

section shall only apply to the following covered entities: free-standing cancer hospitals qualifying under section 340B(a)(4)(M) of the PHSa, critical access hospitals qualifying under section 340B(a)(4)(N) of the PHSa, and rural referral centers and sole community hospitals qualifying under section 340B(a)(4)(O) of the PHSa. The exclusion does not apply to the remaining covered entities that meet the 340B Program eligibility requirements.

(2) When an entity described in this paragraph (b) meets more than one eligibility criterion as a covered entity, the entity shall select its eligibility type and notify the Secretary. These eligible entities are limited to participating in the 340B Program under only one covered entity hospital type and shall abide by all applicable restrictions and requirements for that entity type. A covered entity subject to this provision may only change its participation type to another hospital entity type on a quarterly basis upon express written confirmation from the Secretary.

(c) *Covered entity responsibility to maintain records of compliance.* (1) A covered entity listed in paragraph (b) of this section is responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the FFDCa. A covered entity listed in paragraph (b) of this section that purchases orphan drugs under the 340B Program is required to maintain and provide auditable records on request which document the covered entity's compliance with this requirement available for audit by the Federal Government or, with Federal Government approval, by the manufacturer.

(2) A covered entity may develop an alternative system by which it can prove compliance. Any alternate system must be approved by the Secretary prior to implementation. Each alternate system of compliance will be reviewed on a case-by-case basis.

(3) A covered entity listed in paragraph (b) of this section that cannot or does not wish to maintain auditable records sufficient to demonstrate compliance with this rule, must notify HRSA and purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used. Once a hospital is enrolled in 340B, it may change its decision to purchase all orphan drugs outside of the 340B Program on a quarterly basis by notifying HRSA.

This documentation will be made public. This information will also be verified during the annual recertification process.

(d) *Use of group purchasing organizations by a free-standing cancer hospital.* (1) A free-standing cancer hospital enrolled under section 340B(a)(4)(M) must also comply with the prohibition against using a GPO under section 340B(a)(4)(L)(iii) of the PHSa for the purchase of any covered outpatient drug.

(2) A covered entity that is a free-standing cancer hospital cannot use a GPO to purchase orphan drugs when they are transferred, prescribed, sold, or otherwise used for an indication other than the rare condition or disease for which that orphan drug was designated under section 526 of the FFDCa.

(3) A covered entity that is a free-standing cancer hospital may use a GPO for purchasing orphan drugs when orphan drugs are transferred, prescribed, sold, or otherwise used for the rare disease or condition for which it was designated under section 526 of the FFDCa.

(4) If a covered entity that is a free-standing cancer hospital chooses to use a GPO for purchasing an orphan drug used for a rare disease or condition for which it is designated, it is required to maintain auditable records that demonstrate full compliance with the orphan drug purchasing requirements and limitations. A free-standing cancer hospital covered entity that cannot or does not wish to maintain auditable records sufficient to demonstrate compliance, must notify HRSA and purchase all orphan drugs outside of the 340B Program, regardless of indication for which the drug is used, and is not permitted to use a GPO to purchase those drugs. Once a free-standing cancer hospital is enrolled in 340B, it may change its decision to purchase all orphan drugs outside of the 340B Program on a quarterly basis by notifying HRSA. This documentation will be made public. This information will also be verified during the annual recertification process.

(e) *Identification of orphan drugs.* Designations under section 526 of the FFDCa are the responsibility of and administered by the FDA. Only covered outpatient drugs that match the listing and sponsor of the orphan designation are considered orphan drugs for purposes of this section. HRSA will publish on its public Web site FDA's section 526 list of drugs that will govern the next quarter's purchases.

(f) *Failure to comply.* Failure to comply with this section shall be considered a violation of sections

340B(a)(5) and 340B(e) of the PHSa, as applicable.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[IB Docket No. 11-133; FCC 13-50]

Review of Foreign Ownership Policies for Common Carrier and Aeronautical Radio Licensees

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission (Commission) is correcting a final rule that appeared in the **Federal Register** of July 10, 2013 (78 FR 41314). The document issued final rules that apply to foreign ownership of common carrier, aeronautical en route and aeronautical fixed radio station licensees.

DATES: Effective on August 9, 2013.

