significant effect on the human environment. This rule involves a special local regulation lasting twelve hours that will prohibit entry from MM 48.5 to 52.0 on the Clinch River. It is categorically excluded from further review under paragraph L61 in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Memorandum for Record supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in this preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T08–0215 to read as follows:

§ 100.T08–0215 Oak Ridge, TN. Clinch River mile 48.5 to 52.0.

(a) *Location.* The regulations in this section apply to the following area: All navigable waters of the Clinch River from mile 48.5 to mile 52.0, extending the entire width of the river.

(b) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by Sector Ohio Valley Command Center at 502–779–5422. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(c) *Enforcement period.* This section will be enforced from 6 a.m. to 6 p.m. from May 8, 2021 to May 9, 2021.

(d) *Information broadcast.* The COTP will issue Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and Marine Safety Information Bulletins (MSIBs) about this special local regulation so that waterway users may plan accordingly for this short restriction on transit, and the rule would allow vessels to request permission to enter the zone.

Dated: May 4, 2021.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2021–09725 Filed 5–6–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP64

Adopting Standards for Laboratory Requirements

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, with changes, a proposed rule amending its medical regulations to establish standards for VA clinical laboratories. The Department of Health and Human Services (HHS) has established standards for the staffing, management, procedures, and oversight of clinical laboratories that perform testing used for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. VA is required, in consultation with HHS, to establish standards equal to those applicable to other clinical laboratories. As a matter of policy and practice VA has applied HHS standards to its VA laboratory operations, and this rule formalizes this practice. In response to public comments this final rulemaking amends proposed language to more accurately reflect VA's utilization of CMS-deemed accreditation organizations in the process of inspection, oversight, and operational approval of VA clinical laboratories.

DATES: This final rule is effective June 7, 2021.

FOR FURTHER INFORMATION CONTACT: Quynh Vantu, Health Science Specialist, Pathology and Laboratory Service (1011DIAG2), Office of Clinical Care Services, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave NW, Washington, DC 20420, (202) 632–8418. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on October 17, 2018, VA proposed to amend its medical regulations to establish standards for VA clinical laboratories. 83 FR 52345. We provided a 60-day comment period, which ended on December 17, 2018, and we received four comments.

The Clinical Laboratory Improvement Amendments of 1988 (Public Law (Pub. L.) 100–578) amended section 353 of the Public Health Service Act to establish legal requirements for the staffing, management, procedures, reporting of results and oversight of clinical laboratories that perform testing used for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. These statutory requirements are codified at 42 U.S.C. 263a. The Centers for Medicare & Medicaid Services (CMS), within HHS, has primary responsibility for the administration of the Clinical Laboratory Improvement Amendments (CLIA) program and implementing regulations for CLIA at 42 Code of Federal Regulations (CFR) part 493.

Section 101 of Pub. L. 102–139 (enacted October 28, 1991), required VA, within a specified time-frame and in consultation with HHS, to ''establish standards [by regulation] equal to that [sic] applicable to other medical facility laboratories in accordance with the requirements of section 353(f) of the Public Health Service Act.'' VA's regulations must ''include appropriate provisions respecting compliance with such requirements [set forth in section 353(f) of the Public Health Service Act]'' and may include appropriate provisions respecting waivers and accreditations as described in section 353(d) and 353(e), respectively, of the Public Health Service Act. This final rule complies with the requirement for rulemaking by amending VA's medical regulations to reference the portions of 42 CFR part 493 adopted by VA as they apply to VA medical facility laboratories and clinics, and to clarify that these standards are subject to VA oversight and enforcement by VA only. In addition, this final rule allows VA laboratories to be accredited by an accreditation organization granted deeming authority by CMS under the CLIA program, in accordance with the accreditation requirements in the CLIA regulations at subpart E of 42 CFR part 493, and participate in an HHS approved proficiency testing program.

As explained in the preamble to the proposed rule, VA policy and practice regarding CLIA compliance was developed in consultation with HHS in 1994 and 1998. Additionally, in 2000, after further consultation, VA and CMS entered into an interagency agreement (IAA), which documented the history of the parties' consultations and agreements and granted VA limited authority to act on behalf of CMS.

