Further, in addition to overseeing the safety of drug products when used according to approved drug labeling or as directed by a healthcare provider, the Center for Drug Evaluation and Research (CDER) conducts studies on topics related to the safe and effective use of drug products, and emerging safety issues in areas such as nonmedical use of approved drug products, use of unapproved and falsified (*i.e.,* counterfeit, fake) drug products, use of botanical substances (*e.g.,* cannabis derived products), controlled substance prescribing decisions, bystander response to drug overdoses, and potentially false or misleading information about drug products. Reliable data on these and related topics are a critical first step to understanding whether further studies or action is needed to protect public health.

Because often data on these topics are not collected as part of routine healthcare delivery or via established Federal surveys, FDA requires the development and validation of novel instruments (*i.e.,* interview and focus group guides, questionnaires) and approaches to gathering data on emerging safety issues the methods used to create and validate these instruments may include interviews, focus groups, small group discussions, pilot and test/re-test survey launches, and external validation against benchmark surveys. In conducting research in these areas, FDA will need to employ the following validation methodology: (1) research to assess knowledge, perceptions, and experiences related to topics in the above-mentioned areas with specific target populations; (2) techniques to evaluate sampling and recruitment methods; and (3) evaluations of the validity and reliability of survey questionnaires in target populations.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we have received in the last 3 years and to better reflect the scope of the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews and Surveys	126,770	1	126,770	0.25 (15 minutes)	31,693

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

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 17,300 responses with a corresponding increase of 4,325 hours. We attribute this adjustment to the need to validate information in specific areas.

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08655 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting—Guardant Shield Blood Collection Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on May 23, 2024, from 9:30 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Jarrod.Collier@fda.hhs.gov,* 240–672–5763, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.*htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On May 23, 2024, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Shield test by Guardant Health, Inc. The proposed indication for use statement is as follows: The Shield test is a qualitative in vitro diagnostic test intended to detect colorectal cancer derived alterations in cell-free DNA from blood collected in the Guardant Blood Collection Kit. Shield is intended for colorectal cancer screening in individuals at average risk of the disease, age 45 years or older. Patients with an ''Abnormal Signal Detected'' may have colorectal cancer or advanced adenomas and should be referred for colonoscopy evaluation. Shield is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals. The test is performed at Guardant Health, Inc.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will

be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 10, 2024. Oral presentations from the public will be scheduled on May 23, 2024, between approximately 1:45 p.m. and 2:45 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 7, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 8, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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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: Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Revision

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 June 24, 2024.

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: Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Revision.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), authorized under Title XXVI of the Public Health Service Act, is administered by the HIV/AIDS Bureau within HRSA. HRSA awards funding to recipients in areas of the greatest need to respond effectively to the HIV epidemic, with an emphasis on providing life-saving and life-extending medical care, treatment, and support services for people with HIV in the United States.

The RWHAP reporting requirements include the annual submission of client-level data in the Ryan White HIV/AIDS Program Services Report (RSR). The RSR is designed to collect information from grant recipients and their subawarded service providers, funded under Parts A, B, C, and D of the RWHAP statute.

HRSA is requesting a revision of the current RSR with one proposed update:

Current Questions

- Within your organization/agency, identify the number of physicians, nurse practitioners, or physician assistants who obtained a Drug Addiction Treatment Act of 2000 waiver to treat opioid use disorder with medication assisted treatment (MAT), [*e.g.,* buprenorphine, naltrexone] specifically approved by the U.S. Food and Drug Administration.
- How many of the above physicians, nurse practitioners, or physician assistants prescribed MAT (*e.g.,* buprenorphine, naltrexone) for opioid use disorders in the reporting period?

Proposed Change to Question in 2024 RSR Form

- How many physicians, nurse practitioners, or physician assistants in your organization prescribed medications for opioid use disorder (MOUD) [*e.g.,* buprenorphine, naltrexone] for opioid use disorders during the reporting period?

Need and Proposed Use of the Information: The RWHAP statute specifies HRSA's responsibilities in administering grant funds, allocating funding, assessing HIV care outcomes (*e.g.,* viral suppression), and serving particular populations. The RSR collects data on the characteristics of RWHAP-funded recipients, their contracted service providers, and the patients or clients served. The RSR system consists