

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2020–0654; Airspace Docket No. 20–ASO–17]

RIN 2120–AA66

**Proposed Amendment of V–53, V–115, V–140, V–339, T–215, and T–323, and Revocation of V–339 in the Vicinity of Hazard, KY**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to amend three VHF Omnidirectional Range (VOR) Federal airways, V–53, V–115, and V–140; amend two Area Navigation (RNAV) T-routes, T–215 and T–323; and remove one VOR Federal airway, V–339, in the vicinity of Hazard, KY. The Air Traffic Service (ATS) route modifications are necessary due to the planned decommissioning of the VOR portion of the Hazard, KY, VOR/Distance Measuring Equipment (VOR/DME) navigation aid (NAVAID) which provides navigation guidance for portions of the affected ATS routes. The Hazard VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

**DATES:** Comments must be received on or before September 8, 2020.

**ADDRESSES:** Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–0654; Airspace Docket No. 20–ASO–17 at the beginning of your comments. You may also submit comments through the internet at <https://www.regulations.gov>.

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at [https://www.faa.gov/air\\_traffic/publications/](https://www.faa.gov/air_traffic/publications/). For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov) or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

[www.archives.gov/federal-register/cfr/ibr-locations.html](https://www.archives.gov/federal-register/cfr/ibr-locations.html).

**FOR FURTHER INFORMATION CONTACT:**

Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

**Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2020–0654; Airspace Docket No. 20–ASO–17) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at <https://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: “Comments to FAA Docket No. FAA–2020–0654; Airspace Docket No. 20–ASO–17.” The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing

date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

**Availability of NPRMs**

An electronic copy of this document may be downloaded through the internet at <https://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at [https://www.faa.gov/air\\_traffic/publications/airspace\\_amendments/](https://www.faa.gov/air_traffic/publications/airspace_amendments/).

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX 76177.

**Availability and Summary of Documents for Incorporation by Reference**

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**Background**

The FAA is planning decommissioning activities for the VOR portion of the Hazard, KY, VOR/DME in February, 2021. The Hazard VOR is a candidate VOR identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, “Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),” published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Hazard, KY, VOR/DME is planned for decommissioning, the co-located DME portion of the NAVAID is being retained to support Next Generation Air Transportation System (NextGen) PBN flight procedure requirements.

The ATS route dependencies to the Hazard VOR/DME are VOR Federal airways V-53, V-115, V-140, and V-339. With the planned decommissioning of the VOR portion of the Hazard VOR/DME, the remaining ground-based NAVAID coverage in the areas is insufficient to enable the continuity of the affected VOR Federal airways. As such, proposed modifications to the affected VOR Federal airways would result in gaps in those airways. To overcome the airway gaps, instrument flight rules (IFR) traffic could use adjacent ATS routes, including V-35, V-97, V-178, V-310, and V-493, or receive air traffic control (ATC) radar vectors to fly through or circumnavigate the affected area. IFR pilots equipped with RNAV PBN capabilities could also navigate point to point using the existing fixes that will remain in place to support continued operations through the affected area. Visual flight rules (VFR) pilots who elect to navigate via the airways through the affected area could also take advantage of the air traffic services previously listed.

Additionally, the FAA proposes to extend RNAV routes T-215 and T-323 through the affected area to continue supporting enroute airspace users, as well as ongoing FAA NextGen efforts to transition the NAS to performance-based navigation. Minor editorial amendments to the existing T-215 and T-323 descriptions would also be made, but would not change the existing routes' structure, operational use, or charted depiction.

### The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying VOR Federal airways V-53, V-115, and V-140; modifying RNAV routes T-215 and T-323; and removing VOR Federal airway V-339. The planned decommissioning of the VOR portion of the Hazard, KY, VOR/DME NAVAID has made this action necessary. The proposed VOR Federal airway changes are outlined below.

**V-53:** V-53 currently extends between the Charleston, SC, VOR/Tactical Air Navigation (VORTAC) and the Brickyard, IN, VOR/DME. The airspace within R-3401B is excluded. The FAA proposes to remove the airway segment overlying the Hazard, KY, VOR/DME between the Holston

Mountain, TN, VORTAC and the Lexington, KY, VOR/DME. The unaffected portions of the existing airway would remain as charted.

**V-115:** V-115 currently extends between the Crestview, FL, VORTAC and the Parkersburg, WV, VORTAC. The FAA proposes to remove the airway segment overlying the Hazard, KY, VOR/DME between the Voluntee, TN, VORTAC and the Charleston, WV, VORTAC. The unaffected portions of the existing airway would remain as charted.

**V-140:** V-140 currently extends between the Panhandle, TX, VORTAC and the Casanova, VA, VORTAC. The FAA proposes to remove the airway segment overlying the Hazard, KY, VOR/DME between the London, KY, VOR/DME and the Bluefield, WV, VOR/DME. The unaffected portions of the existing airway would remain as charted.

**V-339:** V-339 currently extends between the Hazard, KY, VOR/DME and the Falmouth, KY, VOR/DME. The FAA proposes to remove the airway in its entirety.

The proposed RNAV T-route changes are outlined below.

