

(3) The cost to the Federal Government of making guarantees under this subsection (g) and under section 503 of the Small Business Investment Act of 1958 (15 U.S.C. 697) during the fiscal year in which the guarantee is made is zero;

* * * * *

(10) A CDC must limit the amount of its loans under this paragraph (g) so that, during any Federal fiscal year, the amount of the new loans approved under this paragraph (g) does not exceed 50% of the total dollar amount of the CDC's 504 loans approved (including the loans approved under this paragraph (g)) during the previous fiscal year. This limitation may be waived upon application by the CDC and upon a determination by SBA that the refinance loan is needed for good cause.

* * * * *

(13) The Third Party Loan may not be sold on the secondary market as a part of a pool guaranteed under subpart J of this part, or any successor to this program, when the debt being refinanced is same institution debt;

* * * * *

(15) * * *
Qualified debt * * *

(vii) * * * For the purposes of this paragraph (vii), "current on all payments due" means that no payment was more than 30 days past due from either the original payment terms or modified payment terms (including deferments) if such modification was agreed to in writing by the Borrower and the lender of the existing debt no less than one year preceding the date of application. * * *

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Maria Contreras-Sweet,
Administrator.

[FR Doc. 2016-12447 Filed 5-23-16; 4:15 pm]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR part 93

[Docket No.: FAA-2006-25755]

Operating Limitations at New York LaGuardia Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Extension to order.

SUMMARY: This action extends the Order Limiting Operations at New York LaGuardia Airport (LGA) published on December 27, 2006, and most recently

extended March 27, 2014. The Order remains effective until October 27, 2018.

DATES: This action is effective on May 25, 2016.

ADDRESSES: Requests may be submitted by mail to Slot Administration Office, AGC-240, Office of the Chief Counsel, 800 Independence Avenue SW., Washington, DC 20591, or by email to: 7-awa-slotadmin@faa.gov.

FOR FURTHER INFORMATION CONTACT: For questions concerning this Order contact: Susan Pfingstler, System Operations Services, Air Traffic Organization, Federal Aviation Administration, 600 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-6462; email susan.pfingstler@faa.gov.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You may obtain an electronic copy using the Internet by:

- (1) Searching the Federal eRulemaking Portal (<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 also may obtain 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.

Background

The FAA has long limited the number of arrivals and departures at LGA during peak demand periods through the implementation of the High Density Rule (HDR), to address constraints based on LGA's limited runway capacity.¹ By statute enacted in April 2000, the HDR's applicability to LGA operations terminated as of January 1, 2007.²

In anticipation of the HDR's expiration, the FAA proposed a long-term rule that would limit the number of scheduled and unscheduled operations at LGA.³ The FAA issued an

¹ 33 FR 17896 (Dec. 3, 1968). The FAA codified the rules for operating at high density traffic airports in 14 CFR part 93, subpart K. The HDR required carriers to hold a reservation, which came to be known as a "slot," for each takeoff or landing under instrument flight rules at the high density traffic airports.

² Aviation Investment and Reform Act for the 21st Century (AIR-21), Public Law 106-181 (Apr. 5, 2000), 49 U.S.C. 41715(a)(2).

³ 71 FR 51360 (August 29, 2006); Docket FAA-2006-25709. The FAA subsequently published a

Order on December 27, 2006, adopting temporary limits pending the completion of the rulemaking.⁴ This Order was amended on November 8, 2007, and August 19, 2008.⁵ On October 10, 2008, the FAA published the Congestion Management Rule for LaGuardia Airport, which would have become effective on December 9, 2008.⁶ That rule was stayed by the U.S. Court of Appeals for the District of Columbia Circuit and subsequently rescinded by the FAA.⁷ The FAA extended the December 27, 2006, Order placing temporary limits on operations at LGA, as amended, on October 7, 2009,⁸ on April 4, 2011,⁹ on May 14, 2013,¹⁰ and on March 27, 2014.¹¹

Under the Order, as amended, the FAA (1) maintains the current hourly limits on scheduled and unscheduled operations at LGA during the peak period; (2) imposes an 80 percent minimum usage requirement for Operating Authorizations (OAs) with defined exceptions; (3) provides a mechanism for withdrawal of OAs for FAA operational reasons; (4) provides for a lottery to reallocate withdrawn, surrendered, or unallocated OAs; and (5) allows for trades and leases of OAs for consideration for the duration of the Order.

