this AD to the U.S. operators to be $197,120, or $320 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. 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.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2008–21–03 Boeing: Amendment 39–15687. Docket No. FAA–2008–0357; Directorate Identifier 2008–NM–005–AD.

Effective Date

(a) This airworthiness directive (AD) is effective November 13, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 737–300, –400, and –500 series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from a report of corrosion damage of the chrome runout on the head side found on all four midspar fuse pins of the nacelle strut. Additionally, a large portion of the chrome plate was missing from the corroded area of the shank. We are issuing this AD to detect and correct damage of the fuse pins of the inboard and outboard midspar fittings of the nacelle strut, which could result in reduced structural integrity of the fuse pins and consequent loss of the strut and separation of the engine from the airplane.

Compliance

(e) Comply with this AD within the compliance times specified, unless already done.

Repetitive Inspections/Corrective Actions

(f) At the applicable time specified in paragraph 1.E., ''Compliance'' of Boeing Special Attention Service Bulletin 737–54–1044, dated December 10, 2007; except, where the service bulletin specifies a compliance time after the date on the service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD: Do a detailed inspection for discrepancies of the fuse pins of the inboard and outboard midspar fittings of the nacelle strut by doing all the actions, including all applicable corrective actions, in accordance with the Accomplishment Instructions of the service bulletin. Do all applicable corrective actions before further flight. Repeat the inspection at the time specified in paragraph 1.E. of the service bulletin.

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, ATTN: Allen Rauschendorfer, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6432; fax (425) 917–6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane.

Material Incorporated by Reference

(h) You must use Boeing Special Attention Service Bulletin 737–54–1044, dated December 10, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on September 29, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–23658 Filed 10–8–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30630; Amdt. No. 3289]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure

Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 9, 2008. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 9, 2008.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Availability—All SIAPs are available online free of charge. Visit *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Harry J. Hodges, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under DOT Regulatory Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on September 19, 2008.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

FDC date	State	City	Airport	FDC No.	Subject
07/10/08	MI	MANISTEE	MANISTEE CO.–BLACKER	8/6401	VOR RWY 27, ORIG
09/04/08	GQ	AGANA	GUAM INTL	8/6576	ILS OR LOC/DME RWY 6L, AMDT 3B
09/05/08	CO	DENVER	ROCKY MOUNTAIN METROPOLITAN	8/6770	GPS RWY 29L, ORIG–A
09/05/08	CO	DENVER	ROCKY MOUNTAIN METROPOLITAN	8/6771	GPS RWY 29R, ORIG–A
09/05/08	MT	BUTTE	BERT MOONEY	8/6864	ILS Y RWY 15, AMDT 6
09/05/08	MT	ANACONDA	BOWMAN FIELD	8/6866	VOR/DME OR GPS A, AMDT 1
09/05/08	OR	EUGENE	MAHLON SWEET FIELD	8/6867	ILS OR LOC/DME RWY 16L, ORIG
09/05/08	AK	PERRYVILLE	PERRYVILLE	8/6868	RNAV (GPS) RWY 2, ORIG
09/08/08	KY	DANVILLE	STUART POWELL FIELD	8/7015	LOC/DME RWY 30, AMDT 1A
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7062	RNAV (GPS) RWY 7, ORIG–B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7064	VOR/DME OR TACAN RWY 7, AMDT 11B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7065	RNAV (GPS) RWY 25, ORIG–B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7067	ILS OR LOC RWY 25, AMDT 21D
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7068	ILS OR LOC RWY 7, ORIG–B
09/08/08	AR	FORT SMITH	FORT SMITH RGNL	8/7069	VOR OR TACAN RWY 25, AMDT 20G
09/10/08	OK	TULSA	TULSA INTL	8/7352	ILS OR LOC RWY 18R, AMDT 7
09/10/08	CA	VAN NUYS	VAN NUYS	8/7460	ILS RWY 16R, AMDT 5A
09/11/08	VA	DUBLIN	NEW RIVER VALLEY	8/7673	ILS OR LOC RWY 6, AMDT 4A
09/12/08	LA	LAFAYETTE	LAFAYETTE REGIONAL	8/7965	TAKEOFF MINIMUMS AND (OBSTACLE) DEPARTURE PROCEDURES (ODP), AMDT 1

[FR Doc. E8–23916 Filed 10–8–08; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket No. FDA–2005–N–0345] (formerly Docket No. 2005N–0428)

Distribution of Certain Drug Products by Registered Blood Establishments and Comprehensive Hemophilia Diagnostic Treatment Centers That Qualify as Health Care Entities; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to allow certain registered blood establishments and comprehensive hemophilia diagnostic treatment centers that are also health care entities to distribute certain drug products. The final rule amends limited provisions of the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA). These regulations, among other things, restrict the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs purchased by hospitals and other health care entities.

DATES: This rule is effective November 10, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0372.

SUPPLEMENTARY INFORMATION:

I. Background

The PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353) on August 26, 1992. The PDMA, as modified, amended the Federal Food, Drug, and Cosmetic Act (the act) to establish restrictions and requirements relating to various aspects of human prescription drug marketing and distribution. Among other things, the PDMA prohibited, with certain exceptions, the sale, purchase, or trade (or offer to sell, purchase, or trade) of any prescription drug that was purchased by a hospital or other health care entity. Section 503(c)(3)(A)(ii)(I) of the act (21 U.S.C. 353(c)(3)(A)(ii)(I)). Section 503(c)(3) also states that ''[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law * * *.''

In the **Federal Register** of March 14, 1994 (59 FR 11842), we issued a proposed rule to implement certain provisions of the PDMA. The proposed rule contained provisions on prescription drug reimportation; wholesale distribution of prescription drugs by unauthorized distributors; the resale of prescription drugs by hospitals, health care entities, and charitable institutions; and distribution of prescription drug samples. After consideration of comments, we issued a final rule in the **Federal Register** of December 3, 1999 (64 FR 67720) (the December 1999 final rule), with an effective date of December 4, 2000.

After publication of the December 1999 final rule, we received many comments on, and held several meetings to discuss the implications of, the final regulations for registered blood establishments that distribute blood-derived products and provide limited health care services to hospitals and patients. According to comments, implementing the December 1999 final rule as published would interfere with longstanding relationships between blood centers and other health care providers such as hospitals and hemophilia treatment centers.

Section 203.20(a) (21 CFR 203.20(a)) of the December 1999 final rule stated, in relevant part, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a health care entity. ''Health care entity,'' in turn, was defined in § 203.3(q) (21 CFR 203.3(q))