U.S. FOOD & DRUG ADMINISTRATION

February 14, 2023

Shakil Ahmed
Sr. Director, Regulatory Affairs and Quality Assurance
Twist Bioscience Corporation
681 Gateway Blvd.
South San Francisco, CA 94080

Re: Revocation of EUA202029

Dear Shakil Ahmed:

This letter is in response to the request from Twist Bioscience Corporation, received via email on January 27, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 NGS Assay issued on March 23, 2021, amended on June 25, 2021, and September 23, 2021, and reissued on July 28, 2022. Twist Bioscience Corporation indicated that they no longer plan to continue marketing the SARS-CoV-2 NGS Assay and requested that the EUA be withdrawn. FDA understands that no SARS-CoV-2 NGS Assay reagents associated with this EUA are available to the United States market.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Twist Bioscience Corporation has requested FDA withdraw the EUA for the SARS-CoV-2 NGS Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202029 for the SARS-CoV-2 NGS Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 NGS Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: March 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04845 Filed 3–8–23; 8:45 am]

BILLING CODE 4164–01–P

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: Expenditures Forms, OMB No. 0915–xxxx—New

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 May 8, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail at: the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 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 Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 594–4394.

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

Information Collection Request Title: Ryan White HIV/AIDS Program: Expenditures Forms—OMB No. 0915–xxxx—New.

Abstract: HRSA administers the Ryan White HIV/AIDS Program (RWHAP) which is authorized under title XXVI of the Public Health Service Act. The RWHAP Allocations and Expenditures Reports (A&E Reports) allow HRSA to monitor and track the use of grant funds for compliance with program and grants policies, and requirements as outlined in the legislation. To avoid duplication and reduce recipient reporting burden, HRSA created an electronic grantee contract management system (GCMS) that includes data required for various reports, including the Expenditures Reports and other HRSA data reports, such as the RWHAP Services Report. Recipients can access GCMS year-round to upload or manually enter data on their service provider contractors or subrecipients, the RWHAP core medical and support services provided, and their funding amounts. Data required for Allocations Reports and other reports are automatically prepopulated from GCMS. Expenditures Report data are not auto-populated in the GCMS and are still manually entered into the data reporting system.

A&E Reports: Recipients funded under RWHAP Parts A, B, C, and D are required to report financial data to HRSA at the beginning (Allocations Report) and at the end (Expenditures Report) of their grant budget period. The A&E Reports request information recipients already collect, including the use of RWHAP grant funds for core medical and support services; and on various program components, such as administration, planning and evaluation, and clinical quality management. RWHAP Parts A and B recipients funded under the Ending the HIV Epidemic in the U.S. (EHE) initiative are also required to report allocations and expenditures of the grant budget period in the EHE A&E Reports. This allows HRSA to track and report progress toward meeting the EHE goals.

The reports are similar in content; however, in the first report, recipients document the allocation of their RWHAP or EHE grant award at the beginning of their grant budget period. In the second report, recipients document actual expenditures of their RWHAP or EHE grant award (including any carryover dollars) at the end of their grant budget period.

HRSA is proposing the following updates to the RWHAP Expenditure Reports.

RWHAP Part A Expenditures Report:

- Revising row and column headers and other language for clarity and alignment with RWHAP requirements;
- Combining the columns for RWHAP Part A Formula and Supplemental Expenditure amounts and updating the title;
- Moving the Prior Fiscal Year (FY) Carryover column row after the Current FY column and updating the title;
- Moving the RWHAP Part A Minority AIDS Initiative (MAI) Award Amount row after the RWHAP Part A Supplemental Award Amount row;
- Re-ordering the MAI rows in the ''RWHAP Part A and MAI Service Category Expenditures'' table as follows: 3. RWHAP Part A Supplemental Award, 4. RWHAP Part A MAI Award Amount, 5. RWHAP Part A MAI Carryover Amount;
- Updating calculations and language in the Legislative Requirements Checklist; and
- Adding a requirement for Financial Officer/Designee to certify subrecipient aggregated administrative expenditures.

RWHAP Part B Expenditures Report:

