proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

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:* Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program; *Use:* Section 302 of the MMA amended section 1847 of the Social Security Act (the Act) to require the implementation of the DMEPOS competitive bidding program. The Act provided the program requirements for the submission of bids in establishing payment rates and the awarding of contracts; provided the requirements for mergers and acquisitions; and a requirement for the Secretary to re-compete contracts not less often than once every 3 years. The MMA also requires the Secretary to re-compete contracts not less often than once every 3 years. The Round 1 Rebid contract period for all product categories except mail-order diabetic supplies expired on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetic testing supplies ended on December 31, 2012.) The competition for the Round 1 Re-compete began in August of 2012. The Round 1 Re-compete contracts and prices became effective on January 1, 2014 and will expire on December 31, 2016. Round 2 and National Mail-Order contracts and prices will expire on June 30, 2016.

The most recent approval for this information collection request (ICR) was issued by OMB on June 10, 2013. That ICR included the estimated burden to collect the information in bidding Forms A and B for the Round 1 Re-compete. We are now seeking approval to collect the information in Forms A and B for competitions that will occur before 2017. For these upcoming competitions CMS will publish a slightly modified version of the RFB instructions and accompanying Forms A and B so that suppliers will be better able to identify and understand the requirements of the program. We decided to modify the Request for Bids (RFB) instructions and forms based on our experience from the last round of competition. The end result is expected to produce more complete and accurate information to evaluate suppliers. No new collection requirements have been added to the modified RFB instructions or Form A or B. Finally, we are retaining without change the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, the Subcontracting Disclosure Form, and Forms C and D and their associated burden under this ICR. We intend to continue use of these forms on an ongoing basis.

Form Number: CMS–10169 (OMB control number: 0938–1016); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Individuals or Households; *Number of Respondents:* 49,625; *Total Annual Responses:* 39,380; *Total Annual Hours:* 235,024. (For policy questions regarding this collection contact Michael Keane at 410–786–4495.)

Dated: June 27, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–15603 Filed 7–2–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Texas Medicaid State Plan Amendment (SPA) 13–0045–MM2 and Texas Children's Health Insurance Program SPA 13–0035

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing: reconsideration of disapproval.

SUMMARY: This notice announces an administrative hearing to be held on August 14, 2014, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room #801, 8th Floor Dallas, Texas 75202 to reconsider CMS' decision to disapprove Texas' Medicaid SPA 13–0045–MM2 and the CHIP SPA 13–0035.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by (15 days after publication).

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786–3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove the Texas Medicaid SPA 13–0045–MM2 and the Children's Health Insurance Program (CHIP) SPA 13–0035 which were submitted to the Centers for Medicare and Medicaid Services (CMS) on December 31, 2013 and disapproved on March 31, 2014. In part, these SPAs request CMS approval of the state's proposed alternative single, streamlined application, both a paper version and online version, for completing an eligibility determination based on modified adjusted gross income (MAGI). Specifically, Texas's proposals requiring all applicants to submit information on assets and provide detailed information on absent parents make the application longer and the information is not necessary for completing an eligibility determination based on MAGI.

The issues to be considered at the hearing are:

- Whether Texas Medicaid SPA 13–0045–MM2, complied with the statutory requirement in section 1902(a)(19) of the Social Security Act (the Act), under which the state plan must assure that eligibility for care and services under

the plan will be determined and provided in a manner consistent with the simplicity of administration and the best interests of the recipients. Requiring applicants to provide additional detailed information, which is not necessary for determining their eligibility for coverage, is inconsistent with simplicity of administration of the state plan and is not in the best interests of Medicaid recipients or applicants.

• Whether Texas CHIP SPA 13–0035, complied with section 2101(a) of the Act which specifies that the state plan must assure that eligibility for care and services must be provided in an effective and efficient manner. Requiring applicants to provide additional detailed information, which is not necessary for determining their eligibility for coverage, is inconsistent with simplicity of administration of the state plan and is not in the best interests of CHIP recipients or applicants.

• Whether the state failed to comply with section 1902(e)(14)(C) of the Act, as added by section 2002 of the Affordable Care Act, and section 2102(b)(1)(B)(v) of the Act, as added by section 2101 of the Affordable Care Act, which prohibit the use of asset or resource tests as criteria for Medicaid and CHIP eligibility among eligibility groups subject to MAGI, including children, pregnant women, parents, and, if eligible in a state, other nondisabled, nonelderly adults. Consistent with these statutory provisions, questions about assets and resources were not included in the Secretary's model single streamlined application, which was released on April 30, 2013.

• Whether the state complied with the requirements of sections 1902(a)(4) and 2101(a) of the Act, as implemented in 42 CFR 435.907 and 42 CFR 457.330, for approval of an alternative single, streamlined application. While an alternative application may be tailored to accommodate state preferences and policies, it must also reflect the general principles of the model application and must comply with the applicable provisions of law and regulation. The regulations at 42 CFR 435.907 and 42 CFR 457.330 note specifically that the alternative application may be no more burdensome on the applicant than the model application. CMS guidance released June 18, 2013 further clarified that the application may only include questions that ''are necessary for determining eligibility for coverage in a Qualified Health Plan (QHP) and all insurance affordability programs, or the administration of these programs.''