The reasons for issuing the Order have not changed appreciably since it was implemented. Runway capacity at LGA remains limited, while demand for access to LGA remains high and average weekday hourly flights are generally scheduled to a level consistent with the limits under this Order. The FAA has reviewed the on-time and other performance metrics in the peak May to August 2014 and 2015 months and found continuing improvements relative to the same period in 2007.¹² Without the operational limitations imposed by this Order, the FAA expects severe congestion-related delays would occur at LGA and at other airports throughout the National Airspace System (NAS). The FAA will continue to monitor performance and runway capacity at LGA to determine if changes are warranted.

Supplemental Notice of Proposed Rulemaking. 73 FR 20846 (Apr. 17, 2008).

⁴ 71 FR 77854.

⁵ 72 FR 63224; 73 FR 48428.

⁶ 73 FR 60574, amended by 73 FR 66517 (Nov. 10, 2008).

⁷ 74 FR 52132 (Oct. 9, 2009).

⁸ 74 FR 51653.

⁹ 76 FR 18616, amended by 77 FR 30585 (May 23, 2012).

¹⁰ 78 FR 28278.

¹¹ 79 FR 17222.

¹² Docket No. FAA-2006-25755 includes a copy of the MITRE analysis completed for the FAA.

On January 8, 2015, the DOT and FAA published a notice of proposed rulemaking “Slot Management and Transparency at LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport.”¹³ The DOT and FAA proposed to replace the Orders limiting scheduled operations at JFK, limiting scheduled operations at Newark Liberty International Airport (EWR), and limiting scheduled and unscheduled operations at LaGuardia Airport (LGA) with a more permanent system for managing slots. The NPRM included certain proposed changes to how slots are currently managed in the New York City area in order to increase transparency and address issues considering anti-competitive behavior.

Since the FAA and DOT first initiated this rulemaking effort there have been significant changes in circumstances affecting New York City area airports, including changes in competitive effects from ongoing industry consolidation, slot utilization and transfer behavior, and actual operational performance at the three airports. Furthermore, the FAA recently announced that slot controls are no longer needed at EWR (81 FR 19861). In light of the changes in market conditions and operational performance at the New York City area airports, the Department is withdrawing the NPRM by **Federal Register** notice published May 16, 2016 (81 FR 30218), to allow for further evaluation of these changes.

Accordingly, the FAA has concluded it is necessary to extend the expiration date of this Order until October 27, 2018. This expiration date coincides with the extended expiration date for the Order limiting scheduled operations at JFK, as also extended by action published in today’s **Federal Register**.¹⁴ No amendments other than the expiration date have been made to this Order.

The FAA finds that notice and comment procedures under 5 U.S.C. 553(b) are impracticable and contrary to the public interest. The FAA further finds that good cause exists to make this Order effective in less than 30 days.

The Amended Order

In consideration of the foregoing, the Order, as amended, is recited below in its entirety:

¹³ 80 FR 1274.

¹⁴ The FAA notes that the Order limiting scheduled operations at EWR will expire October 29, 2016; beginning on October 30, 2016, EWR is designated a Level 2 schedule-facilitated airport consistent with the FAA’s action published in the **Federal Register** on April 6, 2016. See *id.*

A. Scheduled Operations

With respect to scheduled operations at LaGuardia:

1. The final Order governs scheduled arrivals and departures at LaGuardia from 6 a.m. through 9:59 p.m., Eastern Time, Monday through Friday and from 12 noon through 9:59 p.m., Eastern Time, Sunday. Seventy-one (71) Operating Authorizations are available per hour and will be assigned by the FAA on a 30-minute basis. The FAA will permit additional, existing operations above this threshold; however, the FAA will retire Operating Authorizations that are surrendered to the FAA, withdrawn for non-use, or unassigned during each affected hour until the number of Operating Authorizations in that hour reaches seventy-one (71).

