information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Jason Stahl, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

A final rule was published in the **Federal Register** on January 14, 2016 (81 FR 1877), FR Doc. 2015–33095, that reversed the order of points listed in the legal description of RNAV Route Q–35 as published in FAA Order 7400.9, Airspace Designations and Reporting Points. Subsequent to publication, the FAA found that the FAA docket number for this document was inadvertently mistyped. This action corrects the FAA docket number.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, in the **Federal Register** of January 14, 2016 (81 FR 1877), the docket number, as published in the **Federal Register** on January 14, 2016 (81 FR 1877), FR Doc. 2015–33095, amending the legal description of RNAV Route Q–35, is corrected as follows:

§ 71.1 [Amended]

■ On page 1877, column 1, line 4, Remove ''Docket No. FAA–2013–6001'' and add in its place ''Docket No. FAA–2015–6001.

Issued in Washington, DC, on February 25, 2016.

Kenneth Ready,

Acting Manager, Airspace Policy Group.

[FR Doc. 2016–04739 Filed 3–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 252

[Docket No. DOT–OST–2011–0044]

RIN 2105–AE06

Use of Electronic Cigarettes on Aircraft

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The Department of Transportation is issuing a final rule to extend the smoking ban in DOT's regulation to include all charter (*i.e.,* nonscheduled) flights where a flight attendant is a required crewmember. The revised regulation would comport with 49 U.S.C. 41706, which was revised in 2012, to ban smoking on charter flights where a flight attendant is a required crewmember. This final rule also explicitly bans the use of electronic cigarettes (''e-cigarettes'') on all flights where smoking is banned. The Department interprets the existing regulation to prohibit e-cigarette use, but is codifying this interpretation.

DATES: The rule is effective April 4, 2016.

FOR FURTHER INFORMATION CONTACT: Robert M. Gorman, Senior Trial Attorney, or Blane A. Workie, Assistant General Counsel, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *robert.gorman@dot.gov* or *blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (Pub. L. 106–181) was signed into law on April 5, 2000. Section 708 of this statute, ''Prohibitions Against Smoking on Scheduled Flights'' (codified as 49 U.S.C. 41706), banned passengers from smoking on all flights in scheduled passenger interstate and intrastate air transportation, and directed the Secretary of Transportation to prohibit smoking in foreign air transportation (with an exception process for foreign carriers). Shortly thereafter, the Department of Transportation (''DOT,'' or ''the Department'') amended its rule on smoking aboard aircraft, 14 CFR part 252, to implement section 41706. Under part 252, the smoking of tobacco products is banned on all scheduled passenger flights of air carriers, and on all scheduled passenger flight segments of foreign air carriers between points in the United States and between the United States and foreign points. Under part 252, foreign governments may request and obtain a waiver from DOT provided that an alternative smoking prohibition resulting from bilateral negotiations is in effect. Further, part 252 was amended to permit carriers operating single-entity charters to allow smoking throughout the aircraft, but also required a no-smoking section for each class of service (*e.g.,* first class) on other charter flights where smoking is not banned.

Throughout this preamble, we use the terms ''air carrier'' and ''foreign air carrier'' as defined in 49 U.S.C. 40102, in which an ''air carrier'' is a citizen of the United States undertaking to provide air transportation, and a ''foreign air carrier'' is a person, not a citizen of the United States, undertaking to provide foreign air transportation.

The Notice of Proposed Rulemaking

Electronic Cigarettes and Other Nicotine Delivery Systems

On September 15, 2011, the Department published a notice of proposed rulemaking (NPRM) in which it proposed to amend its existing smoking rule (part 252) to explicitly ban the use of e-cigarettes on all flights covered by that rule (*i.e.,* all flights of U.S. air carriers in scheduled passenger interstate, intrastate and foreign air transportation and all scheduled flight segments of foreign air carriers in, to, or from the United States).[1] E-cigarettes typically contain a cartridge or chamber, which contain an atomizer or heating element, a battery and a liquid solution. Most often e-cigarettes contain liquid nicotine but they may contain other chemicals. When a user inhales, the heating element aerosolizes the liquid solution. This produces an aerosol,[2] which requires an inhalation and exhalation similar to smoking cigarettes. In addition to nicotine, e-cigarette aerosol can contain heavy metals, ultrafine particulates that can be inhaled deep into the lungs, and cancer-causing agents like acrolein. Secondhand

[1] *Smoking of Electronic Cigarettes on Aircraft,* Department of Transportation, Office of the Secretary, 14 CFR part 252, [Docket No. DOT–OST–2011–0044], RIN 2105–AE06, 76 FR 57008 (Sept. 15. 2011).

[2] Our NPRM and many commenters referred to the exhaled product of e-cigarettes as a ''vapor.'' It is more accurate to refer to the product as an aerosol. See Grana et al., E-Cigarettes: A Scientific Review, *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4018182/.* Products that create both vapors and aerosols are included in the Department's definition of ''smoking.''

aerosol that is exhaled by users may reduce air quality and is potentially harmful to health. Sometimes e-cigarettes are designed to look like traditional cigarettes, but at times they are also made to look like cigars, pipes, and even everyday products such as pens.

The increased promotion and availability of e-cigarettes raised the issue of whether the statutory ban on smoking on scheduled passenger flights in section 41706 and the existing regulatory prohibition on the smoking of tobacco products in part 252 applied to e-cigarettes. In the NPRM, we explained that the Department views the existing statutory and regulatory framework to be sufficiently broad to include the use of e-cigarettes; however, the purpose of the proposal was to clarify and codify this position. In addition to relying on section 41706 as our statutory authority for the rule, we also relied on 49 U.S.C. 41702, which requires air carriers to provide safe and adequate interstate air transportation. Another Federal statute, 49 U.S.C. 41712, which prohibits airlines from engaging in unfair or deceptive practices or unfair methods of competition in air transportation or the sale of air transportation, provides additional support for the e-cigarette rule. (See ''Authority to Regulate E-Cigarettes under 49 U.S.C. 41712,'' below).

The NPRM stated our position that the reasons supporting the statutory and regulatory ban on smoking also apply to a ban on e-cigarettes: Improving air quality within the aircraft, reducing the risk of adverse health effects on passengers and crewmembers, and enhancing aviation safety and passenger comfort. We also discussed *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. Dec. 7, 2010), in which the court held that the Food and Drug Administration (FDA) could not regulate ''customarily marketed'' electronic cigarettes as drugs or devices under the Federal Food, Drug, and Cosmetic Act (FDCA), but that the FDA could regulate the e-cigarettes at issue as tobacco products under the FDCA as amended by the Family Smoking Prevention and Tobacco Act of 2009 (Tobacco Control Act).

The FDA has express authority under the Tobacco Control Act to regulate only the following tobacco products at this time: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act permits the FDA to extend its tobacco products authority to other types of tobacco products by issuing regulations. On April 25, 2014, the FDA issued a proposed rule to extend FDA's tobacco product authorities to include e-cigarettes and other types of tobacco products.[3]

Similarly, in our NPRM, we proposed to amend DOT's smoking rule so it clearly covers e-cigarettes by including a definition of smoking. For purposes of this rule, we proposed to define smoking as: ''the smoking of tobacco products or use of electronic cigarettes and similar products designed to deliver nicotine or other substances to a user in the form of a vapor,'' with an exemption for ''the use of a device such as a nebulizer that delivers a medically beneficial substance to a user in the form of a vapor.''

In the NPRM, the Department sought comment on: (1) Whether the definition of ''smoking'' in the proposed rule text was so broad that it might unintentionally include otherwise permissible medical devices that produce a vapor; (2) concerns over, and benefits of, the proposal to clarify the prohibition in part 252 to explicitly cover e-cigarettes; and (3) any other information or data relevant to the Department's decision.

Charter (Nonscheduled) Passenger Flights

In addition, the NPRM also stated the Department's intent to consider whether to extend the ban on smoking, including e-cigarettes, to charter flights with aircraft that have a seating capacity of 19 or more passenger seats—*i.e.,* those flights that generally require a flight attendant.[4] The Department proposed banning smoking on charter flights with 19 or more passenger seats, citing public health concerns for flight attendants who may be subject to secondhand smoke on board such charter flights. Thus, the Department sought comment on the benefits and drawbacks of extending the smoking ban to charter flights that have a seating capacity of 19 or more passenger seats.

A ban on smoking on charter flights where a flight attendant is a required crewmember was enacted into law on February 14, 2012, in the FAA Modernization and Reform Act of 2012, Public Law 112–95. Section 401 of the Act amended section 41706, the existing smoking statute, by broadening the smoking prohibition to include aircraft in nonscheduled passenger interstate, intrastate and foreign air transportation, if a flight attendant is a required crewmember on the aircraft (as determined by the Federal Aviation Administration or a foreign government).

Discussion of Comments

Overview

In response to the NPRM, the Department received over 1000 comments, the majority of which were in response to the e-cigarette issue. A majority of the comments received on the NPRM were from individuals. In addition, the Department received comments from the following entities: U.S. carrier and foreign carrier associations, members of Congress, pilot associations, flight attendant associations, consumer organizations, advocacy and special interest organizations, local governments, and medical associations.

The Department has carefully reviewed and considered the comments received. The commenters' positions are summarized below.

Definition of ''Smoking''

In the NPRM, we asked whether the definition of ''Smoking'' in the proposed rule text is too broad in that it may unintentionally include otherwise permissible medical devices that produce a vapor. We proposed the following definition:

> *Smoking* means the smoking of tobacco products or use of electronic cigarettes and similar products designed to deliver nicotine or other substances to a user in the form of a vapor. It does not include the use of a device such as a nebulizer that delivers a medically beneficial substance to a user in the form of a vapor.