**T-215:** T-215 currently extends between the Lexington, KY, VOR/DME and the GAMKE, IN, waypoint (WP). The FAA proposes to extend the route southeastward from the Lexington, KY, VOR/DME to the Holston Mountain, TN, VORTAC. Additionally, the type of facility for Lexington, KY, is corrected from "VORTAC" to "VOR/DME" and the geographic coordinates of each route point are updated to be expressed in degrees, minutes, seconds, and hundredths of a second.

**T-323:** T-323 currently extends between the CROCS, GA, WP and the HIGGI, NC, WP. The FAA proposes to extend the route northward from the HIGGI, NC, WP to the Hazard, KY, DME. Additionally, the geographic coordinates of each route point are updated to be expressed in degrees, minutes, seconds, and hundredths of a second.

All NAVAID radials in the VOR Federal airway descriptions below are unchanged and stated in True degrees.

VOR Federal airways are published in paragraph 6010(a) and RNAV T-routes are published in paragraph 6011 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document would be subsequently published in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is

published yearly and effective on September 15.

### Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

### PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### § 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019 and effective September 15, 2019, is amended as follows:

*Paragraph 6010(a) Domestic VOR Federal Airways.*

\* \* \* \* \*

**V-53 [Amended]**

From Charleston, SC; Columbia, SC; Spartanburg, SC; Sugarloaf Mountain, NC; to Holston Mountain, TN. From Lexington, KY; Louisville, KY; INT Louisville 333° and Brickyard, IN, 170° radials; Brickyard. The airspace within R-3401B is excluded.

\* \* \* \* \*

**V-115 [Amended]**

From Crestview, FL; INT Crestview 001° and Montgomery, AL, 204° radials;

Montgomery; INT Montgomery 323° and Vulcan, AL, 177° radials; Vulcan; Choo Choo, TN; to Volunteer, TN. From Charleston, WV; to Parkersburg, WV.

\* \* \* \* \*

**V-140 [Amended]**

From Panhandle, TX; Burns Flat, OK; Kingfisher, OK; INT Kingfisher 072° and Tulsa, OK, 261° radials; Tulsa; Razorback, AR; Harrison, AR; Walnut Ridge, AR; Dyersburg, TN; Nashville, TN; Livingston,

TN; to London, KY. From Bluefield, WV; INT Bluefield 071° and Montebello, VA, 250° radials; Montebello; to Casanova, VA.

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**V-339 [Removed]**

\* \* \* \* \*

6011 United States Area Navigation Routes.

\* \* \* \* \*

**T-215 Holston Mountain, TN (HMT) to Gamke, IN [Amended]**

Holston Mountain, TN (HMT)	VORTAC	(Lat. 36°26'13.40" N, long. 082°07'46.56" W)
HILTO, VA	WP	(Lat. 36°41'48.46" N, long. 082°26'07.44" W)
FLENR, VA	WP	(Lat. 36°56'44.27" N, long. 082°43'42.75" W)
RISTE, KY	WP	(Lat. 37°09'02.92" N, long. 082°58'24.38" W)
Hazard, KY (AZQ)	DME	(Lat. 37°23'28.52" N, long. 083°15'46.83" W)
HUGEN, KY	FIX	(Lat. 37°31'46.14" N, long. 083°32'58.54" W)
Lexington, KY (HYK)	VOR/DME	(Lat. 37°57'58.86" N, long. 084°28'21.06" W)
GAMKE, IN	WP	(Lat. 38°46'12.99" N, long. 085°14'35.37" W)

\* \* \* \* \*

**T-323 CROCS, GA to Hazard, KY (AZQ) [Amended]**

CROCS, GA	WP	(Lat. 32°27'17.69" N, long. 082°46'29.06" W)
BOBBR, GA	WP	(Lat. 33°19'57.07" N, long. 083°08'19.47" W)
BIGNN, GA	WP	(Lat. 34°20'34.38" N, long. 083°33'06.80" W)
ZPPLN, NC	WP	(Lat. 34°59'47.42" N, long. 083°49'37.73" W)
HIGGI, NC	WP	(Lat. 35°26'46.57" N, long. 083°46'41.05" W)
KIDBE, TN	WP	(Lat. 35°51'16.23" N, long. 083°40'19.66" W)
ZADOT, TN	WP	(Lat. 36°35'32.17" N, long. 083°28'40.09" W)
WELLA, KY	WP	(Lat. 37°02'15.68" N, long. 083°21'31.07" W)
Hazard, KY (AZQ)	DME	(Lat. 37°23'28.52" N, long. 083°15'46.83" W)

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Issued in Washington, DC, on July 20, 2020.

**Scott M. Rosenbloom,**

*Acting Manager, Rules and Regulations Group.*

[FR Doc. 2020-15992 Filed 7-23-20; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 300

[Docket No. FDA-2019-N-5553]

RIN 0910-A136

#### Annual Summary Reporting Requirements Under the Right to Try Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** To facilitate implementation of the reporting requirements of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act), the Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for the deadline and contents of submission of

an annual summary. This proposed rule, if finalized, would implement the statutory requirement under provisions of the Right to Try Act for submission of an annual summary by sponsors and manufacturers who provide an eligible investigational drug for use by an eligible patient.

**DATES:** Submit either electronic or written comments on the proposed rule by September 22, 2020. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by September 22, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 22, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 22, 2020]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for