In 2018, CMS and VA met to begin the process to review and update the 2010 agreement and it was proposed to replace the IAA with a memorandum of understanding (MOU), and to review and renew every six years thereafter. The IAA was converted to an MOU and approved on May 22, 2020. In addition, CMS and VA agreed to meet annually to discuss program issues of mutual importance.

To ensure VA operated laboratories remain current with CMS CLIA requirements, VA participates in the CMS Partners in Laboratory Oversight group, consults with CMS as needed, and participates in at least one formal consultative meeting per year. Additionally, VA provides updated data to CMS for each VA laboratory assigned a CLIA number at least every two years, or as changes occur. Furthermore, VA provides CMS with any requested information regarding the operation and performance of VA laboratories and the operations of the oversight program.

This final rulemaking formalizes VA's application of the CLIA requirements to VA laboratory operations by adding a new section 17.3500 to 38 CFR, ''VA application of 42 CFR part 493 standards for clinical laboratory operations,'' to its medical regulations. Section 17.3500 addresses CLIA regulations found at 42 CFR part 493, by subpart, and how VA will apply those regulations. This rule will also allow VA to continue to assure that medical facility laboratories across our system perform and report out consistent, accurate, and reliable laboratory testing, ensuring the provision of quality testing for our patients in a manner comparable to non-VA laboratories.

In response to the proposed rule, VA received four comments. One commenter expressed support for the rule, and we thank the commenter for supporting the rule.

Another commenter noted a grammatical error in the preamble but did not suggest any edits be made to the rule. Specifically, the commenter noted that in the first paragraph of the Supplemental Information section, we referred to the definition of ''laboratory or clinical laboratory'' found at 42 U.S.C. 263a(a) and quoted from that statutory definition without using quotation marks. The commenter is correct, however no change in the regulatory text is needed. We are not making any edits to this rulemaking based on this comment, and we thank the commenter for their feedback.

Another commenter provided the same comment twice. The comment was supportive of the rule, but provided multiple recommendations regarding: (1) Personnel requirements; (2) scope of practice; and (3) accreditation organizations. The commenter also attached a comment that was submitted to CMS in March 2018 in response to a request for information. In this rulemaking, we will only address the comment that was directed to VA and will not address the comment directed to CMS.

1. Personnel Requirements. The commenter raised concerns over the academic and clinical training requirements for high complexity laboratory personnel to broaden the potential labor force of laboratory professionals while simultaneously ensuring they are properly qualified to provide high quality testing. The commenter recommended that we modify the CLIA personnel requirements to: (1) Allow an earned baccalaureate degree with at least 30 hours (or equivalent) of coursework in biological and chemical sciences (appropriate to a major in one of these sciences) to satisfy the academic degree requirement; (2) clarify that all high complexity testing personnel must complete clinical training, either from an accredited clinical training program or documented laboratory training prior to testing patient samples; (3) create personnel standards for histotechnology professionals, requiring that they complete an associate degree (or equivalent) in the chemical or biological sciences, and complete either an accredited or structured training program under the auspices of a board certified pathologist or designee; and (4) require all high complexity laboratory personnel to pass a national certification examination.

The purpose of this rulemaking is to fulfill the requirements of section 101 of Public Law 102–139 for rules equal to those applicable to other medical facility laboratories subject to the CLIA requirements as implemented under the Public Health Service Act . As previously stated, CMS implemented CLIA regulations at 42 CFR part 493, and VA is amending its medical regulations to incorporate those portions of 42 CFR part 493 as adopted by VA. Personnel requirements for performing non-waived testing are addressed in subpart M of 42 CFR part 493, and VA will apply all standards from this subpart except the requirements to maintain a license in the state where the laboratory is located. In other words, in formalizing VA's application of the CLIA requirements implemented by CMS, VA cannot adopt less rigorous standards than those of CMS.

