is an essential component of this analytic method.

The information collected through the survey will complement the existing data by helping identify factors associated with ADE outcomes of interest from existing data sets such as Medicare claims. For example, claims data can provide information on whether the number of prescriptions for opioids has decreased, but not what has helped to facilitate the decrease. Subsequent to the 60-day **Federal Register** notice which published on July 20, 2018 (83 FR 34593), the collection instrument was revised to clarify wording on questions, adjust the methods for measuring attribution, and nursing homes were removed from the originally-proposed sample. These changes did not result in changes to burden, as additional respondents will be recruited from the pharmacy and practice settings. *Form Number:* CMS–10675 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 1,200; *Total Annual Responses:* 1,200; *Total Annual Hours:* 300. (For policy questions regarding this collection contact Nancy Sonnenfeld at 410–786–1294.)

Dated: November 26, 2018.

William N. Parham, III,

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

[FR Doc. 2018–25978 Filed 11–28–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Allotment Percentages to States for Child Welfare Services State Grants; CFDA Number: 93.645

AGENCY: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of biennial publication of allotment percentages for States under the Title IV–B subpart 1, Stephanie Tubbs Jones Child Welfare Services Program.

SUMMARY: As required by section 423(c) of the Social Security Act, the Department is publishing the allotment percentage for each State under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Program. Under section 423(a), the allotment percentages are one of the factors used in the computation of the Federal grants awarded under the Program.

DATES: The allotment percentages will be effective for Federal Fiscal Years 2020 and 2021.

FOR FURTHER INFORMATION CONTACT: Daniel Jackson, Grants Fiscal Management Specialist, Office of Grants Management, Office of Administration, Administration for Children and Families, 330 C St. SW, Washington, DC 20201. Telephone: (202) 401–3446. Email: *daniel.jackson@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The allotment percentage for each State is determined on the basis of paragraphs (b) and (c) of section 423 of the Social Security Act. These figures are available on the ACF internet homepage at *https://www.acf.hhs.gov/cb.* The allotment percentage for each State is as follows:

ALLOTMENT

State	Percentage
Alabama	60.54
Alaska	43.36
Arizona	59.19
Arkansas	60.16
California	42.50
Colorado	47.06
Connecticut	30.25
Delaware	51.62
District of Columbia	30.00
Florida	53.73
Georgia	57.38
Hawaii	49.16
Idaho	59.41
Illinois	47.37
Indiana	56.44
Iowa	53.57
Kansas	52.37
Kentucky	60.43
Louisiana	57.09
Maine	55.15
Maryland	41.34
Massachusetts	34.73
Michigan	55.31
Minnesota	47.14
Mississippi	64.24
Missouri	56.32
Montana	55.77
Nebraska	49.84
Nevada	55.23
New Hampshire	42.83
New Jersey	37.84
New Mexico	61.06
New York	38.63
North Carolina	57.20
North Dakota	47.32
Ohio	54.67
Oklahoma	56.55
Oregon	53.59
Pennsylvania	48.50
Rhode Island	48.88
South Carolina	59.65
South Dakota	51.47
Tennessee	56.03
Texas	53.39

ALLOTMENT—Continued

State	Percentage
Utah	57.96
Vermont	49.37
Virginia	46.44
Washington	44.42
West Virginia	62.68
Wisconsin	52.48
Wyoming	43.49
America Samoa	70.00
Guam	70.00
Puerto Rico	70.00
N. Mariana Islands	70.00
Virgin Islands	70.00

Statutory Authority: Section 423(c) of the Social Security Act (42 U.S.C. 623(c)).

Elizabeth Leo,

Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2018–25932 Filed 11–28–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4337]

Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; Announcement of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public meeting entitled ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' FDA is also requesting public comments on the subject. The purpose of the meeting and the request for comments is to fulfill FDA's commitment to seek stakeholder input related to data standards and the electronic submission system's past performance, future targets, emerging industry needs, and technology initiatives. FDA will use the information from the public meeting as well as from comments submitted to the docket to provide input into data standards initiatives, the FDA Information Technology (IT) Strategic Plan, and electronic submissions gateway target timeframes.

DATES: The public meeting will be held on April 10, 2019, from 9 a.m. to 4 p.m. Submit either electronic or written comments by April 10, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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 April 10, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 10, 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:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–4337 for ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *chenoa.conley@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to achieve the long-term goal of improving the predictability and consistency of the electronic submission process and enhancing transparency and accountability of FDA information technology-related activities. In the PDUFA VI commitment letter, FDA agreed to hold annual public meetings to seek stakeholder input related to electronic submissions and data standards to inform the FDA IT Strategic Plan and published targets. The commitment letter outlines FDA's performance goals and procedures under the PDUFA program for the years 2018 through 2022. The commitment letter can be found at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

FDA will consider all comments made at this meeting or received through the docket (see **ADDRESSES**).

II. Participating in the Public Meeting

Registration: To register to attend ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards,'' please register at *https://www.eventbrite.com/e/pdufa-vi-public-meeting-on-electronic-submissions-and-data-standards-tickets-49895060469.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. A draft agenda will be posted approximately 1 month prior to the meeting.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting on April 10, 2019, must register by 11:59 p.m. on March 22, 2019, Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

Request for Oral Presentations: During online registration, you may indicate if you wish to present during the public

comment session and which topic(s) you would like to address. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by March 27, 2019. All requests to make oral presentations must be received by the close of registration at 11:59 on March 22, 2019, Eastern Time. If selected for presentation, any presentation materials must be emailed to *cderdatastandards@fda.hhs.gov* no later than April 3, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

If you need special accommodations due to a disability, please contact Chenoa Conley, 301–796–0035, email *Chenoa.Conley@fda.hhs.gov,* no later than April 3, 2019.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https:/www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25958 Filed 11–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5625]

Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies.'' It describes study designs for generating data that supports both 510(k) clearance and CLIA waiver. Use of the Dual 510(k) and CLIA Waiver by Application pathway is optional; however, FDA believes this pathway is in many instances the least burdensome and fastest approach for manufacturers to obtain a CLIA waiver in addition to 510(k) clearance for new in vitro diagnostic (IVD) devices. FDA believes increased use of this pathway will speed up the process of bringing simple and accurate IVD devices to CLIA waived settings, which will better serve patients and providers. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by February 27, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–5625 for ''Recommendations for Dual 510(k) and CLIA Waiver by Application Studies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download