(ii) The PoC intended use must include the following information:

(A) That distribution of the test is limited to clinical laboratories that have an adequate quality assurance program, including planned systematic activities that provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.

(B) That the test is for use only by an agent of a clinical laboratory.

(C) That individuals must receive the ''Subject Information Notice'' prior to specimen collection and appropriate information when test results are provided.

(iii) PoC labeling must include instructions to follow current guidelines for informing the individual of the test result and its interpretation.

(iv) The instructions must state that reactive results are considered preliminary and should be confirmed following current guidelines.

(v) Device verification and validation for the PoC claim must include:

(A) Detailed documentation from a well-conducted multisite clinical study. Performance must be analyzed relative to an FDA cleared or approved comparator. This study must be conducted using patient samples, with appropriate numbers of HIV positive and HIV negative samples in applicable risk categories. Additional subgroup or type claims must be validated using appropriate numbers and types of samples. The samples may be a combination of fresh and repository samples, sourced from within and outside the United States, as appropriate. If the test is intended solely for PoC use, the test must meet only the performance criteria in paragraphs (b)(2)(v)(A)(*1*) and (*2*) of this section and not the criteria in paragraph (b)(2)(ii)(F) of this section:

(1) Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 98 percent.

(2) Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 98 percent.

(B) Premarket notification submissions must include the information contained in paragraph (b)(2)(v)(A) of this section.

(3) If the test is intended for supplemental use in addition to use as an aid in initial diagnosis, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, as appropriate, apply:

(i) For the additional supplemental claim, a clinical study must be performed that includes samples that were initially reactive and repeatedly reactive on a diagnostic test but were negative or indeterminate on a confirmatory test.

(ii) The intended use must include a statement that the test is intended for use as an additional test to confirm the presence of HIV viral nucleic acid in specimens found to be repeatedly reactive by a diagnostic screening test.

(4) If the test is intended solely as a supplemental test, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, except those in paragraphs(b)(1)(ii)(F) and (b)(2)(v)(A) of this section, as appropriate, apply:

(i) The labeling must include a statement that the test is intended for use as an additional test to confirm the presence of HIV viral nucleic acid in specimens found to be repeatedly reactive by a diagnostic screening test.

(ii) The labeling must clearly state that the test is not for use for initial diagnosis or is not intended as a first-line test.

(iii) A clinical study must be performed that includes samples that were initially reactive and repeatedly reactive on a diagnostic test but were negative or indeterminate on a confirmatory test.

(5) If the test is intended to differentiate different HIV types, the following special controls, in addition to those listed in paragraphs (b)(1) through (4) of this section, as appropriate, apply:

(i) The labeling must include the statement that the test is intended for the confirmation of initial results and differentiation of different HIV types.

(ii) Analytical and clinical sensitivity and specificity for each of the types, strains, and subtypes of HIV intended to be differentiated must be evaluated.

(iii) The results interpretation must include instructions for the user on how to interpret the results, including untypeable and co-infection results.

Dated: February 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03515 Filed 2–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 17 and 70

RIN 2900–AQ44

VHA Claims and Appeals Modernization

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations concerning its claims and appeals process governing various programs administrated by the Veterans Health Administration (VHA). The Veterans Appeals Improvement and Modernization Act of 2017 (AMA) amended the procedures applicable to administrative review and appeal of VA decisions on claims for benefits, creating a new, modernized review system. This rulemaking proposes amendments to sunset certain VHA regulations which are inconsistent with AMA.

DATES: Comments must be received on or before April 21, 2020.

FOR FURTHER INFORMATION CONTACT: Erik Shepherd, Program Specialist, Office of Regulatory and Administrative Affairs, Department of Veterans Affairs, 810 Vermont Ave. NW, Washington, DC 20420, (202) 461–9596 (This is not a toll-free number.).

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1064, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to [RIN 2900–AQ44 VHA Appeals Modernization.] Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1064, 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 *www.Regulations.gov*.

SUPPLEMENTARY INFORMATION: Public Law 115–55, the Veterans Appeals Improvement and Modernization Act of 2017 (AMA), changes the processes by which veterans seek review of VA benefits decisions. VA has implemented the AMA in a rulemaking that is generally applicable to benefits administered throughout VA, to include benefits administered by the Veterans Health Administration (VHA). VA Claims and Appeals Modernization, 84 FR 138, 172 (Jan. 18, 2019). That rulemaking specifically provides, ''unless otherwise specified in this final rule, VA amends its regulations applicable to all claims processed under

the new review system, which generally applies where an initial VA decision on a claim is provided on or after the effective date or where a claimant has elected to opt into the new review system under established procedures.'' 84 FR 138.

