paragraph (e) in accordance with the following, unless the Executive Director determines that the project cannot be adequately regulated under this approval by rule.

* * * * *

Dated: September 9, 2019.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2019–19814 Filed 9–12–19; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–497]

Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing the control of *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (also known as benzylfentanyl), including its salts, and *N*-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP) (hereinafter referred to as 4-anilinopiperidine), including its amides, its carbamates, and its salts, as list I chemicals under the Controlled Substances Act (CSA).

Benzylfentanyl and 4-anilinopiperidine are used in, and are important to, the illicit manufacture of the schedule II controlled substance fentanyl. If finalized, this action would subject handlers of benzylfentanyl and 4-anilinopiperidine to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of benzylfentanyl or 4-anilinopiperidine. As such, all transactions of chemical mixtures containing benzylfentanyl or 4-anilinopiperidine will be regulated at any concentration and will be subject to control under the CSA.

DATES: Comments must be submitted electronically or postmarked on or before November 12, 2019. Commenters should be aware that the electronic Federal Docket Management System will not accept any 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 ''Docket No. DEA–497'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The 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 attach a file for lengthier comments. Please go to *http://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 electronic submissions 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, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

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 the DEA for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) 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 *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this proposed rule is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The CSA gives the Attorney General the authority to specify, by regulation, chemicals as list I or list II chemicals. 21 U.S.C. 802(34) and (35). A ''list I chemical'' is a chemical that is used in manufacturing a controlled substance in violation of title II of the CSA and is important to the manufacture of the controlled substance. 21 U.S.C. 802(34). A ''list II chemical'' is a chemical (other than a list I chemical) that is used in manufacturing a controlled substance in violation of title II of the CSA. 21 U.S.C. 802(35). The current list of all listed chemicals is published at 21 CFR 1310.02. Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to designate list I and list II chemicals to the Administrator of the Drug Enforcement Administration.

Background

The DEA is extremely concerned with the increase in the illicit manufacture and distribution of fentanyl. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950's. Fentanyl is controlled in schedule II of the CSA due to its high potential for abuse and dependence, and accepted medical use in treatment in the United States. Fentanyl was introduced

into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. Due to its pharmacological effects, fentanyl can serve as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals.

The unlawful trafficking of fentanyl in the United States continues to pose an imminent hazard to the public safety. Since 2012, fentanyl has shown a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (*i.e.,* heroin, cocaine, and methamphetamine), or in forms that mimic pharmaceutical preparations including prescription opiates and benzodiazepines.

The DEA has noted a significant increase in overdoses and overdose fatalities from fentanyl in the United States in recent years. A recent report [1] from the Centers for Disease Control and Prevention (CDC) highlights this trend. According to this report, of the 41,430 drug overdose deaths occurring in the United States in 2011, 1,662 (4.0%) involved fentanyl.[2] Of the 63,632 drug overdose deaths in 2016, 18,335 (28.8%) involved fentanyl. This was the first time that fentanyl was reported in more drug related fatalities than heroin.

The increase of drug overdose deaths continued into 2017. According to the CDC,[3] there were 70,237 drug overdose deaths in the United States in 2017, an increase from the 63,632 overdose deaths recorded in 2016. Of the 70,237 overdose deaths in 2017, 47,600 (67.8%) involved an opioid. Deaths involving prescription opioids and heroin remained stable from 2016 to 2017; synthetic opioid overdose deaths (other than methadone), which include deaths related to fentanyl, increased 45.2% from 19,413 deaths in 2016 to 28,466 deaths in 2017.

The increase in overdose fatalities involving fentanyl coincides with a dramatic increase of law enforcement encounters of fentanyl. According to the National Forensic Laboratory Information System (NFLIS),[4] submissions to forensic laboratories that contained fentanyl increased exponentially beginning in 2012: 694 in 2012, 1,044 in 2013, 5,537 in 2014, 15,455 in 2015, 37,294 in 2016, 61,382 in 2017, and 70,453 in 2018.

