(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Reason

This AD was prompted by reports of damaged lower lateral fittings of the 80VU rack, and reports of new damage on airplanes on which certain optional service information had been accomplished. The FAA is issuing this AD to address damage or cracking of the 80VU fittings and supports, which could lead to possible disconnection of the cable harnesses to one or more computers, and if occurring during a critical phase of flight, could result in reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0172, dated July 20, 2021 (EASA AD 2021–0172).

(h) Exceptions to EASA AD 2021–0172

(1) Where EASA AD 2021–0172 refers to its effective date, this AD requires using the effective date of this AD.

(2) The remarks section of EASA AD 2021–0172 does not apply to this AD.

(3) Where paragraph (3) of EASA AD 2021–0172 specifies ''any discrepancy,'' for this AD ''any discrepancy'' includes broken fittings, missing bolts, an electronics rack FIN 80VU that is in contact with structure, any bush that has migrated, burred material, and cracks.

(i) Method of Compliance for Paragraphs (1), (2), and (3) of EASA AD 2021–0172

Accomplishing inspections and correctives actions in accordance with the Accomplishment Instruction of Airbus Service Bulletin A320–25–1BKJ, Revision 02, dated April 9, 2020, with corrections referenced in the Airbus Technical Adaptation 80827186/024/2020, Issue 1, dated September 18, 2020, is an acceptable method of compliance for the inspections and corrective actions specified in paragraphs (1), (2), and (3) of EASA AD 2021–0172.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved previously for AD 2013–25–11 are approved as AMOCs for the corresponding provisions of EASA AD 2021–0172 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2021–0172 that contains RC procedures and tests: Except as required by paragraph (j)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2021–0172, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* For Airbus service information, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St. Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. The EASA material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0506.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *sanjay.ralhan@faa.gov.*

Issued on November 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24791 Filed 11–16–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA–759]

RIN 1117–AB74

Regulation of Telepharmacy Practice

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is issuing this advanced notice of proposed rulemaking to obtain further information regarding the practice of telepharmacy. Telepharmacy is not specifically defined by the Controlled Substances Act (CSA) or DEA regulations; however, to the extent telepharmacies dispense controlled substances, they are under the purview of the CSA and DEA. DEA is considering promulgating regulations regarding telepharmacy and seeks to be fully informed about the practice, industry, and state regulation of telepharmacy.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before January 18, 2022. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''RIN 1117–AB74/Docket No. DEA–759'' on all correspondence, including any attachments.

- *Electronic comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that

submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152–2639.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at *https://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) that you voluntarily submit. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as your name, address, etc.) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this advanced notice of proposed rulemaking is available at *https://www.regulations.gov* for ease of reference.

Background and Purpose

I. Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA), (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in 21 CFR parts 1300 to end. These regulations are designed to ensure a sufficient supply of controlled substances for medical, scientific, and other legitimate purposes, and to deter the diversion of controlled substances for illicit purposes.

As mandated by the CSA, DEA establishes and maintains a closed system of control for manufacturing, distribution, and dispensing of controlled substances, and requires any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances to register with DEA, unless they meet an exemption, pursuant to 21 U.S.C. 822. The CSA authorizes the Administrator of DEA (by delegation of authority from the Attorney General) to register an applicant to manufacture, distribute or dispense controlled substances if the Administrator determines such registration is consistent with the public interest. 21 U.S.C. 823. The CSA further authorizes the Administrator to promulgate regulations necessary and appropriate to execute the functions of subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the CSA. 21 U.S.C. 871(b) and 958(f). Pursuant to these authorities, DEA is considering promulgating regulations regarding telepharmacy and seeks to be fully informed about the practice, industry, and state regulation of telepharmacy.

II. Telepharmacy

The term telepharmacy is not currently defined by the CSA or DEA regulation. Generally speaking, however, telepharmacy is considered to be the provision of pharmacist care by a remote pharmacist, through the use of telecommunications and other technologies, to a patient located at a dispensing site. Such pharmacist care may include, but is not limited to: The dispensing and distribution of prescription drugs, drug use review, patient counseling services, and drug therapy monitoring. Depending on the relevant state authority and regulations, telepharmacies may fill paper prescriptions or electronic prescriptions.