However, the VA Claims and Appeals Modernization regulatory amendments did not explicitly revise or remove VHA specific regulations which are inconsistent with AMA. In this rulemaking, VA proposes to sunset multiple VHA regulations that are inconsistent with the AMA and the VA Claim and Appeals Modernization regulatory amendments. Because the AMA and VA's January 2019 regulations apply to VHA, these proposed conforming changes to part 17 will not change the procedures VHA currently follows under the AMA.

First, the authority to reconsider a VHA decision, which is established under VHA's regulations at 38 CFR 17.133, 17.276, 17.904, and 17.1006 and 38 CFR 70.40, is inconsistent with the specific differentiated lanes for seeking review of a VA decision that are established by AMA and implemented in the VA Claims and Appeals Modernization regulatory amendments, particularly the closed record requirement for higher level review. To conform VHA's regulations to the procedures applicable under AMA and implementing regulations, VA proposes to amend §§ 17.133, 17.276, 17.904, 17.1006, and 70.40 to make clear that VHA reconsideration is available only in legacy claims, as defined in Part 3 and 20 of this title.

Similarly, VHA proposes to revise 38 CFR 17.132 regarding appeals of VHA decisions on certain requests for payment or reimbursement for care rendered in the community. Section 17.132 affords only one avenue for disputing a VA decision regarding payment or reimbursement, appeal to the Board of Veterans' Appeals. For payment requests covered by AMA and implementing regulations, this is inconsistent with the three distinct lanes established by that law. Thus, VHA proposes to revise § 17.132 to clarify that it will apply only to payment decisions made for legacy claims as described 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 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). This proposed rule only affects procedures regarding the appeals process; it does not affect the cost of filing an appeal nor any amount duly owed to a small entity. 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 Orders 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. The Office of Information and Regulatory Affairs has determined that this rule is 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 FYTD.

This rule is not expected to be subject to the requirements of Executive Order 13771 because this rulemaking is expected to result in no more than de minimis costs.

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 64.009—Veterans Medical Care Benefits; 64.039—CHAMPVA.

List of Subjects in 38 CFR Parts 17 and 70

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, 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, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, 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. Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on January 10, 2020, for publication.

Consuela Benjamin,

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

For the reasons set out in the preamble, VA proposes to amend 38 CFR parts 17 and 70 as set forth below:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

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

* * * * *

■ 2. Amend § 17.132 by:

■ a. Designating the text as paragraph (b); and

■ b. Adding paragraph (a).

The addition to read as follows:

§ 17.132 Appeals.

(a) This section applies only to legacy claims.

* * * * *

■ 3. Amend § 17.133 by revising paragraph (a) to read as follows:

§ 17.133 Procedures.

(a) *Scope.* This section sets forth reconsideration procedures regarding claims for benefits administered by the Veterans Health Administration (VHA).

This section applies only to legacy claims.

* * * * *

■ 4. Amend § 17.276 by:
■ a. Designating the text as paragraph (b); and
■ b. Adding paragraph (a).
The addition to read as follows:

§ 17.276 Appeal/Review Process

(a) This section applies only to legacy claims.

* * * * *

■ 5. Amend § 17.904 by:
■ a. Designating the text as paragraph (b); and
■ b. Adding paragraph (a).
The addition to read as follows:

§ 17.904 Review and Appeal Process

(a) This section applies only to legacy claims.

* * * * *

§ 17.1006 [Amended].

■ 6. Amend § 17.1006 by removing the words ''reconsideration and'' from the last sentence.

PART 70—VETERANS TRANSPORTATION PROGRAMS

■ 1. The authority citation for part 70 continues to read as follows:

Authority: 38 U.S.C. 101, 111, 111A, 501, 1701, 1714, 1720, 1728, 1782, 1783, and E.O. 11302, 31 FR 11741, 3 CFR, 1966–1970 Comp., p. 578, unless otherwise noted.

■ 2. Amend § 70.40 by:
■ a. Designating the text as paragraph (b); and
■ b. Adding paragraph (a).
The addition to read as follows:

§ 70.40 Administrative Procedures

(a) This section applies only to legacy claims.

