

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; Delayed Effective Date

AGENCY: Office of Inspector General (OIG), Health and Human Services (HHS).

ACTION: Final rule; notification of court-ordered delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the District of Columbia, this action provides notice of the delay of the effective date of certain amendments to the safe harbors to the Federal anti-kickback statute that were promulgated in a final rule (“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 on November 30, 2020. The new effective date for these certain amendments is January 1, 2023.

DATES: As of February 19, 2021, this action delays the published effective date of the amendments to 42 CFR 1001.952(h)(5) published November 30, 2020, at 85 FR 76666, and corrected at 86 FR 7815, February 2, 2021, until January 1, 2023.

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

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 30, 2020, the Department issued a final rule establishing four changes to the regulatory safe harbors to the Federal anti-kickback statute (Social Security Act Section 1128B(b)). Specifically, the final rule (1) amended 42 CFR 1001.952(h)(5) to remove safe harbor protection for reductions in price for prescription pharmaceutical products provided to plan sponsors under Part D; (2) created a new safe harbor at § 1001.952(cc) for certain point-of-sale reductions in price offered by manufacturers on prescription

pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations that meet certain criteria; (3) created a new safe harbor at § 1001.952(dd) for fixed fees that manufacturers pay to pharmacy benefit managers (PBMs) for services rendered to the manufacturers that meet specified criteria; and (4) added new paragraphs (6)–(9) to 42 CFR 1001.952(h), defining certain terms. The final rule was published with an effective date of January 29, 2021, except for the amendments to 42 CFR 1001.952(h)(5), which were to be effective on January 1, 2022.¹

On January 12, 2021, a lawsuit challenging the final rule was filed in the U.S. District Court for the District of Columbia.² On January 30, 2021, the Court issued an order postponing until January 1, 2023 the effective date of all provisions of the final rule that were scheduled to take effect on January 1, 2022.³ Consistent with that order, the Department is taking this action to notify the public that the effective date of the amendments to paragraph 42 CFR 1001.952 (h)(5) in the final rule is now January 1, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of these amendments is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, implementation of this action without opportunity for public comment is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The one-year postponement of the effective date, until January 1, 2023, is required by court order in accordance with the court’s authority to postpone a rule’s effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the

¹ 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, was subsequently delayed until March 22, 2021. 86 FR 7815 (Feb. 2, 2021).

² *Pharmaceutical Care Management Association v. United States Department of Health & Human Services et al.*, No. 1:21-cv-00095 (D. DC. filed Jan. 12, 2021).

³ *Pharmaceutical Care Management Association v. United States Department of Health & Human Services et al.*, No. 1:21-cv-00095 (D. DC. Jan. 30, 2021) (order granting joint stipulation and postponing effective date), Doc. No. 19.

orderly issue and implementation of regulations.

Norris Cochran,
Acting Secretary.

[FR Doc. 2021-03167 Filed 2-18-21; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION**47 CFR Parts 0, 1, 27, 90**

[ET Docket No. 18-295; FCC 20-51; WT Docket No. 17-200; FCC 20-67, FRS 17383]

Unlicensed Use of the 6 GHz Band; Review of the Commission’s Rules Governing the 896-901/935-940 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget has approved the information collection requirements associated with the rules and policies adopted in the Federal Communications Commission’s 6 GHz Report and Order, FCC 20-51, making 1,200 megahertz of spectrum in the 6 GHz band (5.925-7.125 GHz) available for unlicensed use, and 900 MHz Report and Order, FCC 20-67, establishing rules for broadband license operations in the 897.5-900.5/936.5-939.5 MHz segment of the 900 MHz band (896-901/935-940 MHz), and that compliance with the new requirements is now required.

DATES: *Compliance date:* Compliance with 47 CFR 27.1503 and 27.1505, published at 85 FR 43124 on July 16, 2020, is required on February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jaclyn Rosen, Mobility Division, Wireless Telecommunications Bureau, at (202) 418-0154 or Jaclyn.Rosen@fcc.gov.

