

KYSKY, NY

WP

(Lat. 40°46'52.75" N, long. 072°12'21.45" W)

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**Q-481 JAMIE, VA to Deer Park, NY (DPK) [Amended]**

JAMIE, VA	WP	(Lat. 37°36'20.58" N, long. 075°57'48.81" W)
CONFR, MD	WP	(Lat. 38°16'10.90" N, long. 075°24'32.98" W)
MGERK, DE	WP	(Lat. 38°46'16.00" N, long. 075°18'09.00" W)
SOSBY, OA	WP	(Lat. 39°15'24.74" N, long. 074°55'30.57" W)
ECOIL, OA	WP	(Lat. 39°49'58.45" N, long. 074°14'06.07" W)
ZIGGI, NJ	FIX	(Lat. 40°03'07.01" N, long. 074°00'49.34" W)
Deer Park, NY (DPK)	VOR/DME	(Lat. 40°47'30.30" N, long. 073°18'13.17" W)

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Issued in Washington, DC, on October 22, 2024.

**Frank Lias,**

*Manager, Rules and Regulations Group.*

[FR Doc. 2024–24938 Filed 10–25–24; 8:45 am]

**BILLING CODE 4910–13–P**

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1310

[Docket No. DEA–1282]

#### Possible Control of Phenethyl Bromide as a List I Chemical

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Advanced notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) finds that phenethyl bromide is used in the illicit manufacture of the controlled substance fentanyl, as well as fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances because it is often used in synthetic pathways to illicitly manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. Prior to proposing to list phenethyl bromide as a list I chemical under the Controlled Substances Act, DEA is soliciting information on the current uses of phenethyl bromide (other than for the synthesis of fentanyl) in order to properly determine the effect such a proposed action would have on legitimate industry.

**DATES:** Comments must be submitted electronically or postmarked on or before November 27, 2024. 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–1282” on all electronic and

written correspondence, including any attachments.

- **Electronic comments:** The Drug Enforcement Administration (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 <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your comment submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](https://www.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 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

#### SUPPLEMENTARY INFORMATION:

##### Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available for public inspection online at <https://www.regulations.gov>. Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information

voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked “CONTAINS CONFIDENTIAL INFORMATION” and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked “TO BE PUBLICLY POSTED” and must have all claimed PII and business information already redacted. DEA will post only the redacted comment on <https://www.regulations.gov> for public inspection.

For easy reference, an electronic copy of this document and a plain language summary of this advanced notice of proposed rulemaking are available at <https://www.regulations.gov>.

#### Legal Authority

The Controlled Substances Act (CSA) authorizes the Attorney General to specify, by regulation, chemicals as list I chemicals.<sup>1</sup> The Attorney General has delegated his authority to designate list I chemicals to the Administrator of DEA (Administrator).<sup>2</sup> A “list I chemical” is a chemical that is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of the controlled substances.<sup>3</sup> The current list of all listed chemicals is published at 21 CFR

<sup>1</sup> 21 U.S.C. 802(34).

<sup>2</sup> 28 CFR 0.100(b).

<sup>3</sup> Id.

1310.02. DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the **Federal Register** following a published notice of proposed rulemaking with at least 30 days for public comments.

### Background

The clandestine manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances remains extremely concerning as the distribution of illicit fentanyl, fentanyl analogues, and fentanyl-related substances continues to drive drug-related overdose deaths in the United States. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950s. Fentanyl was introduced into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. Yet, due to its pharmacological effects, fentanyl can be used as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals. Therefore, despite its accepted medical use in treatment in the United States, DEA controls fentanyl as a schedule II controlled substance due to its high potential for abuse and dependence.<sup>4</sup>

Moreover, there are a substantial number of fentanyl analogues<sup>5</sup> and fentanyl-related substances<sup>6</sup> that are being distributed on the illicit drug market despite DEA's recent actions adding them as scheduled controlled substances.<sup>7</sup> Illicit manufacturers of fentanyl, fentanyl analogues, and fentanyl-related substances attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls in order to keep manufacturing these substances. This strategy allows for the synthesis of a variety of fentanyl analogues and fentanyl-related substances by making slight modifications to the core fentanyl structure while maintaining the same synthetic methodology used to synthesize fentanyl, fentanyl analogues, and fentanyl-related substances.

