

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

For the reasons set forth in the preamble, CMS corrects 42 CFR parts 405, 427, and 428 by making the following correcting amendments:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.1210 is amended by revising paragraph (b)(3) to read as follows:

§ 405.1210 Notifying eligible beneficiaries of appeal rights when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

* * * * *

(b) * * *

(3) When delivery of the notice is valid. Delivery of the written notice of appeal rights described in this section is valid if—

(i) The eligible beneficiary (or the eligible beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

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PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 3. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w-3a(i), 1302, and 1395hh.

■ 4. Amend § 427.302 by revising the section heading and paragraph (c) introductory text to read as follows:

§ 427.302 Calculation of the per unit Part B rebate.

* * * * *

(c) Identification of the payment amount benchmark quarter. For each Part B rebatable drug, CMS will identify the applicable payment amount benchmark quarter as set forth in paragraphs (c)(1) through (3) of this section, as applicable, subject to paragraphs (c)(4) and (5) of this section,

using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, and using the earliest approval or licensure date of any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed:

* * * * *

§ 427.401 [Amended]

■ 5. Amend § 427.401 in paragraph (b)(2)(iv) by removing the phrase "set forth" and adding in its place the word "described".

■ 6. Amend § 427.501 by revising paragraph (d)(1)(i) introductory text to read as follows:

§ 427.501 Rebate Reports and reconciliation.

* * * * *

(d) * * *

(1) * * *

(i) Preliminary reconciliation. At least 1 month prior to the issuance of a report with the reconciled rebate amount for an applicable calendar quarter as set forth in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the rebate amount for an applicable calendar quarter based on the information set forth in paragraphs (b)(1)(i) through (ix) of this section and provide the information set forth in paragraphs (b)(1) and (d)(1)(i)(A) through (F) of this section to the manufacturer of a Part B rebatable drug for the applicable calendar quarter, if applicable:

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PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

■ 7. The authority citation for part 428 continues to read as follows:

Authority: 42 U.S.C. 1395w-114b, 1302, and 1395hh.

■ 8. Amend § 428.202 by revising the section heading and paragraph (a) to read as follows:

§ 428.202 Calculation of the per unit Part D rebate amount.

(a) Formula for calculating the per unit Part D rebate amount. CMS will calculate the per unit Part D rebate amount for a Part D rebatable drug and applicable period by determining the amount by which the AnMP for the Part D rebatable drug, as calculated in accordance with paragraph (b) of this section, exceeds the inflation-adjusted

payment amount, as calculated in accordance with paragraph (f) of this section.

* * * * *

■ 9. Amend § 428.204—

■ a. In the introductory text by removing the reference "\$ 428.201(a)" and adding in its place the reference "\$ 428.201(a)(1)(i)"; and

■ b. By revising paragraph (b).

The revision reads as follows:

§ 428.204 Treatment of new formulations of Part D rebatable drugs.

* * * * *

(b) Calculation of the inflation rebate amount ratio. The inflation rebate amount ratio is equal to the per unit Part D rebate amount for the initial drug, as determined under § 428.202(a), divided by the AnMP for that initial drug for the applicable period.

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§ 428.301 [Amended]

■ 10. Amend § 428.301 in paragraph (b)(2)(iv) by removing the phrase "set forth" and adding in its place the word "described".

Wilma Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 8

[Docket No. DOI-2024-0017; 256D0102DM, DS6CS00000, DLSN00000.000000, DX6CS25]

RIN 1093-AA29

Joint Policies of the Departments of the Interior and of the Army Relative to Reservoir Project Lands; Delay of Effective Date

AGENCY: Office of the Secretary, Interior. ACTION: Direct final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2025, from President Donald J. Trump, entitled "Regulatory Freeze Pending Review," this action delays the effective date of the direct final rule published on January 16, 2025, to June 16, 2025.

DATES: As of May 16, 2025, the effective date of the rule published on January 16, 2025 (90 FR 4669), delayed until May 16, 2025 (90 FR 15935), is further delayed until June 16, 2025.