- Revising rows and column headers and other language for clarity and alignment with RWHAP requirements;
- Adding the following rows to Table 1: 4b. RWHAP Part B HIV Care Consortia Planning & Evaluation and 4c. RWHAP Part B HIV Care Consortia Clinical Quality Management (CQM);
- Blacking out selected cells in the following rows, columns, or tables:
- 5. Total (including carryover) Percent column:
  - (4a–4c) RWHAP Part B HIV Care Consortia Admin, P&E, and CQM
  - (6) RWHAP Part B Clinical Quality Management
  - (7) RWHAP Part B Recipient Planning & Evaluation Activities
  - (8) Recipient Administration
  - (9) Column Totals
  - (10) Total RWHAP Part B Expenditures (excluding carryover);
- 2. RWHAP Part B Health Insurance Premium & Cost Sharing Assistance and 3. RWHAP Part B Home and Community-based Health Services' amounts and percent:
  - (1) Base Award
  - (2) AIDS Drug Assistance Program (ADAP) Earmark + ADAP Supplemental
  - (3) Emerging Communities Award
  - (4) Total Prior FY Carryover
  - (5) Total (Including Carryover);
- 4b. RWHAP Part B HIV Care Consortia Planning & Evaluation and 4c. RWHAP Part B HIV Care Consortia CQM:
  - (1) Base Award: Prior FY Carryover
  - (2) ADAP Earmark + ADAP Supplemental: Prior FY Carryover, Current FY and Percent
  - (3) Emerging Communities Award: Prior FY Carryover
  - (4) Total Prior FY Carryover: Amount and Percent;
- MAI Expenditure by Program Component:
  - (3) Clinical Quality Management: Prior FY Carryover amount & percent
  - (4) Recipient Planning & Evaluation Activities: Prior FY Carryover amount & percent
  - (5) Recipient Administration: Prior FY Carryover amount & percent
  - (6) Total MAI Expenditures; percent
- Adding a new row: (10) Total RWHAP Part B Expenditures (excluding carryover);
- Displaying previously blacked out cells in the following two rows under the Expenditures Categories table:
- d. Health Insurance Premium and Cost Sharing Assistance for Low-Income Individuals and e. Home and Community-Based Health Services
  - (2) Direct Services
  - (3) Emerging Communities
  - (4) Prior FY Carryover;
- Updating calculations and language in the Legislative Requirements Checklist;
- Removing Consortia Administration and Emerging Communities Administration from the Legislative Requirement from Legislative Requirement
- Removing the following services under the Legislative Requirements Checklist's Core Medical Services:
  - Health Insurance Premium & Cost Sharing Assistance
  - Home and Community-based Health Services; and
- Adding requirement for a Financial Officer/Designee to certify subrecipient aggregated administrative expenditures
  - Adding a row for the recipient to certify that administrative expenses

for the RWHAP Part B does not exceed allowable cap

RWHAP Part C Expenditures Report:

• There are no proposed changes to the RWHAP Part C Expenditures Report.

RWHAP Part D Expenditures Report:

• There are no proposed changes to the RWHAP Part D Expenditures Report.

HAB EHE Expenditures Reports:

• There are no proposed changes to the HAB EHE Expenditures Reports.

Need and Proposed Use of the Information: Accurate allocation, expenditure, and service contract records of the recipients receiving RWHAP and EHE funding are critical to the implementation of the RWHAP legislation and EHE initiative appropriation language and thus are necessary for HRSA to fulfill its monitoring and oversight responsibilities.

Likely Respondents: RWHAP Part A, Part B, Part C, and Part D recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Part A Expenditures Report	52	1	52	4	208
Part B Expenditures Report	54	1	54	6	324
Part C Expenditures Report	346	1	346	4	1,384
Part D Expenditures Report	116	1	116	4	464
EHE Expenditures Report	47	1	47	4	188
Total	615		615		2,568

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–04824 Filed 3–8–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Freedom of Information Act Predisclosure Notice

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

ACTION: Request for comment.

SUMMARY: This notice informs submitters who reported COVID–19 data in 2020 for the High-Impact Area Distribution that HRSA received a Freedom of Information Act (FOIA) request for data reported to HHS that was used in determining COVID–19 High-Impact Area Distribution payments under the Provider Relief Fund. Specifically, the request seeks certain information pertaining to providers who did not receive COVID–19 High-Impact Area Distribution payments. This notice seeks input from these providers so that HRSA can respond to the FOIA request.

DATES: Comments must be received on or before March 23, 2023.

ADDRESSES: Comments should be submitted to the HRSA FOIA Office via email at *hotspotpdn@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Brian A. May, FOIA Officer, 5600 Fishers Lane, Room 13N112, Rockville, Maryland 20857; 301–443–1467, *hotspotpdn@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The FOIA, 5 U.S.C. 552, compels federal agencies to release records in its possession, unless the agency reasonably foresees that disclosure would harm an interested protected by one (or more) of the nine exemptions or disclosure is prohibited by law. FOIA also requires that agencies provide FOIA requesters with reasonably segregated portions of records, which means that agencies must release any portion of the records where an exemption does not apply, unless technically unable to reasonably do so.

Explanation of the Action

The HRSA FOIA Office received a FOIA request for data reported to HHS in 2020 that was used in determining COVID–19 High-Impact Area Distribution payments under the Provider Relief Fund. HHS made the first round of COVID–19 High Impact Area Distribution payments to 395 hospitals that reported they had 100 or more COVID–19 admissions during the period of January 1, 2020. and April 10, 2020. HHS did not make payments to hospitals that reported they had fewer than 100 COVID–19 admissions during the period of January 1, 2020, and April 10, 2020. The FOIA request specifically seeks data on the hospitals that reported they had fewer than 100 COVID–19 admissions during the period of January 1, 2020, and April 10, 2020, and therefore, did not receive a payment in the first round of the COVID–19 High Impact Area Distribution.

This notice *only* applies to hospitals that reported in the first round of reporting to HHS that they had fewer than 100 COVID–19 admissions during the period of January 1, 2020, and April 10, 2020, and, as a result, did not receive a payment in round 1 of the COVID–19 High-Impact Area Distribution. Comments from any entity that does not satisfy these conditions will not be reviewed.

Necessity of the Action

Executive Order No. 12600, 52 FR 23781 (1987), and the HHS FOIA regulations at 45 CFR 5.42(a) require HRSA coordinate predisclosure notifications for records that were