drive the bidding process. CMS maintains and updates each BPT file and releases new versions every April.

The BPT files may be downloaded from the Health Plan Management System website (or HPMS), which is a restricted-access website, so users must obtain approval from CMS before using it. From HPMS, the BPT files may be downloaded as part of the Plan Benefit Package (or PBP) software, or they may be downloaded as stand-alone blank files. These files are made available to users on the first Monday of April every year and an HPMS memo is released announcing the software availability. Plan sponsors are required to upload the completed BPTs to HPMS by the first Monday in June each year.

MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The information provided in the BPT is the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development (from claims data and/or manual rating), administrative expenses, profit levels, and projected plan enrollment information. By statute, completed BPTs are due to CMS by the first Monday of June each year. *Form Number:* CMS–10142 (OMB control number: 0938–0944); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not- for-profit institution; *Number of Respondents:* 555; *Total Annual Responses:* 4,995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410–786–3026.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Contract Year 2020 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* CMS requires that MA and PDP organizations submit a completed Plan Benefit Package (PBP) and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits.

Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization. This allows CMS to review the benefit packages in a consistent way across all submitted bids during with incredibly tight timeframes. This data is also used to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare Medicare Advantage and Prescription Drug plans. *Form Number:* CMS–R–262 (OMB control number 0938–0763); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institution; *Number of Respondents:* 570; *Total Annual Responses:* 6,760; *Total Annual Hours:* 65,354.50 (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid State Plan Base Plan Pages; *Use:* State Medicaid agencies complete the plan pages while we review the information to determine if the state has met all of the requirements of the provisions the states choose to implement. If the requirements are met, we will approve the amendments to the state's Medicaid plan giving the state the authority to implement the flexibilities. For a state to receive Medicaid Title XIX funding, there must be an approved Title XIX state plan. *Form Number:* CMS–179 (OMB control number 0938–0193); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,120; *Total Annual Hours:* 22,400. (For policy questions regarding this collection contact Annette Pearson at 410–786–6958.)

Dated: September 21, 2018.

William N. Parham, III,

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

[FR Doc. 2018–20995 Filed 9–28–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects:

Title: Federal Child Support Portal Registration.

OMB No.: 0970–0370.

Description: The federal Office of Child Support Enforcement (OCSE), Division of Federal Systems, maintains the Child Support Portal (Portal), through which authorized users may view, update, or upload information for child support purposes. To securely access the Portal as an authorized user, OCSE creates profiles within the Portal for employers, insurers, and multistate financial institutions (MSFIs) using information provided in the Employer Service Profile Form and the Debt Inquiry Insurer Profile Form (see OMB No: 0970–0196 for the MSFI Profile Form). State child support agencies manage and authenticate authorization for individual users via the state proxy server; therefore, a profile form is not required.

The federal Child Support Portal Registration information collection activities are authorized by 42 U.S.C. 653(m)(2), which requires the Secretary to establish and implement safeguards to restrict access to confidential information in the Federal Parent Locator Service to authorized persons, and to restrict use of such information to authorized purposes.

Respondents: Employers, Financial Institutions, Insurers, and Child Support Agencies.

Annual Burden Estimates:

Information collection instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Employer Services Profile	2,144	1	0.08	171.52
Debt Inquiry Insurer Profile	22	1	0.08	1.76
Portal Registration Screens	2,338	1	0.15	350.70

Estimated Total Annual Burden Hours (Rounded from 523.98): 524.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, *Attn:* Desk Officer for the Administration for Children and Families.

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–21226 Filed 9–28–18; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities, President's Committee for People With Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

DATES: Thursday, November 8, 2018 from 9:00 a.m. to 4:30 p.m.; and Friday, November 9, 2018 from 9:00 a.m. to 4:30 p.m. These meetings will be open to the general public.

ADDRESSES: These meetings will be held at the U.S. Access Board, located at 1331 F Street NW, Suite 800, Washington, DC 20004. Individuals who would like to participate via conference call may do so by dialing toll-free #: 1–888–949–2790, when prompted enter pass code: 1989852. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Ms. Allison Cruz, Director, Office of Innovation, via email at *Allison.Cruz@acl.hhs.gov,* or via telephone at 202–795–7334, *no later than* Monday, October 19, 2018. The PCPID will attempt to accommodate requests made after this date, *but cannot guarantee the ability to grant requests received after the deadline.* All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

FOR FURTHER INFORMATION CONTACT: Ms. Allison Cruz, Director, Office of Innovation, 330 C Street SW, Switzer Building, Room 1114, Washington, DC 20201. Telephone: 202–795–7334. Fax: 202–795–7334. Email: *Allison.Cruz@acl.hhs.gov*

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expanding employment opportunities; (B) connecting people to services; (C) supporting families and caregivers; (D) strengthening the networks; and (E) protecting rights and preventing abuse.

Agenda: The Committee Members will discuss preparation of the PCPID 2019 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Dated: September 24, 2018.

Mary Lazare,

Principal Deputy Administrator, Administration for Community Living.

[FR Doc. 2018–21319 Filed 9–28–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3275]

Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to an IND, NDA, BLA, or ANDA.'' The draft guidance provides recommendations to industry and FDA staff regarding the content and submission procedures for use-related risk analyses, human factors validation study protocols and reports, threshold analyses, and comparative use human factors study protocols and reports.

DATES: Submit either electronic or written comments on the draft guidance by November 30, 2018 to ensure that the Agency considers your comments in this review.

ADDRESSES: You may submit comments 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