The Air Transport Association of America (now Airlines for America (A4A)), International Air Transport Association (IATA), Regional Airline Association (RAA), and Air Carrier Association of America (ACAA) filed a joint comment stating their view that the proposed definition was adequate as written, and that it would not unintentionally include otherwise permissible medical devices. Also, the American Thoracic Society suggested that the Department consider explicitly stating in its definition that FDA-approved medical devices, such as

[3] *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products,* Department of Health and Human Services, Food and Drug Administration, 14 CFR parts 1100, 1140, and 1143, [Docket No. FDA–2014–N–0189], RIN 0910–AG38, 79 FR 23142 (April 25, 2014).

[4] Generally, pursuant to FAA regulations, a flight attendant is a required crewmember for Part 121, 125, and 135 operations where the aircraft has a seating capacity of more than nineteen. *See* 14 CFR 121.391, 125.269, 135.107. A flight attendant is also a required crewmember for Part 121 operations with airplanes that have a maximum payload capacity of more than 7,500 pounds and a seating capacity of more than nine. 14 CFR 121.269(a)(1).

nebulizers, metered dose inhalers, ventilators, supplemental oxygen and other respiratory assistive devices meeting Federal Aviation Administration (FAA) requirements, are not covered by the definition of smoking.

With respect to comments received from individuals, there was a concern raised by some that the definition could include all inhalers, asthma inhalers, or permissible nicotine replacement products. Some suggested that ''medically beneficial'' is too broad because in some cases, nicotine may be medically beneficial. Therefore, the commenters suggest changing the language to ''medically necessary substances,'' ''FDA-approved devices,'' or ''prescription drugs.'' One commenter stated that the definition is circular because it uses ''smoking'' in the definition of ''smoking.'' In addition, some commenters suggested it would be clearer to add the word ''harmful'' before ''vapor.''

Finally, one commenter suggested the following definition as an alternative to the proposed rule text: ''any inhalation or exhalation of a tobacco product, electronic cigarette, or similar products that emits a smoke, mist, vapor, etc., with the exception of medical devices such as nebulizers.''

DOT Response

Based on the comments received, we have decided to edit our proposed definition of smoking to read as follows:

> *Smoking* means the use of a tobacco product, electronic cigarettes whether or not they are a tobacco product, or similar products that produce a smoke, mist, vapor, or aerosol, with the exception of products (other than electronic cigarettes) which meet the definition of a medical device in section 201(h) of the Federal Food, Drug and Cosmetic Act, such as nebulizers.

We feel this change more succinctly addresses our targeted prohibition and makes clear that products which meet the definition of a medical device (other than electronic cigarettes) in section 201(h) of the Federal Food, Drug and Cosmetic Act, such as nebulizers, are exempt. The use of electronic cigarettes would fall within the smoking ban even if electronic cigarettes were to meet the definition of a medical device.

Coverage of E-Cigarettes

In the NPRM, we explained that we interpret the existing part 252 to ban the use of e-cigarettes on all flights and that we were seeking to codify this interpretation. We solicited comments about the potential benefits or harm of this proposal.

In their joint comment, A4A, IATA, RAA, and ACAA stated their support for the proposed ban, arguing that e-cigarettes should be treated the same as other tobacco products. These organizations voiced concern over the ingredients in e-cigarettes, which could possibly cause airway irritation for users and others nearby. They also named design flaws, inadequate labeling, quality control, and health issues as concerns. Further, the commenters stated, ''in fact, all carriers already prohibit e-cigarette use in the cabin for the same reasons the Department provided.''

The Air Line Pilots Association (ALPA) stated its belief that the proposed rule would prevent degradation of the air quality onboard aircraft, and asserted that the health risks for human use need to be more thoroughly understood for both users and non-users who are subjected to ''secondhand smoke.'' ALPA also noted the possibility of passenger and crewmember confusion in differentiating e-cigarettes from tobacco cigarettes, as the two products can be difficult to distinguish from each other.

The Association of Flight Attendants (AFA) reported that it has received occasional reports of in-flight passenger use of the devices and some confusion among travelers regarding airline policies. AFA stated its support for treating the devices the same as traditional cigarettes. AFA believes that DOT is appropriately applying a precautionary principle because the toxicity of e-cigarettes is not well understood. In addition, the Association of Professional Flight Attendants, representing flight attendants for American Airlines, submitted a comment stating that American Airlines currently bans e-cigarettes, but nonetheless still urged DOT to promulgate a final rule to create consistency across the industry. The Association further noted that the science behind the effects that e-cigarettes may have on third parties is, at best, inconclusive, and that they adamantly advocate for a healthy environment for all flight attendants.

The Independent Pilots Association, the bargaining unit for the pilots of United Parcel Service, stated its support for the rule on safety grounds (based on the inherent dangers of using lithium battery powered e-cigarettes onboard aircraft). However, it also expressed the view that DOT has created a double standard of safety regulations by carving out less safe standards for cargo aircraft operations, and urged that the rule be applied to all aircraft.

We received comments from a number of medical associations, each voicing their support for the proposed ban. The American Academy of Pediatrics (AAP) commented that it was unaware of any data which would suggest that it is safe for children as passengers in aircraft to be in close proximity to exhaled ''vapors'' from e-cigarettes. Further, the AAP noted that FDA data demonstrate that e-cigarette vapor includes known toxicants, carcinogens, and irritants of the respiratory tract. The American Thoracic Society (ATS) commented that while e-cigarette manufacturers claim that the devices are a reduced-risk product, there is little evidence to support this claim, and that the limited research on these products has found significant variation between manufacturers' attestations and the actual dose of nicotine delivered by the products. ATS further stated that it is not aware of any studies that suggest exhaled e-cigarette vapors are risk-free and that the use of these devices in the confined space of an airline cabin should be viewed with extreme caution. The California Medical Association (CMA) stated its support for the prohibition of the use of any nicotine delivery devices not approved by the FDA in places where smoking is already prohibited by law. CMA also noted that several local and State governments have banned e-cigarettes in indoor public spaces and workplaces. The Oncology Nursing Society expressed its support for the ban, citing evidence for the presence of toxic chemicals in e-cigarette aerosol.

The Department also received a letter of support for the proposed rule signed by seven members of the U.S. Senate.[5] The Senators urged a strong final rule, and stated that the devices raise significant public health concerns. They also expressed concern with respect to the manufacturing and quality control of e-cigarettes. In sum, the Senators stated that the proposed rule recognizes the rights of airline passengers to a safe travel environment and promotes public health.

In addition, we received two comments from local governments. The New York City Department of Health and Mental Hygiene (DOHMH) submitted a comment stating its concern that e-cigarettes are not FDA-approved and may contain chemicals that could harm users or those around them, especially in confined spaces such as

[5] Letter from Senators Barbara Boxer, Richard J. Durbin, Tom Harkin, Richard Blumenthal, Jack Reed, and Edward J. Markey to Secretary Anthony Foxx (June 10, 2014) (available in the public docket).

aircraft. DOHMH noted that the proposed rule would make enforcement of the existing smoking ban easier, as e-cigarettes can be difficult to distinguish from traditional cigarettes. Seattle and King County, Washington, which passed a regulation prohibiting the use of e-cigarette devices in places where smoking is prohibited by law, commented that a precautionary approach is warranted as the products are relatively new to the market and research has not conclusively identified the components of the vapor that are exhaled.

We received several comments from other advocacy organizations. The American Cancer Society, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Legacy submitted a joint comment in support of the proposed rule, stating that in the context of smoking prohibitions on aircraft, e-cigarettes should be considered the same as traditional cigarettes. The organizations commented that the health consequences of e-cigarette use are unknown, and therefore restrictions on their use inside aircraft are appropriate until it can be shown with a high degree of certainty that they pose no harm to non-users. The organizations also argued that allowing the use of e-cigarettes on aircraft would create significant confusion for passengers and enforcement challenges for airline personnel, citing an incident on a Southwest Airlines flight on July 13, 2011, where a man was arrested for pelting a flight attendant with peanuts and pretzels after being asked to put away his e-cigarette upon attempting to smoke the device. The organizations also argued that DOT's proposed rule is consistent with the decision in *Sottera.* Finally, the organizations argued that prohibiting e-cigarette use on aircraft promotes the health goal of reducing the use of tobacco products through the promotion of non-smoking environments.

Americans for Nonsmokers' Rights (ANR) submitted a comment in support of the proposed rule, stating its belief that e-cigarettes should be prohibited in all places where the smoking of tobacco products is prohibited. ANR stated that its primary reason for supporting the ban is that the devices' components raise significant health concerns. ANR also asserted that e-cigarettes can undermine and cause confusion over compliance with smoke-free rules when used on airplanes. Finally, ANR noted that there are at least 25 municipalities that define ''smoking'' to include the use of e-cigarettes and prohibit their use in workplaces and public places. Arizonans for Nonsmokers' Rights expressed the view that e-cigarettes posed respiratory hazards to non-users, and that permitting e-cigarettes aboard aircraft may infringe on the rights of individuals with respiratory disabilities.

The Kentucky Center for Smoke-free Policy submitted a comment strongly in support of the proposed ban, stating that although there is a need for rigorous scientific study of e-cigarettes, it is known that the vapor emitted from the devices contains several volatile organic compounds (*e.g.,* acetone, styrene, and ethyl alcohol acetaldehyde) that can cause negative health effects. The Kentucky Center also commented that the use of e-cigarettes on aircraft may lead people to believe that smoking is permitted, and may undermine smoke-free policies. The Tobacco Free Coalition of Pinellas County (FL) expressed similar health concerns.

