

§ 10.22 Covered entity information requests.

(a) A covered entity must submit a written request for additional information necessary to support its claim to the 340B ADR Panel within 20 business days of the claim acceptance date. The 340B ADR Panel will review the information request and notify the covered entity if the information request is beyond the scope of the claim and will permit the covered entity to resubmit a revised information request if necessary.

(b) The 340B ADR Panel will submit the covered entity's information request to the manufacturer who must respond to the request within 20 business days.

(c) The manufacturer must fully respond, in writing, to an information request from the 340B ADR Panel by the response deadline.

(1) A manufacturer is responsible for obtaining relevant information from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities.

(2) If a manufacturer anticipates that it will not be able to respond to the information request by the deadline, it can request one extension by notifying the 340B ADR Panel in writing within 15 business days of receipt of the request.

(3) A request to extend the deadline must include the reason why the current deadline is not feasible and must outline the proposed timeline for fully responding to the information request.

(4) The 340B ADR Panel may approve or disapprove the request for an extension of time and will notify all parties in writing of its decision.

§ 10.23 Final agency decision.

(a) The 340B ADR Panel will review documents submitted by the parties and determine if there is adequate support to conclude that a violation as described in paragraph (a)(1) or (2) of § 10.21 has occurred.

(1) The 340B ADR Panel will prepare a draft agency decision letter based on its review and evaluation of all documents submitted by the parties, including documents provided as required in paragraph (b) of § 10.21, information requests in support of a claim, and responses to a claim.

(2) The draft agency decision letter will be sent to all parties and will include the 340B ADR Panel's preliminary findings regarding the alleged violation.

(3) All parties will have 20 business days to respond to the 340B ADR Panel's draft agency decision letter.

(b) The 340B ADR Panel will review the responses of all parties in producing the final agency decision letter.

(1) The final agency decision letter will represent the decision of a majority of the 340B ADR Panel's findings regarding the claim and discuss the findings supporting the decision.

(2) The 340B ADR Panel will submit the binding final agency decision letter to all parties, and to HRSA, as necessary, for appropriate enforcement action.

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BILLING CODE 4165-15-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 97

[WT Docket No. 16-239; FCC 16-96]

Amateur Radio Service Rules To Permit Greater Flexibility in Data Communications

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on proposed amendments regarding technical standards applicable to data communications that may be transmitted in the Amateur Radio Service. Specifically, we propose to remove limitations on the symbol rate (also known as the baud rate) applicable to data emissions in certain amateur bands. We believe that this rule change will allow amateur service licensees to use modern digital emissions, thereby better fulfilling the purposes of the amateur service and enhancing its usefulness.

DATES: Submit comments on or before October 11, 2016, and reply comments are due on or before November 10, 2016.

ADDRESSES: You may submit comments, identified by WT Docket No. 16-239, by any of the following methods:

- *Federal Communications Commission's Web site:* <http://apps.fcc.gov/ecfs/>. Follow the instructions for submitting comments.
- *Mail:* Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: 202-418-0530 or TTY: 202-418-0432.

FOR FURTHER INFORMATION CONTACT: Scot Stone, Scot.Stone@fcc.gov, Wireless Telecommunications Bureau, (202) 418-0638, or TTY (202) 418-7233.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), adopted July 27, 2016 and released July 28, 2016. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Room CY-A257, Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY-B402, Washington, DC 20554. This document will also be available via ECFS at <http://fjallfoss.fcc.gov/ecfs/>. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to fcc504@fcc.gov or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

I. Introduction

1. In the *NPRM*, we propose, in response to a petition for rulemaking filed by the American Radio Relay League, Inc. (ARRL), to amend part 97 of the Commission's rules regarding technical standards applicable to data communications that may be transmitted in the Amateur Radio Service. Specifically, we propose to remove limitations on the symbol rate (also known as baud rate)—the rate at which the carrier waveform amplitude, frequency, and/or phase is varied to transmit information—applicable to data emissions in certain amateur bands. We believe that this rule change will allow amateur service licensees to use modern digital emissions, thereby better fulfilling the purposes of the amateur service and enhancing its usefulness.