SUPPLEMENTARY INFORMATION: This document announces that the Office of Management and Budget (OMB) approved the information collection requirements in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1) and 47 CFR 27.1505(a), (b), on December 10, 2020. These rules were adopted in the 6 GHz Order, FCC 20-51, published at 85 FR 31390 on May 26, 2020, and, 900 MHz Report and Order, FCC 20-67, published at 85 FR 43124 on July 16, 2020. Compliance with all new or amended rules adopted in the 6 GHz Order that do not require OMB approval

is required as of July 27, 2020, see 85 FR 31390 (May 26, 2020). Compliance with all new or amended rules adopted in the 900 MHz Report and Order that do not require OMB approval is required as of August 17, 2020, see 85 FR 43124 (July 16, 2020).

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Cathy.Williams@fcc.gov, regarding OMB Control Number 3060-0798. Please include the OMB Control Number in your correspondence.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received final OMB approval on December 10, 2020, for the information collection requirements contained in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1) and 27.1505(a), (b). Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number for the information collection requirements in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1), 27.1505(a), (b) is 3060-0798.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104-13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060-0798.

OMB Approval Date: December 10, 2020.

OMB Expiration Date: December 31, 2023.

Title: FCC Application for Radio Service Authorization Wireless Telecommunications Bureau; Public Safety and Homeland Security Bureau.

Form Number: FCC Form 601.

Respondents: Individuals and households; Business or other for-profit entities; State, Local or Tribal Government; Not for profit institutions.

Number of Respondents and Responses: 255,552 respondents; 255,552 responses.

Estimated Time per Response: 0.5 hours to 1.25 hours.

Frequency of Response: Recordkeeping requirement; third party disclosure requirement; on occasion reporting requirement and periodic reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 152, 154, 155(c), 157, 201, 202, 208, 214, 301, 302a, 303, 307, 308, 309, 310, 311, 314, 316, 319, 324, 331, 332, 333, 336, 534, 535 and 554.

Total Annual Burden: 225,808 hours.

Total Annual Cost: \$72,474,000.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: The information collected under this collection will be made publicly available. However, to the extent information submitted pursuant to this information collection is determined to be confidential, it will be protected by the Commission. If a respondent seeks to have information collected pursuant to this information collection withheld from public inspection, the respondent may request confidential treatment pursuant to section 0.459 of the Commission's rules for such information.

Needs and Uses: FCC Form 601 is a consolidated, multi-part application form that is used for market-based and site-based licensing for wireless telecommunications services, including public safety, which are filed through the Commission's Universal Licensing System (ULS) or any other electronic filing interface the Commission develops. FCC Form 601 is composed of a main form that contains administrative information and a series of schedules used for filing technical and other information. This form is used to apply for a new license, to amend or withdraw a pending application, to modify or renew an existing license, cancel a license, request a duplicate license, submit required notifications, request an extension of time to satisfy construction requirements, request an administrative update to an existing license (such as mailing address change), or request a Special Temporary Authority License. Respondents are encouraged to submit FCC Form 601 electronically and are required to do so when applying for an authorization for which the applicant is the winning bidder in a spectrum auction.

On April 23, 2020, the Commission adopted a Report and Order and Further Notice of Proposed Rulemaking in ET

Docket 18-295, FCC 20-51, (6 GHz Report and Order) that requires temporary fixed microwave licensees to register temporary fixed links in the ULS database in order to receive protection from unlicensed devices operating in the 6 GHz band. Automated frequency coordination (AFC) administrators will use this information to determine where unlicensed devices can operate. Temporary fixed licensees were not previously required to file applications with the Commission when they commenced operation, so this is a new filing requirement. In addition to creating this new filing requirement, two new data fields will be required to describe when the temporary fixed links will be operational, so that the AFCs will know when to protect the temporary fixed links. For this purpose, a "start date" and "end date" will be added to the Form 601, Schedule I.

Further, on May 13, 2020, the Commission adopted a Report and Order, 20-67 (900 MHz Report and Order), which realigned the 900 MHz band to make available six of the band's ten megahertz for the deployment of broadband services and technologies. The 900 MHz band currently is designated for narrowband land mobile radio communications by Business/Industrial/Land Transportation (B/ILT) Pool licensees and Specialized Mobile Radio (SMR) providers. The 900 MHz Report and Order realigned the 900 MHz band to enable a broadband transition from interleaved SMR and B/ILT blocks to one broadband segment and two narrowband segments. To facilitate the transition, the Commission adopted a negotiation-based mechanism which, if private agreements are reached, will make available on a county-by-county basis six megahertz of low-band spectrum for the development of broadband technologies and services, while reserving the remaining four megahertz of the band for continued narrowband operations. If negotiations for the acquisition, relocation, and protection of 900 MHz incumbents in a market are successful and granting an application is otherwise in the public interest, the Commission will issue new initial licenses to applicants meeting eligibility requirements.