While VA cannot adopt less rigorous standards, if deemed necessary, VA will further delineate higher personnel qualifications in policy. For example, VA currently maintains a higher personnel qualification standard for medical technologists in policy. Medical technologists are required to possess a combination of a bachelor's degree, or higher, and clinical practice experience. Additionally, medical technologists must possess, or obtain within one year from date of appointment, an appropriate certification from the American Society for Clinical Pathology or the American Medical Technologists. Furthermore, in areas where VA has not implemented a more rigorous standard than CMS, it is because we believe their standards satisfy our specific needs and ensure the safety, efficiency, and reliability of our laboratories. Like all public institutions, VA must balance the goals of verifying staff competency with creating a flexible enough barrier to entry that we can attract the best minds from all areas of clinical laboratory science.

We are not making any changes to this rulemaking based on this comment.

2. Scope of Practice. The commenter sought to confirm their interpretation that this rule does not impact the scope of practice for advanced practice registered nurses (APRNs) to ''order laboratory and imaging studies and integrate the results into clinical decision making, but not to perform or interpret any laboratory test.'' The commenter also ''urged the VA to maintain this policy.''

The commenter is correct that this rule does not impact APRN scope of practice. In a document published in the **Federal Register** on May 25, 2016, VA proposed to amend its regulation to permit full practice authority of four types of APRNs. 81 FR 33155. Proposed 38 CFR 17.415(d)(1)(i)(B) stated in part that a certified nurse practitioner (CNP) may order, perform, or supervise laboratory and imaging studies. Several commenters were concerned with the language, and VA agreed with commenters that the language may be construed as allowing CNPs to perform laboratory studies. In a document published in the **Federal Register** on December 14, 2016, VA published its final rulemaking and amended

§ 17.415(d)(1)(i)(B) to state in part that a CNP may order laboratory and imaging studies and integrate the results into clinical decision making. 81 FR 90198.

With that background, we agree with the commenter that this rulemaking does not impact § 17.415 and reiterate that the intent of this rule is to fulfill the requirements of section 101 of Public Law 102–139 for formal rulemaking to adopt standards equal to those applicable to other medical facility laboratories in accordance with the Public Health Service Act. Additionally, VA maintains requirements in policy that specify all testing must be performed under the authority of a Pathologist serving as the Chief of Pathology (Laboratory Director) and that all point of care testing must be overseen by a Medical Technologist Point of Care Coordinator. We are not making any changes to this rulemaking based on this comment.

3. Accreditation Organizations. The commenter questioned whether CMS-approved accrediting agencies will assess whether VA clinical laboratories are in full compliance with VA requirements and recommended that VA ''require all accrediting agencies providing services to VA laboratories attest that they assess VA laboratories in compliance with applicable VA regulations.''

There are no accrediting organizations that have standards equivalent to VA, and therefore, no accreditation organization can effectively inspect VA laboratories to ensure they are compliant with all VA regulations. VA uses outside accreditation organizations with deeming authority to assess third-party compliance with CLIA regulations. The requirements VA has implemented that are more stringent than CLIA, or unique to the government, are overseen by the VA Office of Inspector General, the Veterans Health Administration (VHA) Office of Medical Inspector, and VHA Pathology and Laboratory Medicine Service National Enforcement Office. We believe this rigorous internal and external oversight provides more thorough oversight than could be accomplished by only an external accreditation organization.

In response to the issues raised by the commenter, VA believes it is necessary to amend the language in proposed § 17.3500(e)(1) to more accurately reflect VA's utilization of CMS deemed-status accreditation organizations in the process of inspection, oversight, and operational approval of VA clinical laboratories. ''Operational approval'' for VA clinical laboratories includes compliance with both standards established by a CMS deemed-status accreditation organization and meeting relevant VA standards. Generally, accreditation organizations determine whether a laboratory is in compliance with the standards established by that organization. If the accrediting organization determines that the laboratory complies with those standards, it issues a certificate of accreditation. That is only one element considered by VA in determining whether the laboratory meets all VA standards. In addition to attaining a certificate of accreditation, the laboratory must also meet relevant VA standards, which may be more stringent than those set by the accrediting organization. Also, in some cases VA establishes a standard for testing that is not covered by standards established by the accrediting organization or addressed in 42 CFR part 493. If the laboratory meets applicable accreditation standards and also relevant VA standards, VA issues a certificate of compliance, meaning that the laboratory is CLIA certified by VA.

