Proposed Project

Evaluation of an Online Prostate Cancer Decision Aid—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC) is requesting a new, three-year OMB approval to conduct a three-arm, randomized controlled trial (RCT) to evaluate the impact of a virtual human decision aid to help improve the quality of prostate cancer screening and treatment decisions. Talk to Nathan About Prostate Cancer Screening (hereafter referred to as Nathan) is DCPC's online, interactive, human simulation decision aid designed to help men learn and make informed decisions about prostate cancer screening. A small, preliminary evaluation of Nathan showed promise in increasing men's knowledge about prostate cancer and likelihood of engaging in shared decision-making about prostate cancer screening with their health care providers. At this time, a larger, more systematic evaluation can help to understand whether Nathan is effective in areas such as improving knowledge, overcoming health literacy barriers, and resolving decisional conflict, especially among priority populations who are most likely to be affected by prostate cancer and least likely to be screened. Further, as some experts consider the digital divide to be the newest social determinant of health, it is important to explore how, where, and for which populations there may be disparities in accessing and using Nathan.

Broadly, the purpose of this information collection is to: (1) assess whether Nathan is more effective at helping men make decisions about prostate cancer screening than an established decision aid or standard educational materials; (2) determine if changes or improvements to Nathan are warranted; and (3) identify ways to incorporate Nathan into primary care. We will select four primary care clinics to participate in this study. The RCT includes a three-group parallel design with one treatment arm and two control arms to test the effectiveness of Nathan for men aged 55–69. We will recruit 900 men aged 55–69 who have an upcoming general health exam at one of the four primary care clinics and randomize them to one of three arms: (1) Nathan (intervention = 300 men); (2) the Massachusetts Department of Public Health's (MDPH's) Patient Decision Aid, Get the Latest Facts about Screening for Prostate Cancer (control 1 = 300 men); and (3) standard educational materials from the National Cancer Institute (NCI), Prostate Cancer Screening (PDQ®)—Patient Version (control 2 = 300 men).

Eight forms of information collection will be implemented to answer our evaluation questions. These include a provider survey; a patient eligibility screener; patient pre-exposure, post-exposure, and post-clinic visit surveys; a patient usability survey; patient user experience interviews; and clinic coordinator interviews. Each instrument will be administered once per respondent throughout the course of the study. The provider survey and clinic coordinator interviews will be conducted in English only. All other information collections will be conducted in English or Spanish. The total response burden is estimated to be 1,129 hours. There are no costs to respondents other than their time to participate in data collection activities.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Primary care providers	Provider survey	40	1	10/60
Men ages 55–69	Patient eligibility screener	900	1	8/60
Men ages 55–69	Pre-exposure survey	900	1	20/60
Men ages 55–69	Post-exposure survey	900	1	20/60
Men ages 55–69	Usability survey	300	1	18/60
Men ages 55–69	User experience interview	30	1	20/60
Men ages 55–69	Post-clinic survey	900	1	20/60
Clinic coordinators	Clinic coordinator interview	4	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10434 #66]

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

AGENCY: Centers for Medicare & Medicaid Services, 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 August 2, 2024.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10434 #66) and the OMB control number (0938–1188). 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–10434 #66/OMB control number: 0938–1188, 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/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRAListing.*

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

SUPPLEMENTARY INFORMATION: Because of system limitations, we are submitting this generic collection of information request on an interim basis under CMS–10434 (OMB 0938–1188). At the appropriate time we will move this request under its proper place (CMS–10398, OMB 0938–1148) and subsequently remove it from CMS–10434 to prevent duplication. The public can monitor the status of such activities at *reginfo.gov.*

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:* Medicaid and Children's Health Insurance Program Eligibility Processing Data Report; *Type of Information Collection Request:* Revision of a previously approved collection of information request; *Use:* The COVID–19 outbreak and implementation of federal policies to address the public health emergency disrupted routine Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program eligibility and enrollment operations. Medicaid and CHIP enrollment grew to historic levels due in large part to the Medicaid continuous enrollment condition that states implemented as a condition of receiving a temporary federal medical assistance percentage (FMAP) increase under section 6008 of the Families First Coronavirus Response Act (Pub. L. 116–127). In March 2022, CMS announced that states were required to submit a one-time baseline report and an ongoing monthly report on renewal activities for their total caseload of Medicaid and CHIP enrollees prior to unwinding, including the dispositions of renewals, for a minimum of 14 months through the submission of the ''Unwinding Data Report'', hereinafter referred to as the ''Eligibility Processing Data Report.''