While the practice of telepharmacy varies from state to state, they generally fall within one of two categories: (i) *Brick and mortar remote sites*; and (ii) *self-service, automated machines. Brick and mortar remote sites* are traditional, storefront businesses, physically staffed by non-pharmacist employees, *e.g.,* pharmacy technicians, who are remotely supervised by a pharmacist located in a separate ''parent'' or ''hub'' pharmacy, via continuous and real-time computer, video, and audio links (*i.e.,* telecommunication connection). Depending on the state, a pharmacy technician may assist the remote pharmacist by receiving and inputting prescriptions into the pharmacy's information management system and preparing prescriptions for dispensing.

Self-service, automated machines are kiosks, resembling an Automatic Teller Machine (ATM), which contain pharmacy prescription medication/inventory, labeling equipment, and the telecommunication technology that connects the patient-user to the remote pharmacist via real-time video and audio links. Such automated machines may accept prescriptions or refill orders, store prepackaged or repackaged medications, label and dispense patient-specific prescriptions, and ultimately dispense the prescription to the patient-user.

Telepharmacy has expanded nationwide over the past two decades to address the need for pharmacy care in rural and other underserved communities, which may have a difficult time recruiting or supporting the employment of a pharmacist full-time. Despite the benefit of increased access to pharmacist care, such telepharmacies may pose a heightened risk of diversion by not having a pharmacist physically present to supervise and oversee remote sites and by not having any in-person monitoring

of automated machines. As many of these telepharmacies may dispense controlled substances, DEA is considering promulgating regulations for a special or modified telepharmacy registration.

III. Online Pharmacies Under the Ryan Haight Act

As telepharmacies utilize the *internet* to dispense controlled substances, they may constitute Online Pharmacies under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) and must therefore either: (1) Obtain a modified registration under 21 CFR 1301.19; or (2) meet one of the exceptions to an Online Pharmacy under 21 CFR 1300.04(h). The terms ''internet'' and ''online pharmacy'' are defined in the CSA. The internet is ''collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.'' 21 U.S.C. 802 (50) and 21 CFR 1300.04(g).

An online pharmacy is defined as any ''person, entity, or internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the internet.'' 21 U.S.C. 802 (52) and 21 CFR 1300.04(h). It is unlawful for any person or entity to operate as an online pharmacy, unless that person or entity is a DEA registered pharmacy under 21 CFR 1301.13 and DEA has approved and issued that person or entity a modified registration. 21 U.S.C. 823(f) and 21 CFR 1301.13(a). DEA may deny registration of an internet pharmacy if it determines the issuance of the necessary license modification would be inconsistent with the public interest. 21 CFR 1301.19(a). To date, there are no online pharmacies registered with DEA.

Paragraph (h) of 21 CFR 1300.04, provides ten exceptions to the definition of ''online pharmacy,'' eight of which come directly from the Ryan Haight Act. 21 CFR 1300.04(h)(1)–(10); 21 U.S.C. 802(52)(B). The first seven exceptions of the regulation provide exemptions for: DEA-registered manufacturers, distributors, and non-pharmacy practitioners; certain hospitals and other health care facilities associated with the United States government, and their respective agents and employees; advertisements that do not attempt to facilitate an actual transaction involving a controlled substance; and non-domestic persons, entities, or internet sites that do not facilitate the delivery, distribution, or dispensing of a controlled substance to persons in the U.S. The last three exceptions exempt pharmacies whose dispensing of controlled substances by means of the internet consists solely of: Filling or refilling prescriptions for controlled substances in schedules III–V; filling prescriptions that were electronically prescribed; and transmitting prescription information between a pharmacy and an automated dispensing system located in a long-term care facility. Telepharmacies may not use the internet to facilitate the dispensing of controlled substances unless they have been issued a modified registration under 21 CFR 1301.19 or fall within one of these exceptions.