Role of These Precursor Chemicals in the Synthesis of Fentanyl

Fentanyl is not a naturally occurring substance. As such, the manufacture of fentanyl requires it to be produced through synthetic organic chemistry. Synthetic organic chemistry is the process in which a new organic molecule is created through a series of chemical reactions, which involve precursor chemicals. In the early 2000's, a synthetic process, commonly known as the Siegfried method, was utilized to manufacture fentanyl in several domestic and foreign clandestine laboratories. 72 FR 20039. At that time, DEA had determined that two primary synthesis routes (*i.e.,* the Janssen method and the Siegfried method) were being used to produce fentanyl clandestinely, although it believed the Janssen synthesis route to be difficult to perform and beyond the rudimentary skills of most clandestine laboratory operators. The Siegfried synthetic route involves two important intermediates, *N*-phenethyl-4-piperidone (NPP) and 4-anilino-*N*-phenethylpiperidine (ANPP). The DEA controlled NPP on April 23, 2007 as a list I chemical through an interim rule (72 FR 20039), which was finalized on July 25, 2008. 73 FR 43355. ANPP was controlled as a schedule II immediate precursor to fentanyl on August 30, 2010. 75 FR 37295.

In 2017, the United Nations Commission on Narcotic Drugs placed NPP and ANPP in Table I of the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (1988 Convention) in response to the international reintroduction of fentanyl on the illicit drug market. As such, member states of the United Nations were required to regulate these precursor chemicals at the national level. In addition, the People's Republic of China regulated NPP and ANPP on February 1, 2018.

Recent law enforcement information indicates that illicit manufacturers of fentanyl may utilize synthetic routes other than the Siegfried method in response to regulations placed on NPP and ANPP. The Janssen method, previously thought to be beyond the skills of most clandestine laboratory operators, is now used with the precursor chemical benzylfentanyl, and other synthetic routes use the precursor chemical 4-anilinopiperidine. The DEA is not aware of any legitimate uses of benzylfentanyl or 4-anilinopiperidine other than in the synthesis of fentanyl.

Benzylfentanyl

The original published synthetic pathway to fentanyl, known as the Janssen method, does not involve NPP or ANPP as a chemical precursor. This synthetic pathway involves the important precursors, benzylfentanyl and norfentanyl. Benzylfentanyl is converted to *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl), the immediate precursor in this synthetic pathway, in one chemical reaction. Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. Norfentanyl is the subject of a Notice of Proposed Rulemaking for control as a schedule II immediate precursor of fentanyl, published elsewhere in this issue of the **Federal Register**.

According to DEA forensic laboratory data, the Janssen method was confirmed as the synthetic route used in 94% of 85 fentanyl drug exhibits that were evaluated to determine the synthetic route. These exhibits were seized in 2018. In addition, the number of law enforcement encounters of benzylfentanyl has increased in 2017 and 2018, which coincides with the international control that placed of NPP and ANPP in Table I of the 1988 Convention in 2017.

According to NFLIS, there was one identification of benzylfentanyl in 2016; however, benzylfentanyl was identified in 195 reports in 2017 and 237 reports in 2018. Since the DEA is not aware of any legitimate uses of benzylfentanyl other than potentially in the synthesis of fentanyl, it is believed that these law enforcement encounters indicate a change in the synthetic route to the Janssen method by some clandestine manufacturers in efforts to evade chemical regulations on NPP and ANPP.

The DEA has determined that benzylfentanyl is commercially available from both domestic and foreign chemical suppliers. The DEA is aware of at least five domestic suppliers and three foreign suppliers in China, two suppliers in Canada, and one supplier in the United Kingdom. Benzylfentanyl is attractive to illicit manufacturers due to the lack of chemical regulations on this substance, it is readily available from chemical suppliers, and it can be converted to the immediate precursor, norfentanyl, in a one-step chemical reaction.

[1] Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011–2016. National Vital Statistics Reports; vol 67 no 9. Hyattsville, MD: National Center for Health Statistics, 2018.

[2] The reported data includes fentanyl, fentanyl metabolites, precursors, and analogs.

[3] Scholl L., Seth P., Kariisa M., Wilson N., Baldwin G. Drug and Opioid-Involved Overdose Deaths— United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427.

[4] The National Forensic Laboratory Information System (NFLIS) is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State and local forensic laboratories in the United States. NFLIS data was queried on March 26, 2019.

