

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR Part 112	Number of respondents	Number of disclosures per respondent	Total disclosures	Average burden per disclosure (in hours)	Total hours
Disclosure under §§ 112.2, 112.6, 112.31, 112.33, and 112.142	77,165	3.459	266,914	1.422	379,551

¹ There are no capital costs or operating or maintenance costs associated with annual disclosure.

Section 112.7 (21 CFR 112.7) requires farms eligible for the qualified exemption in accordance with § 112.5 (21 CFR 112.5) to maintain the records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption, including a written record reflecting that the owner, operator, or agent in charge of the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption. We estimate that 3,285 farms are eligible for the qualified exemption and that each farm will spend an average of 0.5 hours per year to maintain one record. Therefore, 3,285 recordkeepers × 0.5 average hours per recordkeeping = 1,642.5 hours (rounded to 1,643) to meet the recordkeeping requirements of § 112.7.

Section 112.30 (21 CFR 112.30) requires the maintenance of records of required training of personnel, including the date of training, topics covered, and persons trained. We estimate that 24,420 farms will maintain one record of required training and spend an average of 7.25 hours per year on recordkeeping. Therefore, 24,420 recordkeepers × 7.25 average hours per recordkeeping = 177,045 hours to meet the recordkeeping requirements of § 112.30.

Section 112.46 (21 CFR 112.46) requires testing agricultural water subject to the requirements of §§ 112.44 and 112.45 (21 CFR 112.44 and 112.45). We estimate that 48,361 farms that will conduct these tests. Thus, it is estimated that about three (2.990) records for each farm will spend an average of 0.825 hours per record on testing water. Therefore, 48,361 farms × 2.990 records × 0.825 average hours per recordkeeping = 119,294.175 hours (rounded to 119,294) to meet the recordkeeping requirements of §§ 112.44 and 112.45.

For records related to agricultural water, FDA estimates that there are 160,605 recordkeepers each maintaining just over 2 records (2.242), with each recordkeeping taking just over 2 hours (2.160). Therefore, 160,605 recordkeepers × 2.242 records × 2.160 hours = 777,765.046 hours (rounded to

777,765) for the recordkeeping burden related to agricultural water.

Sections 112.144, 112.145, and 112.147 (21 CFR 112.144, 112.145, and 112.147) require testing for sprouts. We estimate that 256 recordkeepers will conduct these tests. Thus, it is estimated that about 245 (245.660) records for each recordkeeper will spend an average of 0.403 hour per record on testing sprouts. Therefore, 256 recordkeepers × 245.660 records × 0.403 average hours per recordkeeping = 25,344.251 hours (rounded to 25,344) to meet the recordkeeping requirements of §§ 112.144, 112.145, and 112.147.

We estimate that there are 1,023 recordkeepers for other records related to sprouts. Thus, it is estimated that about 62 (62.061) records for each recordkeepers will spend an average of 0.174 hour per record. Therefore, 1,023 recordkeepers × 62.061 records × 0.174 average hour per recordkeeping = 11,046.982 (rounded to 11,047) hours for the burden to maintain records related to sprouts.

We estimate 1,023 recordkeepers will utilize the recommendations in the Sprouts draft guidance, once finalized, to maintain additional records related to sprouts. We estimate each recordkeeping will take about an hour for a recordkeeping burden of 1,023 hours.

Section 112.2 relates to documentation supporting compliance. We estimate that there are 4,568 recordkeepers each maintaining a record of compliance. We estimate that each recordkeeper will spend 0.079 hour maintaining their record. Therefore, 4,568 recordkeepers × 0.079 hour = 360.872 (rounded to 361) hours for the burden to maintain documentation supporting compliance.

