intended use. Servicing *cannot* change the intended use(s) of the device from its original purpose(s).

3. *Repair:* Return the device or component to original specifications including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

4. *Refurbish:* Restore device to a condition of safety and effectiveness that is comparable to when new. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

5. *Remanufacture:* Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance, safety specifications, or intended use.

6. *Remarket:* The act of facilitating the transfer of a previously owned device from one party to another by sale, donation, gift, or lease.

B. Evaluation of Risk Associated With These Third-Party and OEM Activities

In addition to obtaining comments that define the key terms applicable to this issue, FDA believes that a need exists for interested persons to comment on the benefits and risks related to the previously defined activities. We invite interested persons to comment on the following questions:

1. Who are the different stakeholders involved with the medical device activities listed previously? What are their respective roles?

2. What evidence exists regarding actual problems with the safety and/or performance of devices that result from these activities? Specific examples should be submitted.

3. What are the potential risks (patients/users) and failure modes (devices) introduced as a result of performing the previously defined activities on medical devices? Please speak to issues common to all devices as well as specific risks with specific devices.

4. These activities are performed by OEMs and various third-party entities, including hospitals and humanitarian organizations. Are the risks different depending on who performs the previously mentioned activities?

5. We are interested in knowing if these activities are more difficult or riskier to perform on certain devices versus others. Please cite specific examples in your response, along with an explanation of the source of this particular complexity.

6. What information do third-party entities need in order to perform these activities in a way that results in safe and effective operation of the medical device? Please provide specific examples.

7. What additional challenges do stakeholders encounter with devices that result from these activities?

III. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 1020 and 1040 have been approved under OMB control number 0910–0025.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Guidance for Industry and Food and Drug Administration Staff on Assembler's Guide to Diagnostic X-Ray Equipment. Available at *http://www.fda.gov/downloads/MedicalDevices/.../UCM257783.pdf.*
2. Guidance for Industry and FDA Staff on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems. Available at *http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf.*
3. *FDA Executive Summary: Effective Reprocessing of Endoscopes Used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures,* FDA. Available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM445592.pdf.*

Dated: February 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04700 Filed 3–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–436]

Schedules of Controlled Substances: Placement of 10 Synthetic Cathinones Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 10 synthetic cathinones: 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); alpha-pyrrolidinobutiophenone (α-PBP) and their optical, positional, and geometric isomers, salts and salts of isomers into schedule I of the Controlled Substances Act. This proposed scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Comments must be submitted electronically or postmarked on or before April 4, 2016. 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.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request

for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before April 4, 2016.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–436'' on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration 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 *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 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/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, 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 Drug Enforcement Administration (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 confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying 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 document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44 (a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).'' 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44 (a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing held in relation to this rulemaking are restricted to: ''(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed . . .'' All requests for hearing and waivers of participation must be sent to the DEA using the address information provided above.

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules

based upon their potential for abuse, their currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed . . .'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-;FMC, 3-FMC, naphyrone, or α-PBP.

Background

On March 7, 2014, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); and alpha-pyrrolidinobutiophenone (α-PBP) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 12938. That final order, which became effective on the date of publication, was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these 10 synthetic cathinones was necessary to avoid an imminent hazard to public safety pursuant to 21 U.S.C. 811(h)(1). At the time the final order took effect, section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)), required that the temporary scheduling of a substance expire at the end of two years from the date of issuance of the scheduling order, and it provided that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance could be extended for up to 1 year. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP expires on March 6, 2016, unless extended. An extension of the temporary order is being ordered by the DEA Administrator in a separate action.

As described in the final order published on March 7, 2014, 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine (MDMA), cathinone, and other related substances. While 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have been used as research chemicals and/or studied due to their misuse and abuse, based on the review of the scientific literature, there are no known currently accepted medical uses for these substances. The Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) has advised that there are no exemptions or approvals in effect for 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP under section 505 (21 U.S.C. 355) of the Federal Food, Drug and Cosmetic Act. As stated by the HHS, 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have no known accepted medical use. They are not the subject of any approved new drug applications (NDAs) or investigational new drug applications (INDs), and are not currently marketed as approved drug products. The HHS recommends that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP and their salts be placed into schedule I of the Controlled Substances Act (CSA).