FOR FURTHER INFORMATION CONTACT: Susan O'Connell or James Ball, Policy Division, International Bureau, FCC, (202) 418-1460 or via the Internet at Susan.OConnell@fcc.gov and James.Ball@fcc.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. 2013-15314 appearing on page 41314 in the **Federal Register** of Wednesday, July 10, 2013, the following corrections are made:

Subpart F—Wireless Radio Services Applications and Proceedings [Corrected]

- 1. On page 41321, in the third column, the heading of the table of contents for §§ 1.990 through 1.994, "Foreign Ownership of U.S.-Organized Entities That Control Common Carrier, Aeronautical en Route, and Aeronautical Fixed Radio Station Licensees" is corrected to read "Foreign Ownership of Common Carrier, Aeronautical en Route, and Aeronautical Fixed Radio Station Licensees".
- 2. On page 41322, in the first column, the undesignated center heading for §§ 1.990 through 1.994, "Foreign Ownership of U.S.-Organized Entities That Control Common Carrier, Aeronautical en Route, and Aeronautical Fixed Radio Station Licensees" is corrected to read "Foreign Ownership of Common Carrier, Aeronautical en Route, and

Aeronautical Fixed Radio Station Licensees”.

§ 1.994 [Corrected]

■ 3. On page 41330, in the third column, in § 1.994(d), under the heading *Example (for rulings issued under § 1.990(a)(2))*, correct the second sentence by removing the open parenthesis at the beginning of the sentence, to read as follows: A U.S. citizen holds the remaining 52 percent equity and voting interests in U.S. Corporation A, and the remaining 51 percent equity and voting interests in Licensee are held by its U.S.-organized parent, which has no foreign ownership.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013-17711 Filed 7-22-13; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 95-91; FCC 12-130]

Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310-2360 MHz Frequency Band

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the revised information collections for Satellite Digital Audio Radio Service (SDARS) terrestrial repeaters adopted in an *Order on Reconsideration* of the Commission's rules to Govern the Operation of Wireless Communications Services in the 2.3 GHz Band; Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310-2360 MHz Frequency Band,” WT Docket No. 07-293, IB Docket No. 95-91 (FCC 12-130). This notice is consistent with the *Order on Reconsideration*, which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES: The amendments to 47 CFR 25.263(b) and 25.263(c) published at 78 FR 9605, February 11, 2013, are effective July 23, 2013.

FOR FURTHER INFORMATION CONTACT: Stephen Duall, Satellite Division,

International Bureau, at (202) 418-1103, or email: *stephen.duall@fcc.gov*.

SUPPLEMENTARY INFORMATION: This document announces that, on June 27, 2013, OMB approved, for a period of three years, the revised information collection requirements relating to the access stimulation rules contained in the Commission's *Order on Reconsideration*, FCC 12-130, published at 78 FR 9605, February 11, 2013. The OMB Control Number is 3060-1153. The Commission publishes this notice as an announcement of the effective date of the rules. 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, Federal Communications Commission, Room 1-C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060-1153, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov*.

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 FCC is notifying the public that it received final OMB approval on June 27, 2013, for the information collection requirements contained in the modifications to the Commission's rules in 47 CFR part 25.

Under 5 CFR 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 is 3060-1153.

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: 3060-1153.

OMB Approval Date: June 27, 2013.

OMB Expiration Date: June 30, 2016.

Title: Satellite Digital Radio Service (SDARS).

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and

Responses: 1 respondent; 54 responses.

Estimated Time per Response: 3-12 hours.

Frequency of Response: Annual and on-occasion reporting requirements; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in sections 4, 301, 302, 303, 307, 309, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 154, 301, 302a, 303, 307, 309, and 332.

Total Annual Burden: 308 hours.

Total Annual Cost: \$97,710.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because the information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

Privacy Act: No impact(s).

Needs and Uses: The Federal Communications Commission (“Commission”) received approval from the Office of Management and Budget (OMB) to revise OMB Control No. 3060-1153 to reflect new and/or modified information collections as a result of an Order on Reconsideration titled “In the Matter of Amendment of part 27 of the Commission's rules to Govern the Operation of Wireless Communications Services in the 2.3 GHz Band; Establishment of Rules and Policies for the Digital Audio Radio Satellite Service in the 2310-2360 MHz Frequency Band,” WT Docket No. 07-293, IB Docket No. 95-91 (FCC 12-130).

On October 17, 2012, the Commission adopted and released an Order on Reconsideration that addressed five petitions for reconsideration of the 2010 WCS R&O and SDARS 2nd R&O. The petitions sought reconsideration or clarification of the Commission's decisions in the 2010 WCS R&O and SDARS 2nd R&O regarding the technical and policy rules governing the operation of WCS stations in the 2305-2320 MHz and 2345-2360 MHz bands and the operation of SDARS terrestrial repeaters in the 2320-2345 MHz band.

As part of the Order on Reconsideration, the Commission adopted proposals to relax the notification requirements for SDARS licensees under § 25.263(b) & (c) of the Commission's rules. As adopted in the 2010 WCS R&O and SDARS 2nd R&O, § 25.263(b) requires SDARS licensees to share with WCS licensees certain technical information at least 10 business days before operating a new