).
Glucose (excluding measurements devices cleared by FDA for home use.)	Target value $\pm 8\%$ or 6 mg/dL (greater).
Hemoglobin A1c	Target value $\pm 8\%$.
Iron, total	Target value $\pm 15\%$.
Lactate dehydrogenase (LDH)	Target value $\pm 15\%$.
Magnesium	Target value $\pm 15\%$.
Phosphorus	Target value $\pm 10\%$ or 0.3 mg/dL (greater).
Potassium	Target value ± 0.3 mmol/L.
Prostate Specific Antigen, total	Target value $\pm 20\%$ or 0.2 ng/mL (greater).
Sodium	Target value ± 4 mmol/L.
Total Iron Binding Capacity (direct measurement)	Target value $\pm 20\%$.
Total Protein	Target value $\pm 8\%$.
Triglycerides	Target value $\pm 15\%$.
Troponin I	Target value $\pm 30\%$ or 0.9 ng/mL (greater).
Troponin T	Target value $\pm 30\%$ or 0.2 ng/mL (greater).
Urea nitrogen	Target value $\pm 9\%$ or 2 mg/dL (greater).
Uric acid	Target value $\pm 10\%$.
Vitamin B12	Target value $\pm 25\%$ or ± 30 pg/mL (greater).

* * * * *

■ 20. Section 493.933 is amended by revising Table 1 to Paragraph (b) and

Table 2 to Paragraph (c)(2) to read as follows:

§ 493.933 Endocrinology.

* * * * *

(b) * * *

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST

Cortisol.
Estradiol.
Follicle stimulating hormone.
Free thyroxine.
Human chorionic gonadotropin (HCG) (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).

TABLE 1 TO PARAGRAPH (b)—ANALYTE OR TEST—Continued

Luteinizing hormone.
Parathyroid hormone.
Progesterone.
Prolactin.
Testosterone.
T3 Uptake.
Triiodothyronine.
Thyroid-stimulating hormone.
Thyroxine.

(c) * * *

(2) * * *

TABLE 2 TO PARAGRAPH (C)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte or test	Criteria for acceptable performance
The criteria for acceptable performance are—	
Cortisol	Target value $\pm 20\%$.
Estradiol	Target value $\pm 30\%$.
Follicle stimulating hormone	Target value $\pm 18\%$ or 2 IU/L (greater).
Free thyroxine	Target value $\pm 15\%$ or ± 0.3 ng/dL (greater).
Human chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	Target value $\pm 18\%$ or 3 mIU/mL (greater) or positive or negative.
Luteinizing hormone	Target value $\pm 20\%$.
Parathyroid hormone	Target value $\pm 30\%$.
Progesterone	Target value $\pm 25\%$.
Prolactin	Target value $\pm 20\%$.
Testosterone	Target value $\pm 30\%$ or 20 ng/dL (greater).
T3 uptake	Target value $\pm 18\%$.
Triiodothyronine	Target value $\pm 30\%$.
Thyroid-stimulating hormone	Target value $\pm 20\%$ or 0.2 mIU/L (greater).
Thyroxine	Target value $\pm 20\%$ or 1.0 mcg/dL (greater).

* * * * *

■ 21. Section 493.945 is amended by revising paragraphs (a), (b) introductory text, (b)(1) and (2), (b)(3)(i), (b)(3)(ii)(B), (b)(3)(ii)(C) introductory text, (b)(3)(ii)(D) introductory text, (b)(3)(ii)(E), (b)(3)(ii)(F) introductory text, and (b)(3)(ii)(G) introductory text to read as follows:

§ 493.945 Cytology; gynecologic examinations.

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides or digital images of the test slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in §§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2). If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set

must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in § 493.855. Proficiency testing programs approved by HHS must have a system in place to monitor the integrity of the testing.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets or digital images of the test slides in which the slides/digital images have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide/digital image), the

program must compare the individual's response for each slide preparation or digital image of slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations or digital images of slide preparations, a 100 percent consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations or digital images of slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under § 493.1449(b) or (e) who routinely interprets gynecologic slide preparations or digital images of the slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets

slide preparations or digital images of the slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) * * *

(i) Each slide set or digital image of the slide set must contain 10 or 20 slides or digital images of the slides with point values established for each slide preparation or digital image of slide preparation based on the significance of the relationship of the interpretation of the slide/digital image to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449(b) or (e) of this part.

