[4910-13]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

Docket No.: FAA-2009-1059; SFAR 106

RIN 2120–AJ77

Use of One Additional Portable Oxygen Concentrator Device on Board Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Special Federal Aviation Regulation 106 (SFAR 106), Rules for Use of Portable Oxygen Concentrator Systems on Board Aircraft, to allow for the use of one additional portable oxygen concentrator (POC) device on board aircraft, provided certain conditions in the SFAR are met. This action is necessary to allow all POC devices deemed acceptable by the FAA for use in air commerce to be available to the traveling public in need of oxygen therapy. When this rule becomes effective, there will be 12 different POC devices the FAA finds acceptable for use on board aircraft. Passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator.

DATES: This amendment becomes effective [Insert date of publication in the Federal Register]

FOR FURTHER INFORMATION CONTACT: DK Deaderick, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW Washington, DC 20591. Telephone: 202-267-8166.

SUPPLEMENTARY INFORMATION:

Authority for this Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code (49 USC). Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

The FAA is authorized to issue this final rule pursuant to 49 USC Section 44701. Under that section, the FAA is authorized to establish regulations and minimum standards for other practices, methods, and procedures the Administrator finds necessary for air commerce and national security.

Background

On July 12, 2005, the FAA published Special Federal Aviation Regulation 106 (SFAR 106) entitled, "Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft" (70 FR 40156). SFAR 106 is the result of a notice the FAA published in July 2004 (69 FR 42324) to address the needs of passengers who must travel with medical oxygen. Before publication of SFAR 106, passengers in need of medical oxygen during air transportation faced many obstacles when requesting service. Many aircraft operators did not provide medical oxygen service aboard flights, and those that did often provided service at a price that travelers could not afford. Coordinating service between operators and suppliers at airports was also difficult, and passengers frequently chose not to fly because of these difficulties.

New medical oxygen technologies approved by the Food and Drug Administration (FDA) reduce the risks typically associated with compressed oxygen and

provide a safe alternative for passengers who need oxygen therapy. Several manufacturers have developed small portable oxygen concentrators (POC) that work by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user with an oxygen concentration of about 90%. The POCs operate using either rechargeable batteries or, if the aircraft operator obtains approval from the FAA, aircraft electrical power.

In addition, the Pipeline and Hazardous Materials Safety Administration (PHMSA) has determined that the POC covered by this amendment is not a hazardous material. Thus, it does not require the same level of special handling as compressed oxygen, and is safe for use on board aircraft, provided certain conditions for its use are met.

SFAR 106 permits passengers to carry on and use certain POCs on board aircraft if the aircraft operator ensures that the conditions specified in the SFAR for their use are met. The devices initially determined acceptable for use in SFAR 106, published July 12, 2005, were the AirSep Corporation's LifeStyle and the Inogen, Inc.'s Inogen One POCs. SFAR 106 was amended on September 12, 2006, (71 FR 53954) to add three additional POC devices, AirSep Corporation's FreeStyle, SeQual Technologies' Eclipse, and Respironics Inc.'s EverGo, to the original SFAR. SFAR 106 was amended on January 15, 2009, (74 FR 2351) in a similar manner to add two more POC devices, Delphi Medical Systems' RS-00400 and Invacare Corporation's XPO2, to the original SFAR. The FAA again amended SFAR 106 on January 6, 2010 (75 FR 739) to add four more POC devices, DeVilbiss Healthcare Inc.'s iGo, International Biophysics Corporation's LifeChoice, Inogen Inc.'s Inogen One G2, and Oxlife LLC.'s Oxlife

Independence Oxygen Concentrator, that may be carried on and used by a passenger on board an aircraft. This final rule adds one more POC device, Invacare SOLO$_2$, that may be carried on and used by a passenger on board an aircraft.

Aircraft operators can now offer medical oxygen service as they did before SFAR 106 was enacted, or they can meet certain conditions and allow passengers to carry on and use one of the POC devices covered in SFAR 106. SFAR 106 is an enabling rule, which means that no aircraft operator is required to allow passengers to operate these POC devices on board its aircraft, but it may allow them to be operated on board. If one of these devices is allowed by the aircraft operator to be carried on board, the conditions in the SFAR must be met.