The Consolidated Appropriations Act of 2023 (Pub. L. 117–238) (CAA, 2023) ended the continuous enrollment condition on March 31, 2023, and required states to meet additional conditions, including conducting renewals consistent with federal requirements or CMS approved strategies, as a condition of receiving increased FMAP through December 2023. The CAA, 2023 also required states to submit and CMS to publicly report data related to redeterminations conducted between April 2023 through June 2024. Some of the data outlined in the CAA, 2023 are collected through the Eligibility Processing Data Report.

States have faced challenges completing the volume of work during unwinding and restoring routine operations, and many states continue to process unwinding related renewals. This package describes the Eligibility Processing Data Report that states will continue to submit to CMS on an ongoing basis to support monitoring and oversight efforts for the remainder of states' unwinding periods and to ensure on-going compliance with federal eligibility renewal requirements beyond unwinding.

CMS is requiring mandatory state reporting of their efforts to restore and maintain eligibility and enrollment operations and understand coverage retention under the authority in sections 1902(a)(4)(A), 1902(a)(6) and 1902(a)(75) of the Social Security Act (the Act), 42 CFR 431.16 to ensure proper and efficient administration of the Medicaid program, and section 2101(a) of the Act to promote the administration of CHIP in an effective and efficient manner. CMS announced that the Eligibility Processing Data Report collection will continue beyond unwinding in State Health Official Letter #24–002.

The Eligibility Processing Data Report is a monthly report containing metrics on application processing, renewals initiated and the dispositions of those renewals and fair hearings that states submit using the existing Performance Indicators portal for submission. States can correct their data as needed. Given that some renewals remain pending at the end of a reporting month, states also submit an update to each monthly report to CMS in the fourth month after the report is first due to provide more complete renewal outcome data for the renewal cohort reflected in the initial report month. States started submitted the monthly Eligibility Processing Data Report to CMS in 2023 when they began their unwinding periods.

In addition to changing the title of this collection of information request, in this July 2024 iteration we are also extending the existing monthly data collection and one-time update to the renewal outcome data in each report for the remainder of unwinding as well as beyond unwinding. States will continue to submit a monthly report in the Eligibility Processing Data Report in the submission portal. States will also continue to provide a one-time update to the data captured in the monthly report concerning renewal outcomes (metrics 5a, 5a(1), 5a(2), 5b, 5c, 5d) in the submission portal. To provide the updated report, states replace renewal outcome data in the initial monthly report in the portal and overwrite their previously submitted data.

The Eligibility Processing Data Report is accompanied by an excel workbook that states may use for planning purposes and a separate instruction document (data specifications). The excel workbook is a planning tool that was provided to states in 2022 so they could see all metrics in the report before they had access to the Eligibility Processing Data Report forms in the submission portal. This workbook is not submitted to CMS, nor are states required to use it. While this workbook is still available on *www.Medicaid.gov*

for states, it is not updated for this 2024 iteration as states have access to the metrics in the submission portal. The data specifications document is updated to reflect the changes made in this 2024 iteration of the Eligibility Processing Data Report.

States submit the application processing data in the Eligibility Processing Data Report until states complete working on pending applications received before unwinding began and report to CMS that zero applications remain pending. When the Eligibility Processing Data Report was first launched, states previously submitted a one-time baseline report prior to submitting the monthly reports and could make corrections to this report as needed. The baseline report form has remained available in the submission portal. CMS is not extending the use of the baseline report in this 2024 iteration since it was intended to be a one-time submission. The baseline report form will also be removed from the submission portal in late summer/early fall 2024.

Additionally, states submitted to CMS a one-time State Report on Plans for Prioritizing and Distributing Renewals Following the End of the Medicaid Continuous Enrollment Provisions (''State Renewals Report'') that was used to assess state's plans for processing renewals and mitigating against inappropriate beneficiary coverage losses when states begin restoring routine Medicaid and CHIP operations after the public health emergency. CMS is not extending the use of this report in this 2024 iteration.

Form Number: CMS–10434 #66 (OMB control number: 0938–1188); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,344; *Total Annual Hours:* 18,816. (For policy questions regarding this collection contact: Shannon Lovejoy at (410) 786–1718.)

William N. Parham III,

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

[FR Doc. 2024–15882 Filed 7–18–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2682]

Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment; 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 ''Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment.'' The draft guidance was prepared by the Division of Gastroenterology in the Center for Drug Evaluation and Research at FDA to help sponsors in the clinical development of drugs to treat pediatric patients with inflammatory bowel disease. The draft guidance provides FDA's recommendations about the necessary attributes of clinical studies for drugs being developed for the treatment of pediatric ulcerative colitis or pediatric Crohn's disease, including study population, study design, efficacy considerations, and safety assessments.

DATES: Submit either electronic or written comments on the draft guidance by September 17, 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–2024–D–2682 for ''Pediatric Inflammatory Bowel Disease: Developing Drugs 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 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://*