FlyersRights.org, a non-profit airline passenger rights advocacy organization, conducted a survey of its members to gauge public opinion on the proposed rule. The survey garnered 987 responses, and those who responded voted overwhelmingly (81.4%) in favor of the NPRM. Support was generally based on the grounds of public health or cabin comfort. Those opposing the ban were almost evenly divided in their reasoning, with some doubting that the e-cigarettes pose any risk, others believing that current research is insufficient to support the regulation, and still others objecting generally to the proposed ban.

The following organizations submitted comments in opposition to the proposed rule. Smokin' Vapor LLC submitted a comment in opposition stating that e-cigarettes do not burn any matter, and that their ingredients (water, flavorings, nicotine—when chosen—and propylene glycol) are safe, and even beneficial to users in some instances. The National Vapers Club submitted a comment stating that e-cigarettes do not produce smoke and therefore do not create the byproducts of combustion. National Vapers stated that banning e-cigarettes is akin to banning the use of Nicotrol inhalers. The organization added that e-cigarettes have not been shown to cause any harm to bystanders; until such harm is proven, the club believes that the ban is unfounded. National Vapers also asserted that it is the responsibility of airlines to explain the use of e-cigarettes to those who are uncomfortable with them, and to alleviate the concerns of those who are not familiar with the products. In addition, Smokers Fighting Discrimination, Inc., submitted a comment in opposition to the proposed ban, stating that e-cigarettes emit water vapor, but not smoke.

Smokefree Pennsylvania submitted a comment that outlined several reasons for its opposition to the proposed ban. The organization challenged the Department's statutory authority to promulgate the rule under 49 U.S.C. 41706. The organization reasoned that the statute does not authorize the ban of e-cigarettes because vapor does not involve combustion, and thus is vastly different from tobacco smoke. Smokefree Pennsylvania stated that the Department falsely alleged that using an e-cigarette is the same as smoking. The organization also challenged the Department's statutory authority under 49 U.S.C. 41702, stating that there is no evidence that e-cigarettes have harmed anyone or that they pose any health or safety risks to users or non-users. The organization alleged that the NPRM deceives the public into believing that e-cigarettes emit smoke and pose health risks to users and non-users similar to those posed by cigarette smoke. Furthermore, it argued that none of the studies cited by the Department had found any hazardous levels of chemicals in e-cigarettes. The organization also asserted that the proposal is unenforceable, as e-cigarette consumers can use the products discreetly without anyone noticing because the vapor that is emitted is not visible. As evidence of this assertion, the organization stated that there have been no citations issued for violating indoor e-cigarette usage bans in New Jersey, Seattle, or other jurisdictions where e-cigarettes have been banned. Finally, the organization noted that violators of the Department's proposed rule would face a $3,300 fine, which the organization claimed is excessive and may violate the 8th Amendment's prohibition against cruel and unusual punishment.

The Consumer Advocates for Smoke-Free Alternatives Association (CASAA) and the Competitive Enterprise Institute (CEI) submitted a comment urging the Department to withdraw its proposed ban, and cited reasons for its opposition similar to those offered by Smokefree Pennsylvania. CASAA and CEI challenged the Department's statutory authority, arguing that the statutory ban on in-flight smoking, 49 U.S.C. 41706, does not extend to smoke-free products such as e-cigarettes. Also, these organizations argued that the Department's reliance on 49 U.S.C § 41702 is misplaced, as there is no research indicating that e-cigarette vapor, with or without nicotine, is harmful to users or bystanders. The organizations cited a Health New Zealand report where e-cigarette mist

was tested for over 50 cigarette smoke toxicants, and no such toxicants were found. CASAA and CEI additionally argued that the Department has failed to perform a cost-benefit analysis and has not demonstrated that the ban would produce any benefits; the American Aviation Institute echoed this view. Lastly, CASAA and CEI stated that the possible civil penalty of $3,300 for violating part 252 is not justified, as e-cigarettes would not impair cabin air quality or cause damage to aircraft seats or carpeting.

We now turn to comments received from the public. By the end of the comment period on November 15, 2011, the Department received approximately 700 total comments; approximately 500 of those were from individuals opposed to the proposed ban. (Many of the comments received in opposition to the proposed rule were identical.) The purported lack of DOT jurisdictional authority to create the proposed rule and lack of research, data, evidence, or proof to support the rule were common themes. Many felt that the Department was overstepping its statutory authority, and argued that e-cigarettes are not smoked, but ''vaped'' (producing water vapor), and as such do not fall within the smoking statute, section 41706. Also, many felt that the Department failed to justify the proposed ban under section 41702 because it did not provide any evidence that e-cigarettes are harmful to bystanders. Some individuals asserted that there have not been any reported health issues with respect to the devices and stated that lack of evidence cannot be the basis for a rule. Many argued that the proposed rule was an example of unnecessary government regulation, and that the better approach would be to allow the industry to devise its own rules for the products. It was also argued that the proposed regulation would be unenforceable because users can easily hide their use of e-cigarettes. Finally, some argued that the civil penalty associated with a violation of the proposed rule is excessive and illegal under the 8th Amendment.

Supporters of the rule generally viewed the Department as having the appropriate authority and stated that the unknown risk and potential harmful effects justified the ban. Many voiced concern over the air quality aboard aircraft, stating that the rights and public health concerns of passengers who are not e-cigarette users should be protected, as these people do not have the option of leaving the space. Supporters also raised the point that potentially vulnerable passengers, such as children, the elderly, and people with asthma should be protected from the effects of e-cigarette vapor. Another reason cited in support of the rule was the elimination of potential passenger and crew confusion; supporters argued that a ban on both traditional cigarettes and e-cigarettes would make enforcement of the smoking regulation easier for crewmembers, because e-cigarettes resemble traditional cigarettes. It was also stated that this proposed rule would create only minimal inconvenience for smokers and ''vapers,'' as the existing smoking ban on aircraft has been in place since 2000.

In more recent years, the Department has noted a substantial increase in individual comments supporting the ban. Of the approximately 350 additional individual comments received after the close of the comment period, approximately 60 opposed the ban while approximately 290 supported it. Most commenters supporting the ban cited health concerns, and expressed the view that e-cigarette aerosol was either already demonstrated to be harmful, or should be banned unless it is proven to be safe. A number of individuals expressed impatience at the Department's slow progress in implementing the ban.

We note that several commenters, both organizations and individuals, cited safety reasons as additional grounds for supporting the proposed ban (*e.g.,* potential fire concerns and hazards associated with the lithium batteries that power the devices).

DOT Response

After fully considering the comments received, the Department has decided to amend its existing smoking rule to explicitly ban the use of e-cigarettes on all flights in passenger interstate, intrastate and foreign air transportation where other forms of smoking are banned. We are primarily concerned with the potential adverse health effects of secondhand exposure to aerosols generated by e-cigarettes, particularly in the unique environment of an aircraft cabin. We further believe that the ban on the use of e-cigarettes fulfills the statutory mandates of sections 41706, 41702, and 41712. We do not address in this rulemaking any safety-related issues that may exist with regard to the use of e-cigarettes aboard aircraft. The Pipeline and Hazardous Materials Safety Administration (PHMSA) regulates hazardous materials safety [6] and the FAA regulates smoking aboard aircraft under its safety mandate. *See* 14 CFR 121.317, 129.29, 135.127.

Authority To Regulate E-Cigarettes Under 49 U.S.C. 41706

We begin with section 41706, the statutory smoking ban. With respect to domestic air transportation, section 41706(a) provides that ''an individual may not smoke in an aircraft in scheduled passenger interstate or intrastate air transportation; or in an aircraft in nonscheduled passenger interstate or intrastate air transportation if a flight attendant is a required crewmember on the aircraft.'' Similarly, with respect to foreign air transportation, section 41706(b) provides that ''the Secretary of Transportation shall require all air carriers and foreign air carriers to prohibit smoking in an aircraft in scheduled passenger foreign air transportation; and in an aircraft in nonscheduled passenger foreign air transportation, if a flight attendant is a required crewmember on the aircraft.''

While section 41706 does not define 'smoking,'' nothing in the text of section 41706 suggests that the definition of ''smoking'' should be limited to the combustion of traditional tobacco products. Instead, Congress vested broad authority in the Department to implement the statutory smoking ban. Specifically, section 41706(d) states that ''the Secretary shall provide such regulations as are necessary to carry out this section.'' We interpret section 41706 as a whole as vesting the Department with the authority to define the term ''smoking,'' and to refine that definition as necessary to effectuate the purpose of the statute while adapting to new technologies and passenger behavior. Like section 41706, the Department's regulation in 14 CFR part 252 did not contain a definition of ''smoking'' prior to the issuance of this final rule. However, the Department has previously taken the position that the prohibition against smoking in 49 U.S.C. 41706 and 14 CFR part 252 should be read to ban the use of electronic cigarettes on U.S. air carrier and foreign air carrier flights in scheduled intrastate, interstate and foreign air transportation, a position that was noted in connection with a June 17, 2010 hearing before the Senate Committee on Commerce, Science and Transportation. This final rule formalizes the Department's interpretation by defining smoking to explicitly include the use of e-cigarettes.

[6] With respect to the Independent Pilots Association's comment that DOT should expand the ban on e-cigarettes to include cargo flights, we note that the Association's concern appears to be largely on the safety hazards of transporting lithium batteries. On August 6, 2014, PHMSA issued a final rule addressing this issue. See 79 FR 46011 (August 6, 2014); PHMSA–2009–0095 (HM–224F).

