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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #85]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 2, 2024.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10398 #85) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 #85/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at 410–786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collection

1. *Title of Information Collection:* 3.1–M State Plan Amendment (SPA) Templates for Eligible Juveniles Who are Inmates of a Public Institution; *Type of Information Collection Request:* New information collection request information request; *Use:* Section 5121 of the Consolidated Appropriation Act of 2023 (CAA, 2023) creates a new mandate for states by amending section 1902(a)(84) of the Social Security Act (the Act) (42 U.S.C. 1396a) to require states to provide specific screening and diagnostic services and targeted case management (including referrals) in the 30 days prior to release from incarceration, and targeted case management (TCM) (including referrals) for at least 30 days post release for eligible juveniles who are inmates of a public institution, post adjudication. The requirements are effective January 1, 2025.

To comply with the amendments states must submit a Medicaid SPA attesting that the state has developed an internal operation plan, and in accordance with such plan, will provide coverage during the statutory pre- and post-release period of screening, diagnostic, and TCM services for eligible juveniles who are within 30 days of release post adjudication.

States have the option to lift the Medicaid inmate payment and CHIP eligibility exclusions and provide coverage of pre-release Medicaid and CHIP services (for electing states) and makes available federal matching funds for the full breadth of Medicaid and CHIP benefits to eligible juveniles who are incarcerated and pending disposition of charges. States selecting this state plan option must provide to eligible juveniles all mandatory and optional services to which they are otherwise entitled under the state plan. During the period when an eligible juvenile is incarcerated and pending disposition of charges, this is essentially a full lifting of the Medicaid inmate payment exclusion and CHIP eligibility exclusion. States cannot choose to provide a limited array of state plan services under this option. An operational plan is not required for this state option.

For states that wish to elect the option in section 5122 of the CAA, 2023, states should submit a SPA attesting to CMS that they are also electing coverage for any Medicaid or CHIP state plan services for eligible juveniles pending disposition of charges to which the beneficiary would otherwise be entitled, if not for their incarceration status.

Form Number: CMS–10398 #85 (OMB control number: 0938–1148); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 4,872. (For policy questions regarding this collection contact: Marlana Thieler at 410–786–6274.)

William N. Parham, III,

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

[FR Doc. 2024–26713 Filed 11–15–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4467]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 information collection associated with FDA's Prescription Drug User Fee program.

DATES: Either electronic or written comments on the collection of information must be submitted by January 17, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 17, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–4467 for ''Prescription Drug User Fee Program.'' 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, 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 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Prescription Drug User Fee Program

OMB Control Number 0910–0297—Revision

This information collection supports implementation of the FDA Prescription Drug User Fee program (called ''PDUFA'' in reference to the Prescription Drug User Fee Act). Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic

Act (FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect annual program fees for prescription drug products approved under certain new drug applications (NDAs) and biologics license applications (BLAs). Also under this authority, pharmaceutical companies pay an application fee for certain NDAs and BLAs submitted to FDA for review. Because the submission of user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted.

PDUFA must be reauthorized every 5 years. On September 30, 2022, the President signed into law the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of PDUFA through September 30, 2027 (*https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027*). PDUFA VII provides for the continued timely review of NDAs and BLAs. Since the initial passage of PDUFA, user fees have played an important role in expediting the drug review and approval process. PDUFA VII reauthorization also includes commitments to meet certain performance goals and procedures. The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress.

We are revising the collection to include our current commitment goals, as set forth in the document ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027,'' found on our website at *https://www.fda.gov/media/151712/download?attachment.* The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to meeting these goals and to continuous operational improvements associated with PDUFA implementation. The commitment goals provide for the development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practices regulations in 21 CFR 10.115, which provide for public comment at any time.

To assist respondents with the information collection, we developed Form FDA 3397 entitled ''Prescription Drug User Fee Cover Sheet.'' Additional information and associated instructions may be found on our website at *https://www.fda.gov/industry/fda-user-fee-programs.* The cover sheet (Form FDA 3397) is submitted for original NDAs, BLAs and resubmissions of these original applications after withdrawal before filing or refusal to file actions. The form is not submitted for certain FDA-regulated products. The list of exempted products is included under the instructions to Form FDA 3397.

Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, exemption and refund requests. We developed the guidance document entitled ''Guidance for Industry—Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products,'' and Form FDA 3971 (Small Business Waiver and Refund Request), which can be found on our website at *https://www.fda.gov/media/131797/download,* as mandated by Congress.