4-Anilinopiperidine

In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl. 4-Anilinopiperidine can serve as an alternative precursor chemical to NPP in the synthesis of ANPP, albeit through a different synthetic process. 4-Anilinopiperidine has been marketed as a replacement to ANPP as a precursor chemical used in the illicit manufacture of fentanyl by foreign chemical suppliers. This is believed to be in response to international controls placed on NPP and ANPP. Although marketed as a replacement for ANPP, DEA understands that 4-anilinopiperidine is not a direct replacement for ANPP in the synthesis of fentanyl. The DEA is not aware of any legitimate uses of 4-anilinopiperidine other than potentially in the synthesis of fentanyl. In contrast to NPP, where two chemical reaction steps are required to synthesize ANPP, 4-anilinopiperidine can be converted to ANPP in a one-step chemical reaction. The resulting ANPP can then be used as the immediate precursor chemical in the illicit manufacture of the schedule II controlled substance, fentanyl. ANPP is controlled in schedule II of the CSA as of August 30, 2010 for this reason. 75 FR 37295 (June 29, 2010).

4-Anilinopiperidine has been imported and identified in law enforcement seizures in the United States. In addition to domestic encounters, the DEA is aware of international encounters of 4-anilinopiperidine beginning as early as July 2018. The International Narcotics Control Board of the United Nations reported 32 international transactions of 4-anilinopiperidine through the International Operations on Novel Psychoactive Substances Communication System IONICS [5] reporting system. These identifications, totaling approximately 30 kg, were reported by Mexico as the destination country. In addition, 4-anilinopiperidine was identified at a clandestine laboratory located in Mexico, which was involved in the illicit manufacture of fentanyl.

These recent law enforcement encounters of 4-anilinopiperidine coincide with the placement of NPP and ANPP in Table I of the 1988 Convention, and the February 1, 2018 regulation of NPP and ANPP in the People's Republic of China. The international encounters of 4-anilinopiperidine at ports of entry in Mexico indicate a change in illicit fentanyl manufacturing methods in efforts to evade international controls on NPP and ANPP.

The DEA determined that 4-anilinopiperidine is commercially available from both domestic and foreign chemical suppliers. The DEA has identified 38 domestic suppliers and 28 foreign suppliers of 4-anilinopiperidine from Canada (3), China (11), Germany (3), Hong Kong (1), India (1), Latvia (1), Lithuania (1), Switzerland (2), and the United Kingdom (5). 4-Anilinopiperidine is attractive to illicit manufacturers due to the lack of chemical controls on this substance, it is readily available from chemical suppliers, and it can easily be converted to the schedule II immediate precursor, ANPP, which can subsequently be converted to fentanyl.

Regulation of Benzylfentanyl, Including Its Salts and 4-Anilinopiperidine, Including Its Amides, Its Carbamates, and Its Salts, as List I Chemicals

The CSA, specifically 21 U.S.C. 802(34), 21 U.S.C. 802(35), and its implementing regulations at 21 CFR 1310.02(c), provide the Attorney General with the authority to specify, by regulation, additional precursor or essential chemicals as ''listed chemicals'' if they are used in the manufacture of controlled substances in violation of the CSA. Recent law enforcement encounters indicate benzylfentanyl and 4-anilinopiperidine are being used in the illicit manufacture of the schedule II controlled substance fentanyl. This proposed rule would regulate benzylfentanyl and 4-anilinopiperidine as list I chemicals because the DEA finds that benzylfentanyl and 4-anilinopiperidine are used in the manufacture of the controlled substance fentanyl, and are important to the manufacture of the controlled substance fentanyl because they cannot be replaced by other chemicals in their respective synthetic pathways in the manufacture of fentanyl.

Chemical Mixtures of Benzylfentanyl and 4-Anilinopiperidine

This proposed rulemaking, if finalized, would specify that chemical mixtures containing benzylfentanyl or 4-anilinopiperidine would not be exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by a benzylfentanyl or 4-anilinopiperidine manufacturer and the application is reviewed and accepted by the DEA under 21 CFR 1310.13 (Exemption by Application Process). The control of chemical mixtures containing any amount of benzylfentanyl or 4-anilinopiperidine is necessary to prevent the illicit extraction, isolation, and use of benzylfentanyl or 4-anilinopiperidine to manufacture fentanyl. This proposed rule would modify the Table of Concentration Limits in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of benzylfentanyl or 4-anilinopiperidine are subject to the CSA chemical control provisions.

Exemption by Application Process

The DEA has implemented an application process to exempt mixtures from the requirements of the CSA and its implementing regulations. 21 CFR 1310.13. Under the application process, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status can be granted if the DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical cannot be readily recovered (*i.e.,* it meets the conditions in 21 U.S.C. 802(39)(A)(vi)).