II. Background

2. The limitations on radioteletype (RTTY) and data transmissions below 450 MHz vary depending on the frequency band, and on whether the digital code used to encode the signal being transmitted is one of the codes specified in section 97.309(a) of the Commission's rules—Baudot, AMTOR, and ASCII (the “specified digital codes”). Section 97.307(f) limits the symbol rate for the specified digital codes, and the bandwidth for unspecified digital codes, as follows:

The specified digital codes may be used with a symbol rate not exceeding 300 bauds for frequencies below 28 MHz (except the 60 meter (5.3305–5.4064 MHz) band), and 1200 bauds in the 10 meter (28–29.7 MHz) band; in the 6 meter (50–54 MHz) and 2 meter (144–148 MHz) bands, the specified digital codes may be used with a symbol rate not exceeding 19.6 kilobauds, and unspecified digital codes may be used with a bandwidth not exceeding 20 kilohertz; in the 1.25 meter (219–225 MHz) and 70 centimeter (420–450 MHz) bands, the specified digital codes may be used with a symbol rate not exceeding 56 kilobauds, and unspecified digital codes may be used with a bandwidth not exceeding 100 kilohertz. An amateur station transmitting a RTTY or data emission using one of the specified digital codes may use any technique whose technical characteristics have been documented publicly, such as CLOVER, G-TOR, or PACTOR, for the purpose of facilitating communications.

III. Discussion

3. *Symbol rate limit.* We tentatively agree with ARRL that the baud rate limits should be eliminated, and propose to amend part 97 accordingly. As ARRL notes, digital emissions were “in their early stages and experimentation with them was limited” at that time, and “the state of the art in HF digital communications has advanced substantially” since then. Indeed, the Commission observed in 1993 that “as technology progresses the rules may become unnecessarily restrictive, particularly with regard to the permissible baud rate.” For example, ARRL points out that PACTOR 3, which has a data rate of up to 3600 bits per second and a symbol rate of 100 bauds, is permitted in the HF bands; but PACTOR 4, which is capable of a data rate of 5800 bits per second without occupying any more spectrum, is prohibited at HF by the current rules because it has a symbol rate of 1800 bauds. Thus, ARRL argues, the current baud rate limits permit, if not actually encourage, inefficient spectrum utilization.

4. Many commenters agree that the baud rate restriction should be eliminated, and we seek comment on the reasons supporting such a view. For example, one commenter states that “part of the purpose of the amateur radio service is the advancement of radio and communications technology. Denying the ability to research and implement higher symbol rates directly contradicts the very purpose for amateur radio.” Another commenter notes that

“[t]he rest of the amateur radio operators in the world do not have this restrictive symbol rate requirement that is in the current part 97” and eliminating this restriction will allow the Emergency Communications Community to “benefit by being better able to meet its mission.” Many commenters cite permitting PACTOR 4 at HF as a reason for changing the rule, particularly to facilitate more efficient transmission of emergency communications. Other commenters, however, are concerned that facilitating faster data throughput will actually increase congestion by encouraging the transmission of larger amounts of data and new types of content.

5. We tentatively agree that a baud rate restriction has become unnecessary due to advances in modulation techniques, and no longer serves a useful purpose. Our rules do not impose a symbol rate limit on data emissions in any other amateur bands or in any other radio service. In addition, removing the baud rate restriction could encourage individuals to more fully utilize the amateur service in experimentation and could promote innovation, more efficient use of the radio spectrum currently allocated to the amateur service, and the ability of the amateur service to support public safety efforts in the event of an emergency. Facilitating the ability of the amateur service to transmit and experiment with technologies currently used in consumer and commercial products furthers this goal. Consequently, we propose to remove the baud rate limits in section 97.307(f). We seek comment on this proposal. In particular, we seek comment on whether eliminating the baud rate limits would improve amateur communications, or would instead increase congestion. Regarding the likelihood that eliminating the baud rate limitation would increase congestion, we seek comment on whether the costs of such an increase are outweighed by the benefits that are likely to flow from the elimination of the limits, and whether there are ways to mitigate these costs without losing the benefits of the proposed initiative. More generally, we seek comment on whether there are other costs and benefits to the proposal and, when weighing all the factors, whether the benefits of the proposal outweigh its costs. Commenters opposed to eliminating the baud rate limits should also explain whether their concerns relate to all of the bands at issue, or only certain spectrum.

6. We decline, however, to propose to add a 2.8 kilohertz bandwidth limitation for RTTY and data emissions in the MF/HF bands as requested by the ARRL

Petition. ARRL cites the 60 meter band as precedent for imposing a 2.8 kilohertz bandwidth limitation on data emissions, which ARRL states “would accommodate the HF data emissions that are in common use today.” The commenters who support eliminating the baud rate restriction also generally agree with the ARRL’s requested 2.8 kilohertz bandwidth limitation, but others who support eliminating the baud rate restriction favor a narrower bandwidth limitation in order to protect low-bandwidth modes of communication.