Some commenters contend that section 41706 cannot be relied upon to reach this result because it prohibits smoking, and e-cigarettes are ''vaped'' and produce a vapor. Although e-cigarettes typically do not undergo combustion, they do produce an aerosol of chemicals and require an inhalation and exhalation action similar to that which is required when smoking traditional cigarettes. E-cigarettes are generally designed to look like and be used in the same manner as conventional cigarettes. Further, the purpose behind the statutory ban on smoking aboard aircraft in section 41706 and the regulatory ban on smoking tobacco products in part 252 were to improve cabin air quality, reduce the risk of adverse health effects on passengers and crewmembers, and enhance passenger comfort. The in-cabin dynamics of e-cigarette use are similar enough to traditional smoking to necessitate including e-cigarette use within the definition of ''smoking.'' Like traditional smoking, e-cigarette use introduces a cloud of chemicals into the air that may be harmful to passengers who are confined in a narrow area within the aircraft cabin without the ability to avoid those chemicals.

A recent study published in the journal *Nicotine & Tobacco Research* found that e-cigarettes are a source of secondhand exposure to nicotine but not to combustion toxicants.[7] The conclusions of the study were that using e-cigarettes in indoor environments may involuntarily expose non-users to nicotine, and that more research is needed to evaluate the health consequences of secondhand exposure to nicotine, especially among vulnerable populations such as children, pregnant women, and people with cardiovascular conditions. More recent research has determined that persistent residual nicotine on indoor surfaces from e-cigarettes can lead to third hand exposure through the skin, inhalation, and ingestion long after the air itself has cleared.[8]

Additionally, we find it significant that the three medical associations that submitted comments cited the unknown health risks of exposure to e-cigarette aerosol in a confined space as a reason for concern. Also citing public health concerns were the American Cancer Society, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Legacy. In addition, each comment received from the airline industry voiced strong support for the rule, based on the unknown ingredients in the devices and their possible health consequences.

While the specific hazards of e-cigarette aerosol have not yet been fully identified, the Department does not believe that it would be appropriate to exempt e-cigarettes from the ban for now, pending a more definitive catalog of those hazards. Since the NPRM was issued, research continues to undermine claims that the use of e-cigarettes would have no adverse health implications on users or others who are nearby. Research has detected toxic chemicals such as formaldehyde and acetaldehyde in the aerosol from certain e-cigarettes.[9] The aerosol was also found to contain acrolein, which can cause irritation to the nasal cavity and damage to the lining of the lungs, and may contribute to cardiovascular disease in cigarette smokers.[10] Another study identified 22 chemical elements in e-cigarette aerosol, including lead, nickel, and chromium, among others that can cause adverse health effects in the respiratory and nervous systems.[11]

Some studies have found that lower levels of toxicants are observed in e-cigarette aerosols than in combusted tobacco smoke.[12] However, research on near real-use conditions of e-cigarettes has found increased indoor air levels of polycyclic aromatic hydrocarbons; 1,2-propanediol; 1,2,3-propanetriol; glycerine; nicotine; fine particles; ultrafine particles; particle number concentrations; and aluminum, all of which raise health concerns.[13] We recognize that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. Because the potential for harm to consumers from second hand aerosol is even greater in the closed environment of an aircraft, we believe a precautionary approach is warranted. In sum, releasing an aerosol that may contain harmful substances or respiratory irritants in a confined space, especially when those who are at a higher risk are present, is contrary to the statutory ban on smoking aboard aircraft.

Authority To Regulate E-Cigarettes Under 49 U.S.C. 41702

We also find an independent source of authority for this rulemaking in section 41702, which mandates safe and adequate interstate air transportation. The Department's predecessor, the Civil Aeronautics Board (CAB), relied upon section 404(a) of the Federal Aviation Act of 1958 (subsequently re-codified as 41702), requiring air carriers ''to provide safe and adequate service, equipment and facilities,'' as authority to adopt its first regulation restricting smoking on air carrier flights (ER–800, 38 FR 12207, May 10, 1973). At that time, CAB issued a ''smoking rule'' under its economic regulations titled, ''Part 252—Provision of Designated 'No Smoking' Areas Aboard Aircraft Operated by Certificated Air Carriers,'' which mandated designated ''no smoking'' areas on commercial flights. See 38 FR 12207 (May 10, 1973). The rule predated a Congressional ban on smoking on scheduled flights. In the preamble to the 1973 rule, the CAB cited a joint study by the FAA and the then Department of Health, Education, and Welfare that concluded that the low levels of contaminants in tobacco smoke did not represent a health hazard to nonsmoking passengers on aircraft; however, the study found that a significant portion of the nonsmokers stated that they were bothered by tobacco smoke. The CAB stated, ''unlike persons in public buildings, nonsmoking passengers on aircraft may be assigned to a seat next to, or otherwise in close proximity to, persons who smoke and cannot escape this

[7] Jan Czogala et al., *Secondhand Exposure to Vapors From Electronic Cigarettes,* 16 Nicotine & Tobacco Research 655 (2014), doi: 10.1093/ntr/ntt203.

[8] ML Goniewicz & L Lee, *Electronic Cigarettes Are a Source of Thirdhand Exposure to Nicotine,* Nicotine Tob Res. 2014 Aug 30. pii:ntu152. [Epub ahead of print]; *see also* WG Kuschner *et al., Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging Health Care Challenges for the Primary Care Provider,* 4 Int J Gen Med. 115 (2011), doi: 10.2147/IJGM.S16908.

[9] Goniewicz, M. L., J. Knysak, M. Gawron, *et al., Levels of Selected Carcinogens and Toxicants in Vapour From Electronic Cigarettes,* 23 *Tobacco Control 133 (2013), doi: 10.1136/tobaccocontrol–2012–050859.*

[10] Goniewicz, M. L., J. Knysak, M. Gawron, *et al., Levels of Selected Carcinogens and Toxicants in Vapour From Electronic Cigarettes,* 23 *Tobacco Control 133 (2013), doi: 10.1136/tobaccocontrol–2012–050859.*

[11] Williams, M., A. Villarreal, K. Bozhilov, *et al., Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol,* 8 *Public Library of Science One* e57987 (2013), doi: 10.1371/journal.pone.0057987.

[12] Goniewicz, M., et al., ''Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes,'' *Tobacco Control,* 23(2):133–139, 2014.

[13] Schober, W., et al., *Use of Electronic Cigarettes (E-Cigarettes) Impairs Indoor Air Quality and Increases FeNO Levels of E-Cigarette Consumers,* 217 Int J Hyg Environ Health 628 (2014), doi: 10.1016/j.ijheh.2013.11.003; Schripp T., D. Markewitz, E. Uhde, and T. Salthammer, *Does E-Cigarette Consumption Cause Passive Vaping?,* 23 Indoor Air 25 (2013), doi: 10.1111/j.1600–0668.2012.00792.x.

environment until the end of the flight.'' The principal basis for the 1973 smoking rule was passenger discomfort issues. Just as the CAB relied on the ''adequate'' prong of the predecessor to section 41702 to adopt a smoking ban in 1973, the Department believes that it has the authority today to ban the use of e-cigarettes under section 41702 to ensure ''adequate'' service by reducing a similar kind of passenger discomfort. In our view, passenger discomfort arises from at least two aspects of e-cigarette aerosol exposure. First, the non-user passenger may feel the direct effects of inhaling the aerosol, which, as noted above, has been shown to contain respiratory irritants. More broadly, passengers may reasonably be concerned that they are inhaling unknown quantities of harmful chemicals, and that they will not be able to avoid the exposure for the duration of the flight.

Authority To Regulate E-Cigarettes Under 49 U.S.C. 41712

In addition to the Department's authority under sections 41716 and 41702, the Department has the authority and responsibility to protect consumers from unfair or deceptive practices in air transportation under 49 U.S.C. 41712. Using this authority, the Department has found practices to be ''unfair'' if they are harmful to passengers but could not be reasonably avoided by them. For example, the Department relied upon section 41712 and its ''unfair'' practice component when promulgating the ''Tarmac Delay Rule,'' [14] in which the Department addressed problems consumers face when aircraft sit for hours on the airport tarmac. In doing so, the Department considered the harm to the consumer and the fact that the harm was unavoidable. The Department concluded that regulatory action was necessary and that a three-hour time limit is the maximum time after which passengers must be permitted to deplane from domestic flights given the cramped, close conditions in aircraft and the inability of passengers to avoid lengthy tarmac delays. Here, as with the tarmac delay rule, the Department believes that the practice of allowing use of e-cigarettes onboard aircraft would be potentially harmful to passengers and there is no way for the passenger to reasonably avoid the harm. The harms include the potential for decreased cabin air quality, confusion about whether the passenger is being exposed to traditional cigarette smoke, and possible health risks arising from exposure to the chemicals contained in e-cigarette aerosol. These harms are unavoidable because passengers who do not wish to be exposed to e-cigarette aerosol cannot escape this environment until the end of the flight.

In sum, we are amending our existing smoking regulation to explicitly ban the use of e-cigarettes because we view the ban to be consistent with the statutory mandates of sections 41706, 41702 and 41712. We do not believe that it is appropriate, as some commenters have suggested, to allow the airline industry to adopt its own standards with respect to the inclusion of electronic cigarettes within the prohibition on smoking. We recognize that the industry has generally banned the use of electronic cigarettes on flights, either as a matter of preference or in recognition of the Department's well-publicized enforcement policy. On the other hand, we believe that without a clear, uniform regulation, some carriers may feel free to adopt policies that allow the use of e-cigarettes onboard aircraft. In light of the potential health hazards posed to flight attendants and fellow passengers, as well as the potential diminution in air cabin quality posed by the use of electronic cigarettes in an aircraft cabin, we do not believe that a free-market approach is appropriate or desirable.