We also developed Form FDA 4068, ''Prescription Drug User Fee Act; Waivers, Refunds, and Exemptions,'' along with accompanying instructions, to enable sponsors of designated orphan products to request an exemption from applicable fees under PDUFA and included the form in the information collection when the prior renewal was submitted for approval. Use of the form will provide the information required for analysis and application of the orphan exemption from user fees, organizing the requested information for easier data collection and streamlining the review request. We find, however, with this renewal, that use of the form has not been implemented yet, pending development of the OneNexus system for management of the user fee systems. Use of the form is anticipated once the OneNexus system is developed and implemented for the PDUFA program.

The PDUFA information collection and all user fee cover sheets, including the ''Prescription Drug User Fee Cover Sheet'' (Form FDA 3397), are accessed and submitted electronically, as required by statute, through FDA's electronic systems such as the Document Archiving Reporting and Regulatory Tracking System (DARRTS), Electronic Submission Gateway (ESG), and Panorama.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 735 and 736 of the FD&C Act (PDUFA waivers and exemptions, not including small business waiver requests).	99	1.828	181	17	3,077
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers).	35	1	35	2	70
Reconsideration Requests	13	1.69	22	24	528
Appeal Requests	4	1.5	6	12	72
User Fee Cover Sheet Form FDA 3397 submission with original NDAs and BLAs.	132	1.24	164	0.5 (30 minutes)	82
Total			408		3,829

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C)) of the FD&C Act) is 181, submitted by 99 different applicants.

We estimate that 35 respondents will each submit a small business waiver request annually. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses

requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that their application is their first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 22 requests for reconsideration annually (including small business waiver reconsiderations) and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving six requests annually for appeal of user fee waiver determinations, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume a total of 82 hours of burden for completing and submitting the 164 forms FDA 3397 (Prescription Drug User Fee Coversheet) along with submission of NDAs or BLAs. The burdens associated with submission of NDAs and BLAs are included in OMB control numbers 0910–0001 and 0910–0338, respectively.

The information collection reflects changes and adjustments. We have clarified that the scope of the collection includes provisions found in our current commitment goals letter, negotiated with industry, pertaining to the assessment of fees, waivers, refunds, and exemptions under PDUFA VII. Cumulatively these changes and adjustments have resulted in an increase of three responses and 203 burden hours annually since the prior renewal of the information collection. We attribute this to the steady state of incoming requests for waivers and reconsiderations and normal fluctuations in types of submissions or waivers received.

Dated: October 30, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26801 Filed 11–15–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Generic Information Collection Request for Health Resources and Services Administration Hotlines, Chatlines, and Online Portals

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 17, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Generic Information Collection Request for Collections Related to HRSA Hotlines, Chatlines, and Online Portals, OMB No. 0906–New.

Abstract: HRSA currently administers approximately 15 hotlines, chatlines, and online portals for use by customers, members of the public, and HRSA funding recipients. These hotlines, chatlines, and online portals are administered by HRSA or a contractor on behalf of HRSA. The purpose of information collections under this generic umbrella ICR package is to allow HRSA to collect information on the operation of such HRSA hotlines, chatlines, and online portals to assist HRSA in improving their operation and determining if these services are helpful. In addition to collecting basic demographic information, the information collections would include questions such as reasons for inquiry, topics covered by inquiry, feedback on provided guidance or the hotline/chatline/online portal user experience. No protected information, such as personal health information or trade secrets, will be disclosed unless specifically required by law.

An illustrative, but not exhaustive, list of examples of information collection activities that would fall under this collection include standardized questions that are asked during the interaction with the public; surveys about their interaction; and information collected about their experience in use of hotlines, chatlines, and online portals. This generic umbrella ICR covers responses to standardized and survey questions relating to public use of HRSA's hotlines, chatlines, and online portals, pursuant to the ''Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act'' 2010 White House guidance memo. The memo can be found at: *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/inforeg/SocialMediaGuidance_04072010.pdf.*

Need and Proposed Use of the Information: The purpose of collections under this generic umbrella ICR is for accountability, program management, and oversight purposes. Collecting feedback from members of the public about their interaction with these services will help ensure that HRSA hotlines, chatlines, and online portals are operating to the best of their abilities. While HRSA can evaluate the general need for and the overall practical utility of such information collection in advance, HRSA is unable to determine the details of the specific individual collection methodologies until a later time. Using a generic umbrella ICR will allow HRSA to quickly and nimbly respond to public needs and efficiently provide vital services to grantees and the general public, as the standard 6 to 9 month timeline to comply with a full request under the Paperwork Reduction Act could inhibit HRSA's ability to collect information to inform these activities that involve rapid updates to be responsive to their users. The information collected is expected to be voluntary and low-burden. Therefore, a generic umbrella ICR clearance is requested to allow for quick turnaround