and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. Through delivery of this standardized notice, a Part D plan sponsor's network pharmacies are in the best position to inform enrollees at point of sale about how to contact their Part D plan if the prescription cannot be filled. *Form Number:* CMS–10147 (OMB control number: 0938–0975); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits; *Number of Respondents:* 72,900; *Number of Responses:* 55,215,940; *Total Annual Hours:* 919,898. (For policy questions regarding this collection contact Sabrina Edmonston at 410–786–3209 or *Sabrina.edmonston@cms.hhs.gov*).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Service Level Data Collection for Initial Determinations and Appeals; *Use:* The Part C and D Reporting Requirements, as set forth in §§ 422.516(a) and 423.514(a), provide CMS with the ability to collect more granular data related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions. This includes collecting more timely data with greater frequency or closer in real-time. The proposed data elements listed in the Technical Specifications document in this proposed PRA would provide key data to CMS on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits.

CMS staff will use this information to monitor health plans and to hold them accountable for their performance. CMS users include group managers, division managers, branch managers, account managers, and researchers. Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry and other interested stakeholders about beneficiary access to the items, services, and drugs, including service level data for initial determinations and appeals, and other factors pertaining to use of government funds, as well the performance of MA plans. *Form Number:* CMS–10905 (OMB control number: 0938-New); *Frequency:* Quarterly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits and Federal Government State, Local; *Number of Respondents:* 728; *Number of Responses:* 2,912; *Total Annual Hours:* 728. (For policy questions regarding this collection contact Sabrina Edmonston at 410–786–3209 or *sabrina.edmonston@cms.hhs.gov*).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–17773 Filed 8–8–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Child Abuse and Neglect Background Checks for Child Care and Early Education Project (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF) is proposing an information collection activity for the Child Abuse and Neglect Background Checks for Child Care and Early Education (CAN Checks for CCEE) Project. The goal of the project is to better understand how states and territories use findings from CAN registry background checks, as required by the Child Care and Development Block Grant Act of 2014 (CCDBG), to make child care employment eligibility determinations. The study will also be used to understand state and territory variation, facilitators, and challenges in implementing CAN registry background checks; and explore any resulting within- or across-state/territory equity implications.

DATES: *Comments due within 30 days of publication. The Office of Management and Budget (*OMB) must make a decision about 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed information collections for the CAN Checks for CCEE Project is designed to explore how states and territories implement CAN registry background checks for child care employment eligibility decisions. While the CCDBG Act of 2014 clearly describes procedures and exclusionary criteria pertaining to the use of criminal and sexual offender registry background checks to inform child care employment eligibility decisions, requirements for the use of CAN registry background checks are less clear. The findings will be of interest to ACF, and, in particular, to OPRE and the Office of Child Care, who are interested in the effective and equitable implementation of CAN registry background checks for prospective and current child care staff. Findings will also be of interest to Child Care and Development Fund (CCDF) state/territory lead agencies that oversee the CCDF program in their states/territories and the state/territory offices that oversee early care and education. The results of this study also have implications for child care programs and staff. Further, given the U.S. Congress' interest in prior exploratory work on this topic, it may also be informative to federal lawmakers.

CCDF lead agency staff that participate in this information collection will be asked to complete a voluntary, one-time web-based survey. The survey will focus on the practices and policies related both to in-state/territory and interstate CAN registry checks, including what data they request and receive, as well as how they use it in making child care employment eligibility decisions.

Respondents: Each state, territory, and the District of Columbia will be invited to complete one web-based survey. Given that each agency may have multiple staff members with relevant knowledge of different survey topics and no one staff member may possess all of the knowledge to complete the survey, CCDF Lead Agencies may have multiple staff members work together to complete the survey. For burden estimates, we are assuming up to 3 respondents may work on the survey

per state/territory (up to 168 total individuals). Only one survey will be submitted for each state/territory.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Instrument 1: CCDF Lead Agency Survey	168	1	*0.75	126

*Note that this is the estimated time to complete the full survey, which could be completed by one individual or multiple individuals. Surveys completed by multiple individuals will take less time for each individual to provide a response.

Authority: Research funding set-aside authorized by the CCDBG Act of 2014 and funded by CCDF. Section 658O(a)(5) of CCDBG (as codified at 42 U.S.C. 9857 et seq) grants the Secretary of HHS the authority to reserve up to ½ percent of the total Discretionary and Mandatory CCDF funding ''to conduct research and demonstration activities, as well as periodic external, independent evaluations of the impact of the program described by this subchapter on increasing access to child care services and improving the safety and quality of child care services, using scientifically valid research methodologies, and to disseminate the key findings of those evaluations widely and on a timely basis.''

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–17723 Filed 8–8–24; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0342]

Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment; Revised 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 ''Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drug and biological products for the treatment of patients with bacillus Calmette-Guérin (BCG)-unresponsive nonmuscle invasive bladder cancer (NMIBC). This draft guidance reflects proposed revisions to the final guidance entitled ''BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment,'' published in February 2018, and incorporates changes based on review experience as well as the evolving landscape of drug development in bladder cancer, as noted by external experts.

DATES: Submit either electronic or written comments on the draft guidance by October 8, 2024 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–2018–D–0342 for ''BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drug and Biological Products for Treatment.'' 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, 240–402–7500.

- 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