IV. Electronic Prescriptions of Controlled Substances (EPCS) Exception

The one exception DEA finds applicable in the context of telepharmacy is the Electronic Prescriptions of Controlled Substances (EPCS) exception. The EPCS exception provides that a DEA-registered pharmacy is not an Online Pharmacy if: ''. . . [its] dispensing of controlled substances by means of the internet consists solely of *filling prescriptions that were electronically prescribed* in a manner authorized by [chapter II of title 21 of the CFR] and otherwise in compliance with the [Controlled Substances Act]'' (emphasis added). 21 CFR 1300.04(h)(9). Pharmacies are authorized to fill electronically transmitted prescriptions for controlled substances provided that the pharmacy complies with the requirements of parts 1306 and 1311 of the regulations. 21 CFR 1306.08. Under this EPCS exception, telepharmacies are permitted to fill electronic prescriptions of controlled substances in compliance with DEA's EPCS regulations; however, they are not permitted to fill paper prescriptions of controlled substances. The EPCS exception does not, however, constitute a legal safe harbor that would excuse or cure other regulatory violations; telepharmacies must still otherwise comply with DEA regulations regarding registration, prescriptions, security, recordkeeping, and reporting.

V. State Regulations

DEA is aware that several states have authorized telepharmacy practice under their general legislative authority and through a variety of state regulatory entities, including state boards of pharmacy and state licensing commissions. While DEA has obtained some information regarding state telepharmacy regulations, it does not believe that the information it has is complete. Therefore, as discussed further below, DEA is specifically seeking information from state regulatory authorities regarding states' legislative and/or regulatory requirements for telepharmacy licensing and regulations.

Comments Requested

DEA is soliciting information from the state regulatory authorities, national and professional associations, industry, telepharmacy vendors and servicers, and the general public so that DEA may obtain a better understanding of telepharmacy and how it is currently working. DEA seeks to promulgate requirements for telepharmacies in light of the growth of this telehealth service nationwide, particularly in how they dispense controlled substances. Commenters are encouraged to include the question number enumerated below in their response (*e.g.,* ''I.4'' or ''II.20''). Although all comments are welcome, DEA is particularly interested in comments regarding the questions listed below and any other pertinent information and input on telepharmacy.

I. State Regulatory Authorities

1. Please describe the organization and operation of telepharmacy practices authorized in your state. *E.g.,* does your state permit or license both remote dispensing sites and automated machines?

2. How many telepharmacies are currently authorized or licensed in your state? Do you foresee even greater growth of telepharmacies in your state?

3. Please describe the telepharmacy licensing process in your state, including the criteria by which a licensing application is or will be approved or denied.

4. Is a patient-practitioner relationship required prior to telepharmacy services for a controlled and/or non-controlled drug product?

5. How many remote dispensing sites/automated machines can one remote pharmacist supervise at one time? If multiple remote sites, what happens when the pharmacist is needed by multiple remote dispensing sites at the same time?

6. Are there limits to how many remote pharmacists or organizations can access a dispensing site or automated machine?

7. Is there a controlled substance volume limit/restriction with telepharmacies?

8. What additional policies and procedures are required of telepharmacies that are not required of other pharmacies?

9. What additional security requirements are required of telepharmacies that are not required of other retail or community pharmacies?

10. Are there any regulatory considerations or policies regarding transfer of controlled and/or non-controlled substances to remote sites (in cases where drugs are stored at the remote site)?

11. Do remote dispensing sites or automated machines need to be at the same location as (or within a certain distance from) the remote pharmacist? Do the remote dispensing sites or automated machines need to be a certain distance from another remote dispensing site or automated machine?

12. Does the remote pharmacist need to be in the same state (board jurisdiction) as the remote sites or automated machines?

13. Are there other restrictions on where a remote site or automated machine may be located? *E.g.,* are they only permitted at hospitals? Can an automated machine be placed outside a gas station or convenience store, or in proximity to a school? Does your state allow telepharmacy services in nursing homes, assisted living facilities, or for hospice programs?

14. Does your state allow interstate practice of telepharmacy, *i.e.* the practice of telepharmacy across state lines? Do out-of-state pharmacists providing telepharmacy services into your state need to register with your state board?