An additional benefit of this rule is that it eliminates passenger or crewmember confusion with regard to the permissibility of e-cigarettes by creating an explicit ban. In our notice, we stated that through Congressional correspondence, anecdotal evidence, and online sources, including blogs, we were made aware that some passengers have attempted to use e-cigarettes onboard aircraft. The Association of Flight Attendants also stated in comments submitted to the Department that it receives occasional reports of in-flight passenger use and confusion among travelers regarding airline policies. In the absence of regulation, e-cigarette users may believe that an airline's policy banning e-cigarettes is merely a preference, and that they may continue to use such devices because they are not prohibited by federal law. This rule would eliminate any such arguments with respect to the use of e-cigarettes, and provide flight crew with the clear message that e-cigarettes are placed firmly on the same footing as traditional tobacco products. The traveling public would also have the benefit of knowing with certainty that e-cigarettes are prohibited onboard aircraft, Moreover, to the extent that carriers may be inclined to permit e-cigarettes on the ground that the Department's enforcement policy is not consistent with the regulatory text, this rule would preclude that option.

Charter (Non-Scheduled) Flights

Section 401 of the FAA Modernization and Reform Act of 2012 prohibited smoking on domestic nonscheduled (charter) passenger flights that require a flight attendant, and directed the Department to prohibit smoking on nonscheduled (charter) passenger flights in foreign air transportation that require a flight attendant. In the NPRM in this proceeding, we sought comment on the issue of banning smoking on most charter flights. We received few comments on this issue; however, those that did comment overwhelmingly supported the proposal. The Association of Flight Attendants (AFA) stated its support for the ban, claiming that it would be beneficial to the occupational health of flight attendants and the health of the traveling public. AFA stated that there is virtually universal agreement that exposure to environmental tobacco smoke is harmful to health, and requested that DOT acknowledge these findings and expand the smoking ban to all charter operations.

The Association of Professional Flight Attendants, representing American Airlines flight attendants, stated its support of the ban to create consistency across the industry and argued that no flight attendant should be subjected to cigarette smoke on an airplane, given what is known about secondhand smoke.

The American Cancer Society, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Legacy stated that the health effects of secondhand smoke are well established in scientific literature. The organizations argued that charter flight staff should not be exposed at their workplace to secondhand smoke, which has been shown to increase risk of heart disease, stroke, and cancer. These organizations expressed their concern that charter flight passengers are potentially exposed to secondhand smoke for extended periods of time in a confined space. The organizations argued that there is no safe level of exposure to secondhand smoke, regardless of the type of plane or flight one takes, and that the current regulations do not effectively protect public health. We received a few comments from the public on this issue, with most stating their support for the proposal and some suggesting extending the ban to all flights.

[14] See 74 FR 68983 (December 30, 2009) and 76 FR 23110 (April 25, 2011).

DOT Response

We are amending the rule text of part 252 to implement section 401 of the FAA Modernization and Reform Act. Section 401 requires U.S. and foreign air carriers to ban smoking in nonscheduled passenger interstate, intrastate, and foreign air transportation where a flight attendant is a required crewmember. The amendment to part 252 is necessary to harmonize the Departmental regulation with the new statutory requirement.[15] The 2011 NPRM sought comment on banning smoking on charter flights that use aircraft with 19 or more passenger seats. In view of the statutory smoking ban in section 401 that was signed into law in 2012, this final rule conforms part 252 to the requirement in the statute. Consequently, this new rule bans smoking on all nonscheduled passenger air transportation where a flight attendant is a required crewmember of the aircraft.

The rule also continues a ban on smoking on nonscheduled passenger air transportation where a flight attendant is *not* a required crewmember of the aircraft, except for single entity charters and on-demand services of air taxi operators. Under the existing sections 252.2 and 252.13, U.S. carriers are required to ban smoking on all flights (scheduled and charter) that use aircraft with 30 or fewer passenger seats except for the on-demand services of air taxi operators. Section 252.19 of the existing rule permits smoking on single-entity charter flights of U.S. air carriers. In other words, under the existing rule, smoking is allowed on single-entity charter flights and on-demand services of air taxi operators regardless of aircraft size. For U.S. carriers, smoking is prohibited on all other charter flights that use aircraft with 30 or fewer passenger seats.

If an aircraft has more than 30 seats, under section 252.7 of the existing rule the air carrier operating the charter flight (other than single-entity charters or on-demand services of air taxi operators) must establish a non-smoking section for each class of service. As an organizational matter, we are eliminating this section as it is no longer needed because section 401 bans smoking on charter flights where a flight attendant is a required crewmember. All charter flights covered under section 252.7 would require a flight attendant as that section only applies to aircraft with more than 30 seats.

The only change that is not directly required by the statute is eliminating the requirement in the existing rule for carriers to give notice to each passenger on a single-entity charter of the smoking procedures for that flight. It would be of limited usefulness to have such a requirement where smoking on single-entity charters would not be banned by this rule (*i.e.,* on aircraft where a flight attendant is not a required crewmember, which essentially means aircraft with 19 seats or less).

[15] For the reasons discussed in the prior section, this ban will include the use of e-cigarettes.

Regulatory Analysis and Notices

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review) and DOT Regulatory Policies and Procedures

This final rule has been determined to be significant under Executive Order 12866 and the Department of Transportation's Regulatory Policies and Procedures. It has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review) and is consistent with the requirements in both orders.

The Final Regulatory Evaluation, included in this section, qualitatively evaluates the benefits and costs of the final rule. Both benefits and costs are expected to be very small because the final rule only represents a modest change, if any, to existing industry practice. Nonetheless, the Department believes that the rule is necessary for the reasons noted below. As discussed below, DOT was unable to find any airline that explicitly states that it allows smoking of any type or includes accommodating smokers in its business plan, including e-cigarettes and their users, and as such, would be affected by this rule. In fact, the overwhelming majority of passenger seats are on scheduled flights where smoking traditional cigarettes is already banned. Moreover and again as discussed below, commercial airlines have interpreted the existing DOT smoking ban to cover e-cigarettes and do not allow their use. Due to the inability to identify any specific airlines that would have to change their policies in response to the final rule, it was not possible to quantify benefits or costs. However, DOT does not rule out the possibility that a few airlines may at times provide services that could be affected by the rule, and therefore provides a qualitative analysis of potential benefits and costs for those situations.

The Final Regulatory Evaluation

Introduction

In April 2000, the *Wendell H. Ford Aviation Investment and Reform Act for the 21st Century* (Pub. L. 106–181) was signed into law. Section 708 of the Act amended 49 U.S.C. 41706 to impose a ban on smoking on all *scheduled* passenger interstate, intrastate, and foreign air transportation. DOT subsequently incorporated this ban in its rule on smoking on commercial airline flights. Because of confusion as to whether the use of e-cigarettes was allowed on aircraft, in September 2011, DOT issued a NPRM (see 79 FR 57008), which proposed to amend 14 CFR part 252 to explicitly include the use of e-cigarettes in the smoking ban. Specifically, the NPRM proposed to define smoking as, ''the smoking of tobacco products or use of electronic cigarettes and similar products designed to deliver nicotine or other substances to a user in the form of vapor.'' The NPRM also considered whether to extend the smoking ban (including e-cigarettes) to nonscheduled passenger flights or air carriers and foreign air carriers between points in the United States and between the United States and any foreign point with aircraft that have a designed seating capacity of 19 or more passenger seats.

In February 2012, the *FAA Modernization and Reform Act of 2012* (Pub. L. 112–95) (the Act) was signed into law. Section 401 of the Act amended 49 U.S.C. 41706 to extend the smoking prohibition to aircraft in *nonscheduled* passenger interstate, intrastate, and foreign air transportation, offered by both U.S. and foreign carriers, if a flight attendant is a required crewmember.

This final rule primarily makes two regulatory changes. First, it amends the existing smoking ban in 14 CFR part 252 to explicitly ban the use of e-cigarettes whenever smoking is banned by revising the definition of smoking to cover the use of e-cigarettes. Second, the rule amends 14 CFR part 252 to implement section 401 of the FAA Modernization and Reform Act and extends the smoking ban to flights in nonscheduled interstate, intrastate, and foreign passenger air transportation where a flight attendant is required.

Current Industry Practice/Regulatory Baseline

In 2014, there were a total of 104 U.S. carriers and 151 foreign air carriers providing service in the United States. About 75 percent of these carriers provided scheduled service and the remaining 25 percent provided only

charter service. However, the overwhelming majority of air passenger service is provided by the 75 percent of scheduled service carriers; in 2014, roughly 99 percent of U.S. passenger enplanements were associated with scheduled flights.[16] Table A.1 provides an overview of the carriers providing service in the United States in 2014.

TABLE A.1—CARRIERS OPERATING IN THE U.S. MARKET BY SIZE AND TYPE OF SERVICE

	Seats on largest aircraft	Total carriers	Charter only	Scheduled service
U.S. Carriers	>60	41	13	28
	30–60	15	2	13
	<30	48	11	37
U.S. Carrier Total		104	26	78
Foreign Carriers	>60	123	12	111
	30–60	2	0	2
	<30	26	25	1
Foreign Carrier Total		151	37	114

Source: DOT contractor estimates based on 2014 T–100 segment database, 2013 B–43 aircraft inventory, Regional Airline Association 2014 Annual Report and review of carrier Web sites.

14 CFR part 252 currently bans smoking on all scheduled passenger interstate, intrastate, and foreign air transportation. Thus, as noted above, the overwhelming majority of flights are covered by the general smoking ban (75 percent of carriers representing 99 percent of passenger enplanements). No regulatory definition of ''smoking'' is included in the existing Part 252, and questions have emerged regarding its applicability to e-cigarettes. DOT has stated that e-cigarettes are covered by its existing smoking rule, part 252.[17] Based upon DOT review of individual Web sites, U.S. and foreign carriers generally appear to be in compliance with this interpretation and do not allow their use. While some carriers provide no explanation for their interpretation, some airlines cite a ''nuisance factor,'' concerns for triggering smoke detection equipment, and concerns for other passengers' health. Exhibit A.1 lists some typical examples of e-cigarette policies taken from a select number of the 104 individual U.S. carrier and 151 foreign carrier Web sites.