(ii) * * *

* * * * *

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (–5) points for an incorrect response on a 10-slide/digital image test set. For example, if the correct response on a slide/digital image of the slide is “high grade squamous intraepithelial lesion” (category “D” on the scoring system chart) and an examinee calls it “normal or negative” (category “B” on the scoring system chart), then the examinee’s point value on that slide/digital image of the slide is calculated as minus five (–5). Each slide/digital image of the slide is scored individually in the same manner. The individual’s score for the testing event is determined by adding the point value achieved for each slide preparation/digital image of the slide, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide/digital image test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (e):

* * * * *

(D) Criteria for scoring system for a 10-slide/digital image test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

* * * * *

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this

section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (–10) points for an incorrect response on a 20-slide/digital image test set.

(F) Criteria for scoring system for a 20-slide/digital image test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (e):

* * * * *

(G) Criteria for scoring system for a 20-slide/digital image test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

* * * * *

§ 493.1100 [Amended]

■ 22. Section 493.1100 is amended by removing paragraphs (a) and (b).

■ 23. Section 493.1101 is amended by revising paragraph (e) to read as follows:

§ 493.1101 Standard: Facilities.

* * * * *

(e) Records, and, as applicable, slides, blocks, digital images, digital data, and tissues must be maintained and stored under conditions that ensure proper preservation.

■ 24. Section 493.1105 is amended by revising paragraphs (a) introductory text, (a)(3) introductory text, (a)(7), and (b) to read as follows:

§ 493.1105 Standard: Retention requirements.

(a) The laboratory must retain its records, digital images, digital data, and, as applicable, slides, blocks, and tissues as follows:

* * * * *

(3) *Analytic systems records.* Retain quality control and patient test records (including instrument printouts, digital images, and digital data, if applicable) and records documenting all analytic systems activities specified in §§ 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

* * * * *

(7) *Slide, digital image, block, and tissue retention—*

(i) *Slides.*

(A) Retain cytology slide preparations and digital images for at least 5 years from the date of examination (see § 493.1274(f) for proficiency testing exception).

(B) Retain histopathology slides and digital images for at least 10 years from the date of examination.

(ii) *Blocks.* Retain pathology specimen blocks for at least 2 years from the date of examination.

(iii) *Tissue.* Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records, digital images, digital data, and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.

■ 25. Section 493.1231 is amended by adding paragraph (a) to read as follows:

§ 493.1231 Standard: Confidentiality of patient information.

* * * * *

(a) The laboratory must have policies that ensure virtual access is performed in a confidential environment on a secure network connection.

(b) [Reserved].

■ 26. Section 493.1251 is amended by revising paragraph (b)(2) to read as follows:

§ 493.1251 Standard: Procedure manual.

* * * * *

(b) * * *

(2) Microscopic and digital imaging examination, including the detection of inadequately prepared slides or digital images.

* * * * *

■ 27. Section 493.1256 is amended by revising paragraph (a) to read as follows:

§ 493.1256 Standard: Control procedures.

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process including testing performed via virtual access.

* * * * *

■ 28. Section 493.1273 is amended by revising paragraph (c) to read as follows:

§ 493.1273 Standard: Histopathology.

* * * * *

(c) Gross tissue examination results must be reviewed by the technical supervisor before the final test report is issued.

* * * * *

■ 29. Section 493.1283 is amended by adding paragraph (a)(5) to read as follows:

§ 493.1283 Standard: Test records.

(a) * * *

(5) Records of virtual access including the identity of the personnel who performed the test(s), the software version (as applicable), and the electronic device used.

* * * * *

■ 30. Section 493.1291 is amended by revising paragraphs (a)(2) and (c)(2) to read as follows:

§ 493.1291 Test report.

(a) * * *
(2) Results and patient-specific data electronically reported using virtual access, network or interfaced systems.

* * * * *

(c) * * *
(2) The CLIA number, name of the laboratory as it appears on the CLIA certificate, and address of the laboratory location where the test was performed.

* * * * *

§ 493.1359 [Amended]

■ 31. Section 493.1359 is amended by removing paragraphs (c)(1) through (5) and (d).