15. Can a remote pharmacist with an out-of-state license, who is authorized under federal law to care for patients in your state (*e.g.,* Department of Veterans Affairs pharmacists), serve as the pharmacist for a dispensing site or automated machine?

16. What recordkeeping and reporting requirements are there for telepharmacies?

17. Please describe the state's inspection process for telepharmacies.

18. Do the pharmacy technicians that staff remote sites need to be certified or licensed by the state? Can telepharmacies hire pharmacy technicians with criminal histories?

19. Does your state limit the type or manner of prescriptions that can be filled by the remote site or automated machine? Are they only allowed to fill non-controlled substances? Do they only fill electronic prescriptions as opposed to paper prescriptions? Are faxed prescriptions permitted?

20. Are there any specific regulations or considerations regarding prescribing and dispensing of opioid reversal agents by telepharmacy or automated machines?

21. Please provide examples of major issues associated with telepharmacy that have been reported to your state regulatory authorities?

22. Please provide any information that could be used to help DEA quantify or discuss qualitatively the potential costs and benefits of a rule that would either promote or restrict the use of telepharmacy.

II. Industry and Health Care Providers

23. Are the remote sites or automated machines typically owned and operated by the owner of the parent or hub pharmacy? If they do not share owners, how is recordkeeping handled?

24. How are locations selected for the remote sites or automated machines? If locations are based on the sociodemographic of a region or community, can you provide the data or information considered.

25. What additional training, if any, do you provide telepharmacy pharmacists and telepharmacy support staff?

26. With the absence of the pharmacist at the remote site and automated machine, how does the pharmacist adequately supervise and oversee telepharmacy technicians and staff?

27. If controlled substances are dispensed at your telepharmacy practice, are they stored and accounted for separately from non-controlled substances?

28. If your practice has not implemented the use of electronic prescriptions, what is preventing you from full implementation?

29. For those that have not adopted telepharmacy, what are the reasons or barriers to adopting telepharmacy?

30. How does the pharmacist make his or her final verification of the filled prescription remotely?

31. Is your remote site or automated machine registered with the DEA? If so, under what business activity?

32. If you are a remote pharmacist at a telepharmacy, how many remote sites and automated machines can you adequately supervise during the same period of time?

33. Please provide any information that could be used to help DEA quantify or discuss qualitatively the potential costs and benefits of a rule that would either promote or restrict the use of telepharmacy.

III. Telepharmacy Vendors and Servicers

34. Please describe how telepharmacy technology and systems safeguard against diversion by the public at large, as well as by employees at remote sites and automated machines.

35. From a design standpoint, how are automated machines used in telepharmacy practices similar and dissimilar from the Automatic Dispensing Systems (ADSs) used at Long Term Care Facilities?

36. Are your telepharmacy technology and systems Health Insurance Portability and Accountability Act compliant?

37. Are your telepharmacy technology and systems accessible for individuals with disabilities, *e.g.,* such as hearing impaired or blind persons?

38. Do you offer 24/7 surveillance of the telepharmacy remote site or automated machine?

39. Please provide any information that could be used to help DEA quantify or discuss qualitatively the potential costs and benefits of a rule that would either promote or restrict the use of telepharmacy.

Statutory and Executive Order Review

This advanced notice of proposed rulemaking (ANPRM) has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review.'' The Office of Management and Budget has determined that this ANPRM is a significant regulatory action under Executive Order 12866, section 3(f), and accordingly this ANPRM has been reviewed by the Office of Management and Budget. However, this action does not propose or impose any requirements.

Furthermore, the requirements of the Regulatory Flexibility Act (RFA) do not apply to this action because, at this stage, it is an ANPRM and not a ''rule'' as defined in 5 U.S.C. 601. Following review of the comments received in response to this ANPRM, if DEA proceeds with a notice or notices of proposed rulemaking regarding this matter, DEA will conduct all relevant analyses as required by statute or Executive order.

Anne Milgram,

Administrator.

[FR Doc. 2021–24948 Filed 11–16–21; 8:45 am]

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