EXHIBIT A.1—ELECTRONIC CIGARETTE POLICIES FOR SELECTED CARRIERS

AirTran Airways—''In addition to smoking, the use of chewing tobacco and electronic cigarettes are not permitted onboard any scheduled or private charter AirTran Airways flight.''

Alaska Airlines—''Smoking, chewing tobacco, smokeless tobacco, and the use of electronic smoking devices are not permitted on any Alaska Airlines flight.''

American—''You can travel with electronic cigarettes in your carry-on baggage, but you are not allowed to use them onboard at any time.''

Delta—''E-cigarettes cannot be operated at any time on a Delta or Delta Connection Aircraft.''

JetBlue—''While the majority of electronic cigarettes may be non-hazardous, JetBlue does NOT allow the USE of them on any of our flights, but will allow them in checked or carry-on baggage. It is considered a nuisance item as small amounts of vapor are expelled from the cigarette.''

Southwest—''Electronic Cigarettes and Smoking Devices'' are ''never permitted'' for use on board.

United—''The use of electronic, simulated smoking materials (such as electronic cigarettes, pipes or cigars) is prohibited on United Airlines.''

Air France—''Use of e-cigarettes is prohibited on all Air France flights. The vapor emitted by these devices may trigger the cabin smoke detectors.''

Air New Zealand—''The use and charging of electronic cigarettes (eCigarettes) is also not permitted as the vapour may contain levels of nicotine that are unacceptable to other passengers.''

British Airways—''We have a no smoking policy on board all our aircraft and in our airport lounges. This includes electronic cigarettes (e-cigarettes), as they emit a small amount of mist which can make it appear that a customer is actually smoking.''

KLM—''All KLM flights are non-smoking flights. Smoking is not permitted at any place or at any time on board our aircraft. This also applies to artificial cigarettes.''

Lufthansa—''Please note, however, that you are not permitted to smoke electronic cigarettes on board Lufthansa flights.''

Source: Individual carrier Web sites.

For the remaining 25 percent of carriers providing only charter service (representing about one percent of passenger enplanements), smoking is not prohibited by law in all cases. On flights where smoking is not banned by law, airlines must have a non-smoking section and must accommodate in that section every passenger who has complied with the airline's check-in deadline and who wishes to be seated there.

Apparently, however, charter airlines have taken a direction similar to rental car companies and hotels, where nonsmoking policies are now the norm.[18] Finding a charter that allows in-flight smoking or guarantees a smoker's right to engage in the activity has become difficult, if not impossible. According to one Web site that assists in booking charters:

''. . . some charter operators such as GlobeAir have a strict no-smoking policy across their fleet. 'It got to the point where we felt that smoking on board not only posed

[16] Source: Bureau of Transportation Statistics, T–100 Market and Segment (*http://www.rita.dot.gov/bts/data_and_statistics/by_mode/airline_and_airports/airline_passengers.html*).

[17] See *https://www.transportation.gov/sites/dot.gov/files/docs/PolicyOnECigarettes.pdf*.

[18] *http://usatoday30.usatoday.com/travel/hotels/2008-11-17-smoke-free-hotels-no-smoking_N.htm*; *http://consumertraveler.com/today/still-smoking-be-careful-before-you-rent-a-car/*.

a health hazard but also increases the risk of fire,' says Bernhard Fragner, CEO.'' [19]

And another:

''Alot (sic) of the air charter aircraft are now non-smoking due to fact that all airline flights are now non-smoking flights. Charter operators complain that the tobacco smell from smoking gets into the fabric of their airplanes and bothers the next passenger(s).'' [20]

And, according to a charter company: [21]

''All Skyward Aviation aircraft prohibit smoking to ensure the complete safety of passengers and flight crew members.'' [22]

While some charters address the use of e-cigarettes and include them in their smoking prohibitions, it is unknown whether this is standard practice.

There are incentives for charter airlines to voluntarily adopt smoking bans despite the lack of a legal requirement. In the case of domestic charters, assuring the accommodation of nonsmoking passengers in a nonsmoking section in accordance with the law could create some planning difficulties unless a service provider knows in advance the smoking status of each passenger; it is easier and requires less planning to simply disallow the activity. Moreover, to attract customers, many of these carriers advertise receipt of various safety certifications (*e.g.,* the FAA's Diamond Award of Excellence, Argus rated, AACA Medallion) as part of their marketing strategy. Permitting passengers to smoke onboard would be at odds with the standards of the certifying organizations. Finally, and perhaps most importantly, it is more costly to operate aircraft where smoking is permitted. Smoking increases hardware costs since cabin air filters have to be changed more frequently and avionics need to be cleaned more often. The higher expense associated with maintenance of aircraft in which smoking is allowed deters carriers from allowing the activity, unless of course, the increase in expense is justified by a net increase in demand from smokers (and thus revenues) to cover these costs.[23] It is unclear whether these incentives apply to e-cigarettes.

An internet search yields a few anecdotes suggesting some smokers have been frustrated by the lack of options for those who wish to smoke during flight, which is a further indication that the industry norm has tended toward smoking prohibition, at least for traditional cigarettes. There have been some limited attempts to market flights for smokers or create a ''smokers airline'' which would allow or even encourage passengers to smoke during flight. However, none of these efforts have been successful to date.[24] This probably reflects that a consumer's decision regarding which flight to purchase is complicated, involving price, availability, safety record or perceptions, and multiple other attributes. The ability to smoke on a flight would only be one aspect, and probably a very small one, in the overall decision. In addition, one would expect that at least some customers would purposely avoid flights that allowed smoking. Due to relative importance of other attributes (*i.e.* price), there are limits to how successful carriers who focus exclusively on attracting smokers can be.

In sum, at least 99 percent of passenger enplanements occur on flights that prohibit smoking of any type, including both traditional cigarettes and e-cigarettes. The remaining one percent of enplanements appears to be on charter flights that largely prohibit smoking of traditional cigarettes. Some of the charter companies also extend the prohibition to e-cigarettes, but the extent of that practice is unknown.

Need for the Rule

The involuntary exposure to second-hand smoke or e-cigarette aerosol in an airplane cabin represents one classic example of a market failure, an externality; the smoker (of either traditional or electronic cigarettes) does not bear the full cost of the activity. Part of the cost of smoking in an airplane cabin is borne by nearby passengers or flight crew who are unable to regulate their exposure. The costs of involuntary exposure to smoke or aerosol are in the form of actual adverse health consequences, perception and fear of adverse health consequences and annoyance or irritation regarding undesirable odors. Even if a carrier were to disclose that it allowed smoking (of either traditional cigarettes or e-cigarettes), patrons may not receive this information prior to departure or in the case of some smaller markets, they may not have a convenient option to avoid exposure by choosing an airline that disallowed use (which could represent another type of market failure, but not one that is the primary concern of this regulatory action).

Regarding e-cigarettes specifically, they typically do not involve combustion. However, they require an inhalation and exhalation action similar to smoking traditional cigarettes and they produce a cloud of aerosol which can be mistaken for smoke. E-cigarettes are generally designed to look like and be used in the same manner as conventional cigarettes. Passengers who do not engage in or understand the process of e-cigarette use can easily mistake the act for traditional smoking. Thus, even if second-hand exposure to e-cigarette aerosol were ever determined to not lead to the same type of health consequences as exposure to tobacco smoke, nearby passengers may still experience discomfort, stress or some in cases display aggression or fear because they believe their health is threatened. Currently, the state of knowledge regarding the effects of secondhand exposure to e-cigarette aerosol does not rule out the possibility of actual adverse health effects to nearby individuals who do not directly choose to engage in this activity. In fact, some research supports the case that bystanders incur actual adverse health effects when exposed to secondhand e-cigarette aerosol.

In the absence of a rule, carriers are free to make their own determinations regarding the use of e-cigarettes. Charter operations have historically had additional flexibility regarding smoking in general, as long as they accommodate nonsmoking patrons in accordance with the law (*e.g.,* no-smoking sections). Scheduled service providers have chosen to prohibit e-cigarette use and charters typically do not allow smoking of traditional cigarettes (some charters also prohibit e-cigarettes but the degree to which this is standard practice is unknown). Without this rule, it is

[19] *http://corporatejetinvestor.com/articles/how-to-charter-private-jet-503/.*

[20] *http://www.usskylink.com/resource/air-charter-faq-details.asp?fldNAME=Air%20Charter%20Flights.*

[21] A few other examples of explicit smoking prohibitions are as follows: Charter Air Transport, Inc. states ''Smoking is prohibited on all flights. . . . NOTE: This includes electronic cigarettes'' (see *http://www.charterairtransport.com/*); Avjet Corporation indicates that their entire charter fleet is nonsmoking (*http://www.avjet.com/*); Atlas Air's policy is that ''Smoking is prohibited on our Flights (*www.atlasair.com/aa/*); and Dynamic Airways conditions of service include ''Dynamic flights are non-smoking. Smoking cigarettes, regular and electronic, is not allowed onboard our aircraft, but chewing tobacco is allowed'' (*https://www.airdynamic.com*) . Interestingly one carrier addresses e-cigarette use with no reference to traditional smoking, ''You're not allowed to use electronic cigarettes on the plane'' (*http://www.thomson.co.uk/flight/0.*

[22] *http://www.skywardaviation.com/76/FAQ.html.*

[23] The increase would need to be net of the reduction in demand from passengers with an aversion to smoking.