We also note that VA laboratories performing minimally complex tests are not required to be inspected and accredited by CMS deemed-status accreditation organizations, but rather are inspected and CLIA certified by VA. Similarly, VA laboratories that perform provider performed microscopy testing as outlined in 42 CFR 493.19, are not required to be inspected and accredited by CMS deemed-status accreditation organizations, but rather are inspected and CLIA certified by VA. We amend § 17.3500(e)(1) to state that VA relies on CMS to grant deeming authority for accreditation organizations. VA uses only an accreditation agency with deeming authority to determine whether a laboratory is in compliance with standards established by the accreditation organization. VA determines whether the laboratory is in compliance with any additional standard established by VA which is: (i) More stringent than that required for accreditation purposes, or (ii) not addressed by accreditation standards or 42 CFR part 493. In addition to public comments received, HHS was afforded the opportunity to review the rule and provided the following comments and suggestions, which we are adopting. First, HHS noted that VA cannot enforce 42 CFR part 493 because it is a function of CMS and suggested that language in the first sentence of the proposed introductory paragraph of § 17.3500 be rephrased to reflect that VA laboratories must meet VA's alternative requirements under 38 CFR. We agree with this suggestion and have removed the phrase ''administered, and enforced'' from the first sentence, and combined the first and second sentences to clarify that laboratory testing within VA performed for the diagnosis, prevention, or treatment of any disease or impairment of, or health assessment of, human beings must meet at a minimum, requirements established under subparts 42 CFR part 493 as implemented by VA. We also removed the phrase ''comply with the listed requirements established by the Department of Health and Human Services (HHS) under the following subparts of 42 CFR part 493'' in the first sentence and replaced it with ''requirements established under the following subparts of 42 CFR part 493'' because we believe the previous reference to HHS is superfluous since 42 CFR part 493 is a regulation established by HHS. We believe these revisions clarify that VA laboratories must meet VA's additional standards as well as CLIA regulations.

Second, HHS commented that the intent of the third sentence in the proposed introductory paragraph was adequately addressed in the three sentences immediately following it. We agree with this comment and have removed it; however we have added the phrase ''as well as contracted laboratory services performed on site at VA laboratories, outreach clinics or other'' to the fourth sentence to clarify that VA implements the functions and responsibilities assigned to CMS in 42 CFR part 493 at VA laboratories and outreach clinics, as well as with contracted laboratory services performed on site at VA laboratories or other testing sites.

Third, HHS questioned the legal basis for the language used in the fourth sentence of the proposed introductory paragraph regarding VA's assumption of the functions and responsibilities assigned to CMS in 42 CFR part 493. Upon review of HHS' comment, we have amended this sentence by replacing the phrase ''assumed by VA'' with ''implemented by VA.'' We believe this revision clarifies that VA only performs the functions and responsibilities assigned to CMS in 42 CFR part 493 at VA laboratories and outreach clinics, as well as with contracted laboratory services performed on site at VA laboratories or other testing sites.

Fourth, HHS questioned if VA staff have the requisite knowledge to perform validation inspections of VA laboratories as proposed in paragraph (e)(4) and suggested that the phrase ''performs validation inspections,'' be replaced with ''performs inspections.''

We agree with the suggestion provided by HHS because a validation inspection is performed by CMS whereas VA performs inspections on VA laboratories. We are amending the phrase by removing the term ''validation.''

Fifth, HHS noted that the language provided in (m)(2) was not clear and suggested we revise the sentence. Proposed (m)(2) stated ''Due process protections afforded by CMS-certified for laboratories facing sanctions are not applicable to laboratories operating under this section.'' We agree that this sentence is unclear and have amended it to state, ''Due process protections afforded by CMS to CMS certified laboratories facing sanctions are not applicable to laboratories operating under this section.''

Based on the rationale set forth in the proposed rule and in this document, VA is adopting the provisions of the proposed rule as a final rule with the changes noted above.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). It would affect only the operations of VA medical facility laboratories and any small entity which chooses to enter into a contract with VA to provide laboratory services. VA estimates that this final rule potentially impacts 37 small entities within NAICS Code 621511 (Medical Laboratories), which represents 1.3 percent of small entities covered by NAICS Code 621511. The small medical laboratories impacted by this rulemaking provide contracted medical laboratory services at various VA medical facilities, to include VA outpatient clinics and VA Community Based Outpatient Clinics. This rulemaking decreases the regulatory burden for the 37 small entities who provide contract medical laboratory services to VA. Under this rulemaking functions and responsibilities assigned to the Centers for Medicare & Medicaid Services (CMS) in 42 CFR part 493 are assumed by VA, and provisions that are specific to oversight by state licensure programs are not applicable. For services performed under a VA contract for medical laboratory services the contractors would not be subject to potential CMS sanctions under subpart R of 42 CFR part 493 because VA does not participate in Medicare or Medicaid programs, and VA is responsible for both oversight and enforcement of clinical laboratory standards. In addition, state onsite monitoring and monetary penalties imposed by CMS as an alternate sanction are not applicable. However, VA may cease laboratory testing immediately at any site subject to this section upon notification of immediate jeopardy to patients. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published from FY 2004 Through Fiscal Year to Date.''

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.008—Veterans Domiciliary Care; 64.011—Veterans Dental Care; 64.029—Purchase Care Program; 64.033—VA Supportive Services for Veteran Families Program; 64.040—VA Inpatient Medicine; 64.041—VA Outpatient Specialty Care; 64.042—VA Inpatient Surgery; 64.043—VA Mental Health Residential; 64.044—VA Home Care; 64.045—VA Outpatient Ancillary Services; 64.046—VA Inpatient Psychiatry; 64.047—VA Primary Care; 64.048—VA Mental Health clinics; 64.049—VA Community Living Center; 64.050—VA Diagnostic Care; 64.054—Research and Development.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on March 22, 2021 and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set forth in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The general authority citation for part 17 continues, and an entry for § 17.3500 is added in numerical order, to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections:

* * * * *

Section 17.3500 is also issued under Pub. L. 102–139 sec. 101.

* * * * *

■ 2. Add an undesignated center heading following § 17.3250 to read as follows:

Clinical Laboratory Standards

■ 3. Add § 17.3500 to read as follows:

§ 17.3500 VA application of 42 CFR part 493 standards for clinical laboratory operations.

Laboratory testing within VA performed for the diagnosis, prevention, or treatment of any disease or impairment of, or health assessment of, human beings must meet, at a minimum, requirements established under the following subparts of 42 CFR part 493 as implemented by VA. Except as noted below, functions and responsibilities assigned to the Centers for Medicare & Medicaid Services (CMS) in 42 CFR part 493 are implemented by VA at VA laboratories and outreach clinics, as well as with contracted laboratory services performed on site at VA laboratories or other testing sites. Provisions that are specific to oversight by state licensure programs are not applicable. VA administers the application of the relevant provisions of 42 CFR part 493 to VA laboratories as follows:

(a) *General provisions.* All provisions in subpart A of 42 CFR part 493 apply to VA with the following exceptions:

(1) Functions assigned to HHS in this subpart are performed by VA.

(2) While 42 CFR part 493 requires laboratories that perform waived, moderate and high complexity tests to meet the regulations, VA requires VA laboratories meet or exceed the requirements of 42 CFR part 493.

(b) *Certificate of waiver.* All provisions in subpart B of 42 CFR part 493 apply to VA, except that:

(1) Certificates issued by HHS under this subpart are instead issued by VA pursuant to an agreement between CMS and VA.

(2) CMS does not require remittance of a fee from laboratories for any certificate issued by the VA under this subpart.

(c) *Registration certificate, certificate for provider-performed microscopy procedures, and certificate of compliance.* All provisions in subpart C of 42 CFR part 493 apply to VA, except that:

(1) Certificates issued by HHS under this subpart are instead issued by VA pursuant to an agreement between CMS and VA.