2. The final Order takes effect on January 1, 2007, and will expire on October 27, 2018.

3. The FAA will assign operating authority to conduct an arrival or a departure at LaGuardia during the affected hours to the air carrier that holds equivalent slot or slot exemption authority under the High Density Rule of FAA slot exemption rules as of January 1, 2007; to the primary marketing air carrier in the case of AIR-21 small hub/nonhub airport slot exemptions; or to the air carrier operating the flights as of January 1, 2007, in the case of a slot held by a non carrier. The FAA will not assign operating authority under the final Order to any person or entity other than a certificated U.S. or foreign air carrier with appropriate economic authority under 14 CFR part 121, 129 or 135. The Chief Counsel of the FAA will be the final decision maker regarding the initial assignment of Operating Authorizations.

4. For administrative tracking purposes only, the FAA will assign an identification number to each Operating Authorization.

5. An air carrier may lease or trade an Operating Authorization to another carrier for any consideration, not to exceed the duration of the Order. Notice of a trade or lease under this paragraph must be submitted in writing to the FAA Slot Administration Office, facsimile (202) 267-7277 or email 7-AWASlotadmin@faa.gov, and must come from a designated representative of each carrier. The FAA must confirm and approve these transactions in writing prior to the effective date of the transaction. However, the FAA will approve transfers between carriers under the same marketing control up to 5 business days after the actual

operation. This post-transfer approval is limited to accommodate operational disruptions that occur on the same day of the scheduled operation.

6. Each air carrier holding an Operating Authorization must forward in writing to the FAA Slot Administration Office a list of all Operating Authorizations held by the carrier along with a listing of the Operating Authorizations actually operated for each day of the two-month reporting period within 14 days after the last day of the two-month reporting period beginning January 1 and every two months thereafter. Any Operating Authorization not used at least 80 percent of the time over a two-month period will be withdrawn by the FAA except:

A. The FAA will treat as used any Operating Authorization held by an air carrier on Thanksgiving Day, the Friday following Thanksgiving Day, and the period from December 24 through the first Saturday in January.

B. The FAA will treat as used any Operating Authorization obtained by an air carrier through a lottery under paragraph 7 for the first 120 days after allocation in the lottery.

C. The Administrator of the FAA may waive the 80 percent usage requirement in the event of a highly unusual and unpredictable condition which is beyond the control of the air carrier and which affects carrier operations for a period of five consecutive days or more.

7. In the event that Operating Authorizations are withdrawn for nonuse, surrendered to the FAA or are unassigned, the FAA will determine whether any of the available Operating Authorizations should be reallocated. If so, the FAA will conduct a lottery using the provisions specified under 14 CFR 93.225. The FAA may retire an Operating Authorization prior to reallocation in order to address operational needs. When the final Order expires, any Operating Authorizations reassigned under this paragraph, except those assigned to new entrants or limited incumbents, will revert to the FAA for reallocation according to the reallocation mechanism prescribed in the final rule that succeeds the final Order.

8. If the FAA determines that a reduction in the number of allocated Operating Authorizations is required to meet operational needs, such as reduced airport capacity, the FAA will conduct a weighted lottery to withdraw Operating Authorizations to meet a reduced hourly or half-hourly limit for scheduled operations. The FAA will provide at least 45 days’ notice unless otherwise required by operational

needs. Any Operating Authorization that is withdrawn or temporarily suspended will, if reallocated, be reallocated to the air carrier from which it was taken, provided that the air carrier continues to operate scheduled service at LaGuardia.

