preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from June 16, 2022, through December 6, 2022, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- Genabio Diagnostics Inc.'s Genabio COVID–19 Rapid Self-Test Kit, issued July 8, 2022;
- Watmind USA's Speedy Swab Rapid COVID–19 Antigen Self-Test, issued July 8, 2022;
- Predicine, Inc.'s Predicine SARS–CoV–2 RT–PCR Test, issued July 19, 2022;
- Aptitude Medical Systems Inc.'s Metrix COVID–19 Test, issued October 18, 2022;
- Nanobiosym Precision Testing Services's The Nano Test for COVID–19, issued November 8, 2022;
- ANP Technologies, Inc.'s NIDS COVID–19 Antigen Home Test, issued November 17, 2022;
- Beijing Hotgen Biotech Co., Ltd.'s Hotgen COVID–19 Antigen Home Test, issued November 17, 2022;
- Premier Medical Laboratory Services's Diversified Medical Healthcare SARS–CoV–2 Assay, issued November 18, 2022;
- CorDx, Inc.'s CorDx COVID–19 Ag Test, issued November 21, 2022;
- Azure Biotech Inc.'s Fastep COVID–19 Antigen Home Test, issued November 21, 2022;
- ACON Laboratories, Inc.'s Flow*flex* COVID–19 Antigen Rapid Test, issued December 6, 2022.

FDA is hereby announcing the following Authorization for a multianalyte test:

- Lucira Health, Inc.'s Lucira COVID–19 and Flu Test, issued November 22, 2022.[4]

FDA is hereby announcing the following Authorization for a serology test:

- Diazyme Laboratories, Inc.'s Diazyme SARS–CoV–2 Neutralizing Antibody CLIA Kit, issued December 6, 2022.[5]

In addition, on November 1, 2022, FDA issued a letter to Developers of Antigen In Vitro Diagnostics (IVDs) Authorized for Emergency Use for Coronavirus Disease 2019 (COVID–19) as of Today's Date (November 1, 2022) for Revisions Related to Serial (Repeat) Testing for the EUAs of Antigen IVDs.[6]

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01180 Filed 1–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0945–0003]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 22, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0945–0003–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[4] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus RNA, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[5] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing recent or prior infection with SARS–CoV–2 by identifying individuals with an adaptive immune response to the virus that causes COVID–19, and that the known and potential benefits of the product, when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] FDA concluded revisions to the EUAs of the tests that are within the scope of the November 1, 2022, letter is appropriate to protect the public health or safety and revised all such EUAs pursuant to section 564(g)(2)(C) of the FD&C Act, including to revise the authorized use and to establish the additional condition set forth in the letter, as permitted by section 564(e) of the FD&C Act. The action is based on the available scientific evidence on the impact of serial testing on the performance of SARS–CoV–2 antigen tests. (Refer to: ''Performance of Screening for SARS–CoV–2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS–CoV–2 Infection: findings from the Test Us at Home prospective cohort study'' at *https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1.*) The letter revised all current EUAs for antigen SARS–CoV–2 IVD devices as of November 1, 2022, by: (1) revising the authorized use to be for serial testing at least twice over 3 days for individuals with symptoms of COVID–19 and, for tests previously authorized for testing individuals without symptoms, revising the authorized use to be for serial testing at least thrice over 5 days for individuals without symptoms of COVID–19, (2) establishing a new condition of authorization regarding updating authorized labeling, and (3) eliminating a condition of authorization regarding evaluating clinical performance to support the serial screening claim.

information, including any of the following subjects: (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.

Title of the Collection: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR parts 160 and 164.

Type of Collection: Extension

OMB No. 0945–0003: Office for Civil Rights (OCR)–Health Information Privacy Division

Abstract: OCR requests approval to extend this existing, approved collection for three years without changing any collection requirements. No public comments were received. In 2021, OCR published a Notice of Proposed Rulemaking (NPRM) proposing modifications to the HIPAA Rules that would affect the hourly burdens associated with the HIPAA Rules. 86 FR 6446. OCR is reviewing public comment received on the NPRM about existing burdens associated with compliance with the HIPAA Rules, and on changes in burden that could result from the modifications proposed in the NPRM. On December 2, 2022, OCR published a second NPRM proposing additional modifications to the HIPAA Rules, available at 87 FR 74216. OCR will also review public comment received on the 2022 NPRM, and will update this ICR to reflect the input we receive on this notice and through the rulemaking process.

Type of respondent: HIPAA covered entities, business associates, individuals, and professional and trade associations of covered entities and business associates.