When SFAR 106 was published, the FAA committed to establishing a single standard for all POCs so the regulations wouldn't apply to specific manufacturers and models of device. Whenever possible, the FAA tries to regulate by creating performance-based standards rather than approving by manufacturer. In the case of SFAR 106, the most efficient way to serve both the passenger and the aircraft operator was to allow the use of the devices determined to be acceptable by the FAA in SFAR 106 in a special, temporary regulation. As the FAA stated in the preamble discussion of the final rule that established SFAR 106, "while we are committed to developing a performance-based standard for all future POC devices, we do not want to prematurely develop standards that have the effect of stifling new technology of which we are unaware." The FAA developed and published SFAR 106 so passengers who otherwise could not fly could do so with an affordable alternative to what existed before SFAR 106 was published.

The FAA continues to pursue the performance-based standard for all POCs. This process is time-consuming, and the FAA intends to publish a notice in the Federal Register and offer the public a chance to comment on the proposal when it is complete. In the meantime, manufacturers continue to create new and better POCs, and one has requested that its product also be included as an acceptable device in SFAR 106. This manufacturer is Invacare Corporation, which has formally petitioned the FAA for inclusion in SFAR 106 by submitting documentation of the device to the Department of Transportation's Docket Management System. That documentation is available at http://www.regulations.gov under docket number: FAA-2009-1059.

As stated in Section 2 of SFAR 106, no covered device may contain hazardous materials as determined by PHMSA (written documentation necessary), and each device must also be regulated by the FDA. Invacare Corporation included technical specifications for the devices in its request for approval and the required documentation from PHMSA and the FDA. Invacare Corporation provided the FAA with the required documentation for the Invacare $SOLO_2$ device.

The Rule

This amendment to SFAR 106 will include the Invacare $SOLO_2$ device in the list of POC devices authorized for use in air commerce. The FAA has reviewed the device and accepted the documentation provided by the manufacturer. That documentation includes letters provided to the manufacturer by PHMSA and the FDA affirming the status of the device as it applies to the requirements stated in SFAR 106. After reviewing the applicable FDA safety standards and the PHMSA findings, the device was determined by the FAA to be acceptable for use in air commerce.

Additionally, the FAA inadvertently included an incorrect model number reference for one POC device in SFAR 106 that was added on January 15, 2009 (74 FR 2351). Therefore, the FAA is changing the reference from "Invacare XPO100" to "Invacare XP02."

Good Cause for Adoption of this Final Rule without Notice and Comment

SFAR 106 was published on July 12, 2005. The FAA stated in the preamble of that final rule that the AirSep LifeStyle and Inogen One POC devices were the only known acceptable devices when the rule was published. The FAA also stated in that final rule that "we cannot predict how future products may be developed and work." The FAA initiated a notice and comment period for the use of POC devices on board aircraft on July 14, 2004, (69 FR 42324) and responded to the comments received in response to that NPRM in the final rule published in 2005. Therefore, it is unnecessary to publish a notice to request comments on this amendment because all issues related to the use of POC devices on board an aircraft have already been discussed. Further notice and comment would also delay the acceptance of the Invacare $SOLO_2$ POC device as authorized for use on board aircraft, which would delay its availability for passengers in need of oxygen therapy.

Therefore, I find that notice and public comment under 5 U.S.C. 553(b) is unnecessary and contrary to the public interest. Further, I find that good cause exists for making this rule effective immediately upon publication.