■ 32. Section 493.1405 is amended 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; or

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

(C) Have at least 1 year of laboratory training during medical residency or fellowship; or

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

(B) Hold an earned doctoral degree; and

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

(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS; and

(ii)(A) Have at least 20 CE credit hours in laboratory practice that cover the

laboratory director responsibilities defined in § 493.1407; or

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

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

(B)(1) Meet bachelor's degree equivalency; and

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

(C)(1) Meet bachelor's degree equivalency; and

(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science and an approved thesis or research project; and

(ii)(A) Have at least 1 year of supervisory laboratory experience in nonwaived testing; or

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

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

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

(1) Forty-eight (48) semester hours of medical laboratory science or medical laboratory technology courses; or

(2) Forty-eight (48) semester hours of science courses that include—

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

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

(iii) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and

(ii)(A) Have at least 1 year of supervisory laboratory experience in nonwaived testing; or

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

(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 or high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

■ 33. Section 493.1407 is amended by revising paragraph (c) to read as follows:

§ 493.1407 Standard; Laboratory director responsibilities.

* * * * *

(c) Laboratory directors must be accessible to the laboratory as needed.

* * * * *

■ 34. Section 493.1411 is amended by revising paragraph (b)(6)(i) to read as follows:

§ 493.1411 Standard; Technical consultant qualifications.

* * * * *

(b) * * *

(6) * * *

(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or

* * * * *

■ 35. Section 493.1417 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 493.1417 Standard; Clinical consultant qualifications.

* * * * *

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

(c) Notwithstanding any other provision of this section, an individual is considered qualified as a clinical consultant under this section if they were qualified and serving as a clinical consultant for moderate or high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

■ 36. Section 493.1423 is amended by revising paragraph (b)(7) to read as follows:

§ 493.1423 Standard; Testing personnel qualifications.

* * * * *

(b) * * *

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

(i) Be qualified under paragraph (b)(1), (2), (3), (4), (5), or (6) of this section; or

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

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

* * * * *

■ 37. Section 493.1443 is amended by—
■ a. Revising paragraphs (b)(2) and (3); and

■ b. Adding paragraph (b)(6).

The revisions and addition read as follows:

§ 493.1443 Standard; Laboratory director qualifications.

* * * * *

(b) * * *

(2)(i) 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

(ii)(A) Have at least 1 year of experience directing or supervising high complexity testing; or

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

(C) Have at least 1 year of laboratory training during medical residency or fellowship; or

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

(B) Hold an earned doctoral degree; and

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

(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS; and

(ii)(A) Have at least 1 year of experience directing or supervising high complexity testing; or

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

* * * * *

(6) For tests in dermatopathology, meet one of the following requirements:

(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) Meet one of the following requirements:

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(B) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or

(C) Be certified in dermatology by the American Board of Dermatology, American Osteopathic Board of Dermatology, or American Board of Physician Specialties.

■ 38. Section 493.1445 is amended by revising paragraph (c) to read as follows:

§ 493.1445 Standard; Laboratory director responsibilities.

* * * * *

(c) The laboratory director must be accessible to the laboratory as needed.

* * * * *

■ 39. Section 493.1449 is amended by—

■ a. Revising paragraphs (c)(4)(i)(C)(2) and (f)(2)(i)(B)(3);

■ b. Adding paragraph (f)(4); and

■ c. Revising paragraph (i)(2)(ii).

The revisions and addition read as follows:

§ 493.1449 Standard; Technical supervisor qualifications.

* * * * *

(c) * * *

(4) * * *

(i) * * *

(C) * * *

(2) Have at least 16 semester hours in a combination of graduate level coursework and an approved thesis or research project in biology, chemistry, medical technology, or clinical or medical laboratory science; and

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) * * *

(3) Be certified in dermatology by the American Board of Dermatology, American Osteopathic Board of Dermatology, or American Board of Physician Specialties; or

* * * * *

(4) For tests in neuromuscular 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) Successfully completed an American Academy of Neurology Committee for Neuromuscular Pathology Training Program or the United Council for Neurologic Subspecialties training program; or

(ii) An individual qualified under paragraph (b) or (f)(4)(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)(4)(i)(B) of this section, the responsibility for examination and interpretation of neuromuscular pathology specimens; or

* * * * *

(i) * * *

(2) * * *

(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

Note 1 to paragraphs (b) through (i): 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.

* * * * *

■ 40. Section 493.1455 is amended by—

■ a. Revising paragraphs (a) and (b); and

■ b. Adding paragraph (c).

The revision and addition read as follows:

§ 493.1455 Standard; Clinical consultant qualifications.

* * * * *

(a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), (3), (4), or for the subspecialty of oral pathology, § 493.1443(b)(5), or for tests in dermatopathology, § 493.1443(b)(6); or

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

(c) Notwithstanding any other provision of this section, an individual is considered qualified as a clinical consultant under this section if they were qualified and serving as a clinical consultant for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

■ 41. Section 493.1461 is amended by—

■ a. Removing paragraph (c)(3);

■ b. Redesignating paragraph (c)(4) as (c)(3); and

■ c. Revising paragraph (e) introductory text.