The unlawful trafficking of fentanyl, fentanyl analogues, and fentanyl-related substances in the United States continues to pose an imminent hazard to 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), and in forms that mimic pharmaceutical preparations including prescription opiates and benzodiazepines.<sup>8</sup>

DEA has noted a significant increase in overdoses and overdose fatalities

from fentanyl, fentanyl analogues, and fentanyl-related substances in the United States in recent years. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids (which includes fentanyl), are predominantly responsible for drug overdose deaths in recent years. According to CDC WONDER,<sup>9</sup> drug-induced overdose deaths involving synthetic opioids (excluding methadone) in the United States increased from 36,359 in 2019, to 56,516 in 2020, and to 70,601 in 2021. Based on provisional data, the predicted number of drug overdose deaths involving synthetic opioids (excluding methadone) in the United States for the 12 months ending March 2023 is 76,472 individuals, or approximately 69.2 percent of all drug-induced overdose deaths for that time period.<sup>10</sup> The increase in overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl, fentanyl analogues, and fentanyl-related substances. According to the National Forensic Laboratory Information System (NFLIS-Drug),<sup>11</sup> reports from forensic laboratories of drug items containing fentanyl, fentanyl analogues, and fentanyl-related substances increased dramatically since 2014, as shown in Table 1.

TABLE 1—ANNUAL REPORTS OF FENTANYL AND SELECT FENTANYL ANALOGUES AND FENTANYL-RELATED SUBSTANCES IDENTIFIED IN DRUG ENCOUNTERS

Year	2014	2015	2016	2017	2018	2019	2020	2021	2022
Annual Fentanyl Reports .....	5,554	15,461	37,154	61,642	89,967	108,133	126,0099	165,104	165,920
Annual Reports of select fentanyl analogues and fentanyl-related substances	78	2,317	7,624	21,980	16,033	20,864	7,774	26,363	29,404

### Role of Phenethyl Bromide in the Synthesis of Fentanyl

Fentanyl, fentanyl analogues, and fentanyl-related substances are not naturally occurring substances. As such, the manufacture of these substances requires them 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. Through chemical reactions, the chemical structures of precursor chemicals are modified in a desired fashion. These chemical reaction sequences, also known as synthetic pathways, are designed to create a

desired substance. Several synthetic pathways to fentanyl, fentanyl analogues, and fentanyl-related substances have been identified in clandestine laboratory settings; these include the original “Janssen method,” the “Siegfried method,” and the “Gupta method.” In response to the illicit manufacture of fentanyl, fentanyl

<sup>4</sup> 21 U.S.C. 812(c) Schedule II(b)(6); 21 CFR 1308.12(c).

<sup>5</sup> Schedules of Controlled Substances: Temporary Placement of Seven Fentanyl-Related Substances in Schedule I. 83 FR 4580 (Feb. 1, 2018).

<sup>6</sup> Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I. 83 FR 5188 (Feb. 6, 2018).

<sup>7</sup> Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I. 86 FR 22113 (Apr. 27, 2021).

<sup>8</sup> United Nations Office on Drugs and Crime, Global SMART Update Volume 17, March 2017.

[https://www.unodc.org/documents/scientific/Global\\_SMART\\_Update\\_17\\_web.pdf](https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf).

<sup>9</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018–2021, and from provisional data for years 2022–2023, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on March 16, 2023.

<sup>10</sup> Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. Accessed at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> on August 17, 2023.

<sup>11</sup> NFLIS-Drug 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. While NFLIS-Drug 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). NFLIS-Drug data was queried on July 31, 2023, and August 17, 2023.

analogues, and fentanyl-related substances using these methods, DEA controlled *N*-phenethyl-4-piperidone (NPP),<sup>12</sup> *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), *N*-phenylpiperidin-4-amine (4-anilinopiperidine; including its amides and carbamates),<sup>13</sup> and 4-piperidone (piperidin-4-one)<sup>14</sup> as list I chemicals, and 4-anilino-*N*-phenethylpiperidine (ANPP)<sup>15</sup> and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)<sup>16</sup> as schedule II immediate precursors under the CSA.