Requirements for Handling List I Chemicals

If this rule is finalized as proposed, benzylfentanyl and 4-anilinopiperidine will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. Upon publication of a final rule, persons potentially handling benzylfentanyl or 4-anilinopiperidine, including regulated chemical mixtures containing benzylfentanyl or 4-anilinopiperidine, will be required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who manufactures, distributes, imports, or exports benzylfentanyl or 4-anilinopiperidine, or proposes to engage in the manufacture, distribution, importation, or exportation of benzylfentanyl or 4-anilinopiperidine, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309.

The DEA recognizes that it is not possible for persons who are subject to

[5] IONICS is a free communication platform dedicated to real-time communication of incidents involving suspicious shipments, trafficking, manufacture or production of Novel Psychoactive Substances (NPS). IONICS reports were collected up to April 1, 2019.

the registration requirements to immediately complete and submit an application for registration, and for the DEA to immediately issue registrations for those activities. Therefore, to allow any continued legitimate commerce in benzylfentanyl and 4-anilinopiperidine, the DEA is proposing to establish in 21 CFR 1310.09, a temporary exemption from the registration requirement for persons desiring to engage in activities with benzylfentanyl or 4-anilinopiperidine, provided that the DEA receives a properly completed application for registration or application for exemption of a chemical mixture under 21 CFR 1310.13 on or before 30 days after publication of a final rule implementing regulations regarding benzylfentanyl and 4-anilinopiperidine. The temporary exemption for such persons will remain in effect until the DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would become effective on the effective date of the final rule. This is necessary because a delay in regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption for registration does not suspend applicable Federal criminal laws relating to benzylfentanyl or 4-anilinopiperidine, nor does it supersede State or local laws or regulations. All handlers of benzylfentanyl or 4-anilinopiperidine must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to benzylfentanyl and 4-anilinopiperidine pursuant to 21 U.S.C. 830 and in accordance with 21 CFR part 1310. Pursuant to 21 CFR 1310.04, a record must be kept for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical will be required to submit manufacturing, inventory, and use data on an annual basis. 21 CFR 1310.05(d). Existing standard industry reports containing the required information are acceptable, provided the information is separate or readily retrievable from the report.

3. *Importation and Exportation.* All importation and exportation of benzylfentanyl or 4-anilinopiperidine would need to be done in compliance with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants would be required to provide effective controls against theft and diversion of list I chemicals in accordance with 21 CFR 1309.71–1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A. 21 U.S.C. 880.

6. *Liability.* Any activity involving benzylfentanyl or 4-anilinopiperidine not authorized by, or in violation of, the CSA, would be unlawful, and would subject the person to administrative, civil, and/or criminal action.

Solicitation for Information

As part of this proposed rulemaking, the DEA is soliciting information on any possible legitimate uses of benzylfentanyl and 4-anilinopiperidine unrelated to fentanyl production (including industrial uses) in order to assess the potential commercial impact of controlling benzylfentanyl and 4-anilinopiperidine. The DEA has searched information in the public domain for legitimate uses of these two chemicals, and has not documented a legitimate commercial use for benzylfentanyl or 4-anilinopiperidine other than as intermediary chemicals in the production of fentanyl. The DEA seeks, however, to document any unpublicized use(s) and other proprietary use(s) of benzylfentanyl and 4-anilinopiperidine that are not in the public domain. Therefore, the DEA is soliciting comment on the uses of benzylfentanyl and 4-anilinopiperidine in the legitimate marketplace.

The DEA is soliciting input from all potentially affected parties regarding: (1) The types of legitimate industries using benzylfentanyl and 4-anilinopiperidine; (2) the legitimate uses of benzylfentanyl and 4-anilinopiperidine, if any; (3) the size of the domestic market for benzylfentanyl and 4-anilinopiperidine; (4) the number of manufacturers of benzylfentanyl and 4-anilinopiperidine; (5) the number of distributors of benzylfentanyl and 4-anilinopiperidine; (6) the level of import and export of benzylfentanyl and 4-anilinopiperidine; (7) the potential burden these proposed regulatory controls of benzylfentanyl and 4-anilinopiperidine may have on any legitimate commercial activities; (8) the potential number of individuals/firms that may be adversely affected by these proposed regulatory controls (particularly with respect to the impact on small businesses); and (9) any other information on the manner of manufacturing, distribution, consumption, storage, disposal, and uses of benzylfentanyl and 4-anilinopiperidine by industry and others. The DEA invites all interested parties to provide any information on any legitimate uses of benzylfentanyl and 4-anilinopiperidine in industry, commerce, academia, research and development, or other applications. The DEA seeks both quantitative and qualitative data.

