CMS–10286 Notice of Research Exception under the Genetic Information Nondiscrimination

CMS–10325 Disclosure and Recordkeeping Requirements for Grandfathered Health Plans under the Affordable Care Act

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. 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS–10286 (OMB control number: 0938–1077); *Frequency:* Occasionally; *Affected Public:* Private Sector; State, Local or Tribal governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 0.5. For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosure and Recordkeeping Requirements for Grandfathered Health Plans under the Affordable Care Act; *Use:* Section 1251 of the Affordable Care Act provides that certain plans and health insurance coverage in existence as of March 23, 2010, known as grandfathered health plans, are not required to comply with certain statutory provisions in the Act. The final regulations titled ''Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections'' (80 FR 72192, November 18, 2015) require that, to maintain its status as a grandfathered health plan, a plan must maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents that are necessary to verify, explain or clarify status as a grandfathered health plan. The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a state or federal agency official. A grandfathered health plan is also required to include a statement in any summary of benefits under the plan or health insurance coverage, that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act, and providing contact information for participants to direct questions and complaints. In addition, a grandfathered group health plan that is changing health insurance issuers is required to provide the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph § 147.140(g)(1) of the final regulations are exceeded. It is also required that, for an insured group health plan (or a multiemployer plan) that is a grandfathered plan, the relevant policies, certificates, or contracts of insurance, or plan documents must disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year. *Form Number:* CMS–10325 (OMB control number: 0938–1093); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Local or Tribal governments; *Number of Respondents:* 14,669; *Total Annual Responses:* 2,651,523; *Total Annual Hours:* 40. For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.

Dated: January 6, 2022.

William N. Parham, III,

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

[FR Doc. 2022–00344 Filed 1–10–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Judicial, Court, and Attorney Measures of Performance (New Collection)

AGENCY: Children's Bureau; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Children's Bureau, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new descriptive study, Judicial, Court, and Attorney Measures of Performance (JCAMP).

DATES: *Comments due within 60 days of publication.* In compliance with the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing

infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This study will collect information from Court Improvement Program (CIP) staff to (1) understand data capacity and current use of performance measures and (2) gather feedback from the performance measure pilot process. This will be accomplished using two instruments:

JCAMP CIP Data Capacity Survey

The survey asks CIPs about their current capacity to collect specific data elements from the following six categories of measurement: (1) Legal and judicial context (*e.g.,* court docketing), (2) Practices (*e.g.,* attorney pre-petition legal practice), (3) Short-term outcomes that happen during hearings (*e.g.,* discussion of key issues), (4) Intermediate outcomes that happen during the case (*e.g.,* judicial continuity), (5) Long-term outcomes that happen after case closure (*e.g.,* child safety), and (6) Cross-cutting themes (*e.g.,* equity). The survey asks about capacity broadly and then specifically for a series of subcategories.

JCAMP Pilot Site Debrief Form

The JCAMP Pilot Site Debrief Form is a survey developed to be administered to CIP staff who have assisted with piloting of the performance measures. The survey asks participants about the challenges and successes in collecting pilot data for the measures, their confidence in collecting the data going forward, and suggestions for improving future efforts.

Respondents: Respondents include CIP Administrators and staff.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
JCAMP CIP Data Capacity Survey	106	1	.83	264	88
JCAMP Pilot Debrief Form	24	1	.25	18	6

Estimated Total Annual Burden Hours: 94.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 5106, Public Law 111–320, the Child Abuse Prevention and Treatment Act Reauthorization Act of 2010, and titles IV–B and IV–E of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–00238 Filed 1–10–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0053]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act; 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 ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States. This guidance is intended to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products that will help prevent or mitigate shortages of such devices during or in advance of a public health emergency. FDA is issuing this guidance to implement amendments to the FD&C Act by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as it relates to device shortages and potential device shortages during or in advance of a public health emergency. 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 March 14, 2022 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