

(2) If it has not already done so, provide the respondent with a written summary of the legal basis for the allegation(s). In addition, the Commission may, but is not required to provide a response to the defenses raised by respondent;

(3) Provide a written basis for any monetary or other relief including the calculations underlying the initial conciliation proposal, and an explanation thereof. A written explanation is not required for subsequent offers and counteroffers;

(4) If it has not already done so, advise the respondent in writing that the Commission has designated the case as systemic, class, or pattern or practice, if the designation has been made at the time of the conciliation, and the basis for the designation; and

(5) Provide the respondent at least 14 calendar days to respond to the Commission's initial conciliation proposal.

(c) The Commission shall not disclose any information pursuant to paragraph (b) of this section where another federal law prohibits disclosure of that information or where the information is protected by privilege.

(d) Any information the Commission provides pursuant to paragraph (b) of this section to the respondent, except for information about another charging party or aggrieved individual, will also be provided to the charging party, upon request. Any information the Commission provides pursuant to paragraph (b) of this section to the respondent about an aggrieved individual will be provided to the aggrieved individual, upon request.

■ 3. Amend § 1626.15 by adding a new sentence to the end of paragraph (d) to read as follows:

§ 1626.15 Commission enforcement.

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(d) * * * Any conciliation process under this paragraph shall follow the procedures as described in § 1626.12.

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POSTAL SERVICE

39 CFR Part 233

Inspection Service Authority; Civil Monetary Penalty Inflation Adjustment

AGENCY: Postal Service™.

ACTION: Interim final rule.

SUMMARY: This document updates postal regulations by implementing inflation

adjustments to civil monetary penalties that may be imposed under consumer protection and mailability provisions enforced by the Postal Service pursuant to the Deceptive Mail Prevention and Enforcement Act and the Postal Accountability and Enhancement Act. These adjustments are required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. This document includes the adjustments for 2021 for statutory civil monetary penalties subject to the 2015 Act.

DATES: *Effective date:* January 14, 2021.

FOR FURTHER INFORMATION CONTACT: Steven Sultan, (202) 268-7385, SESultan@uspis.gov.

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), Public Law 114-74, 129 Stat. 584, amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (1990 Act), Public Law 101-410, 104 Stat. 890 (28 U.S.C. 2461 note), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Section 3 of the 1990 Act specifically includes the Postal Service in the definition of “agency” subject to its provisions.

Beginning in 2017, the 2015 Act requires the Postal Service to make an annual adjustment for inflation to civil penalties that meet the definition of “civil monetary penalty” under the 1990 Act. The Postal Service must make the annual adjustment for inflation and publish the adjustment in the **Federal Register** by January 15 of each year. Each penalty will be adjusted as instructed by the Office of Management and Budget (OMB) based on the Consumer Price Index (CPI-U) from the most recent October. OMB has furnished detailed instructions regarding the annual adjustment for 2021 in memorandum M-21-10, *Implementation of Penalty Inflation Adjustments for 2021, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (December 23, 2020), <https://www.whitehouse.gov/wp-content/uploads/2020/12/M-21-10.pdf>. This year, OMB has advised that an adjustment multiplier of 1.01182 will be used. The new penalty amount must be rounded to the nearest dollar.

The 2015 Act allows the interim final rule and annual inflation adjustments to be published without prior public notice or opportunity for public comment.

Adjustments to Postal Service Civil Monetary Penalties

Civil monetary penalties may be assessed for postal offenses under sections 106 and 108 of the Deceptive Mail Prevention and Enforcement Act, Public Law 106-168, 113 Stat. 1811, 1814 (*see*, 39 U.S.C. 3012(a), (c)(1), (d), and 3017 (g)(2), (h)(1)(A)); and section 1008 of the Postal Accountability and Enhancement Act, Public Law 109-435, 120 Stat. 3259-3261 (*see*, 39 U.S.C. 3018 (c)(1)(A)). The statutory civil monetary penalties subject to the 2015 Act and the amount of each penalty after implementation of the annual adjustment for inflation are as follows:

39 U.S.C. 3012(a)—False Representations and Lottery Orders

Under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may issue administrative orders prohibiting persons from using the mail to obtain money through false representations or lotteries. Persons who evade, attempt to evade, or fail to comply with an order to stop such prohibited practices may be liable to the United States for a civil penalty under 39 U.S.C. 3012(a). The regulations implemented pursuant to this section currently impose a \$73,951 penalty for each mailing less than 50,000 pieces, \$147,899 for each mailing of 50,000 to 100,000 pieces, and \$14,791 for each additional 10,000 pieces above 100,000 not to exceed \$2,957,993. The new penalties will be as follows: A \$74,825 penalty for each mailing less than 50,000 pieces, \$149,647 for each mailing of 50,000 to 100,000 pieces, and \$14,966 for each additional 10,000 pieces above 100,000 not to exceed \$2,992,956.