Handling of Confidential or Proprietary Information

Confidential or proprietary information may be submitted as part of a comment regarding this Notice of Proposed Rulemaking. Please see the ''POSTING OF PUBLIC COMMENTS'' section above for a discussion of the identification and redaction of confidential business information and personally identifying information.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This proposed rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition,

jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. The DEA has determined that this proposed rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f).

Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation.[6] In furtherance of this requirement, Executive Order 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.[7] According to guidance provided by OMB, the requirements of Executive Order 13771 only apply to each new ''significant regulatory action that . . . imposes costs.'' [8] This proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866.

If finalized as proposed, benzylfentanyl and 4-anilinopiperidine will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. Benzylfentanyl and 4-anilinopiperidine are used in, and are important to, the illicit manufacture of the schedule II controlled substance fentanyl. The distribution of illicitly manufactured fentanyl has caused an unprecedented outbreak of thousands of fentanyl-related overdoses in the United States in recent years.

The DEA has searched information in the public domain for any legitimate uses of these two chemicals, and has not documented a use for benzylfentanyl or 4-anilinopiperidine other than as intermediary chemicals in the production of fentanyl. Based on the review of import and quota information for NPP, ANPP, and fentanyl, The DEA believes the vast majority of, if not all, legitimate pharmaceutical fentanyl is produced via a synthetic route involving NPP and ANPP as intermediaries, not benzylfentanyl (and norfentanyl) or 4-anilinopiperidine. The quantities of NPP and ANPP indicated in import and quota documents generally correspond with the quantities of legitimate pharmaceutical fentanyl produced in the U.S. Therefore, the DEA concludes the vast majority of, if not all, benzylfentanyl or 4-anilinopiperidine is used for the manufacturing of illicit fentanyl.

The DEA cannot rule out the possibility that minimal quantities of benzylfentanyl or 4-anilinopiperidine are used for the manufacturing of legitimate pharmaceutical fentanyl. However, if there are any quantities of benzylfentanyl or 4-anilinopiperidine used for the manufacturing of legitimate pharmaceutical fentanyl, the quantities are believed to be small and economically insignificant. The DEA welcomes any public comment on these quantities and their economic significance.

The DEA evaluated the costs and benefits of this proposed action.

Costs

The DEA believes the market for benzylfentanyl or 4-anilinopiperidine for the legitimate manufacturing of pharmaceutical fentanyl is minimal. As stated above, the only use for benzylfentanyl and 4-anilinopiperidine of which the DEA is aware is as intermediaries for the manufacturing of fentanyl. Any manufacturer, distributor, importer, or exporter of benzylfentanyl or 4-anilinopiperidine for the production of legitimate pharmaceutical fentanyl, if they exist at all, would incur costs if this proposed rule were finalized. The primary costs associated with this proposed rule would be the annual registration fees for scheduled drugs or list I chemicals ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters). However, any manufacturer that uses benzylfentanyl or 4-anilinopiperidine for legitimate pharmaceutical fentanyl production would already be registered with the DEA and have all security and other handling processes in place because of the controls already in place on fentanyl, resulting in minimal cost to those entities. While different forms of handling the scheduled substance versus the list I chemical (distribution of fentanyl vs exporting benzylfentanyl), could require a separate registration for the different handling of the substances, if an entity is already registered to handle, manufacture, import, or export a scheduled substance, the entity would not need an additional registration for the list I chemical, provided it is handling the list I chemical in the same manner that it is registered for with the scheduled substance, or as a coincident activity permitted by § 1309.21. Even with the possibility of these additional registrations, the DEA believes that the cost will be minimal.