(2) CMS does not require remittance of a fee from laboratories for any certificate issued by VA under this subpart.

(d) *Certificates of accreditation.* All provisions in subpart D of 42 CFR part 493 apply to VA, except that:

(1) Certificates issued by HHS under this subpart are instead issued by VA pursuant to an agreement between CMS and VA.

(2) CMS does not require remittance of a fee from laboratories for any certificate issued by VA under this subpart.

(e) *Accreditation by a private, nonprofit accreditation organization or exemption under an approved state laboratory program.* All provisions in subpart E of 42 CFR part 493 apply to VA, to the extent that this subpart addresses accreditation by a private, nonprofit accreditation organization. VA applies this subpart as follows:

(1) VA relies on CMS to grant deeming authority for accreditation organizations. VA uses only an accreditation agency with deeming authority to determine whether a laboratory is in compliance with standards established by the accreditation organization. VA determines whether the laboratory is in compliance with any additional standard established by VA which is:

(i) More stringent than that required for accreditation purposes, or

(ii) Not addressed by accreditation standards or 42 CFR part 493.

(2) VA uses only CMS-approved proficiency testing providers.

(3) Proficiency testing providers release proficiency testing results directly to VA.

(4) VA, rather than CMS, performs inspections of VA laboratories.

(5) Oversight and enforcement functions under this subpart are performed by VA.

(f) *General administration.* Subpart F of 42 CFR part 493 sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act and the Federal validation of accredited laboratories and of CLIA-exempt laboratories. This subpart is inapplicable to VA, as CMS does not collect fees for certification of VA laboratories.

(g) *Participation in proficiency testing for laboratories performing nonwaived testing.* All provisions in subpart H of 42 CFR part 493 apply to VA, except that all enforcement and oversight functions related to proficiency testing which are assigned to HHS in this subpart are performed by VA.

(h) *Proficiency testing programs for nonwaived testing.* All provisions in subpart I of 42 CFR part 493 apply to VA, and VA employs scoring criteria under this subpart. VA uses only CMS approved proficiency testing providers. Enforcement and oversight functions related to proficiency testing which are assigned to HHS in this subpart are performed by VA.

(i) *Facility administration for nonwaived testing.* VA applies standards established in Subpart J of 42 CFR part 493.

(j) *Quality system for nonwaived testing.* VA applies standards established in Subpart K of 42 CFR part 493.

(k) *Personnel for nonwaived testing.* VA applies standards established in subpart M of 42 CFR part 493, except that requirements regarding maintaining a license in the state where the laboratory is located are not applicable.

(l) *Inspection.* VA applies standards established in subpart Q of 42 CFR part 493, except that all enforcement and oversight functions, which are assigned to HHS in this subpart are performed by VA.

(m) *Enforcement procedures.* VA applies standards established in subpart R of 42 CFR part 493, except:

(1) Enforcement and oversight functions which are assigned to HHS in this subpart are performed by VA.

(2) Due process protections afforded by CMS to CMS certified laboratories facing sanctions are not applicable to laboratories operating under this section.

(3) Suspension of the right to Medicare or Medicaid payments as an available sanction is not applicable. VA does not participate in these programs.

(4) State onsite monitoring and monetary penalties imposed by CMS as an alternate sanction under 42 CFR 493.1806(c) are not applicable.

(5) VA may cease laboratory testing immediately at any site subject to this section upon notification of immediate jeopardy to patients.

(6) VA does not participate in laboratory registry under 42 CFR 493.1850. VA may disclose laboratory information useful in evaluating the performance of laboratories under 5 U.S.C. 552.

(n) *Consultations.* Subpart T of 42 CFR part 493 requires HHS to establish a Clinical Laboratory Improvement Advisory Committee (CLIAC) to advise and make recommendations on technical and scientific aspects of the provisions of part 493. This subpart does not apply to VA.

[FR Doc. 2021–08157 Filed 5–6–21; 8:45 am]

BILLING CODE 8320–01–P