Paperwork Reduction Act

Information collection requirements associated with this final rule have been approved previously by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and have been assigned OMB Control Number 2120-0702. This final rule requires that if a passenger carries a POC device on board the aircraft with the intent to use it during the flight, he or she must inform the pilot in command of that flight. Additionally, the passenger who plans to use the device must provide a written statement signed by a licensed physician that verifies the passenger's ability to operate the device, respond to any alarms, the extent to which the passenger must use the POC (all or a portion of the flight), and prescribes the maximum oxygen flow rate. The Paperwork Reduction Act paragraph in the final rule that established SFAR 106 still applies to this amendment. The availability of a new POC device will likely increase the availability and options for a passenger in need of oxygen therapy, but the paperwork burden discussed in the original final rule is unchanged. Therefore, the OMB Control Number associated with this collection remains 2120-0702.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The

FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Regulatory Evaluation, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Public Law 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Public Law 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the

preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

This action amends SFAR 106 to allow for the use of the Invacare $SOLO_2$ POC device on board aircraft, provided certain conditions in the SFAR are met. This action is necessary to allow an additional POC device deemed acceptable by the FAA to be available to the traveling public in need of oxygen therapy, for use in air commerce. When this rule becomes effective, there will be a total of 12 different POC devices the FAA finds acceptable for use on board aircraft, and passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator. As the rule increases acceptable POC devices on board aircraft, the rule does not increase costs and provides additional benefits. The FAA has, therefore, determined that this final rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866, and is not "significant" as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Public Law 96-354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration." The RFA covers a wide-

range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule adds Invacare $SOLO_2$ device to the list of authorized POC devices in SFAR 106. This economic impact is minimal. Therefore, as the FAA Administrator, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of $143.1 million in lieu of $100 million.

This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The FAA determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the FAA has determined that this final rule does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

Regulations that Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The FAA has determined that it is not a "significant energy action" under the executive order because it is not a "significant regulatory action" and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Federal eRulemaking Portal at http://www.regulations.gov;

(2) Visiting the FAA's Regulations and Policies web page at http://www.faa.gov/regulations_policies/; or

(3) Accessing the Government Printing Office's web page at http://www.gpoaccess.gov/fr/index.html.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the amendment number or docket number of this rulemaking.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact its local FAA official, or the person listed under FOR FURTHER INFORMATION CONTACT. You can find out more about SBREFA on the Internet at http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in 14 CFR Part 121

Air carriers, Aircraft, Airmen, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends SFAR No. 106 to Chapter II of Title 14, Code of Federal Regulations, as follows:

PART 121 – OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1153, 40101, 40102, 40103, 40113, 41721, 44105, 44106, 44111, 44701-44717, 44722, 44901, 44903, 44904, 44906, 44912, 44914, 44936, 44938, 46103, 46105.

2. Amend SFAR 106 by revising sections 2 and 3(a) introductory text to read as follows:

Special Federal Aviation Regulation 106—Rules for use of portable oxygen concentrator systems on board aircraft

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Section 2. Definitions – For the purposes of this SFAR the following definitions apply: Portable Oxygen Concentrator: means the AirSep FreeStyle, AirSep LifeStyle, Delphi RS-00400, DeVilbiss Healthcare iGo, Inogen One, Inogen One G2, International Biophysics LifeChoice, Invacare XPO2, Invacare Solo$_2$ Oxlife Independence Oxygen Concentrator, Respironics EverGo, and SeQual Eclipse Portable Oxygen Concentrator medical device units as long as those medical device units: (1) do not contain hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration;

(2) are also regulated by the Food and Drug Administration; and (3) assist a user of medical oxygen under a doctor's care. These units perform by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user.

Section 3. Operating Requirements –

(a) No person may use and no aircraft operator may allow the use of any portable oxygen concentrator device, except the AirSep FreeStyle, AirSep LifeStyle, Delphi RS-00400, DeVilbiss Healthcare iGo, Inogen One, Inogen One G2, International Biophysics LifeChoice, Invacare XPO2, Invacare Solo$_2$, Oxlife Independence Oxygen Concentrator, Respironics EverGo, and SeQual Eclipse Portable Oxygen Concentrator units. These units may be carried on and used by a passenger on board an aircraft provided the aircraft operator ensures that the following conditions are satisfied:

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Issued in Washington, DC on 07/01/2010

/s/

J. Randolph Babbitt
Administrator

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