The DEA has identified 38 domestic suppliers of benzylfentanyl, 4-anilinopiperidine, or both. Only one is registered to handle list I chemicals, the remaining 37 are not registered with the DEA to handle list I chemicals. It is difficult to estimate how much benzylfentanyl and 4-anilinopiperidine is distributed by these suppliers. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the review of import and quota information for NPP, ANPP, and fentanyl, where the quantities of NPP and ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, the DEA believes any quantity of sales from these distributors for legitimate pharmaceutical fentanyl manufacturing is minimal. If this proposed rule is finalized, suppliers for the legitimate use of benzylfentanyl or 4-anilinopiperidine are expected to choose the least-cost option, and stop selling the minimal quantities, if any, of benzylfentanyl or 4-anilinopiperidine, rather than incur the registration cost. Because the DEA believes the quantities of benzylfentanyl or 4-anilinopiperidine supplied for the legitimate manufacturing of pharmaceutical fentanyl are minimal, the DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this proposed rule is minimal. The DEA welcomes any public comment regarding this estimate.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacturing and distribution of benzylfentanyl or 4-anilinopiperidine for the production of manufacturing illicit fentanyl. As a law enforcement organization and as a matter of principle, the DEA believes considering the economic utility of facilitating the manufacture of illicit fentanyl would be improper.

Benefits

Controlling benzylfentanyl and 4-anilinopiperidine is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substance, fentanyl. As list I chemicals, handling of benzylfentanyl

[6] Sec. 2(a).

[7] Sec. 2(c).

[8] OMB Guidance Implementing Executive Order 13771 titled ''Reducing Regulation and Controlling Regulatory Costs'' (April 5, 2017).

and 4-anilinopiperidine would require registration with the DEA and various controls and monitoring as required by the CSA. This proposed rule is also expected to assist preventing the possible theft or diversion of benzylfentanyl and 4-anilinopiperidine from any legitimate firms. The DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing benzylfentanyl and 4-anilinopiperidine and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire unregulated intermediary chemicals for the purpose of manufacturing illicit fentanyl.

In summary, the DEA conducted a qualitative analysis of costs and benefits. The DEA believes this proposed action, if finalized, will minimize the diversion of benzylfentanyl and 4-anilinopiperidine. The DEA believes the market for benzylfentanyl and 4-anilinopiperidine for the legitimate manufacturing of pharmaceutical fentanyl is minimal. Therefore, any potential cost as a result of this regulation is minimal.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. This proposed rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. As discussed above, if finalized as proposed, benzylfentanyl and 4-anilinopiperidine will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. Benzylfentanyl and 4-anilinopiperidine are used in, and are important to, the illicit manufacture of the schedule II controlled substance fentanyl. The distribution of illicitly manufactured fentanyl has caused an unprecedented outbreak of thousands of fentanyl-related overdoses in the United States in recent years. The DEA has not identified any legitimate industrial use for benzylfentanyl and 4-anilinopiperidine, other than their role as intermediary chemicals in the production of fentanyl. However, the DEA believes the vast majority, if not all, of legitimate pharmaceutical fentanyl is produced via a synthetic route involving NPP and ANPP as intermediaries, not benzylfentanyl (and norfentanyl) or 4-anilinopiperidine. The review of import and quota information for fentanyl, ANPP, and NPP supports this belief. Therefore, the DEA believes the vast majority, if not all, of benzylfentanyl or 4-anilinopiperidine is used for the illicit manufacturing of fentanyl. The primary costs associated with this proposed rule are the annual registration fees ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters). Additionally, any manufacturer that uses benzylfentanyl or 4-anilinopiperidine for legitimate pharmaceutical fentanyl production would already be registered with the DEA and have all security and other handling processes in place, resulting in minimal cost.The DEA has identified 38 domestic suppliers of benzylfentanyl, 4-anilinopiperidine, or both, 37 of which are not registered with the DEA to handle list I chemicals. All 37 non-registered domestic suppliers are affected, of which 35 (94.5%, based on Small Business Administration size standard for chemical distributors and Statistics of U.S. Business data) are estimated to be small entities. It is impossible to know how much benzylfentanyl or 4-anilinopiperidine is distributed by these suppliers. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the review of import and quota information for NPP, ANPP, and fentanyl, where the quantities of NPP and ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, the DEA believes any quantity of sales from these distributors for legitimate pharmaceutical fentanyl manufacturing is minimal. Therefore, the DEA estimates the cost of this rule on any affected small entity is minimal. The DEA welcomes any public comment regarding this estimate. Based on these factors, the DEA projects that this rule, if promulgated, will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This proposed action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1310

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1310 as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

■ 1. The authority citation for 21 CFR part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 2. In § 1310.02 add paragraphs (a)(32) and (33) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

(32) *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts	8334
(33) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, and its salts	8335

* * * * *

■ 3. In § 1310.04:

■ a. Redesignate paragraphs (g)(1)(viii) through (xi) as paragraphs (g)(1)(x) through (xiii), respectively;

■ b. Redesignate paragraph (g)(1)(vii) as paragraph (g)(1)(viii); and

■ c. Add new paragraphs (g)(1)(vii) and (ix).

