

of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 890.5800 to subpart F to read as follows:

§ 890.5800 Virtual reality behavioral therapy device for pain relief.

(a) *Identification.* A virtual reality behavioral therapy device for pain relief is a device intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display that utilizes a software program containing the behavioral therapy content.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing under the labeled conditions for use must validate the model of behavioral therapy as implemented by the device and evaluate all adverse events.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(5) Labeling must include the following:

(i) A warning regarding the risk of nausea and motion sickness;

(ii) A warning regarding the risk of discomfort from the device; and

(iii) A summary of the clinical testing with the device.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00014 Filed 1-5-23; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 36 and 42

RIN 2900-AR79

Federal Civil Penalties Inflation Adjustment Act Amendments

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations

to adjust for inflation the amount of civil monetary penalties that are within VA's jurisdiction. These adjustments comply with the requirement in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, to make annual adjustments to the penalties.

DATES: This rule is effective January 6, 2023.

FOR FURTHER INFORMATION CONTACT:

Stephanie Li, Chief, Regulations Team, Loan Guaranty Service (26), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632-8862. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act) (Pub. L. 114-74, sec. 701, 129 Stat. 584, 599-600), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410, sec. 5, 104 Stat. 890, 891-892), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The amended statute, codified in a note following 28 U.S.C. 2461, requires agencies to publish annual adjustments for inflation, based on the percentage change between the Consumer Price Index (defined in the statute as the Consumer Price Index for all-urban consumers (CPI-U) published by the Department of Labor) for the month of October preceding the date of the adjustment and the prior year's October CPI-U. 28 U.S.C. 2461 note, secs. 4(a) and (b) and 5(b)(1). This rule implements the 2023 calendar year inflation adjustment amounts.

Under 38 U.S.C. 3710(g)(4)(B), VA is authorized to levy civil monetary penalties against private lenders that originate VA-guaranteed loans if a lender falsely certifies that they have complied with certain credit information and loan processing standards, as set forth by chapter 37, title 38 U.S.C. and part 36, title 38 CFR. Under section 3710(g)(4)(B), any lender who knowingly and willfully makes such a false certification shall be liable to the United States Government for a civil penalty equal to two times the amount of the Secretary's loss on the loan involved or to another appropriate amount, not to exceed \$10,000, whichever is greater. VA implemented the penalty amount in 38 CFR 36.4340(k)(1)(i) and (k)(3). On December 15, 2022, the Office of Management and Budget (OMB) issued Circular M-23-05.

This circular reflects that the October 2021 CPI-U was 276.589 and the October 2022 CPI-U was 298.012, resulting in an inflation adjustment multiplier of 1.07745. Accordingly, the calendar year 2023 inflation revision imposes an adjustment from \$25,076 to \$27,018.

Under 31 U.S.C. 3802, VA can impose monetary penalties against any person who makes, presents, or submits a claim or written statement to VA that the person knows or has reason to know is false, fictitious, or fraudulent, or who engages in other covered conduct. The statute permits, in addition to any other remedy that may be prescribed by law, a civil penalty of not more than \$5,000 for each claim. 31 U.S.C. 3802(a)(1) and (2). VA implemented the penalty amount in 38 CFR 42.3(a)(1)(iv) and (b)(1)(ii). As previously noted, OMB Circular M-23-05 reflects an inflation adjustment multiplier of 1.07745. Therefore, the calendar year 2023 inflation revision imposes an adjustment from \$12,537 to \$13,508.

Accordingly, VA is revising 38 CFR 36.4340(k)(1)(i) and (3) and 38 CFR 42.3(a)(1)(iv) and (b)(1)(ii) to reflect the 2023 inflationary adjustments for civil monetary penalties assessed or enforced by VA.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to dispense with the opportunity for prior notice and public comment and to publish this rule with an immediate effective date. The statute requires agencies to make annual adjustments for inflation to the allowed amounts of civil monetary penalties "notwithstanding section 553 of title 5, United States Code." 28 U.S.C. 2461 note, sec. 4(a) and (b). The penalty adjustments, and the methodology used to determine the adjustments, are set by the terms of the statute. VA has no discretion to make changes in those areas. Therefore, an opportunity for prior notice and public comment and a delayed effective date are unnecessary.