Section 1116 of the Act and federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Texas announcing an administrative hearing to reconsider the disapproval of its SPAs reads as follows:

Ms. Kay Ghahremani, State Medicaid Director, Texas Health and Human Services Commission, P.O. Box 13247, Austin, TX 78711.

Dear Ms. Ghahremani:

I am responding to your request for reconsideration of the decision to disapprove Texas's Medicaid state plan amendment (SPA) 13–0045–MM2 and the Children's Health Insurance Program (CHIP) SPA 13–0035, which were submitted to the Centers for Medicare and Medicaid Services (CMS) on December 31, 2013 and disapproved on March 31, 2014. I am scheduling a hearing on your request for reconsideration to be held on August 14, 2014, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room #801, Dallas, Texas 75202.

In part, these SPAs request CMS approval of the state's proposed alternative single, streamlined application, both a paper version and online version, for completing an eligibility determination based on modified adjusted gross income (MAGI). Specifically, Texas's proposals requiring all applicants to submit information on assets and provide detailed information on absent parents make the application longer and the information is not necessary for completing an eligibility determination based on MAGI.

In your request for reconsideration, you described changes that the state is considering with respect to these SPAs, and we will continue to talk with you about these changes. In the event that CMS and the state come to agreement on resolution of the issues, which formed the basis for disapproval, these SPAs may be moved to approval prior to the scheduled hearing.

The issues to be considered at the hearing are:

• Whether Texas Medicaid SPA 13–0045–MM2, complied with the statutory requirement in section 1902(a)(19) of the Social Security Act (the Act), under which the state plan must assure that eligibility for care and services under the plan will be determined and provided in a manner consistent with simplicity of administration and the best interests of the recipients. Requiring applicants to provide additional detailed information, which is not necessary for determining their eligibility for coverage, is inconsistent with the simplicity of administration of the state plan and is not in the best interests of Medicaid recipients or applicants.

• Whether Texas CHIP SPA 13–0035, complied with section 2101(a) of the Act which specifies that the state plan must assure that eligibility for care and services must be provided in an effective and efficient manner. Requiring applicants to provide additional detailed information, which is not necessary for determining their eligibility for coverage, is inconsistent with simplicity of administration of the state plan and is not in the best interests of CHIP recipients or applicants.

• Whether the state failed to comply with section 1902(e)(14)(C) of the Act, as added by section 2002 of the Affordable Care Act, and section 2102(b)(1)(B)(v) of the Act, as added by section 2101 of the Affordable Care Act which prohibit the use of asset or resource tests as criteria for Medicaid and CHIP eligibility among eligibility groups subject to MAGI, including children, pregnant women, parents, and, if eligible in a state, other nondisabled, nonelderly adults. Consistent with these statutory provisions, questions about assets and resources were not included in the Secretary's model single streamlined application, which was released on April 30, 2013.

• Whether the state complied with the requirements of sections 1902(a)(4) and 2101(a) of the Act, as implemented in 42 CFR 435.907 and 42 CFR 457.330, for approval of an alternative single, streamlined application. While an alternative application may be tailored to accommodate state preferences and policies, it must also reflect the general principles of the model application and must comply with the applicable provisions of law and regulation. The regulations at 42 CFR 435.907 and 42 CFR 457.330 note specifically that the alternative application may be no more burdensome on the applicant than the model application. CMS guidance released June 18, 2013 further clarified that the application may only include questions ''that are necessary for determining eligibility for coverage in a Qualified Health Plan (QHP) and all insurance affordability programs, or for the administration of these programs.''

If the hearing date is not acceptable, I would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact the Mr. Cohen at (410) 786–3169. In order to

facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the state at the hearing.

Sincerely,

Marilyn Tavenner,
Administrator.

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18)

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: June 27, 2014.

Marilyn Tavenner,

Administrator, Center for Medicare & Medicaid Services.

[FR Doc. 2014–15615 Filed 7–2–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on export notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, cosmetics, and tobacco that may not be marketed or sold in the United States.

DATES: Submit either electronic or written comments on the collection of information by September 2, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Exports: Notification and Recordkeeping Requirements—21 CFR 1.101 (OMB Control Number 0910–0482)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring exports (Exports: Notification and Recordkeeping Requirements—§ 1.101 (21 CFR 1.101)) which pertain to the exportation of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products are not be sold in the United States.

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or markets in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (e.g. name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods, cosmetics, and tobacco products that may not be sold in the United States and maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

On March 30, 2012, OMB approved ''Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products,'' OMB control number 0910–0690, which amended, among other sections, § 1.101 to incorporate tobacco products. This amendment reflects the Agency's authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) and added tobacco products to the list of products covered under § 1.101(a) and (b).

FDA estimates the burden of this collection of information as follows: