PART 250—FORMS

1. The authority citation for part 250 continues to read as follows:


2. Amend § 250.16 by revising paragraph (e) (1) to read as follows:

   § 250.16 Format of compliance plan

   * * * * *

   (e) Penalty for failure to comply. (1) Any person who transports gas for

   subject, pursuant to sections 311(c), 501,

   and 358.5 of this chapter will be

   subject to certain conditions for

   devices, from 510(k) requirements,

   contractions). This order exempts

   of skin ulcers or contractures (muscle

   must maintain a prone or supine

   intended for medical purposes for use

   code INK). These devices are battery-

   notification (510(k)) requirements for

   request under this section within 180

   the safety and effectiveness of the

   that a 510(k) is not necessary to assure

   interested person, if FDA determines

   from 510(k) requirements on its own

   from 510(k) requirements, of class II
devices, from 510(k) requirements,
subject to certain conditions for
exemption. This exemption from 510(k)
requirements is immediately in effect for
powered wheeled stretchers. FDA is
publishing this order in accordance with
the section of the Federal Food,
Drug, and Cosmetic Act (FD&C Act)
permitting the exemption of a device
from the requirement to submit a 510(k).

DATES: This order is effective January

FOR FURTHER INFORMATION CONTACT: Eric
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SUPPLEMENTARY INFORMATION:

I. Statutory Background

   Section 510(k) of the FD&C Act (21
   U.S.C. 360(k)) and its implementing
   regulations in part 807, subpart E (21
   CFR part 807, subpart E) require persons
   who propose to begin the introduction
   or delivery for introduction into
   interstate commerce for commercial
   distribution of a device intended for
   human use to submit a 510(k) to FDA.
   The device may not be marketed until
   FDA finds it “substantially equivalent”
   within the meaning of section 513(i)
   of the FD&C Act (21 U.S.C. 360(c)(i)) to a
   legally marketed device that does not
   require premarket approval.

   On November 21, 1997, the President
   signed into law the Food and Drug
   Administration Modernization Act of
   1997 (Pub. L. 105–115), section 206 of
   which added section 510(m) to the
   FD&C Act, which was amended on
   December 13, 2016, by the 21st Century
   Cures Act (Pub. L. 114–255). Section
   510(m)(1) of the FD&C Act requires FDA
to publish in the Federal Register a
notice that contains a list of each type
of class II device that does not require a
report under section 510(k) of the
FD&C Act to provide reasonable
assurance of safety and effectiveness
of the device. Section 510(m) of the FD&C
Act further provides that a 510(k) will
no longer be required for these devices
upon the date of publication of the list
in the Federal Register. FDA published
that list in the Federal Register of

II. Criteria for Exemption

   There are a number of factors FDA
may consider to determine whether a
510(k) is necessary to assure the safety
and effectiveness of the device. These
factors are discussed in the
guidance that the Agency issued on
February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification.” (Class II 510(k) Exemption Guidance). That guidance can be obtained through the internet at https://www.fda.gov/downloads/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf or by sending an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

III. Petition

On July 10, 2019, FDA received a petition requesting an exemption from premarket notification for powered wheeled stretchers (see Docket No. FDA–2019–P–3347). These devices are currently classified under 21 CFR 890.3690, powered wheeled stretchers.

In the Federal Register of September 16, 2019 (84 FR 48623), FDA published a notice that this petition had been received and provided opportunity for interested persons to submit comments on the petition by November 15, 2019. FDA received no comments.

FDA has assessed the need for 510(k) clearance for this type of device against the criteria laid out in the Class II 510(k) Exemption Guidance. Based on this review, FDA believes that premarket notification is not necessary to assure the safety and effectiveness of the device, as long as certain conditions are met. FDA believes that the risks posed by the device and the characteristics of the device necessary for its safe and effective performance are well established. FDA believes that changes in the device that could affect safety and effectiveness will be readily detectable by visual examination. Therefore, after reviewing the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of powered wheeled stretchers, as long as the conditions in section IV are met. FDA responded to the petition by letter dated December 31, 2019, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Conditions for Exemption

This final order provides conditions for exemption from premarket notification for the powered wheeled stretcher.¹ The conditions that must be met for the device to be 510(k)-exempt are as follows: Appropriate analysis and nonclinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure; appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety; appropriate analysis and nonclinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device; appropriate analysis and nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented; appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable; appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device; adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds and mitigation strategy to reduce entrapment.