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 are required to regulate these precursor chemicals at the national level. Importantly, the People's Republic of China regulated NPP and ANPP on February 1, 2018.<sup>17</sup> Subsequently, in 2022, the United Nations Commission on Narcotic Drugs placed norfentanyl, 1-boc-4-anilinopiperidine, and 4-anilinopiperidine in Table I of the 1988 Convention in response to the international reintroduction of fentanyl on the illicit drug market and the introduction of new precursors used in the illicit manufacture of fentanyl.

### Phenethyl Bromide

The original published synthetic pathway to fentanyl, known as the Janssen method, involves the list I chemical benzylfentanyl<sup>18</sup> and schedule II immediate precursor norfentanyl.<sup>19</sup> In this synthetic

pathway, benzylfentanyl, a list I chemical under the CSA, is then converted to norfentanyl, the schedule II immediate precursor in this synthetic pathway. Norfentanyl is reacted with phenethyl bromide (also known as 2-bromoethyl benzene) to complete the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Phenethyl bromide also serves as a precursor chemical in the Siegfried method. In this synthetic pathway, phenethyl bromide is reacted with 4-piperidone, a list I chemical under the CSA, to produce NPP, another list I chemical, which is further converted to ANPP,<sup>20</sup> the schedule II immediate precursor in the Siegfried method. One additional step completes the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl, one of which is known as the Gupta method. In this synthetic pathway, 4-piperidone, a list I chemical under the CSA, is used to synthesize 4-anilinopiperidine, another list I chemical under the CSA,<sup>21</sup> which serves as an alternative precursor chemical to NPP, a list I chemical, in the synthesis of ANPP, a schedule II immediate precursor, albeit through a different synthetic process. 4-Anilinopiperidine is reacted with phenethyl bromide to produce ANPP, which is then converted to the schedule II controlled substance, fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

### Phenethyl Halides and Sulfonates

Phenethyl bromide is attractive to illicit manufacturers due to the lack of regulations on this chemical; it is readily available from chemical suppliers. Additionally, related phenethyl halides (*i.e.*, phenethyl chloride, phenethyl iodide, etc.) and phenethyl sulfonates (*i.e.*, phenethyl tosylate, phenethyl mesylate, etc.) can be used as substitutes for phenethyl bromide in many of the known synthetic pathways. These pathways

can be easily used, and modified, in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances.

### Solicitation for Information

With this advanced notice of proposed rulemaking, DEA is soliciting information on any possible legitimate uses of phenethyl bromide, and related halides and sulfonates, unrelated to fentanyl production (including industrial uses) in order to assess the potential economic impact of controlling phenethyl bromide as a list I chemical. DEA seeks to document any unpublicized use(s) and other proprietary use(s) of phenethyl bromide, and related halides and sulfonates, that are not in the public domain. Therefore, DEA is soliciting comment on the uses of phenethyl bromide, and related halides and sulfonates, in the legitimate marketplace.

DEA is soliciting input from all potentially affected parties regarding: (1) the types of legitimate industries using phenethyl bromide, and related halides and sulfonates; (2) the legitimate uses, legitimate needs, and quantities produced, used, and distributed of phenethyl bromide, and related halides and sulfonates; (3) the size of the domestic market for phenethyl bromide, and related halides and sulfonates, if any; (4) the number of manufacturers of phenethyl bromide, and related halides and sulfonates; (5) the number of distributors of phenethyl bromide, and related halides and sulfonates; (6) the level of import and export of phenethyl bromide, and related halides and sulfonates; (7) the potential burden that controlling phenethyl bromide, and related halides and sulfonates, as a list I chemical may have on any legitimate industry and trade; (8) the potential number of individuals/firms that may be adversely affected by such 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 phenethyl bromide, and related halides and sulfonates, by industry and others. DEA invites all interested parties to provide any information on any legitimate uses of phenethyl bromide, and related halides and sulfonates, in industry, commerce, academia, research and development, or other applications. DEA seeks both quantitative and qualitative data.

