

the Act authorizes the Secretary to waive such requirements of Titles XI and XVIII, as well as sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5)) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. Consistent with this standard, we will continue to waive the same provisions of Title XVIII for the extension of this model as have been waived for purposes of testing the model over the previous five years. Additionally, we have determined that the implementation of this model does not require the waiver of any fraud and abuse law, including sections 1128A, 1128B, and 1877 of the Act. Thus ambulance suppliers affected by this model must comply with all applicable fraud and abuse laws.

We will continue to use this prior authorization process to help ensure that all relevant clinical or medical documentation requirements are met before services are furnished to beneficiaries and before claims are submitted for payment. The prior authorization process further helps to ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

The use of prior authorization does not create new clinical documentation requirements. Instead, it requires the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization allows ambulance suppliers to address coverage issues prior to furnishing services.

The prior authorization process under the extension of the model under 1115A authority will continue to apply in the nine states listed previously for the following codes for Medicare payment:

- A0426 Ambulance service, advanced life support, non-emergency transport, Level 1 (ALS1).
- A0428 Ambulance service, BLS, non-emergency transport.

While prior authorization is not needed for the mileage code, A0425, a prior authorization decision for an A0426 or A0428 code will automatically include the associated mileage code.

Under the model extension under section 1115A authority, we will continue our outreach and education efforts to ambulance suppliers, as well as beneficiaries, through such methods as updating the operational guide, frequently asked questions (FAQs) on our website, a physician letter explaining the ambulance suppliers' need for the proper documentation, and

educational events and materials issued by the Medicare Administrative Contractors (MACs).

We will continue to work to limit any adverse impact on beneficiaries and to educate beneficiaries about the model process. If a prior authorization request is non-affirmed, and the claim is still submitted by the ambulance supplier, the claim will be denied, but beneficiaries will continue to have all applicable administrative appeal rights. We will also continue our initiative to help find alternative resources for beneficiaries who do not meet the requirements of the Medicare repetitive scheduled non-emergent ambulance transport benefit.

Additional information is available on the CMS website at <http://go.cms.gov/PAAmbulance>.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

This document announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. Therefore, there are no regulatory impact implications associated with this notice.

Authority: Section 1115A of the Social Security Act.

Dated: August 22, 2019.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-19886 Filed 9-13-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-153]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 16, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR*, Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of

information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection*

Request: Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.*, allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form*

Number: CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

Dated: September 11, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–19967 Filed 9–13–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 5, 2019. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, effective March 7, 2019. The document erroneously included ANDA 077895 for Ursodiol Capsules USP, 300 milligrams, held by Impax Laboratories, LLC. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993, 301–348–3035.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Tuesday, February 5, 2019 (84 FR 1745), in FR Doc. 2019–01129, the following correction is made:

1. On page 1746, in the table, the entry for ANDA 077895 is removed.

In a separate notice published in this issue of the **Federal Register**, FDA is withdrawing the approval of ANDA 077895 under 21 CFR 314.150(d).

Dated: September 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19920 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–3347]

Medical Devices; Exemption From Premarket Notification: Class II; Powered Wheeled Stretcher; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for powered wheeled stretchers. These devices are battery-powered tables with wheels that are intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions). FDA is publishing this notice to obtain comments in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by November 15, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 15, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 15, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way: