Legislative Branch Appropriations highlighted the need for the Office to decrease its processing times in its hearing on the Library of Congress's fiscal year 2019 budget request.[80] While inquiring about the appropriate turnaround time for completing a copyright registration, Chairman Kevin Yoder emphasized that the aim is to make the registration system ''more efficient and quicker.'' [81] It is believed that this proposal would further significantly decrease burdens on both copyright owners and the Copyright Office by simplifying registration requirements and the examination process, and subsequently decreasing pendency times.

When an applicant sends a physical deposit with their application for registration, that deposit must be sent offsite to be screened and decontaminated for possible pathogens. Once the deposit is delivered to the Office, the Office's Receipt Analysis and Control Division (''RAC'') must manually match the physical deposit to its corresponding pending application and deliver the deposit to an examiner.[82] This time consuming process can delay examination. And if the examiner later discovers that the applicant submitted an incorrect deposit, this process may be repeated, which would delay examination and re-set the EDR to the date that an acceptable deposit was received by the Office. Additionally, physical deposits are often heavy and unwieldy. The Office moves these deposits multiple times during the examination process, which increases the risk that they may be damaged, misplaced, mismatched, or lost.

By contrast, when an applicant uploads a digital deposit to the electronic registration system, the Office receives the deposit as soon as the application is submitted. An examiner can immediately access the deposit when they open the application. Examiners do not need to move deposits around the Office. Electronic deposits allow examiners to process more claims per hour, thereby cutting processing times significantly.

The Office is interested in hearing from copyright owners on how this digital approach may or may not incentivize the routine registration of copyrighted works and improve the efficiency of the registration system. The Office also seeks comments on how this approach may affect copyright owners with regard to their compliance with mandatory deposit.

16. Digital Deposit Security

Any approach that increases the deposit of digital formats must be supported by a robust security system. Users have expressed concern regarding the capacity of the Office's current IT infrastructure to handle an increase in digital deposits, as well as the Office's mechanisms for securing these deposits.

The Office currently utilizes a multi-level security design to ensure the confidentiality, integrity, and availability of the data within the eCO system. The system is certified to operate at the National Institute of Standards and Technology (''NIST'') Moderate security level.[83] The entire eCO system operates on hardware and software dedicated to this system and it does not share any computer or storage resources. Strict access controls are in place throughout the system for public users, staff, and system administrators, enforcing the principle of least privilege, which means that users in each role may only access what is needed for their role. The system is also protected by multiple levels of network firewalls and other network-based security, such as anti-malware protection. Finally, the eCO system is under continuous monitoring, both operational and security, to ensure that these security controls are and remain effective.

The Office, working with OCIO, plans to implement these same controls in the new online registration system. Additionally, the Office's IT infrastructure is being updated to support increased numbers of digital deposits. The Office welcomes comment on the current and future state of the Office's deposit security as well as any additional approaches to this issue.

E. Additional Considerations

The Office is dedicated to developing a robust and efficient registration system and invites comment on any additional considerations that it should take into account during its modernization process.

Dated: October 11, 2018.

Karyn Temple,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

[FR Doc. 2018–22486 Filed 10–16–18; 8:45 am]

BILLING CODE 1410–30–P

[80] *See Legislative Branch Appropriations for 2019, Hearings Before the Subcomm. on Legislative Branch of the H. Comm. on Appropriations, Part 2,* 115th Cong., 2d Sess. 325, 357–359 (2018)(statement from Rep. Kevin Yoder, Chairman, Subcomm. on Legislative Branch concerning registration processing times, noting ''we really want the Copyright Office to be successful and [] efficient''), *available at https://www.gpo.gov/fdsys/pkg/CHRG-115hhrg30357/pdf/CHRG-115hhrg30357.pdf.*

[81] *Legislative Branch Appropriations for 2019, Hearings Before the Subcomm. on Legislative Branch of the H. Comm. on Appropriations, Part 2,* 115th Cong., 2d Sess. at 358 (2018).

[82] When an applicant submits an online application and sends the deposit through the mail, they are expected to print and attach a ''shipping slip'' to the deposit. This document contains a barcode generated by the electronic registration system that is used to connect the deposit with the appropriate registration application. Unfortunately, large quantities of deposits are submitted without a shipping slip. In such cases, RAC staff must correspond with the applicant to obtain the ten-digit case numbers that have been assigned to all of the applications submitted by that party, and then search for those applications in the electronic registration system. Before delivering the deposit to the examiner for a substantive review, RAC staff must match each application to its corresponding deposit by manually generating a new shipping slip with an identifying barcode.

[83] *See* National Institute of Standards and Technology, Minimum Security Requirements for Federal Information and Information Systems, FIPS PUB 200, available at *https://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.200.pdf;* National Institute of Standards and Technology, Security and Privacy Controls for Information Systems and Organizations, SP 800–53, *available at https://csrc.nist.gov/CSRC/media//Publications/sp/800-53/rev-5/draft/documents/sp800-53r5-draft.pdf.*

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP64

Adopting Standards for Laboratory Requirements

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend 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 health assessment 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 proposed rule would formalize this practice. The proposed rule would establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. Specifically, it would address how VA applies regulations as the controlling

standards for VA medical facility laboratories.

DATES: Comments must be received on or before December 17, 2018.

ADDRESSES: Written comments may be submitted through *www.regulations.gov*; by mail or hand-delivery to the Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP64—Adopting 42 CFR Part 493 Laboratory Requirements.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Quynh Vantu, Health Science Specialist, Pathology and Laboratory Service (10P11P), Office of Specialty Care Services, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1063B, Washington, DC 20420, (202) 632–8418. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Clinical Laboratory Improvement Amendments of 1988 (Pub. L. (PL) 100–578) amended section 353 of the Public Health Service Act to establish legal requirements 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 health assessment of, human beings. These statutory requirements are codified at 42 U.S.C. 263a. The term ''laboratory'' or ''clinical laboratory'' are defined at 42 U.S.C. 263a(a) as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Centers for Medicare & Medicaid Services (CMS), within HHS, promulgated regulations for the Clinical Laboratory Improvement Amendments (CLIA) at title 42, Code of Federal Regulations (CFR), Part 493. CMS has primary responsibility for the administration of the CLIA program.

''. . . [T]o assure consistent performance of medical facility laboratories under the jurisdiction of the Secretary [of Veterans Affairs] of valid and reliable laboratory examinations and other procedures,'' section 101 of Public Law 102–139 (''1991 Act'') was enacted, requiring VA, within a specified time-frame and in consultation with HHS, ''to establish standards [by regulation] equal to that 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 described in sections 353(d) and 353(e), respectively, of the Public Health Service Act. As a matter of policy and practice, VA believes it has met these statutory requirements; however, VA is issuing this proposed rule to comply with the requirement for formal rulemaking. Since enactment of section 101(a) of the 1991 Act, VA has collaborated with HHS in reviewing VA requirements and in developing standards for VA's medical facility laboratories that meet the requirements of law.

VA policy and practice regarding CLIA compliance was developed in consultation with HHS in 1994 and 1998. VA laboratories are accredited by accrediting organizations granted deeming authority by CMS (*i.e.,* HHS-approved accreditation organization) to ensure its laboratories are in compliance with current CLIA regulations. Based on consultation with CMS in 1994 and 1998, the accreditation organization(s) provide oversight for proficiency testing in VA laboratories, as set forth in CLIA. Deeming authority is granted to an accrediting organization by CMS after a determination that the organization's accreditation oversight program requires that laboratories comply with or exceed CLIA standards. CMS has granted ''deeming authority'' to several other organization allowing them to accredit laboratories and inspect the laboratories in CMS's stead. The history of the process of the development of CLIA equivalent VHA standards in consultation with CMS is documented in the interagency agreement (IAA) between VA and CMS.

In 2000, after further consultation, VA and CMS entered into an IAA, which documented the history of the parties' consultations and agreements and granted VA limited authority to act on behalf of CMS. Specifically, the IAA authorized VA to issue CMS CLIA numbers and CLIA certificates to VA laboratories, which requires VA to notify CMS when VA suspends or retires CLIA numbers assigned to VA laboratories.

This agreement was renewed in 2010, and CMS and VA have agreed to review and update the interagency agreement as necessary in 2018, and every 6 years thereafter. In addition, CMS and VA agree to meet annually to discuss program issues of mutual importance.

To ensure VA remains current with CMS CLIA requirements, VA participates in the CMS Partners in Laboratory Oversight group, consults will CMS as needed, and participates in at least one formal consultative meeting per year. These engagements with CMS facilitates ongoing communication and coordination, and promotes effective oversight necessary to coordinate major activities, and expeditious, effective response to complaints, survey findings, and publicly volatile situations. VA staff attend State Agency Surveyor training, and CLIA surveyor webinars. VA has also convened ad hoc conferences with CMS when the exchange of information on CLIA may be needed. VA provides updates at the annual partners meeting and participates in audio conferences as requested. The CMS CLIA Program Director participates in VA's annual conference in which CMS, VA, and Department of Defense provide updates on laboratory issues and enforcement of laboratory regulations. As discussed below, VA laboratories that perform testing are all accredited and inspected by accrediting organizations granted deeming authority by CMS. As such, VA has documentation that its laboratories meet current CLIA standards.

VA provides updated data to CMS for each VA laboratory assigned a CLIA number at least every two years, or as changes occur. VA provides CMS with any requested information regarding the operation and performance of VA laboratories and the operations of the oversight program.

Under the 1991 Act, the definition of ''medical facility laboratories'' has the same meaning previously used to define the terms ''laboratory'' or ''clinical laboratory'' pursuant to section 353(a) of the Public Health Service Act, codified at 42 U.S.C. 263a(a). VA concluded that it should adopt 42 CFR part 493 regulations that were applicable to clinical laboratory operations but keep oversight and enforcement of these regulations as applied to VA laboratories within VA, rather than

HHS. Under current VA practice, VA fulfills all laboratory oversight of and enforcement functions for VA laboratories that CMS fulfills for HHS with respect to laboratories subject to CLIA. VA has the authority and responsibility to provide enforcement of the CLIA regulations for VA laboratories, including imposing sanctions and discontinuing laboratory testing. VA believes this determination is consistent with the fact that Congress passed an entirely separate law (Pub. L. 102–139) for VA medical facility laboratories under the exclusive jurisdiction and control of the Secretary of Veterans Affairs.

The 42 CFR part 493 regulations are very detailed and include multiple subparts that address clinical laboratory tests. The laboratory regulations include requirements for proficiency testing; facility administration; quality systems; personnel qualifications; responsibilities for laboratory personnel, including laboratory directors and testing personnel; laboratory inspections; and enforcement. Several subparts are not directly applicable to VA medical facility laboratories because they address administration of the oversight and enforcement functions performed by CMS under 42 CFR part 493. Sections of 42 CFR part 493 that refer to the interactions with state programs, collections of fees, suspension of payments, creation of an advisory committee, and civil action are not applicable to VA, as discussed in greater detail below.

Although the requirement for consultation between HHS and VA was accomplished over 20 years ago, we are now proposing to formalize, document, and update, as necessary, VA's application of the CLIA requirements to VA laboratory operations. VA proposes to amend its 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, the proposed rule would require VA laboratories to be accredited by an accreditation organization granted deeming authority by CMS, in accordance with the accreditation requirement in CLIA, and participate in an HHS approved proficiency testing program.

Through this proposed rulemaking, in accordance with current VA policy and practice, VA can continue to assure that medical facility laboratories across our system perform consistent, accurate and reliable laboratory testing, ensuring the provision of quality testing for our veteran-patients in a manner comparable to non-VA laboratories.

We note that, in addition to 42 CFR part 493 standards, VA recognizes and adheres to worker safety standards established by the Occupational Safety and Health Administration (OSHA) and the U.S. Nuclear Regulatory Commission (NRC). In addition, the U.S. Food and Drug Administration (FDA) regulates the collection of blood and blood components intended for transfusion or for further manufacturing use, such as to make clotting factors, and establishes standards for blood and blood products. FDA also regulates related products such as cell separation devices, blood collection containers and HIV screening tests that are intended for use in the manufacture of blood or blood products. FDA develops and enforces quality standards, inspects blood establishments, and monitors reports of errors, accidents and adverse clinical events. Those additional standards are beyond the scope of this proposed rule.

VA proposes to add a new section 17.3500, ''Adopting 42 CFR Part 493 Laboratory Requirements,'' to its medical regulations. There, we would address CLIA regulations found at 42 CFR part 493, by subpart, and how VA would apply those regulations.

We state that all laboratory testing within VA performed for the diagnosis, treatment, and prevention of disease, and assessment of health in patients would comply with the relevant requirements established by HHS under 42 CFR part 493 as enforced by VA. VA laboratory testing must meet, at a minimum, requirements established in 42 CFR part 493. These requirements must be met for any laboratory service offered by a VA medical facility, as well as contracted laboratory services performed on site at VA laboratories, outreach clinics, or testing sites. Provisions that are specific to oversight by state licensure programs are not applicable, since VA as a federal entity is not subject to state licensing requirements. Except as noted in the proposed rule, functions and responsibilities assigned to CMS in 42 CFR part 493 are assumed by VA with respect to laboratories operated by or on behalf of VA.

Part 493 subpart A covers general provisions. We propose that all provisions of subpart A would apply to VA with several exceptions intended to reflect that VA has the authority, responsibility, and duty to administer 42 CFR part 493 standards within VA. We state that functions assigned to HHS in this subpart would be performed by VA. This is consistent with an IAA previously entered into between VA and CMS. The regulation would set forth that the respective provisions of 42 CFR part 493 apply to VA laboratories performing waived, moderate, and high complexity tests.

Subparts B through D address certificates issued by CMS. Subpart B focuses on Certificates of Waiver. Subpart C addresses Registration Certificates, Certificates for PPM procedures, and Certificates of Compliance. PPM procedures are a select group of moderately complex microscopy tests commonly performed by specific health care providers during patient office visits. Tests included in PPM procedures do not meet the criteria for waiver because they are not simple procedures; they require training and specific skills for test performance. Subpart D focuses on Certificates of Accreditation. These subparts establish standards for CMS-issuance of the listed certificates as well as fees that must be remitted to CMS by regulated laboratories in order to apply for and receive certification. We state that all provisions of these subparts would apply to VA laboratories, except that certificates issued by HHS under these subparts are instead issued by VA pursuant to the previously noted interagency agreement between CMS and VA. As certificates are issued by VA rather than CMS, CMS does not require remittance of a fee from laboratories for any certificate issued by VA under these subparts.

Subpart E addresses accreditation by a private, nonprofit accreditation organization or exemption under an approved State laboratory program. Under this subpart, a laboratory may meet individual VA and CLIA program requirements through accreditation by a CMS approved nonprofit accreditation organization (AO). The subpart establishes an application and approval process for an accreditation organization seeking to be granted deeming authority by CMS, as well as a process in which CMS may validate findings of an accreditation organization by reinspection of a laboratory following an inspection by that accreditation organization. CLIA has granted ''deeming authority'' to several accreditation organizations allowing them to accredit laboratories and inspect the laboratories. These accreditation organizations must impose organizations' requirements equal to or more stringent than those contained in 42 CFR part 493 at the condition level. The subpart also establishes standards for CLIA exemptions under an approved State laboratory program. All provisions would apply to VA, to the extent that

this subpart addresses accreditation by a private, nonprofit accreditation organization. However, the provisions related to approved State laboratory program do not apply to VA.