Such information may be submitted electronically to the address listed above and is requested by November 27, 2024. This information will be used to properly determine the effect that

<sup>12</sup> Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as a List I Chemical, 72 FR 20039 (Apr. 23, 2007).

<sup>13</sup> Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (Apr. 15, 2020).

<sup>14</sup> Designation of 4-Piperidone as a List I Chemical, 88 FR 21902 (Apr. 12, 2023).

<sup>15</sup> Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 75 FR 37295 (June 29, 2010).

<sup>16</sup> Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 85 FR 21320 (Apr. 17, 2020).

<sup>17</sup> <https://www.dea.gov/press-releases/2018/01/05/china-announces-scheduling-controls-two-fentanyl-precursor-chemicals>. Accessed March 9, 2022.

<sup>18</sup> Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (April 15, 2020).

<sup>19</sup> Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a

Schedule II Controlled Substance, 85 FR 21320 (April 17, 2020).

<sup>20</sup> Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 75 FR 37295 (June 29, 2010).

<sup>21</sup> Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (April 15, 2020).

proposed regulations to make phenethyl bromide a list I chemical under the CSA would have on industry.

### Handling of Confidential or Proprietary Information

Confidential or proprietary information may be submitted as part of a comment regarding this advanced 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

This ANPRM was developed in accordance with the principles of Executive Order (E.O.) 12866, “Regulatory Planning and Review,” E.O. 13563, “Improving Regulation and Regulatory Review,” and E.O. 14094, “Modernizing Regulatory Review.” Because this action is an ANPRM, the requirement of E.O. 12866 to assess the costs and benefits of this action does not apply.

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

### Signing Authority

This document of the Drug Enforcement Administration was signed on October 10, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

**Heather Achbach,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2024–24616 Filed 10–25–24; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

#### 49 CFR Part 236

[Docket No. FRA–2023–0064]

RIN 2130–AC95

#### Positive Train Control Systems

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

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

**SUMMARY:** FRA is proposing to amend certain regulations governing positive train control (PTC) systems. Since December 31, 2020, by law, PTC systems have generally governed rail operations on PTC-mandated main lines, which encompass nearly 59,000 route miles today. Through FRA’s oversight and continued engagement with the industry, FRA has found that its existing PTC regulations do not adequately address temporary situations during which PTC technology is not enabled, including after certain initialization failures or in cases where a PTC system needs to be temporarily disabled to facilitate repair, maintenance, infrastructure upgrades, or capital projects. FRA expects PTC systems to be reliable and robust, further reducing the occurrence of initialization failures and outages. This NPRM proposes to establish strict parameters and operating restrictions under which railroads may continue to operate safely in certain necessary scenarios when PTC technology is temporarily not governing rail operations. The purpose of this NPRM is to enable continued, safe operations and improve rail safety by facilitating prompt repairs, upgrades, and restoration of PTC system service.

**DATES:** Written comments must be received by December 27, 2024. FRA believes a 60-day comment period is appropriate to allow the public to comment on this proposed rule. FRA will consider comments received after that date to the extent practicable.

#### ADDRESSES:

*Comments:* Comments related to Docket No. FRA–2023–0064 may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

*Instructions:* All submissions must include the agency name, docket number (FRA–2023–0064), and Regulation Identifier Number (RIN) for this rulemaking (2130–AC95). All

comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

*Docket:* For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

#### FOR FURTHER INFORMATION CONTACT:

Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: [Gabe.Neal@dot.gov](mailto:Gabe.Neal@dot.gov); or Stephanie Anderson, Attorney Adviser, telephone: 202–834–0609, email: [Stephanie.Anderson@dot.gov](mailto:Stephanie.Anderson@dot.gov).

#### SUPPLEMENTARY INFORMATION:

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#### I. Executive Summary

Section 20157 of title 49 of the United States Code (U.S.C.) mandates each Class I railroad, and each entity providing regularly scheduled intercity or commuter rail passenger transportation, to implement an FRA-certified PTC system on: (1) its main lines over which poison- or toxic-by-inhalation hazardous materials are transported, if the line carries five million or more gross tons of any annual traffic; (2) its main lines over which intercity or commuter rail passenger transportation is regularly provided; and (3) any other tracks the Secretary of Transportation (Secretary) prescribes by