ESTIMATED ANNUALIZED BURDEN TABLE

Section	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response [1]	Total burden hours
160.204	Process for Requesting Exception Determinations (states or persons).	1	1	16	16
164.308	Risk Analysis—Documentation [2]	1,700,000	1	10	17,000,000
164.308	Information System Activity Review—Documentation.	1,700,000	12	0.75	15,300,000
164.308	Security Reminders—Periodic Updates	1,700,000	12	1	20,400,000
164.308	Security Incidents (other than breaches)—Documentation.	1,700,000	52	5	442,000,000
164.308	Contingency Plan—Testing and Revision	1,700,000	1	8	13,600,000
164.308	Contingency Plan—Criticality Analysis	1,700,000	1	4	6,800,000
164.310	Maintenance Records	1,700,000	12	6	122,400,000
164.314	Security Incidents—Business Associate reporting of incidents (other than breach) to Covered Entities.	1,000,000	12	20	240,000,000
164.316	Documentation—Review and Update [3]	1,700,000	1	6	10,200,000
164.404	Individual Notice—Written and E-mail Notice (drafting) [4].	58,482	1	0.5	29,241
164.404	Individual Notice—Written and E-mail Notice (preparing and documenting notification).	58,482	1	0.5	29,241
164.404	Individual Notice—Written and E-mail Notice (processing and sending) [5].	58,482	1,941	0.008	908,108
164.404	Individual Notice—Substitute Notice (posting or publishing) [6].	2,746	1	1	2,746
164.404	Individual Notice—Substitute Notice (staffing toll-free number) [7].	2,746	1	3.42	9,391
164.404	Individual Notice—Substitute Notice (individuals' voluntary burden to call toll-free number for information) [8], [9].	113,264	1	0.125	14,158
164.406	Media Notice [10]	267	1	1.25	334
164.408	Notice to Secretary (notice for breaches affecting 500 or more individuals).	267	1	1.25	334
164.408	Notice to Secretary (notice for breaches affecting fewer than 500 individuals) [11].	58,215	1	1	58,215
164.410	Business Associate notice to Covered Entity—500 or more individuals affected.	20	1	50	1,000
164.410	Business Associate notice to Covered Entity—Less than 500 individuals affected.	1,165	1	8	9,320
164.414	500 or More Affected Individuals (investigating and documenting breach).	267	1	50	13,350
164.414	Less than 500 Affected Individuals (investigating and documenting breach)—affecting 10–499.	2,479	1	8	19,832
164.414	Less than 500 Affected Individuals (investigating and documenting breach)—affecting <10.	55,736	1	4	222,944
164.504	Uses and Disclosures—Organizational Requirements.	700,000	1	0.083333333	58,333
164.508	Uses and Disclosures for Which Individual authorization is required.	700,000	1	1	700,000
164.512	Uses and Disclosures for Research Purposes [12].	113,524	1	0.083333333	9,460

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Section	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response [1]	Total burden hours
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by paper mail) [13], [18].	100,000,000	1	0.004166667	416,667
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by electronic mail) [19].	100,000,000	1	0.002783333	278,333
164.520	Notice of Privacy Practices for Protected Health Information (health care providers—dissemination and acknowledgement) [14].	613,000,000	1	0.05	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information [15].	20,000	1	0.05	1,000
164.524	Access of Individuals to Protected Health Information (disclosures) [16].	200,000	1	0.05	10,000
164.526	Amendment of Protected Health Information (requests).	150,000	1	0.083333333	12,500
164.526	Amendment of Protected Health Information (denials).	50,000	1	0.083333333	4,167
164.528	Accounting for Disclosures of Protected Health Information [17].	5,000	1	0.05	250
Total			2,070		921,158,940

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2023–01196 Filed 1–20–23; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Privacy Act of 1974; System of Records

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act, the Department of Health and Human Services (HHS) is establishing a new system of records to be maintained by the Office of Infectious Disease and HIV/AIDS Policy within the Office of the Assistant Secretary for Health (OASH/OIDP), System No. 09–90–2101 ''HIV Prevention Medication Distribution Records.'' The new system of records will consist of records about individual patients who participate in the Ending the HIV Epidemic—Pre-Exposure Prophylaxis Implementation and Distribution Services Program (PrEP Program), which will provide donated HIV prevention medication to patients in the United States who are at substantial risk of acquiring the human immunodeficiency virus (HIV).

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is effective upon publication, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by February 22, 2023.

ADDRESSES: The public should submit comments on the new system of records by email to *ann.abercrombie@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: General questions about the system of records may be submitted to Ann Abercrombie, OASH/OIDP at (202) 401–9588, or *ann.abercrombie@hhs.gov.*

SUPPLEMENTARY INFORMATION: Within the U.S. Department of Health and Human Services (HHS), the Office of the Assistant Secretary for Health (OASH) leads development of agency-wide public health policy recommendations and oversees core public health offices, including the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps, as well as 10 regional health offices across the nation and 10 presidential and secretarial advisory committees. The mission of the Office of Infectious Disease and HIV/AIDS Policy (OIDP) is to provide strategic leadership and management, while encouraging collaboration, coordination, and innovation among federal agencies and stakeholders to reduce the burden of infectious diseases, including the human immunodeficiency virus (HIV).

The initiative to End the HIV Epidemic in the U.S. is part of a national HIV prevention and control effort to reduce the number of new HIV infections by 75% in five years and 90% in 10 years. A key component of the initiative is expanding access to HIV prevention medication for patients who are at substantial risk of acquiring the disease. Pursuant to a donation agreement executed May 8, 2019, a drug manufacturer, Gilead Sciences, Inc. (Gilead), donated certain HIV prevention medication (emtricitabine/tenofovir disoproxil fumarate and emtricitabine/tenofovir alafenamide tablets, collectively referred to as ''Product'') to HHS for distribution through the Ending the HIV Epidemic—Pre-Exposure Prophylaxis (PrEP) Implementation and Distribution Services Program (PrEP Program), which will be administered by OASH/OIDP subject to the terms of the donation agreement between Gilead and HHS. Under the terms of the donation agreement, Gilead will donate Product for up to 200,000 individuals each year up to end of 2030 or earlier. The PrEP Program, through a contractor engaged by OASH/OIDP, will issue an enrollment card or electronic enrollment confirmation, containing a unique identification number, to each qualified eligible patient in the United States who applies to the program (up to 200,000 individuals per year). This will enable the patient to obtain the Product at no cost, either in person or by mail, from a participating pharmacy. The contractor will operate a mail order pharmacy to acquire the Product from Gilead and dispense it to patients who elect to receive the Product by mail. The