

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of Inspector General****42 CFR Part 1001**

RIN 0936-AA08

**Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees****AGENCY:** Office of Inspector General (OIG), Health and Human Services (HHS).**ACTION:** Final rule; delay of effective date; correction.

**SUMMARY:** In accordance with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” and given the pendency of litigation, *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services, et al.*, Civil Action No. 21–95 (JDB) (D.D.C.), challenging the final rule, this action temporarily delays for 60 days from the date of the memorandum the effective date of certain amendments as promulgated by the final rule titled “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees,” published in the November 30, 2020, **Federal Register**. This document announces that the effective date for the certain provisions of the final rule is delayed until March 22, 2021, the first business day after 60 days from the date of the memorandum. This document also corrects a technical error in the amendatory instructions.

**DATES:** As of January 29, 2021, the effective date of the amendments to 42 CFR 1001.952 (h)(6) through (9), (cc), and (dd) published at 85 FR 76666, November 30, 2020, is delayed until March 22, 2021.

This correction is effective as of March 22, 2021. The amendatory instructions in FR 2020–25841 (85 FR 76666), published on November 30, 2020 is corrected.

**FOR FURTHER INFORMATION CONTACT:** Aaron Zajic, (202) 619–0335.

**SUPPLEMENTARY INFORMATION:** The January 20, 2021 memorandum from the

Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” instructed Federal agencies to consider delaying the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days from the date of the memorandum to permit review of the rule. This action is consistent with that memorandum insofar as the Department has decided to review the rule at issue, and needs time to determine what additional action, if any, is appropriate.

The Department also has good cause to delay this rule’s effective date without advance notice and comment under 5 U.S.C. 553(b)(B) because of the pendency of litigation challenging the final rule, and the Department’s interest in evaluating its position in that litigation. The litigation includes both procedural and substantive challenges to the rule and its effective date. Though the provisions of the rule being delayed by this notice do not fully overlap with the provisions at issue in the pending litigation, the intersections between the rule’s various provisions and the overall regulatory framework are complex. HHS intends to evaluate those interactions as part of its regulatory review process, but needs additional time to do so beyond the current effective date of January 29, 2021.

Accordingly, this final rule delays the effective date of certain portions of the safe harbor regulation concerning discounts for prescription pharmaceutical products at 42 CFR 1001.952. The effective date of new paragraphs (h)(6) through (9), (cc), and (dd) of that rule, which would have been January 29, 2021, is now March 22, 2021. The temporary delay in the effective date of this final rule is necessary to give Department officials the opportunity for further review and consideration of the revisions to paragraphs (h)(5)(vi) and (viii), as well as the addition of new paragraphs (h)(5)(iii), (6) through (9), (cc), and (dd) of 42 CFR 1001.952, consistent with the memorandum of January 20, 2021.

Separately, November 2020 final rule contained a technical error in the amendatory instructions that would have prevented the Office of the Federal Register from properly incorporating the amendments to § 1001.952 into the CFR. This document also corrects that error.

■ In FR 2020–25841 (85 FR 76666), published on November 30, 2020, the following corrections are made:

**§ 1001.952 [Corrected]**

■ 1. On page 76730, third column, instruction 2 (including a. and b.) is corrected to read as follows:

■ 2. Section 1001.952 is amended by adding paragraphs (h)(6) through (9), (cc), and (dd) to read as follows:

**§ 1001.952 [Corrected]**

■ 2. On page 76731, first column, § 1001.952 is corrected by removing “(5) \* \* \*”, and the text of paragraphs (vi) through (viii).

**§ 1001.952 [Corrected]**

■ 3. On page 76731, third column, add amendatory instruction 3 to read as follows:

3. Effective January 1, 2022, § 1001.952 is amended by revising paragraphs (h)(5)(vi) and (vii) and adding paragraph (h)(5)(viii) to read as follows:

**§ 1001.952 Exceptions.**

\* \* \* \* \*

(h) \* \* \*

(5) \* \* \*

(vi) Services provided in accordance with a personal or management services contract;

(vii) Other remuneration, in cash or in kind, not explicitly described in this paragraph (h)(5); or

(viii) A reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.