The additions read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(vii) *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts

* * * * *

(ix) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, and its salts

* * * * *

■ 4. In § 1310.09 add paragraphs (o) and (p) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(o)(1) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts, including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that the DEA receives a proper application for registration or application for exemption for a chemical mixture containing benzylfentanyl pursuant to § 1310.13 on or before 30 days after the publication of a rule finalizing this action. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts whose application for exemption is subsequently denied by the DEA must obtain a registration with the DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption is denied, provided that the DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until the DEA takes final action on their registration application.

(p)(1) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine, 4–AP) and its amides, its carbamates, and its salts, including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that the DEA receives a proper application for registration or application for exemption for a chemical mixture containing 4-anilinopiperidine pursuant to § 1310.13 on or before 30 days after the publication of a rule finalizing this action. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP) and its amides, its carbamates, and its salts whose application for exemption is subsequently denied by the DEA must obtain a registration with the DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption is denied, provided that the DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until the DEA takes final action on their registration application.

■ 5. In § 1310.12, the Table of Concentration Limits in paragraph (c) is amended by adding entries for *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP) in alphabetical order to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code No.	Concentration	Special conditions
* * *	*	*	* *
N-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), including its salts.	8334	Not exempt at any concentration.	Chemical mixtures containing any amount of benzylfentanyl are not exempt.
N-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), including its amides, its carbamates, and its salts.	8335	Not exempt at any concentration.	Chemical mixtures containing any amount of 4-anilinopiperidine are not exempt.
* * *	*	*	* *

* * * * *

Dated: September 6, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–19787 Filed 9–12–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 232

[Docket No. FR 6022–P–01]

RIN 2502–AJ46

Federal Housing Administration (FHA): Section 232 Healthcare Facility Insurance Program—Memory Care Residents

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Proposed rule.

SUMMARY: HUD's Section 232 program insures mortgage loans to facilitate the construction, substantial rehabilitation, purchase, and refinancing of nursing homes, intermediate care facilities, board and care homes, and assisted-living facilities. Through this rule, HUD proposes changes to update the requirements for the location of bathrooms in board and care and assisted living facilities to allow providers to configure the facilities to meet the needs of memory care residents and allow for flexibility of the bathroom requirement when financing or refinancing existing facilities.

DATES: *Comment due date:* November 12, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule. All submissions must refer to the above docket number and title. There are two methods for submitting public comments.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile (FAX) Comments. FAX comments are not acceptable.

Public Inspection of Public Comments. HUD will make available all properly submitted comments and communications for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, you must schedule an appointment in advance to review the public comments by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: John M. Hartung, Director, Policy, Risk Analysis & Lender Relations Division, Office of Residential Care Facilities, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 1222 Spruce Street, St. Louis, MO 63103–2836; telephone number 314–418–5238 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 232, 223(a)(7), and 223(f) of the National Housing Act (12 U.S.C. 1715w, 12 U.S.C. 1715n(a)(7), and 12 U.S.C. 1715n(f)(4), respectively), FHA insures mortgages to finance the purchase or refinance of nursing homes, intermediate care facilities, board and care homes, and assisted living facilities (collectively, residential healthcare facilities). To meet the needs of residents living in the Section 232 program facilities and those seeking to insure projects under the Section 232 program, HUD proposes to revise the current regulation at § 232.7 regarding bathroom requirements to meet the needs of memory care residents. Memory care residents are those patients in assisted living or board and care settings that have cognitive impairments, such as Alzheimer's disease and other dementias who require care in a secure setting. HUD proposes the revision to add flexibility for financing existing residential healthcare facilities.

A. Memory Care Residents

Residents of assisted living facilities need assistance with their ''activities of daily living'' (ADL). Activities of daily living include, but are not limited to, such things as bathing, dressing, eating, getting in or out of bed, using the toilet, preparing meals, taking medications,