The 900 MHz Report and Order established license application requirements, including requirements that an applicant for a new 900 MHz broadband license demonstrate, as part of its application, that it satisfies the eligibility conditions (Eligibility Certification) and submit a plan for transitioning the 900 MHz band in a particular county (Transition Plan), to assess whether a grant of a 900 MHz

broadband license is in the public interest.

In addition, the Commission adopted a two-fold performance requirement whereby a 900 MHz broadband licensee must: (1) Provide reliable signal coverage and offer broadband service; and (2) meet either (a) a population coverage requirement, or (b) a geographic coverage requirement.

The information required in this collection will be used to ensure that a grant of a 900 MHz broadband license is in the public interest and to ensure that licensees use 900 MHz spectrum productively, provide service in a timely manner, and promote the provision of innovative services and technologies in unserved areas, particularly rural markets. The collection is also necessary for the Commission to satisfy its oversight responsibilities and/or agency specific/government-wide reporting obligations.

Federal Communications Commission.

Marlene Dortch,
Secretary.

[FR Doc. 2021-00782 Filed 2-18-21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160426363-7275-02]

RTID 0648-XA879

Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; 2020-2021 Commercial Hook-and-Line Closure for King Mackerel in the Gulf of Mexico Southern Zone

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) to close the hook-and-line component of the commercial sector for king mackerel in the Gulf of Mexico (Gulf) southern zone. This closure is necessary to protect the Gulf king mackerel resource.

DATES: This temporary rule is effective from 12:01 a.m., local time, on February 22, 2021, through June 30, 2021.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727-824-5305, email: 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) through 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 sector for Gulf king mackerel is divided into western, northern, and southern zones. The southern zone encompasses an area of the exclusive economic zone (EEZ) off Collier and Monroe Counties in south Florida. The southern zone includes 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 annual catch limit (ACL) for Gulf king mackerel is divided into separate ACLs for the hook-and-line and run-around gillnet components of the commercial sector. The commercial hook-and-line quota (equivalent to the commercial hook-and-line ACL) for Gulf king mackerel in the southern zone is 575,400 lb (260,997 kg) for the current fishing year of July 1, 2020, through June 30, 2021 (50 CFR 622.384(b)(1)(iii)(A)).

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 with the Office of the Federal Register. NMFS has determined the 2020-2021 hook-and-line commercial quota for Gulf king mackerel in the southern zone will be reached by February 22, 2021. Accordingly, the hook-and-line component of the commercial sector for Gulf king mackerel in the southern zone is closed from February 22, 2021, through the end of the fishing year on June 30, 2021. The commercial hook-and-line component for Gulf king mackerel in the southern zone will reopen on July 1, 2021.

NMFS has also determined that the Gulf king mackerel commercial quota for vessels using run-around gillnet gear in the southern zone was reached on January 28, 2021, and therefore on that date, NMFS closed the southern zone to

commercial king mackerel fishing using run-around gillnet gear (86 FR 7815, February 2, 2021). Accordingly, all commercial fishing for Gulf king mackerel in the southern zone is closed effective at 12:01 a.m. local time on February 22, 2021. The commercial run-around gillnet component for Gulf king mackerel in the southern zone will reopen at 6 a.m. local time on January 18, 2022.

A person aboard a vessel that has a valid Federal commercial permit for king mackerel may continue to retain king mackerel under the recreational bag and possession limits specified in 50 CFR 622.382(a)(1)(ii) and (a)(2), as long as the recreational sector for Gulf king mackerel is open (50 CFR 622.384(e)(1)).

During the commercial closure, king mackerel caught with hook-and-line gear from the closed zone may not be purchased or sold, including those harvested under the recreational bag and possession limits. This prohibition does not apply to king mackerel caught with hook-and-line gear from the closed 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 time required to provide notice and an opportunity for public comment. There is a need to immediately implement the closure to protect the Gulf king mackerel resource, because 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.

For the aforementioned reasons, there is good cause under 5 U.S.C. 553(d)(3)