FOR FURTHER INFORMATION CONTACT:

Roland Springer, Acting Regional Director—Bureau of Reclamation, Interior Region 9—Columbia-Pacific Northwest, rspringer@usbr.gov; telephone at (208) 378-5006. Individuals who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The direct final rule, “Joint Policies of the Departments of the Interior and of the Army Relative to Reservoir Project Lands,” published on January 16, 2025, at 90 FR 4669, included a 60-day public comment period that ended on March 17, 2025. The effective date of the direct final rule was April 16, 2025. A notice to delay the effective date of the direct final rule was published in the **Federal Register** on April 16, 2025, at 90 FR 15935 delaying the effective date to May 16, 2025. This notice further delays the effective date to June 16, 2025. The Department of the Interior is taking this action in response to Memorandum M-25-10 of January 20, 2025, from the Executive Office of the President, Office of Management and Budget, Implementation of Regulatory Freeze, regarding the postponement of effective dates of certain published regulations. The memorandum directed the heads of Executive Departments and Agencies to consider postponing for 60 days from the date of the memorandum the effective date for any rules that have been published in the **Federal Register**, or any rules that have been issued in any manner but have not taken effect, for the purpose of reviewing any questions of fact, law, and policy that the rule may raise. The Department of the Interior is delaying the effective date of the direct final rule published at 90 FR 4669 to June 16, 2025.

The Department of the Interior is delaying the effective date of the direct final rule without opportunity for public comment and making the delay effective immediately, based on the good cause exemptions in 5 U.S.C. 553(b)(B) and 553(d)(3), in that seeking public comment on the delay is impracticable, unnecessary, and contrary to the public interest. The delay in effective date until June 16, 2025, is necessary to give Department officials the opportunity for further review and consideration of new regulations, consistent with the memorandum of the President, dated

January 20, 2025. Given the imminence of the effective date of the direct final rule, seeking prior public comment on this delay is impractical, and contrary to the public interest in the orderly promulgation and implementation of regulations. For the foregoing reasons, the good cause exception in 5 U.S.C. 553(d)(3) also applies to the Department of the Interior’s decision to make this action effective immediately.

Tyler Hassen,

Acting Assistant Secretary—Policy, Management, and Budget.

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DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 231101-0256; RTID 0648-XE866]

Fisheries of the South Atlantic; 2025 Recreational Fishing Season Announcement and Closure for Blueline Tilefish in the South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; recreational fishing season and closure.

SUMMARY: NMFS announces the 2025 recreational fishing season for blueline tilefish in the exclusive economic zone (EEZ) of the South Atlantic. Announcing the length of the recreational fishing season is the accountability measure (AM) for the recreational sector. NMFS estimates that recreational landings of blueline tilefish will reach the recreational annual catch limit (ACL) during the 2025 fishing year. NMFS announces the season length and closure date for the recreational harvest of blueline tilefish in the South Atlantic to allow recreational fishermen to maximize their opportunities while NMFS manages recreational harvest to protect the blueline tilefish resource.

DATES: This temporary rule is effective from July 22 through December 31, 2025.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727-824-5305, email: mary.vara@noaa.gov.

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South

Atlantic includes blueline tilefish and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and NMFS, approved by the Secretary of Commerce, and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Regulations at 50 CFR 622.193(z)(2) specify the recreational ACL for blueline tilefish of 116,820 pounds (lb) or 52,989 kilograms (kg) in round weight, and the recreational AM. The recreational AM states that NMFS will project the length of the recreational fishing season for blueline tilefish based on catch rates from the previous fishing year and announce the end date of the recreational season based on when NMFS projects the recreational ACL will be met [50 CFR 622.193(z)(2)]. While the fishing year for blueline tilefish started on January 1, 2025, the recreational season for blueline tilefish harvested in or from the South Atlantic EEZ is closed from January 1 through April 30, and September 1 through December 31 each year [50 CFR 622.183(b)(7)]. Data from the NMFS Southeast Fisheries Science Center informed NMFS’ projection that recreational landings of blueline tilefish will reach the recreational ACL for 2025 by July 22. Therefore, the recreational season and harvest of blueline tilefish in the South Atlantic EEZ is closed starting on July 22, 2025, and will continue to be closed through the end of the calendar year. During the recreational closure, the bag and possession limits for blueline tilefish in or from the South Atlantic EEZ are zero. The next recreational fishing season for blueline tilefish begins on May 1, 2026.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.193(z)(2), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule that established the recreational ACL and AM for blueline tilefish has already been subject to notice and comment,