of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Little is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Little is a prohibited act.

Dated: May 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12066 Filed 5–31–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0945–0005]

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 July 3, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov, PRA@hhs.gov,* or by calling (202) 264–0041.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0945–0005 and project title for reference to Sherrette A. Funn, the Reports Clearance Officer, email *Sherrette.Funn@hhs.gov, PRA@hhs.gov,* or call (202) 264–0041.

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

Type of Collection: Reinstatement with Change of Previously Approved Collection.

OMB No. 0945–0005: Office for Civil Rights (OCR)—Health Information Privacy Division.

Abstract: This information collection consists of 39 online survey questions that will be sent to 207 covered entities and business associates that participated in the 2016–2017 OCR HIPAA Audits.

The survey will gather information relating to the effect of the audits on the audited entities and the entities' opinions about the audit process.

OCR is conducting a review of the 2016–2017 HIPAA Audits to determine its efficacy in assessing the HIPAA compliance efforts of covered entities.

As part of that review, the online survey will be used to:

- Measure the effect of the 2016–2017 HIPAA Audits on covered entities' and business associates' subsequent actions to comply with the HIPAA Rules.
- Provide entities with an opportunity to give feedback on the Audit and its features, such as the helpfulness of HHS' guidance materials and communications, the utility of the online submission portal, whether the Audit helped improve entity compliance, and the entities' responses to the Audit-report findings and recommendations.
- Provide OCR with information on the burden imposed on entities to collect audit-related documents and to respond to audit-related requests; and
- Seek feedback on the effect of the HIPAA Audit program on the entities' day-to-day business operations. The information, opinions, and comments collected using the online survey will be used to improve future OCR HIPAA Audits.

Type of Respondent: Privacy Officers, Security Officers, and/or Administrators of HIPAA covered entities and business associates.

ANNUALIZED BURDEN HOUR TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Covered Entity Privacy and Security Officer(s) or Administrators	166	1	45/60	124.5
Business Associate Privacy and Security Officer(s) or Administrators	41	1	45/60	30.75
Total	207			155.25

Sherrette A. Funn,

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

[FR Doc. 2024–12083 Filed 5–31–24; 8:45 am]

BILLING CODE 4153–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0260]

Agency Information Collection Request; 60-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 August 2, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0260–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of 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: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Type of Collection: 3-year extension of a currently approved collection.

OMB No. 0990–0260

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990–0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research; and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Likely Respondents: institutions and institutional review boards.

Annualized Burden Hour Tables

TABLE 1—ESTIMATED ANNUAL IRB RECORDKEEPING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.115 [Pre-2018 and 2018 Requirement]—Preparation and documentation of IRB activities	6,000	16	96,000	12	1,152,000
Total			96,000		1,152,000

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
.109(d) [Pre-2018 and 2018 Requirements]—Written notification of IRB approval or disapproval of research	6,000	25	150,000	0.5	75,000
.116(a) and (b) (Pre-2018 Requirements)/.116 (b), (c) and (d) [2018 Requirements]—Elements of informed consent and broad consent	6,000	25	150,000	0.5	75,000
.116(h)—[2018 Requirements]—Posting clinical trial consent form	425	5	2,125	0.5	1,063
.117(a) [Pre-2018 and 2018 Requirements]—Documentation of informed consent	6,000	20	120,000	0.5	60,000
.117(c)(2) [Pre-2018 and 2018 Requirements]—Written statement about the research when informed consent documentation is waived	6,000	5	30,000	.5	15,000
Total			452,125		308,563

Sherrette A. Funn,

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

[FR Doc. 2024–12111 Filed 5–31–24; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–