[24] The names of these airlines were: Great American Smokers' Club, Smokers Express, Freedom Air, and Smintair. None ever commenced commercial operation (see, for example, *http://www.sourcewatch.org/index.php/Smokers_Express_Airlines; http://articles.chicagotribune.com/1993-10-03/travel/9310030004_1_flights-american-trans-air-smokers; http:///articles.chicagotribune.com/1993-10-03/travel/9310030027_1_freedom-air-smokers-passengers; http://www.nytimes.com/2006/09/03/business/worldbusiness/03iht-smoke.2683305.html*)

possible that some airlines could relax their current policies, which would increase passenger and flight crew secondhand exposure to aerosols and quite possibly, traditional tobacco smoke in the case of some charters.

Impacts, Benefits and Costs of the Final Rule

In general, the impacts of the rule will be very modest, and generate little in terms of measurable benefits and costs. There will probably be no change to the current baseline for scheduled passenger operations. The existing regulation prohibits smoking on such flights and as described above, airlines that provide scheduled passenger service treat the smoking ban as covering e-cigarettes. Scheduled operations represent roughly 99 percent of passenger enplanements and thus, the rule can do little to impact current industry practice overall.

For charter (nonscheduled) flight operations, the impacts should also be small. Based upon review of carrier Web sites and their advertisements, charter companies appear to prohibit smoking of traditional cigarettes. Operating a nonsmoking airline is less costly, makes accommodating non-smoking patrons in accordance with the law easier, and assists in the receipt of certain safety certifications and perhaps the award of government contracts that may serve as useful marketing tools. While it is not known with any certainty whether the prohibitions apply to e-cigarette use, the widespread and seamless adoption of e-cigarette bans in the scheduled service component of the industry suggests that extending the prohibitions to e-cigarettes can be accomplished without too much difficulty or cost.

Including E-Cigarettes in the General Smoking Ban: Benefits and Costs

As noted above, the inclusion of e-cigarettes in the general smoking ban will not affect, but will simply reinforce, current industry practice in the scheduled service segment of the airline industry. Consequently, the final rule probably will produce close to zero benefits and zero costs over the current baseline when considering impacts solely to and resulting from scheduled service providers. The inclusion of e-cigarettes may potentially have greater impact on nonscheduled or charter service and these potential impacts, as well as benefits and costs, are discussed below.

Conversely, if DOT were to determine that e-cigarettes were not covered under the ban, the current industry environment could be affected, more so than would be expected under this final rule. First, some carriers could incur new costs relative to the baseline due to the need to more actively enforce their prohibitions. This could occur if some consumers mistakenly interpret DOT's failure to enact a federal prohibition as ensuring their right to engage in e-cigarette use in an airplane cabin. Alternatively, some carriers might lift their prohibitions, which could reduce the burden on the minority of the population that uses e-cigarettes and whose activities are now restricted. However, removing e-cigarette restrictions would reduce benefits relative to the current baseline by exposing other passengers and flight crew to secondhand aerosols. Additionally, airlines would probably need to offer additional training to crew members and the pre-flight briefing would have to be longer, to educate and explain what, when and where particular smoking products may and may not be used.

The nonscheduled segment of the industry could potentially experience greater impact than the scheduled service segment, because while some charter airlines explicitly prohibit e-cigarette use, the extent to which this practice is standard or typical is unknown. However, the widespread adoption of an e-cigarette ban on the part of scheduled service airlines suggests that implementing an e-cigarette prohibition is not particularly costly, at least when a general smoking ban is already in place. To the extent that e-cigarette use is allowed on charter flights, a ban will add a burden to smoking patrons who will no longer be able to engage in the activity while in flight. The burden to smoking patrons will probably constitute the primary burden of the rule with respect to e-cigarettes. However, benefits will accrue to nearby passengers and crew who no longer are exposed to secondhand aerosol.

Implementation of Section 401 of the FAA Modernization and Reform Act: Benefits and Costs

The rule amends 14 CFR part 252 to implement section 401 of the FAA Modernization and Reform Act and extends the general smoking ban to nonscheduled interstate, intrastate, and foreign passenger air transportation when a flight attendant is required. To the extent that charter airlines allow smoking, the final rule will produce benefits in terms of reduced secondhand exposure to tobacco smoke, and the resulting positive health effects to nonsmoking passengers and flight crew. Again based upon a review of charter airline Web sites, most already prohibit smoking on their flights so the benefits of this nature are expected to be small.

There is no cost to operators for hardware related to smoking bans. In fact, smoking bans reduce hardware costs as cabin air filters do not have to be changed as frequently and avionics do not have to be cleaned as often, which is one reason that charter flights have opted to prohibit smoking, even when allowed by law. The American Aviation Institute, in its comments on the NPRM, raised the issue of additional costs due to new placards and notification lights, and re-printing of airline manuals.[25] These should not be significant costs associated with this final rule since all aircraft are already required to be equipped with no-smoking signs and lights. Some operators may feel the need to update documents used to communicate to passengers and employees the activities prohibited by law. However, such document update is not a direct requirement of the final rule and would be voluntary on the part of affected airlines. The costs of updating such materials should be small since most charter flights already do not allow smoking and probably have developed documents in support of their policies. In addition, such documents are routinely updated since laws regarding prohibited behaviors and security concerns are constantly evolving. An operator could reduce the costs of updating documents to reflect changes as they pertain to smoking by waiting until there is a more general need for updating.

To the extent that the rule, in effect, expands the existing ban on smoking (for traditional tobacco products and its extension to electronic cigarettes), there could be a cost to operators in the form of lost revenue or profits due to a reduction in demand for flights from customers who would wish to smoke on those flights. Such costs are largely speculative since they would apply to operators who allow smoking and consumers who chose their particular flights based primarily on the ability to smoke; DOT was unable to identify any businesses, successful or otherwise, operating under this model. Given that smokers will not have a smoking flight alternative (except perhaps chartering their own private flight where a flight attendant is not required), they will need to choose another transportation mode such as driving to their destination or if an alternative mode is

[25] Comments of the American Aviation Institute in the Matter of Smoking of Electronic Cigarettes on Aircraft, Docket DOT–OST–2011–0044, September 26, 2011.

not feasible, they would need to choose to not travel at all, if the ability to smoke was the primary consideration in their decision-making process. Or they might choose alternate nicotine delivery systems, such as patches and gum. The lack of flight alternatives coupled with the presence of alternative nicotine delivery systems will likely limit the reduction in demand that the small number of operators who would allow smoking could experience. In addition, any reduction in demand from smokers may, to some extent, be offset by increased demand from non-smokers.

Comparison of Costs to Benefits

Due to the inability to identify any specific carrier that would need to change its current practices significantly, DOT was unable to quantify the costs and the benefits of the rule, but believes both are probably very small. The overwhelming majority of passengers travel on scheduled service where smoking, including the use of e-cigarettes, is already prohibited. If smoking were to be allowed on nonscheduled flights, benefits of a ban would include reductions in potential exposure to secondhand smoke for passengers and crewmembers. Expanding the ban on smoking to cover e-cigarettes could reduce health hazards related to secondhand exposure to exhaled aerosols. The costs to operators should be minimal, but some passengers could experience some costs due to a reduced opportunity to smoke.

The risks and resulting adverse health consequences associated with secondhand exposure to tobacco smoke are well-documented.[26] Existing evidence indicates that e-cigarettes may also have adverse health impacts, not just for users, but for those nearby. Those seated next to users may not want to expose themselves (or their babies or older children) to the risks of these adverse health impacts and at least some crewmembers may prefer to work in an environment free of these risks since they fly far more frequently than most passengers. Due to the involuntary nature of the risk of secondhand exposure, the Department believes that it is prudent to give greater weight to the potential benefits of the rule than to the inconvenience costs incurred by smoking passengers or any small incremental costs incurred by airline operators.

Alternatives

DOT has identified only one viable regulatory alternative: A final rule that is limited in scope to solely to implementing Section 401 of the FAA Modernization and Reform Act. Such a rule would not alter the definition of smoking to cover e-cigarettes. DOT has determined that the alternative of ''no regulatory action'' (*i.e.* the status quo) is not viable since the Department is required to implement Section 401 of the FAA Modernization and Reform Act, at a minimum.

Restricting the rule to Section 401 implementation would represent the minimum regulatory action that the Department could undertake. To the extent that smoking of traditional cigarettes is occurring on nonscheduled interstate, intrastate, and foreign passenger air transportation when a flight attendant is a required crew member, there would still be some benefits related to reduced secondhand smoke exposure from traditional cigarettes.

This alternative would continue to allow airlines to develop their own policies regarding use of e-cigarettes, allowing them to change their current policies if they desire. If a carrier chose to change its policy, this would expose passengers and crewmembers to potentially harmful health risks. Also, any change in policy to allow for the use of e-cigarettes would require flight attendants to distinguish among various cigarettes and devices to determine which are acceptable. For example, the Air Line Pilots Association (ALPA) noted in their comments the possibility of passenger and crewmember confusion in differentiating e-cigarettes from tobacco cigarettes, as the two products can be difficult to distinguish from each other. In addition, carriers that do not change their policies could incur new costs due to the need to more actively enforce their prohibitions. This could occur if some consumers mistakenly interpret the lack of a federal prohibition as ensuring their right to engage in e-cigarette use in an airplane cabin. For these reasons, DOT rejected this alternative.

B. Regulatory Flexibility Analysis

DOT has examined the economic implications of this final rule for small entities as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Unless an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would lessen the economic effect of the rule on small entities. As discussed below, DOT finds that this final rule will not have a significant economic impact on a substantial number of small entities.