The proposed rule states that VA would use only accreditation agencies with CMS-granted deeming authority to accredit VA laboratories. This is consistent with current, longstanding, VA practice. CMS has an established process for determining whether an accreditation organization should be granted deeming authority, and experience in making that determination. VA has determined that there is no need to duplicate that process and relying on CMS' approval of an accreditation organization ensures that VA would not reach any conclusions on deeming authority that are inconsistent with CMS.

A validation inspection is a quality control measure performed by CMS under Subpart E. It involves CMS reinspection of a laboratory that has recently been inspected by an accreditation organization with deeming authority, to validate that AO's survey findings. We state that validation inspections performed by CMS under subpart E would be performed instead by VA. This is consistent with current practice, and VA's authority under the 1991 Act to provide oversight and enforcement of the requirements set forth in 42 CFR part 493, as oversight and enforcement functions under this subpart as applied to VA laboratories are performed by VA.

General administration provisions related to 42 CFR part 493 are found at Subpart F. This subpart sets forth the methodology for determining the amount of 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. We state that provisions of Subpart F would not be applicable to VA, as CMS does not collect fees for certification of VA laboratories

Subpart H addresses participation in proficiency testing for laboratories performing nonwaived testing. Nonwaived testing is the term used by CMS to refer collectively to moderate and high complexity testing. We state that all provisions of this subpart would apply to VA, and VA employs scoring criteria under this subpart.

Subpart I focuses on the approval of proficiency testing programs. The proposed rule states that VA would rely on HHS to approve proficiency testing programs. VA would continue to use only HHS approved proficiency testing programs. HHS has an established process for proficiency testing program approval and experience in making that determination. VA has determined that there is no need to duplicate that process and relies on HHS program approvals.

Subpart J addresses facility administration for nonwaived testing, and sets standards for facility construction, transfusion services, and records retention. We state that all provisions of this subpart would apply to VA.

Subpart K focuses on quality systems for nonwaived testing. Under this subpart, each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems. Laboratory quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates, and resolves problems. The laboratory's quality system must be appropriate for the specialties and subspecialties of testing that the laboratory performs, services it offers, and clients it serves. This subpart establishes requirements for different specialties and subspecialties of laboratory tests and VA would apply all established requirements.

Personnel requirements for performing non-waived testing are addressed in subpart M. All applicable personnel requirements would meet CLIA requirements with the exception of state-specific licensing requirements. Subpart M requires that certain personnel maintain a license in the state in which the laboratory is located. While VA health care providers must be licensed in a state, there is no requirement that the health care provider be licensed in the state where the VA facility at which the provider works is located. See, 38 U.S.C. 7402 (requiring licensure in any state for eligibility to an appointment as VHA health care provider regardless of VHA facility location).

Subpart Q establishes inspection requirements for all CLIA-certified and CLIA-exempt state laboratories. We state that all provisions would apply to VA, except that all enforcement and oversight functions that are assigned to HHS in this subpart are performed by VA.

Subpart R sets forth enforcement procedures, including the policies and procedures CMS uses to enforce CLIA requirements, as well as appeal rights of laboratories on which CMS imposes sanctions. We state that all provisions would apply to VA with the following exceptions. Suspension of the right to Medicare or Medicaid payments as an available sanction against VA laboratories is not applicable because VA laboratories do not participate in these programs. Enforcement and oversight functions would be performed by VA rather than HHS or CMS. VA is responsible for ensuring its laboratories comply with these CLIA requirements, and taking immediate action in the jeopardy to patients. See, Public Law 102–139, section 101; 42 CFR 493.1218. Due process protections afforded by CMS-certified laboratories facing sanctions would not apply to laboratories operating by or under contract with VA. If VA had a substantial testing issue with a non-VA CMS-certified laboratory, VA would notify CMS of that instant. Laboratories subject to this proposed rule are operated by VA or under contract with VA. Finally, we state that VA would not participate in laboratory registry under 42 CFR 493.1850. This is consistent with longstanding VA policy and practice. The laboratory registry operated by CMS under part 493 includes collection of data that is not applicable to VA. Examples include a list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks; all appeals and hearing decisions; a list of laboratories against which CMS has sued under § 493.1846 and the reasons for those actions; and, a list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion. VA has made VA laboratory information available to the public in accordance with the Freedom of Information Act, 5 U.S.C. 552. VA believes this would provide the public with greater access to information than that found in the private sector.