A number of these conditions involve “appropriate analysis and nonclinical testing,” the details of which are outlined in, among other places, certain FDA-recognized consensus standards. The following is a list of FDA recognized consensus standards that may be used to meet the listed conditions of exemption. Specifically, those standards include FDA-recognized editions of:

- ANSI/AAMI ES60601–1: Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
- ISO 7176–14: Wheelchairs—Part 14: Power and control systems for electrically powered wheelchairs and scooters—Requirements and test methods
- ISO 7176–21: Wheelchairs—Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ANSI/AAMI/ISO 10993–1: Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process
- IEC 62304: Medical device software—Software life cycle processes

We also recommend you consider FDA’s guidance entitled “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment” when considering the appropriate risk assessment referenced in the conditions set forth above.

Firms are now exempt from 510(k) requirements for powered wheeled stretchers as long as they meet these conditions, subject to the limitations on exemption in 21 CFR 890.9. Firms must comply with the particular conditions set forth in the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved FDA collections of
information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. The authority citation for part 890 continues to read as follows:


2. In §890.3690, revise paragraph (b) to read as follows:

§890.3690 Powered wheeled stretcher.

(b) Classification. Class II (performance standards). The powered wheeled stretcher is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to §890.9, and the following conditions for exemption:

(1) Appropriate analysis and nonclinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and nonclinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and nonclinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide user with an expected service life of the device;

(4) Appropriate analysis and nonclinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and nonclinical testing must validate that the device components are found to be nonflammable;

(9) Appropriate analysis and nonclinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device;

(10) Adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and

(11) Appropriate risk assessment including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds, and mitigation strategy to reduce entrapment.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2020–00295 Filed 1–13–20; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 35, 103, 127, and 138

[RIN 1400–AF00]

Department of State 2020 Civil Monetary Penalties Inflationary Adjustment

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule is issued to adjust the civil monetary penalties (CMP) for regulatory provisions maintained and enforced by the Department of State. The revised CMP amounts will apply only to those penalties assessed on or after the effective date of this rule, regardless of the date on which the underlying facts or violations occurred.

DATES: This final rule is effective on January 14, 2020.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

The Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, as amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, required the head of each agency to adjust its CMPs for inflation no later than October 23, 1996 and required agencies to make adjustments at least once every four years thereafter. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Section 701 of Public Law 114–74 (the 2015 Act) further amended the 1990 Act by requiring agencies to adjust CMPs, if necessary, pursuant to a “catch-up” adjustment methodology prescribed by the 2015 Act, which mandated that the catch-up adjustment take effect no later than August 1, 2016. Additionally, the 2015 Act required agencies to make annual adjustments to their respective CMPs in accordance with guidance issued by the Office of Management and Budget (OMB).

Based on these statutes, the Department of State (the Department) published a final rule in June 2016 to implement the “catch-up” provisions; and annual updates to its CMPs in January 2017, January 2018, and March 2019 (delayed due to the government shutdown).

On December 16, 2019, OMB notified agencies that the annual cost-of-living adjustment multiplier for 2020, based on the Consumer Price Index, is 1.01764. Additional information may be found in OMB Memorandum M–20–05, at: https://www.whitehouse.gov/wp-content/uploads/2019/12/M-20-05.pdf. This final rule amends Department CMPs for fiscal year 2019.

Overview of the Areas Affected by This Rule

Within the Department of State (title 22, Code of Federal Regulations), this rule affects four areas:


(2) Part 103, which implements the Debt Collection Improvement Act of 1996 (DCIA), codified at 31 U.S.C. 3721–3727;