* * * * *

[FR Doc. 2020–03432 Filed 2–20–20; 8:45 am]

BILLING CODE 8320–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3010

[Docket No. RM2020–5; Order No. 5433]

Market Dominant Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing revisions to its rules concerning rate incentives for market dominant products to clarify the definition of ''rate of general applicability'' within the context of a market dominant price adjustment proceeding; to add an additional criterion for a rate incentive to be included in a percentage change in rates calculation at discounted prices; and to state clearly what information the Postal Service must file to support a claim that a rate incentive meets the necessary criteria to be included in a percentage change in rates calculation at discounted prices. The Commission invites public comment on the propose rules.

DATES: *Comments are due:* March 23, 2020.

ADDRESSES: For additional information, Order No. 5433 can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Background

The Commission's rules permit the Postal Service, when adjusting market dominant rates as part of a market dominant rate adjustment proceeding, to include discounted prices for rate incentives that the Postal Service plans to offer in the percentage change in rates calculation, as long as the rate incentive meets certain criteria. 39 CFR 3010.23(e). These criteria are: (1) That the rate incentive is in the form of a discount or can be easily translated into a discount; (2) that sufficient billing determinants are available for the rate incentive to be included in the percentage change in rates calculation; and (3) that the rate incentive is a rate of general applicability. 39 CFR 3010.23(e)(2). The Commission's rules also require the Postal Service to provide ''sufficient information to demonstrate that the rate incentive is a rate of general applicability.'' 39 CFR 3010.12(b)(9)(i).

When the Commission promulgated rules with regard to the treatment of market dominant rate incentives, it included a specific definition of ''rate of general applicability'' in the context of market dominant rate adjustments which provided, *inter alia,* that ''[a] rate is not a rate of general applicability if eligibility for the rate is dependent on factors other than the characteristics of the mail to which the rate applies.'' 39 CFR 3010.1(g). The Commission explained that mail volume sent by a mailer in a previous year is not a characteristic of the mail to which rates under an incentive program apply.[1]

In the most recent market dominant rate adjustment proceeding, the Postal Service sought to include a rate incentive in the percentage change in rates calculation that featured the following terms. First, a 2-cent ''base'' credit per qualifying mailpiece was offered to mailers who sent out Business Reply Mail, Courtesy Reply Mail, and/or Share Mail enclosures which were subsequently returned or forwarded by the recipients.[2] For new participants, there was no required volume threshold in order to be eligible to participate in the incentive program. *Id.* For repeat participants, they had to meet or exceed 93 percent of their returns from the prior year in order to remain eligible. *Id.* In addition, repeat participants whose returns exceeded 100 percent of their returns from the prior year were eligible for an additional 2-cent ''bonus'' credit (for a total of 4 cents per qualifying mailpiece). *Id.* A question arose as to whether the ''base'' tier of the incentive program, the ''bonus'' tier, both, or neither constituted ''rates of general applicability'' appropriate for inclusion in the percentage change in rates calculation at discounted prices. *Id.* at 17, 19–24.

The Commission found that the Postal Service had failed to provide sufficient information to demonstrate that the rate incentive in question was a rate of general applicability, as required by § 3010.12(b)(9)(i). *Id.* at 22. Nevertheless, upon considering the matter, the Commission determined that a potential ambiguity existed in the Commission's rules concerning whether a rate incentive featuring a mailer-specific volume threshold based on historical volume data could constitute a ''rate of general applicability.'' *Id.* at 23–24. The Commission permitted both tiers of the promotion to be included in the percentage change in rates calculation in Docket No. R2020–1, but indicated that it would initiate a rulemaking to clarify this issue. *Id.*

II. Basis for Proposed Rule Change

The Commission proposes to clarify its rules by making three revisions. First, the Commission proposes to amend § 3010.1(g) to clarify that in order to qualify as a rate of general

[1] *See* Docket No. RM2014–3, Order Adopting Final Rules on the Treatment of Rate Incentives and De Minimis Rate Increases for Price Cap Purposes, June 3, 2014, at 15–16 (Order No. 2086).

[2] Docket No. R2020–1, Order on Price Adjustments for USPS Marketing Mail, Periodicals, Package Services, and Special Services Products and Related Mail Classification Changes, November 22, 2019, at 16–17 (Order No. 5321).