For purposes of rules promulgated by the Office of the Secretary of Transportation regarding aviation economic and consumer matters, an airline is a small entity for purposes of the Regulatory Flexibility Act if it provides air transportation only with aircraft having 60 or fewer seats and no more than 18,000 pounds payload capacity. Referring to Table A.1, this final rule applies to 63 (15 + 48) small U.S. carriers.[27] Of these small carriers, 50 (13 + 37), or about 79 percent, provide scheduled service and are subject to the general smoking ban. As noted above, scheduled service providers have overwhelmingly adopted prohibitions on e-cigarette use. DOT is unaware of any small scheduled service carrier that would need to change its e-cigarette policy in response to this final rule. In addition, the widespread industry ban on e-cigarettes suggests that it is quite easy to cover e-cigarettes once a smoking ban is in place. Thus, it is expected that the typical small scheduled service airline will experience no impacts due to this rule.

The remaining 13 (2 + 11) small airlines, or roughly 21 percent, provide nonscheduled or charter services. Based upon a review of their individual Web sites, none of these carriers cater their businesses to smoking patrons (smokers of either traditional or e-cigarettes). As noted above, providers of charter airplane service have several incentives to prohibit smoking of traditional cigarettes, including lower operating costs, ease of accommodating nonsmoking patrons, and meeting the standards necessary for receipt of safety certifications and government contracts. In addition, several of the small charter airlines have fleets that consist of extremely small aircraft (*i.e.* Cessnas or other planes that seat fewer than 10 passengers), and smoking is already banned on these aircraft (see existing section 252.13). Moreover, some of these companies provide medical transportation services, which is likely at odds with a permissive smoking policy. While it is not known with any certainty whether these factors also represent incentives to restrict e-cigarette use, the swift adoption of e-cigarette bans in the scheduled service component of the industry suggests that extending the prohibitions to e-

[26] See, for example: *http://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/*/ ; *http://www.lung.org/stop-smoking/smoking-facts/health-effects-of-secondhand-smoke.html?referrer=https://www.google.com/*

[27] RFA analysis is typically limited to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities.

cigarettes can be accomplished without too much difficulty or cost once a ban on smoking is already in place.

For the reasons described about, the final rule is unlikely to produce a significant financial impact on any small carrier, and probably will not affect their operations in any meaningful way. Therefore, the Secretary of Transportation certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 13132 (Federalism)

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This regulation has no substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. It does not contain any provision that imposes substantial direct compliance costs on State and local governments. It does not contain any provision that preempts state law, because states are already preempted from regulating in this area under the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13084

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the measures in the rule will significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing notice of and a 60-day comment period on, and otherwise consult with members of the public and affected agencies concerning, each proposed collection of information. This rule imposes no new information reporting or record keeping necessitating clearance by the Office of Management and Budget.

F. National Environmental Policy Act

The Department has analyzed the environmental impacts of this final rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. *Id.* Paragraph 3.c.6.i of DOT Order 5610.1C categorically excludes ''[a]ctions relating to consumer protection, including regulations.'' The purpose of this rulemaking is to extend the smoking ban in 14 CFR part 252 to include all charter flights where a flight attendant is a required crewmember and to ban the use of e-cigarettes. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

G. Unfunded Mandates Reform Act

The Department analyzed the final rule under the factors in the Unfunded Mandates Reform Act of 1995. The Department considered whether the rule includes a 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 annually for inflation) in any one year. The Department has determined that this final rule will not result in such expenditures. Accordingly, this final rule is not subject to the Unfunded Mandates Reform Act.

List of Subjects in 14 CFR Part 252

Air carriers, Aircraft, Consumer protection, Smoking.

Issued in Washington, DC, on February 19, 2016 under authority delegated in 49 CFR 1.27(n).

Kathryn B. Thomson,

General Counsel.

For the reasons stated in the preamble, the Office of the Secretary of Transportation amends 14 CFR part 252 as set forth below:

PART 252—[AMENDED]

■ 1. The authority citation for 14 CFR part 252 is revised to read as follows:

Authority: Pub. L. 101–164; 49 U.S.C. 40102, 40109, 40113, 41701, 41702, 41706 as amended by section 708 of Pub. L. 106–181 and section 401 of Pub. L. 112–95, 41711, and 46301.

■ 2. Section 252.1 is revised to read as follows:

§ 252.1 Purpose.

This part implements a ban on smoking as defined in § 252.3, including the use of electronic cigarettes and certain other devices, on flights by air carriers and foreign air carriers.

■ 3. Section 252.2 is revised to read as follows:

§ 252.2 Applicability.

This part applies to operations of air carriers engaged in interstate, intrastate and foreign air transportation and to foreign air carriers engaged in foreign air transportation.

■ 4. Section 252.3 is revised to read as follows:

§ 252.3 Definitions.

As used in this part:

Air carrier means a carrier that is a citizen of the United States undertaking to provide air transportation as defined in 49 U.S.C. 40102.

Foreign air carrier means a carrier that is not a citizen of the United States undertaking to provide foreign air transportation as defined in 49 U.S.C. 40102.

Smoking means the use of a tobacco product, electronic cigarettes whether or not they are a tobacco product, or similar products that produce a smoke, mist, vapor, or aerosol, with the exception of products (other than electronic cigarettes) which meet the definition of a medical device in section 201(h) of the Federal Food, Drug and Cosmetic Act, such as nebulizers.

■ 5. Section 252.4 is added to read as follows:

§ 252.4 Smoking ban: air carriers.

Air carriers shall prohibit smoking on the following flights:

(a) Scheduled passenger flights.

(b) Nonscheduled passenger flights, except for the following flights where a flight attendant is not a required crewmember on the aircraft as determined by the Administrator of the Federal Aviation Administration:

(1) Single entity charters.

(2) On-demand services of air taxi operators.

(c) Nothing in this section shall be deemed to require air carriers to permit smoking aboard aircraft.

■ 6. Section 252.5 is revised to read as follows:

§ 252.5 Smoking ban: foreign air carriers.

(a)(1) Foreign air carriers shall prohibit smoking on flight segments that

occur between points in the United States, and between the United States and any foreign point, in the following types of operations:

(i) Scheduled passenger foreign air transportation.

(ii) Nonscheduled passenger foreign air transportation, if a flight attendant is a required crewmember on the aircraft as determined by the Administrator of the Federal Aviation Administration or a foreign carrier's government.

(2) Nothing in this section shall be deemed to require foreign air carriers to permit smoking aboard aircraft.

(b) A foreign government objecting to the application of paragraph (a) of this section on the basis that paragraph (a) provides for extraterritorial application of the laws of the United States may request and obtain a waiver of paragraph (a) from the Assistant Secretary for Aviation and International Affairs, provided that an alternative smoking prohibition resulting from bilateral negotiations is in effect.

§ 252.7 [Removed]

■ 7. Section 252.7 is removed.

■ 8. Section 252.8 is revised to read as follows:

§ 252.8 Extent of smoking restrictions.

The restrictions on smoking described in §§ 252.4 and 252.5 shall apply to all locations within the aircraft.

§§ 252.13 and 253.15 [Removed]

■ 9. Sections 252.13 and 253.15 are removed.

■ 10. Section 252.17 is revised to read as follows:

§ 252.17 Enforcement.

Air carriers and foreign air carriers shall take such action as is necessary to ensure that smoking by passengers or crew is not permitted where smoking is prohibited by this part, including but not limited to aircraft lavatories.

§ 252.19 [Removed]

■ 11. Section 252.19 is removed.

[FR Doc. 2016–04799 Filed 3–3–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801 and 830

[Docket No. FDA–2011–N–0090]

Unique Device Identification System; Editorial Provisions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the Unique Device Identification (UDI) System regulation to make editorial changes. This technical amendment updates the email address associated with FDA's UDI system, which allows FDA to obtain information and offer support and assistance on medical devices through their distribution and use, ensuring consistency with the requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This change is necessary to ensure that the UDI team continues to maintain regular email communications with device labelers.

DATES: This rule is effective March 4, 2016.

FOR FURTHER INFORMATION CONTACT: Adaeze Teme, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5574, Silver Spring, MD 20993–0002, 240–402–0768.

SUPPLEMENTARY INFORMATION: FDA is updating the UDI email address in the following regulations that set forth the procedures for notifying the Agency when: (1) Requesting an exception from or alternative to a unique device identifier requirement (§ 801.55 (21 CFR 801.55)); (2) requesting continued use of legacy FDA identification numbers assigned to devices (§ 801.57 (21 CFR 801.57)); and (3) applying for accreditation as an issuing Agency (§ 830.110 (21 CFR 830.110)).

Specifically, the Agency is removing an old email address and replacing it with a new one, thereby maintaining consistency with the requirements of the FD&C Act (21 U.S.C. 321 *et seq.*).

In the **Federal Register** of September 24, 2013 (78 FR 58786), FDA issued a final rule to establish a system to adequately identify devices through distribution and use. The rule required the label of medical devices to include a UDI, except where an exception or alternative applies. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID). The final rule incorporated a direct avenue for the labeler to communicate with FDA's GUDID via a UDI email address. This rule updates §§ 801.55(b)(2), 801.57(c)(2), and 830.110(a) by replacing the old email address with a new one.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 830

Administrative practice and procedure, Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801and 830 are amended as follows:

PART 801—LABELING

■ 1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 2. In § 801.55, revise paragraph (b)(2) to read as follows:

§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.

* * * * *

(b) * * *

(2) In all other cases, by email to: *GUDIDSupport@fda.hhs.gov,* or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993–0002.

* * * * *

■ 3. In § 801.57, revise the second sentence of paragraph (c)(2) to read as follows:

§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

* * * * *

(c) * * *

(2) * * * * A request for continued use of an assigned labeler code must be submitted by email to: *GUDIDSupport@fda.hhs.gov,* or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993–0002.

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