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**Norris Cochran,**

*Acting Secretary.*

[FR Doc. 2021–02132 Filed 1–29–21; 8:45 am]

**BILLING CODE 4152–01–P**

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

[Docket No. 160426363–7275–02; RTID 0648–XA837]

**Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; 2020–2021 Closure of Commercial Run-Around Gillnet for King Mackerel**

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS implements an accountability measure (AM) through this temporary rule for commercial harvest of king mackerel in the southern zone of the Gulf of Mexico (Gulf exclusive economic zone (EEZ) using run-around gillnet gear. NMFS has determined that the commercial annual catch limit (ACL) for king mackerel using run-around gillnet gear in the southern zone of the Gulf EEZ has been reached. Therefore, NMFS closes the southern zone to commercial king mackerel fishing using run-around gillnet gear in the Gulf EEZ on January 28, 2021. This closure is necessary to protect the Gulf king mackerel resource.

**DATES:** The closure is effective from 12 p.m. local time on January 28, 2021, until 6 a.m. local time on January 18, 2022.

**FOR FURTHER INFORMATION CONTACT:** Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727-824-5305, email: [kelli.odonnell@noaa.gov](mailto:kelli.odonnell@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The fishery for coastal migratory pelagic fish in the Gulf includes king mackerel, Spanish mackerel, and cobia, and is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils 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. All weights for Gulf migratory group king mackerel (Gulf king mackerel) apply as either round or gutted weight.

The commercial fishery for Gulf king mackerel is divided into western, northern, and southern zones. The southern zone for Gulf king mackerel encompasses an area of the Gulf EEZ off Collier and Monroe Counties in south Florida, which is the EEZ south of a line extending due west from the boundary of Lee and Collier Counties on the Florida west coast, and south of a line extending due east from the boundary of Monroe and Miami-Dade Counties on the Florida east coast (50 CFR 622.369(a)(1)(iii)).

The commercial ACL for Gulf king mackerel is divided into separate ACLs for hook-and-line and run-around gillnet gear. The use of run-around gillnets for king mackerel is restricted to the Gulf southern zone. The commercial gillnet quota (equivalent to the commercial gillnet ACL) for Gulf king

mackerel is 575,400 lb (260,997 kg) during the fishing year from July 1, 2020, through June 30, 2021 (50 CFR 622.384(b)(1)(iii)(B)).

Regulations at 50 CFR 622.388(a)(1) require NMFS to close any component of the king mackerel commercial sector when its applicable quota has been reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that for the 2020–2021 fishing year, the commercial quota for Gulf king mackerel on vessels using run-around gillnet gear in the southern zone has been reached. Accordingly, commercial fishing using such gear in the southern zone is closed at 12 p.m. local time on January 28, 2021, until 6 a.m. local time on January 18, 2022, the beginning of the next fishing season, *i.e.*, the day after the 2022 Martin Luther King, Jr. Federal holiday. Vessel operators that have been issued a Federal commercial permit to harvest Gulf king mackerel using run-around gillnet gear in the southern zone must have landed ashore and bartered, traded, or sold such king mackerel prior to 12 p.m. local time on January 28, 2021.

Persons aboard a vessel using hook-and-line gear in the southern zone for which a Federal commercial permit for Gulf king mackerel has been issued, except persons aboard such a vessel also issued a Federal commercial permit to harvest Gulf king mackerel using run-around gillnet gear, may fish for or retain Gulf king mackerel unless the southern zone commercial quota for hook-and-line gear has been met and the hook-and-line component of the commercial sector has been closed. In addition, as long as the recreational sector for Gulf king mackerel is open (50 CFR 622.384(e)(1)), a person aboard a vessel that has a valid Federal commercial gillnet permit for king mackerel may continue to retain king mackerel under the recreational bag and possession limits set forth in 50 CFR 622.382(a)(1)(ii) and (a)(2).

During the commercial closure, Gulf king mackerel harvested using run-around gillnet gear in the southern zone may not be purchased or sold. This prohibition does not apply to Gulf king mackerel harvested using run-around gillnet gear in the southern zone that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor (50 CFR 622.384(e)(2)).

#### Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR

622.388(a)(1), 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 is unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulations associated with the commercial quota and associated AM for Gulf king mackerel have already been subject to notice and public comment, and all that remains is to notify the public of the closure. Prior notice and opportunity for public comment on this action is contrary to the public interest because of the need to immediately implement the closure to protect the Gulf king mackerel resource. The capacity of the fishing fleet allows for rapid harvest of the commercial quota, and any delay in the closure could result in the commercial quota being exceeded. Prior notice and opportunity for public comment would require time and would potentially result in a harvest that exceeds the commercial quota.

For the aforementioned reasons, there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness of this action.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: January 27, 2021.

**Jennifer M. Wallace,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2021-02134 Filed 1-28-21; 4:15 pm]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 200221-0062; RTID 0648-XA780]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Pot Gear in the Central Regulatory Area of the Gulf of Alaska

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific cod by vessels using pot gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action