Proposed Determination To Schedule 4-MEC, 4-MePPP, α-PVP, Butylone, Pentedrone, Pentylone, 4-FMC, 3-FMC, Naphyrone, and α-PBP

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by the Attorney General, or her delegate, the DEA Administrator. On December 30, 2014, the DEA requested scientific and medical evaluations and scheduling recommendations from the Assistant Secretary of Health for the HHS for 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP pursuant to 21 U.S.C. 811(b). Upon receipt of the scientific and medical evaluation and scheduling recommendations from the HHS on March 2, 2016, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each of the eight factors as analyzed by the HHS and the DEA, and as considered by the DEA in its proposed scheduling action. Please note that both the DEA 8-Factor and the HHS 8-Factor analyses are available in their entirety under the tab ''Supporting Documents'' of the public docket for this action at *http://www.regulations.gov* under Docket Number ''DEA–436.''

1. *The Drug's Actual or Relative Potential for Abuse:* The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests that the DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse: [2]

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); *reprinted in* 1970 U.S.C.C.A.N. 4566, 4603.

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

As described by the HHS, the abuse potentials of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are associated with their abilities to produce psychoactive effects that are similar to those produced by mephedrone, methylone, MDPV, and other schedule I and II substances such as amphetamine, methamphetamine, cocaine, methcathinone, and MDMA that have a high potential for abuse.

The substances 4–MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have no approved medical uses in the United States and they have been encountered on the illicit market with adverse outcomes on the public health and safety. Because these substances are not approved drug products, a practitioner may not legally prescribe them, and they cannot be dispensed to an individual. Therefore, the use of these substances is without medical advice, leading to the conclusion that the 10 synthetic cathinones are being abused for their psychoactive properties. There are no legitimate drug channels for these synthetic cathinones as marketed drugs but the DEA notes that the 10 synthetic cathinones have use in scientific research. However, despite the limited legitimate use of these substances, reports from public health and law enforcement communicate that these substances are being abused and taken in amounts sufficient to create a hazard to an individual's health. This misuse is evidenced by emergency department admissions and deaths, representing a significant safety issue for those in the community. Papers published in the medical literature (*e.g.,* case reports) related to 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP describe the effects of these substances to be similar to those of the schedule I cathinone substances MDPV, mephedrone, and methylone and other stimulant and hallucinogenic substances to include methamphetamine, cocaine and MDMA. In particular, the responses in humans to the 10 synthetic cathinones are stimulant-like and include paranoia, agitation, palpitations, tachycardia, hypertension, hyperthermia, and seizures. Data from forensic databases are used as indicators of illicit activity with drugs and abuse [3] within the United States and include data from the System to Retrieve Information from Drug Evidence (STRIDE),[4] STARLiMS, and the National Forensic Laboratory Information System (NFLIS).[5] From January 2010 through December 2015 (query dates: February 10 & 11, 2016), STRIDE, STARLiMS and NFLIS databases registered a total of 20,090 reports pertaining to the 10 synthetic cathinones (4–MEC—2,820 reports; 4-MePPP—438 reports; α-PVP—13,295 reports; butylone—789 reports; pentedrone—1,645 reports; pentylone—411 reports; FMC—375 reports; naphyrone—84 reports; α-PBP—233 reports). These drug reports represent all of the 10 synthetic cathinones reported to these databases by participating DEA, State, local, and other forensic laboratories. Consequently, the data indicate that these substances are being abused, and they present safety hazards to the health of individuals who consume them due to their stimulant properties, making them a hazard to the safety of the community.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* Studies show that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP produce pharmacological effects that are similar to those produced by schedule I and II substances such as methamphetamine, cocaine, MDMA, mephedrone, MDPV, and methylone. Similar to schedule I and II stimulants, the 10 synthetic cathinone substances affect monoamine transmission. The 10 synthetic cathinones, similar to methamphetamine, cocaine, MDMA, mephedrone, MDPV, methylone, and other related schedule I and II substances, bind to transporters for the dopamine, serotonin, and/or norephinephrine neurotransmitters and are uptake inhibitors of these neurotransmitters. Additionally, behavioral studies in animals demonstrate that the 10 synthetic cathinones produce locomotor behavior and discriminative stimulus effects that are similar to those of the schedule I and II substances methamphetamine and cocaine. Furthermore, the 10 synthetic cathinone produce rewarding properties as demonstrated in self-administration and conditioned place preference (CPP) studies. Drugs that have rewarding effects in animals are likely to produce rewarding effects in humans, which is indicative of abuse potential. Overall, these data indicate that the 10 synthetic cathinones produce pharmacological effects and stimulant-like behaviors that are similar to those of the schedule I substances (MDMA, mephedrone, MDPV, methylone), as well as the schedule II stimulants (methamphetamine and cocaine).