Subpart T 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. The committee is managed by the Centers for Disease Control and Prevention (CDC), provides scientific and technical advice and guidance to HHS. The Committee includes diverse membership across laboratory specialties, professional roles, (laboratory management, technical, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer

representative. VA benefits from the diversity, broad knowledge, and expertise of government and non-government participants that make up CLIAC, because any issues addressed that result in changes to the part 493 regulations, then also become a requirement for VA. Since VA complies with part 493 regulations, VA ultimately benefits from revisions for improvement to standards initiated by CLIAC. CLIAC is governed by the Federal Advisory Committee Act (FACA), Public Law 92–463. FACA was enacted in 1972 to establish guidelines on federal advisory committee structures and operations. As VA does not have a similar FACA-level advisory committee, this subpart would not apply to VA.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This proposed 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 proposed rule would 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. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866, 13563 and 13771

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. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, 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, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866, because it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. 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.'' This proposed rule is not expected to be subject to the requirements of E.O. 13771 because this proposed rule is expected to result in no more than *de minimis* costs using a post-statutory baseline reflecting current practices within VA.

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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

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

The Secretary of Veterans Affairs, or designee, approved this document 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. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on September 19, 2017, for publication.

Dated: October 11, 2018.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

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

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding a sentence immediately following the statutory authority citation for section 17.655 to read as follows:

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

* * * * *

Section 17.3500 is also issued under Public Law 102–139 sec. 101.

■ 2. Add an undesignated center heading and § 17.3500 to read as follows:

Clinical Laboratory Standards

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

All laboratory testing within VA performed for the diagnosis, prevention, or treatment of any disease or impairment of, or health assessment of, human beings must comply with the listed requirements established by the Department of Health and Human Services (HHS) under the following subparts of 42 CFR part 493 as interpreted, administered, and enforced by VA. VA laboratory testing must meet, at a minimum, requirements established in 42 CFR part 493. These standards must be met for any laboratory service offered within a VA medical facility or outreach clinics, as well as contracted laboratory services performed on site at VA laboratories, outreach clinics, or testing sites. Except as noted below, functions and responsibilities assigned to the Centers for Medicare & Medicaid Services (CMS) in 42 CFR part 493 are assumed by VA. 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) *Subpart A—General provisions.* All provisions 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) *Subpart B—Certificate of waiver.* All provisions 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) *Subpart C—Registration certificate, certificate for provider-performed microscopy procedures, and certificate of compliance.* All provisions 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) *Subpart D—Certificates of accreditation.* All provisions 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) *Subpart E—Accreditation by a private, nonprofit accreditation organization or exemption under an approved state laboratory program.* All provisions 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 these accreditation agencies with deeming authority to accredit VA laboratories.

(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 validation inspections of VA laboratories.

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

(f) *Subpart F—General administration.* This subpart 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) *Subpart H—Participation in proficiency testing for laboratories performing nonwaived testing.* All provisions 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) *Subpart I—Proficiency testing programs for nonwaived testing.* All provisions 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) *Subpart J—Facility administration for nonwaived testing.* VA applies standards established in this subpart.

(j) *Subpart K—Quality system for nonwaived testing.* VA applies standards established in this subpart.

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

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

(m) *Subpart R—Enforcement procedures.* VA applies standards established in this subpart, 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-certified for 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) *Subpart T—Consultations.* This subpart 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. 2018–22452 Filed 10–16–18; 8:45 am]

BILLING CODE 8320–01–P