39 U.S.C. 3012(c)(1)—False Representation and Lottery Penalties in Lieu of or as Part of an Order

In lieu of or as part of an order issued under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may assess a civil penalty. Currently, the amount of this penalty, set in the implementing regulations to 39 U.S.C. 3012(c)(1), is \$36,975 for each mailing that is less than 50,000 pieces, \$73,951 for each mailing of 50,000 to 100,000 pieces, and an additional \$7,395 for each additional 10,000 pieces above 100,000 not to exceed \$1,478,996. The new penalties will be \$37,412 for each mailing that is less than 50,000 pieces, \$74,825 for each mailing of 50,000 to 100,000 pieces, and an additional \$7,482 for each additional 10,000 pieces above 100,000 not to exceed \$1,496,478.

39 U.S.C. 3012(d)—Misleading References to the United States Government; Sweepstakes and Deceptive Mailings

Persons may be liable to the United States for a civil penalty under 39 U.S.C. 3012(d) for sending certain deceptive mail matter described in 39 U.S.C. 3001(h)–(k), including:

- Solicitations making false claims of Federal Government connection or approval;
- Certain solicitations for the purchase of a product or service that may be obtained without cost from the Federal Government;
- Solicitations containing improperly prepared “facsimile checks”; and
- Certain solicitations for “skill contests” and “sweepstakes” sent to individuals who, in accordance with 39 U.S.C. 3017(d), have requested that such materials not be mailed to them.

Currently, under the implementing regulations, this penalty is not to exceed \$14,791 for each mailing. The new penalty will be \$14,966.

39 U.S.C. 3017(g)(2)—Commercial Use of Lists of Persons Electing Not To Receive Skill Contest or Sweepstakes Mailings

Under 39 U.S.C. 3017(g)(2), the Postal Service may impose a civil penalty against a person who provides information for commercial use about individuals who, in accordance with 39 U.S.C. 3017(d), have elected not to receive certain sweepstakes and contest information. Currently, this civil penalty may not exceed \$2,957,993 per violation, pursuant to the implementing regulations. The new penalty may not exceed \$2,992,956 per violation.

39 U.S.C. 3017(h)(1)(A)—Reckless Mailing of Skill Contest or Sweepstakes Matter

Currently, under 39 U.S.C. 3017(h)(1)(A) and its implementing regulations, any promoter who recklessly mails nonmailable skill contest or sweepstakes matter may be liable to the United States in the amount of \$14,791 per violation for each mailing to an individual. The new penalty is \$14,966 per violation.

39 U.S.C. 3018(c)(1)(A)—Hazardous Material

Under 39 U.S.C. 3018(c)(1)(A), the Postal Service may impose a civil penalty payable into the Treasury of the United States on a person who knowingly mails nonmailable hazardous materials or fails to follow postal laws on mailing hazardous materials. Currently, this civil penalty is at least \$320, but not more than \$127,525 for

each violation, pursuant to the implementing regulations. The new penalty is at least \$324, but not more than \$129,032 for each violation.

List of Subjects in 39 CFR Part 233

Administrative practice and procedure, Banks, Banking, Credit, Crime, Infants and children, Law enforcement, Penalties, Privacy, Seizures and forfeitures.

For the reasons set out in the preamble, the Postal Service amends 39 CFR part 233 as follows:

PART 233—INSPECTION SERVICE AUTHORITY

- 1. The authority citation for part 233 continues to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005(e)(1), 3012, 3017, 3018; 12 U.S.C. 3401–3422; 18 U.S.C. 981, 983, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 104–208, 110 Stat. 3009; Secs. 106 and 108, Pub. L. 106–168, 113 Stat. 1806 (39 U.S.C. 3012, 3017); Pub. L. 114–74, 129 Stat. 584.

§ 233.12 [Amended]

- 2. In § 233.12:
- a. In paragraph (a), remove “\$73,951” and add in its place “\$74,825”, remove “\$147,899” and add in its place “\$149,647”, remove “\$14,791” and add in its place “\$14,966”, and remove “\$2,957,993” and add in its place “\$2,992,956”.
- b. In paragraph (b), remove “\$36,975” and add in its place “\$37,412”, remove “\$73,951” and add in its place “\$74,825”, remove “\$7,395” and add in its place “\$7,482”, and remove “\$1,478,996” and add in its place “\$1,496,478”.
- c. In paragraph (c)(4), remove “\$14,791” and add in its place “\$14,966”.
- d. In paragraph (d), remove “\$2,957,993” and add in its place “\$2,992,956”.
- e. In paragraph (e), remove “\$14,791” and add in its place “\$14,966”.
- f. In paragraph (f), remove “\$320” and add in its place “\$324” and remove “\$127,525” and add in its place “\$129,032”.

Joshua Hofer,

Attorney, Federal Compliance.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–3372–F]

RIN 0938–AT88

Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). The Medicare Coverage of Innovative Technology (MCIT) pathway will result in 4 years of national Medicare coverage starting on the date of FDA market authorization or a manufacturer chosen date within 2 years thereafter. This rule also implements regulatory standards to be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B.

DATES: This final rule is effective on March 15, 2021.

FOR FURTHER INFORMATION CONTACT: Tamara Syrek Jensen and JoAnna Baldwin, (410) 786–2281 or CAGInquiries@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Department is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. Section 6 of the October 3, 2019 Executive Order 13890 (E.O. 13890) “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors,”¹ directs the Secretary to “propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients” including by “streamlining the approval, coverage, and coding process”.² The E.O. 13890 explicitly

¹ Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors, available at <https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/>.

² *Id.*