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are synthetic cathinones (β-keto-phenethylamines) of the larger phenethylamine structural class (amphetamines, cathinones, 2C compounds, aminoindanes, etc.). These substances share the core phenethylamine structure with a keto functional group [carbonyl (C=O)] at the β-position and substitutions at the α-position and on the phenyl ring and nitrogen atom. Available data demonstrate that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are β-ketophenethylamines (*i.e.,* synthetic cathinones) and are structurally and pharmacologically similar to amphetamine, MDMA, cathinone, mephedrone, methylone, MDPV, and other related substances. Metabolism studies demonstrate that humans metabolize synthetic cathinones to their corresponding amphetamines followed by reduction of the beta-keto group to the corresponding alcohol. According to the HHS, 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone,

[3] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[4] STRIDE was a database that collected analyses of results from drug evidence sent to DEA laboratories. Evidence was submitted by the DEA, other Federal agencies, and select local law enforcement agencies. On October 1, 2014, STARLiMS replaced STRIDE as the DEA system of record for forensic laboratory drug evidence data.

[5] NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses.

and α-PBP have no known accepted medical use. They are not the subject of any approved new drug applications (NDAs) or investigational new drug applications (INDs), and are not currently marketed as approved drug products in the U.S or in any other country. The HHS also states that there are no reported clinical trials with the 10 synthetic cathinones. Accordingly, the DEA is not aware of any accepted medical use for 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP in the United States. In addition, although the chemistry of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP is known and has been reproduced, no studies have been undertaken to evaluate the efficacy, toxicology, and safety of these substances in humans.

4. *Its History and Current Pattern of Abuse:* 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are synthetic cathinones that emerged on the U.S. illicit drug market around the time of the scheduling of mephedrone, methylone, and MDPV on October 21, 2011. These synthetic cathinone substances, like the schedule I synthetic cathinones (mephedrone, methylone, and MDPV), are promoted as being 'legal' alternatives to cocaine, methamphetamine, and MDMA. As reported in the medical literature, synthetic cathinones can induce stimulant effects, especially under high dose conditions, including tachycardia, palpitations, hypertension, tremor, seizures, hallucinations, paranoia, delusions, hyperthermia, sweating, headache, hyponatremia, and rhabdomyolysis. Products that contain 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are falsely marketed as ''research chemicals,'' ''jewelry cleaner,'' ''stain remover,'' ''plant food or fertilizer,'' ''insect repellants,'' or ''bath salts'' and are sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations. They can also be purchased on the Internet under a variety of product names (*e.g.,* ''White Dove,'' ''Explosion,'' ''Tranquility''). They are commonly encountered in the form of powders, crystals, resins, tablets, and capsules. The packages of these commercial products usually contain the warning ''not for human consumption.'' Information from published scientific studies indicate that the most common routes of administration for synthetic cathinone substances is ingestion by swallowing capsules or tablets, or nasal insufflation by snorting the powder tablets. Evidence from poison centers and published reports suggest that the main users of methylone are young adults. There is evidence that these synthetic cathinone substances are ingested with other substances including other synthetic cathinones, common cutting agents, or other recreational substances.

5. *The Scope, Duration, and Significance of Abuse:* 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP, like mephedrone, methylone, and MDPV, are popular recreational drugs. Evidence that these synthetic cathinone substances are being abused and trafficked is confirmed by law enforcement encounters of these substances and reports from national databases. Forensic laboratories have analyzed drug exhibits received from state, local, or Federal law enforcement agencies that were found to contain 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP. NFLIS registered over 17,000 reports from State, local, and other forensic laboratories identifying these substances in drug-related reports for the period from January 2010 to December 2015 from 47 states. STRIDE & STARLiMS registered over 2,000 reports from DEA forensic laboratories from January 2010 to December 2015. Encounters of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP by law enforcement have occurred in several states. Additionally, large seizures of these substances have occurred by the U.S. Customs and Border Protection (CBP). Concerns over the abuse of these synthetic cathinone substances have prompted many States to regulate them. These data demonstrate that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have a scope, duration, and significance of abuse that supports scheduling under the CSA.

6. *What, if Any, Risk There is to the Public Health:* Available evidence on the overall public health risks associated with the use of synthetic cathinones indicates that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP can cause acute health problems leading to emergency department (ED) admissions, violent behaviors causing harm to self or others, or death. Law enforcement, forensic laboratories, case reports, and public health officials have reported toxic exposure to some of the 10 synthetic cathinones that demonstrate the public health risks associated with these substances. Serious adverse effects have resulted in documented hospital ED admissions from the ingestion of butylone, 4-FMC, or naphyrone. Individuals under the influence of 4-MEC or α-PVP have acted violently and unpredictably causing harm, or even death, to themselves or others. Butylone has been directly implicated in two fatalities reported in the medical literature. Other synthetic cathinones, such as α-PVP, pentedrone, and pentylone, have also been implicated in the deaths of individuals. Acute effects of these substances are those typical of a sympathomimeticagent (*e.g.,* cocaine, methamphetamine, amphetamine) and include among other effects tachycardia, headache, palpitations, agitation, anxiety, mydriasis, tremor, fever or sweating, and hypertension. Other effects, with possible public health risk implications, that have been reported from the use of synthetic cathinone substances include psychological effects such as psychosis, paranoia, hallucinations, and agitation. Finally, the possibility of death for individuals abusing 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP also indicates that these substances pose a serious public health threat. In addition to the recognized harm from ingesting and abusing synthetic cathinones, abusers risk harm when they obtain these drugs through unknown sources. Products containing these synthetic cathinone substances often do not bear labeling information regarding their ingredients and if they do, they may not contain the expected active ingredients or identify the health risks and potential hazards associated with these products. Thus, the limited knowledge about product contents, its purity and lack of information about its effects may pose another level of risk to users.

7. *Its Psychic or Physiological Dependence Liability:* The DEA is unaware of any clinical studies that have evaluated the dependence potential of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α-PBP; however, according to the HHS, synthetic cathinones have rewarding properties in rodents similar to those of schedule II stimulants. Generally, there is a strong correlation between drugs that serve as reinforcers in animals, and drugs associated with problems of addiction, dependence, or abuse by humans. In a self-administration study,

α-PVP and pentedrone were self-administered by rodents. In the intracranial self-stimulation (ICSS) assay, α-PVP and 4-MEC significantly reduced the ICSS threshold compared to vehicle control. In drug discrimination studies, all 10 synthetic cathinone substances fully generalize to the discriminative stimulus effects produced by the schedule II stimulants—cocaine and methamphetamine. In conditioned place preference (CPP) studies, α-PBP, α-PVP, and pentedrone produce CPP in rodents. Thus, these data indicate that 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have behavioral and rewarding properties in rodents similar to those of schedule II stimulants and, consequently, psychic dependence on these substances can develop and may contribute to the continued use among individuals who abuse them despite their adverse consequences.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP are not considered immediate precursors of any controlled substance of the CSA.

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS's recommendation, and the DEA's own eight-factor analysis, the DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP. As such, the DEA hereby proposes to schedule 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4–FMC, 3-FMC, naphyrone, and α-PBP as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for the HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have a high potential for abuse that is comparable to other schedule I and schedule II substances such as mephedrone, methylone, MDPV, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine;

2. 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP have no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of 4-MEC, 4-MePPP, α-PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α-PBP under medical supervision.

Based on these findings, the Administrator of the DEA concludes that 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP); alpha-pyrrolidinopentiophenone (α-PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone); alpha-pyrrolidinobutiophenone (α-PBP) and their optical, positional, and geometric isomers, salts and salts of isomers, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 4–MEC, 4–MePPP, α–PVP, Butylone, Pentedrone, Pentylone, 4–FMC, 3–FMC, Naphyrone, and α–PBP

If this rule is finalized as proposed, 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, and α–PBP would continue [6] to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importing, research, conduct of instructional activities, and exporting of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, conducts instructional activities or chemical analysis with, or possesses) 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP, or who desires to handle 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP would be required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP would need to be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers would be permitted to manufacture 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person who becomes registered with the DEA on or after the effective date of the final rule must take an initial inventory of all stocks of controlled substances (including 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, and α–PBP) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, and α–PBP) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, and/ or α–PBP pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. Order Forms. Every DEA registrant who distributes 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP would be required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC,

[6] 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 79 FR 12938, Mar. 7, 2014.

naphyrone, or α–PBP would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. Liability. Any activity involving 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and could subject the person to administrative, civil, and/ or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 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

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

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It 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 Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, 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. On March 7, 2014, the DEA published a final order to temporarily place 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, and α–PBP into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA estimates that all entities handling or planning to handle 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP are currently registered to handle these substances. There are currently 43 registrations authorized to handle 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 43 registrations represent 31 entities, of which 11 are small entities. Therefore, the DEA estimates that 11 small entities are affected by this proposed rule.

A review of the 43 registrations indicates that all entities that currently handle 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP also handle other schedule I controlled substances, and have established and implemented (or currently maintain) the systems and processes required to handle 4–MEC, 4–MePPP, α–PVP, butylone, pentedrone, pentylone, 4–FMC, 3–FMC, naphyrone, or α–PBP. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 11 affected small entities. Therefore, the DEA has concluded that this proposed rule will not have a significant effect on the small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* the DEA has determined and certifies 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 UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This 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 1308

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

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Add paragraphs (d)(58) through (d)(67);

■ b. Remove paragraphs (h)(11) through (h)(20),

■ c. Redesignate paragraphs (h)(21) through (h)(25) as (h)(11) through (h)(15);

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(58) 4–methyl–*N*–ethylcathinone (4MEC)	(1249)
(59) 4–methyl–*alpha*–pyrrolidinopropiophenone (4–MePPP)	(7498)
(60) *alpha*–pyrrolidinopentiophenone (α–PVP)	(7545)
(61) 1–(1,3–benzodioxol–5–yl)–2–(methylamino)butan–1–one (butylone, bk–MB	(7541)
(62) 2–(methylamino)–1–phenylpentan–1–one (pentedrone)	(1246)
(63) 1–(1,3–benzodioxol–5–yl)–2–(methylamino)pentan–1–one (pentylone, bk–MBDP)	(7542)
(64) 4–fluoro–*N*–methylcathinone (4–FMC; flephedrone).	(1238)
(65) 3–fluoro–*N*–methylcathinone (3–FMC)	(1233)
(66) 1–(naphthalen–2–yl)–2–(pyrrolidin–1–yl)pentan–1–one (naphyrone).	(1258)
(67) *alpha*–pyrrolidinobutiophenone	(7546)

* * * * *

Dated: March 2, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–05002 Filed 3–3–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–127923–15]

RIN 1545–BM97

Consistent Basis Reporting Between Estate and Person Acquiring Property From Decedent

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking, and notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains proposed regulations that provide guidance regarding the requirement that a recipient's basis in certain property acquired from a decedent be consistent with the value of the property as finally determined for Federal estate tax purposes. In addition, these proposed regulations provide guidance on the reporting requirements for executors or other persons required to file Federal estate tax returns. Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** provide transition relief to executors and other persons required to file or furnish certain statements. The text of those temporary regulations (TD 9757) published in the Rules and Regulations section of this issue of the **Federal Register** also serves as the text of the proposed regulations regarding the transition relief. These proposed regulations as well as TD 9757 published elsewhere in the Rules and Regulations section of this issue of this **Federal Register** affect executors or other persons who file estate tax returns after July 31, 2015. The proposed regulations also affect beneficiaries who acquire certain property from these estates, and subsequent transferees to whom beneficiaries transfer the property in transactions that do not result in the recognition of gain or loss for Federal income tax purposes.

DATES: Written or electronic comments and requests for a public hearing must be received by June 2, 2016.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–127923–15), Internal Revenue Service, Room 5203, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–127923–15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224; or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–127923–15).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Theresa M. Melchiorre, at (202) 317–6859; concerning submissions of comments or, to request a hearing, Regina Johnson, at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by *May 3, 2016.*

Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service (IRS), including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The reporting requirements in these proposed regulations are in § 1.6035–1(a) and (d) and require executors and other persons required to file a return under section 6018 to furnish a statement to the IRS and to each beneficiary providing information regarding the value of the property the beneficiary acquires from the decedent. The IRS will use this information to determine whether the beneficiary (or transferee) reports a basis for that property that is consistent with the value of that property as finally determined for Federal estate tax purposes when the beneficiary (or transferee) depreciates the property, or sells, exchanges, or otherwise disposes of some or all of that property in transactions that result in the recognition of gain or loss for Federal income tax purposes.

The collection of information may vary depending on the property includible in the gross estate and the number of beneficiaries receiving the property. The following estimates are based on the information that is available to the IRS. A respondent may require more or less time, depending on the circumstances.

Estimated total annual reporting burden. The estimated total annual reporting burden per respondent is 5.31 hours.

Estimated annual number of respondents. The estimated annual number of respondents is 10,000.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

1. Overview

On July 31, 2015, the President of the United States signed into law H.R. 3236, the *Surface Transportation and Veterans Health Care Choice Improvement Act of 2015,* Public Law 114–41, 129 Stat. 443 (Act). Section 2004 of the Act enacted sections 1014(f), 6035, 6662(b)(8), 6662(k), 6724(d)(1)(D), and 6724(d)(2)(II) of the Internal Revenue Code (Code). This document contains proposed regulations that amend 26 CFR parts 1 and 301 under those Code provisions to achieve consistency between a recipient's basis in certain property acquired from a