7. After reviewing the record, we tentatively conclude that a specific bandwidth limitation for RTTY and data emissions in the MF/HF bands is not necessary. We note that only the digital codes specified in section 97.309(a) may be used for MF/HF data emissions, and our rules do not impose any specific bandwidth limitation on use of the specified digital codes in any frequency band other than the 60 meter band. The 60 meter band cited by ARRL is a special case, however, given that amateur operators are permitted to operate only on specific frequencies rather than across the entire band, and are permitted to use only particular data and RTTY emission designators, in order to protect primary Federal voice operations in the band. Section 97.307(a) of the Commission’s rules already provides that no amateur station transmission shall occupy more bandwidth than necessary for the information rate and emission type being transmitted, in accordance with good amateur practice, and section 97.307(c) already prohibits interference from spurious emissions (*i.e.*, emissions outside the necessary bandwidth). The methods to be used in calculating the necessary bandwidth of various emissions are specified in section 2.202 of the Commission’s rules. We tentatively conclude that such rules are sufficient to help protect against inefficient use or other abuse of the spectrum identified by commenters, and will accomplish ARRL’s stated reason for proposing a bandwidth limitation of facilitating sharing among amateur licensees.

8. We also observe that while a 2.8 kilohertz bandwidth limitation would accommodate HF data emissions that are in common use today, such a limitation could, at the same time, undermine the goal—fundamental to the amateur service—of encouraging advances in technology if amateur radio operators were thereby prevented from stepping beyond today’s radio science. Imposing a maximum bandwidth would result in a loss of flexibility to develop

and improve technologies as licensees' operating interests change and new technologies are developed. We seek comment on these tentative conclusions.

9. While we tentatively conclude that a specific bandwidth limitation for RTTY and data emissions in the MF/HF bands is not necessary, we nonetheless request comment on whether we should establish emission bandwidth standards for amateur service MF/HF RTTY and data emissions. Commenters favoring such action should address what the maximum bandwidth should be, the basis for the particular limitation the commenter proposes, and whether the limit should apply across the bands or only in particular subbands. Commenters should explain the grounds for departing from the generally applicable standards.

IV. Conclusion

10. In summary, we believe that the public interest may be served by revising the amateur service rules to eliminate the current baud rate limitations for data emissions consistent with ARRL's Petition to allow amateur service licensees to use modern digital emissions, thereby furthering the purposes of the amateur service and enhancing the usefulness of the service. We do not, however, propose a bandwidth limitation for data emissions in the MF and HF bands to replace the baud rate limitations, because the rules' current approach for limiting bandwidth use by amateur stations using one of the specified digital codes to encode the signal being transmitted appears sufficient to ensure that general access to the band by licensees in the amateur service does not become unduly impaired.

V. Procedural Matters

11. *Initial Regulatory Flexibility Certification.* The Regulatory Flexibility Act (RFA) requires an initial regulatory flexibility analysis to be prepared for notice and comment rulemaking

proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

12. In the NPRM, we propose to amend the amateur service rules to change a technical rule applicable to data emissions that an amateur radio operator may use in his or her communications with other amateur radio operators. Because "small entities," as defined in the Regulatory Flexibility Act, do not include a "person" as the term is used in this proceeding or an individual, the proposed rules do not apply to "small entities." Rather, they apply exclusively to individuals who hold certain Commission authorizations. Therefore, we certify that the proposal in this NPRM, if adopted, will not have a significant economic impact on a substantial number of small entities.

13. *Paperwork Reduction Analysis.* This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4).

VI. Ordering Clauses

14. *It is ordered* that, pursuant to Sections 4(i), 303(r), and 403 of the

Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(r), and 403, that this Notice of Proposed Rulemaking is *hereby adopted*.

15. *It is further ordered* that, pursuant to section 1.407 of the Commission's rules, 47 CFR 1.407, the Petition for Rulemaking, RM-11708, filed by the American Radio Relay League, Inc., on November 15, 2013 is *granted* to the extent indicated herein, and is otherwise *denied*.

16. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 97

Radio.
Federal Communications Commission.
Gloria J Miles,
Federal Register Liaison Officer, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 97 as follows:

PART 97—AMATEUR RADIO SERVICE

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303. Interpret or apply 48 Stat. 1064-1068, 1081-1105, as amended; 47 U.S.C. 151-155, 301-609, unless otherwise noted.

■ 2. Section 97.305 is amended by revising the entry for 28.0-28.3 MHz in the table in paragraph (c) to read as follows:

§ 97.305 Authorized emission types.

* * * * *
(c) * * *

| Wavelength band | Frequencies | Emission types authorized | Standards see § 97.307(f), paragraph: |
|-----------------|---------------------|---------------------------|---------------------------------------|
| HF: | | | |
| 10 m | 28.0-28.3 MHz | RTTY, data | (3). |

■ 3. Section 97.307 is amended by revising paragraph (f)(3), removing and reserving paragraph (f)(4), and revising paragraphs (f)(5) and (6) to read as follows:

§ 97.307 Emission standards.

* * * * *

(f) * * *

(3) Only an RTTY or data emission using a specified digital code listed in § 97.309(a) of this part may be transmitted.

(4) [Reserved]

(5) An RTTY, data or multiplexed emission using a specified digital code listed in § 97.309(a) of this part may be transmitted. An RTTY, data or multiplexed emission using an unspecified digital code under the limitations listed in § 97.309(b) of this part also may be transmitted, provided the bandwidth does not exceed 20 kHz.

(6) An RTTY, data or multiplexed emission using a specified digital code listed in § 97.309(a) of this part may be transmitted. An RTTY, data or multiplexed emission using an unspecified digital code under the limitations listed in § 97.309(b) of this part also may be transmitted, provided the bandwidth does not exceed 100 kHz.

* * * * *

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS-HQ-MB-2016-0051; FF09M21200-156-FXMB1231099BPP0]

RIN 1018-BB40

Migratory Bird Hunting; Supplemental Proposals for Migratory Game Bird Hunting Regulations for the 2017-18 Hunting Season; Notice of Meetings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; supplemental.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), proposed in an earlier document this year to establish annual hunting regulations for certain migratory game birds for the 2017-18 hunting season. This supplement to that proposed rule provides the regulatory alternatives for the 2017-18 duck hunting seasons, announces the Service Migratory Bird Regulations Committee (SRC) and Flyway Council meetings, and provides Flyway Council recommendations resulting from their March meetings.

DATES: *Comments:* We will accept comments on this proposed rule and any subsequent proposed rules resulting from upcoming SRC meetings until January 15, 2017.

Meetings: The SRC will meet to consider and develop proposed regulations for the 2017-18 migratory game bird hunting seasons on October 25-26, 2016. Meetings on both days will commence at approximately 8:30 a.m.

ADDRESSES: You may submit comments on the proposals by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS-HQ-MB-2016-0051.

- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS-HQ-MB-2016-0051; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041.

We will not accept emailed or faxed comments. We will post all comments on <http://www.regulations.gov>. This generally means that your entire submission—including any personal identifying information—will be posted on the Web site. See the Public Comments section, below, for more information.

Meetings: The October 25-26, 2016, SRC meeting will be at the U.S. Fish and Wildlife Service, 5600 American Boulevard, Bloomington, MN 55437.

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel at: Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, MS: MB, 5275 Leesburg Pike, Falls Church, VA 22041; (703) 358-1714.

SUPPLEMENTARY INFORMATION:

New Process for the Annual Migratory Game Bird Hunting Regulations

As part of the Department of the Interior's retrospective regulatory review, we developed a schedule for migratory game bird hunting regulations that is more efficient and provides hunting season dates much earlier than was possible under the old process. The new process makes planning much easier for the States and all parties interested in migratory bird hunting. Beginning last year with the development of the 2016-17 hunting seasons, we are using a new schedule for establishing our annual migratory game bird hunting regulations. We combine the previously used early- and late-season regulatory processes into a single process, and make decisions for harvest management based on

predictions derived from long-term biological information and established harvest strategies to establish migratory bird hunting seasons much earlier than the system we used for many years. Under the new process, we develop proposed hunting season frameworks for a given year in the fall of the prior year. We then finalize those frameworks a few months later, thereby enabling the State agencies to select and publish their season dates in early summer. We provided a detailed overview of the new process in the June 10, 2016, **Federal Register** (81 FR 38050). This proposed rule is the second in a series of proposed and final rules for the establishment of the 2017-18 hunting seasons.

Service Migratory Bird Regulations Committee Meetings

The SRC will meet October 25-26, 2016, to review information on the current status of migratory game birds and develop 2017-18 migratory game bird regulations recommendations for these species. In accordance with Departmental policy, these meetings are open to public observation. You may submit written comments to the Service on the matters discussed.

Announcement of Flyway Council Meetings

Service representatives will be present at the individual meetings of the four Flyway Councils this August, September, and October. Although agendas are not yet available, these meetings usually commence at 8 a.m. on the days indicated.

Atlantic Flyway Council: October 6-7, 2016, Hyatt Regency, 225 East Coastline Drive, Jacksonville, FL.

Mississippi Flyway Council: August 25-26, 2016, Hyatt Regency, 311 South 4th Street, Louisville, KY.

Central Flyway Council: September 22-23, 2016, Sheraton Steamboat Resort, 2200 Village Inn Court, Steamboat Springs, CO.

Pacific Flyway Council: September 30, 2016, Sun Valley Resort, 1 Sun Valley Road, Sun Valley, ID.

Regulatory Schedule for 2017-18

On June 10, 2016, we published a proposal to amend title 50 of the Code of Federal Regulations (CFR) at part 20 (81 FR 38050). The proposal provided a background and overview of the migratory bird hunting regulations process, and addressed the establishment of seasons, limits, and other regulations for hunting migratory game birds under §§ 20.101 through 20.107, 20.109, and 20.110 of subpart K. This document is the second in a series