Executive Orders 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. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, is not applicable to this rulemaking because notice of proposed rulemaking is not required. 5 U.S.C. 601(2), 603(a), 604(a).

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.

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).

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).

List of Subjects

38 CFR Part 36

Condominiums, Housing, Individuals with disabilities, Loan programs—housing and community development, Loan programs—veterans, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements, Veterans.

38 CFR Part 42

Administrative practice and procedure, Claims, Fraud, Penalties.

Signing Authority: Denis McDonough, Secretary of Veterans Affairs, approved this document on December 20, 2022, 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.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR parts 36 and 42 as set forth below:

PART 36—LOAN GUARANTY

■ 1. The authority citation for part 36 continues to read as follows:

Authority: 38 U.S.C. 501 and 3720.

§ 36.4340 [Amended]

■ 2. In § 36.4340, amend paragraphs (k)(1)(i) introductory text and (k)(3) by removing “\$25,067” and adding in its place “\$27,018”.

PART 42—STANDARDS IMPLEMENTING THE PROGRAM FRAUD CIVIL REMEDIES ACT

■ 3. The authority citation for part 42 continues to read as follows:

Authority: Pub. L. 99–509, secs. 6101–6104, 100 Stat. 1874, codified at 31 U.S.C. 3801–3812.

§ 42.3 [Amended]

■ 4. In § 42.3, amend paragraphs (a)(1)(iv) and (b)(1)(ii) by removing “\$12,537” and adding in its place “\$13,508”.

[FR Doc. 2022–28481 Filed 1–5–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 19

[FRL–5906.7–01–OECA]

Civil Monetary Penalty Inflation Adjustment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating this final rule to adjust the level of the maximum (and minimum) statutory civil monetary penalty amounts under the statutes the EPA administers. This action is mandated by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended through the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (“the 2015 Act”). The 2015 Act prescribes a

formula for annually adjusting the statutory maximum (and minimum) amount of civil monetary penalties to reflect inflation, maintain the deterrent effect of statutory civil monetary penalties, and promote compliance with the law. The rule does not establish specific civil monetary penalty amounts the EPA may seek in particular cases, as appropriate given the facts of particular cases and applicable agency penalty policies. The EPA’s civil penalty policies, which guide enforcement personnel on how to exercise the EPA’s discretion within statutory penalty authorities, take into account a number of fact-specific considerations, *e.g.*, the seriousness of the violation, the violator’s good faith efforts to comply, any economic benefit gained by the violator as a result of its noncompliance, and the violator’s ability to pay.

DATES: This final rule is effective January 6, 2023.

FOR FURTHER INFORMATION CONTACT:

David Smith-Watts, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, Mail Code 2241A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone number: (202) 564–4083; smith-watts.david@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The 2015 Act¹ requires each Federal agency to adjust the level of statutory civil monetary penalties under the laws implemented by that agency with annual adjustments to account for inflation. Section 4 of the 2015 Act requires each Federal agency to publish these adjustments by January 15 of each year. The purpose of the 2015 Act is to maintain the deterrent effect of civil monetary penalties by translating originally enacted statutory civil penalty amounts to today’s dollars and rounding statutory civil penalties to the nearest dollar.

Since January 15, 2017, the EPA has made six annual adjustments: on January 12, 2017, effective on January 15, 2017 (82 FR 3633); on January 10, 2018, effective on January 15, 2018 (83 FR 1190); on February 6, 2019, effective the same day (84 FR 2056), with a subsequent correction on February 25, 2019 (84 FR 5955); on January 13, 2020, effective the same day (85 FR 1751); on December 23, 2020, effective the same day (85 FR 83818); and on January 12,

¹ The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701 of Pub. L. 114–74) was signed into law on November 2, 2015, and further amended the Federal Civil Penalties Inflation Adjustment Act of 1990.