9. The FAA will enforce the final Order through an enforcement action seeking a civil penalty under 49 U.S.C. 46301(a). An air carrier that is not a small business as defined in the Small Business Act, 15 U.S.C. 632, would be liable for a civil penalty of up to \$25,000 for every day that it violates the limits set forth in the final Order. An air carrier that is a small business as defined in the Small Business Act would be liable for a civil penalty of up to \$10,000 for every day that it violates the limits set forth in the final Order. The FAA also could file a civil action in U.S. District Court, under 49 U.S.C. 46106, 46107, seeking to enjoin any air carrier from violating the terms of the final Order.

*B. Unscheduled Operations:*¹⁵

With respect to unscheduled flight operations at LaGuardia, the FAA adopts the following:

1. The final order applies to all operators of unscheduled flights, except helicopter operations, at LaGuardia from 6 a.m. through 9:59 p.m., Eastern Time, Monday through Friday and from 12 noon through 9:59 p.m., Eastern Time, Sunday.

2. The final Order takes effect on January 1, 2007, and will expire on October 27, 2018.

3. No person can operate an aircraft other than a helicopter to or from LaGuardia unless the operator has received, for that unscheduled operation, a reservation that is assigned by the David J. Hurley Air Traffic Control System Command Center's Airport Reservation Office (ARO). Additional information on procedures for obtaining a reservation will be available via the Internet at <http://www.fly.faa.gov/ecvrs>.

4. Three (3) reservations are available per hour for unscheduled operations at LaGuardia. The ARO will assign reservations on a 30-minute basis.

5. The ARO receives and processes all reservation requests. Reservations are assigned on a "first-come, first-served" basis, determined as of the time that the ARO receives the request. A cancellation of any reservation that will not be used as assigned would be required.

6. Filing a request for a reservation does not constitute the filing of an instrument flight rules (IFR) flight plan, as separately required by regulation. After the reservation is obtained, an IFR flight plan can be filed. The IFR flight plan must include the reservation number in the "remarks" section.

7. Air Traffic Control will accommodate declared emergencies without regard to reservations. Nonemergency flights in direct support of national security, law enforcement, military aircraft operations, or public use aircraft operations will be accommodated above the reservation limits with the prior approval of the Vice President, System Operations Services, Air Traffic Organization. Procedures for obtaining the appropriate reservation for such flights are available via the Internet at <http://www.fly.faa.gov/ecvrs>.

8. Notwithstanding the limits in paragraph 4, if the Air Traffic Organization determines that air traffic control, weather, and capacity conditions are favorable and significant delay is not likely, the FAA can accommodate additional reservations over a specific period. Unused operating authorizations can also be temporarily made available for unscheduled operations. Reservations for additional operations are obtained through the ARO.

9. Reservations cannot be bought, sold, or leased.

Issued in Washington, DC, on May 18, 2016.

Daniel E. Smiley,

Vice President, System Operations Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2012-N-1173]

Cardiovascular Devices; Reclassification of External Cardiac Compressor; Reclassification of Cardiopulmonary Resuscitation Aids

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify external cardiac compressors (ECC) (under FDA product code DRM), a preamendments class III device, into class II (special controls). FDA is also creating a separate classification regulation for a subgroup of devices previously included within this classification regulation, to be called cardiopulmonary resuscitation (CPR) aids, and reclassifying these devices from class III to class II for CPR aids with feedback and to class I for CPR aids without feedback.

DATES: This order is effective on May 25, 2016.

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1652, Silver Spring, MD 20993, 301-796-6351, hina.pinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act (Pub. L. 108-214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and

¹⁵ Unscheduled operations are operations other than those regularly conducted by an air carrier between LaGuardia and another service point. Unscheduled operations include general aviation, public aircraft, military, charter, ferry, and positioning flights. Helicopter operations are excluded from the reservation requirement. Reservations for unscheduled flights operating under visual flight rules (VFR) are granted when the aircraft receives clearance from air traffic control to land or depart LaGuardia. Reservations for unscheduled VFR flights are not included in the limits for unscheduled operators.