The revision reads as follows:

§ 493.1461 Standard; General supervisor qualifications.

* * * * *

(e) For histopathology, oral pathology, dermatopathology, and ophthalmic pathology, the individual providing

general supervision must be qualified as follows:

* * * * *

- 42. Section 493.1463 is amended by—
- a. Removing paragraph (a)(3);
- b. Redesignating paragraph (a)(4) as (a)(3);
- c. Revising paragraph (b)(4); and
- c. Removing paragraph (c).

The revision reads as follows:

§ 493.1463 Standard: General supervisor responsibilities.

* * * * *

(b) * * *

(4) Evaluating and documenting the competency of both moderate and high complexity testing personnel.

- 43. Section 493.1489 is amended by revising paragraphs (b)(2)(i) and (ii); (b)(3)(i) and (ii); and (b)(7) to read as follows:

§ 493.1489 Standard; Testing personnel qualifications.

* * * * *

(b) * * *

(2) * * *

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

(ii) Be qualified under the requirements of §§ 493.1443(b)(3)(i)(A), 493.1443(b)(3)(i)(B)(1) or (2), or 493.1449(c)(4)(i)(A), 493.1449(c)(4)(i)(B)(1) and (2), 493.1449(c)(4)(i)(C)(1) and (2), 493.1449(c)(5)(i)(A), or 493.1449(c)(5)(i)(B)(1) or (2)(i) through (iii); or

(3) * * *

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

(ii) Have education and training equivalent to that specified in paragraph (b)(3)(i) of this section that includes—

* * * * *

(7) For histopathology—

(i) Meet the qualifications of § 493.1449(b) or (f) to perform tissue examinations.

(ii) For gross tissue examinations, meet the qualifications of paragraphs (b)(1) through (5) of this section.

- 44. Section 493.1495 is amended by—
- a. Revising paragraph (b)(5) and (6); and
- b. Removing paragraphs (b)(7) and (c);

The revisions read as follows:

§ 493.1495 Standard; Testing personnel responsibilities.

* * * * *

(b) * * *

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

- 45. Section 493.1810 is amended by revising paragraph (d)(2) to read as follows:

§ 493.1810 Imposition and lifting of alternative sanctions.

* * * * *

(d) * * *

(2) CMS's revocation of the laboratory's CLIA certificate becomes effective.

* * * * *

- 46. Section 493.1826 is amended by revising paragraph (a)(2) to read as follows:

§ 493.1826 Suspension of part of Medicare payments.

(a) * * *

(2) CMS suspends Medicare payment for those specialties or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

* * * * *

- 47. Section 493.1832 is amended by revising paragraph (c)(2) to read as follows:

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

* * * * *

(c) * * *

(2) The directed plan of correction continues in effect until the revocation of the laboratory's CLIA certificate is effective.

- 48. Section 493.1834 is amended by revising paragraph (b) to read as follows:

§ 493.1834 Civil money penalty.

* * * * *

(b) Scope. This section sets forth the procedures that CMS follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance,

registration certificate, certificate of accreditation, certificate for PPM procedures, or certificate of waiver of a laboratory that is found to have conditional level deficiencies.

* * * * *

§ 493.1834 [Amended]

- 49. Section 493.1834 is amended by removing paragraph (d)(2)(iii).

- 50. Section 493.1834(f)(2)(iii) is amended by revising paragraph (f)(2)(iii) to read as follows:

§ 493.1834 Civil money penalty.

* * * * *

(f) * * *

(2) * * *

(iii) CMS suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, certificate for PPM procedures, or certificate of waiver.

* * * * *

- 51. Section 493.1834 is amended in paragraph (e)(1)(ii)(D) by removing the reference “§ 493.1810(c)” and adding in its place the reference “§ 493.1810(b)”.

- 52. Section 493.1836 is amended by revising paragraph (c)(3) to read as follows:

§ 493.1836 State on-site monitoring.

* * * * *

(c) * * *

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

- 53. Section 493.2001 is amended by revising paragraph (a) to read as follows:

§ 493.2001 Establishment and function of the Clinical Laboratory Advisory Committee.

(a) HHS may establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–20613 Filed 10–7–26; 8:45 am]

BILLING CODE 4169–69–P