Sections 112.2, 112.6, 112.31, 112.33, and 112.142 (21 CFR 112.2, 112.6, 112.31, 112.33, and 112.142) require third-party disclosures. We estimate that 77,165 respondents are making these disclosures. Thus, it is estimated that each respondent has around three (3.459) disclosures and will spend an average of 1.422 hours per disclosure. Therefore, 77,165 respondents × 3.459 disclosures × 1.422 average hours per

disclosure = 379,551.331 hours (rounded to 379,551) for the third-party disclosure burden to meet the requirements of §§ 112.2, 112.6, 112.31, 112.33, and 112.142.

The burden estimate reflects adjustments resulting in an overall decrease of 19,847 hours. We have removed one-time burden that has been realized since establishing the regulations; however, we have added burden we attribute to our estimate of recordkeepers following the recommendations in the Sprouts draft guidance.

Dated: February 25, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0407]

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 April 29, 2019.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-0407-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov*, or call 202-795-7714.

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: Think Cultural Health (TCH) website Quality Improvement Effort—OMB No. 0990–0407—Revision—HHS/OS/OMH.

Abstract: The Office of Minority Health (OMH), Office of the Secretary (OS), Department of Health and Human Services (HHS) is requesting approval by OMB on a revision to a previously approved data collection. The Think Cultural Health (TCH) website is an initiative of the HHS OMH’s Center for Linguistic and Cultural Competence in Health Care (CLCCHC), and is a repository of the latest resources and tools to promote cultural and linguistic competency in health and health care. The TCH website is unlike other government websites in that its suite of e-learning programs affords health and health care professionals the ability to earn continuing education credits

through training in cultural and linguistic competency. The revision to this information collection request includes the online website registration form, course/unit evaluations specific to the resource or e-learning program course/unit completed, follow up surveys, focus groups, and key informant interviews.

Need and Proposed Use of the Information: The data will be used to ensure that the offerings on the TCH website are relevant, useful, and appropriate to their target audiences. The findings from the data collection will be of interest to HHS OMH in supporting maintenance and revisions of the offerings on the TCH website.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondent	Number of respondent	Number responses per respondent	Average burden per response (hours)	Total burden (hours)
Registration Form	Health and Health Care Professionals	9,460	1.00	3/60	473
Course/unit Evaluation Form.	Health and Health Care Professionals	9,460	1.00	5/60	788
Follow-Up Survey	Health and Health Care Professionals	4,208	1.00	10/60	701
Follow-Up Survey	Community Health Workers	6	2.00	10/60	2
Focus Groups	Health and Health Care Professionals	15	1.00	120/60	29
Key Informant Interviews	Health and Health Care Professionals	13	1.00	60/60	13
Key Informant Interviews	Community Health Workers	25	1.00	60/60	25
Total	23,187	2,031

Terry Clark,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Health Service Strategic Plan Fiscal Year 2019–2023

AGENCY: Indian Health Service, IHS.

ACTION: Notice.

SUMMARY: In follow-up to the Indian Health Service (IHS) request for comments on the Draft IHS Strategic Plan Fiscal Year (FY) 2018–2022 issued in the **Federal Register** (FR) on July 24, 2018, (see 83 FR 35012; July 24, 2018; hereafter “July 2018 FR document”), the IHS is announcing the final plan entitled: IHS Strategic Plan FY 2019–2023. The IHS is also making available on the IHS Strategic Plan website, a response to comments document that addresses comments received on the Draft IHS Strategic Plan from the July 2018 FR document.

FOR FURTHER INFORMATION CONTACT:

RADM Francis Frazier, Director, Office of Public Health Support, IHS, 5600 Fishers Lane, Mail Stop: 09E10D, Rockville, Maryland 20857. Telephone number: 301–443–0222 (This is not a toll-free number), email address: IHSStrategicPlan@ihs.gov. In addition, progress on the IHS Strategic Plan will be periodically updated on the IHS website at: <https://www.ihs.gov/strategicplan/>.

SUPPLEMENTARY INFORMATION:

General Information

The IHS, an agency within the U.S. Department of Health and Human Services (HHS), is responsible for providing federal health services to American Indians and Alaska Natives. The provision of health services to members of federally-recognized Tribes grew out of the special government-to-government relationship between the federal government and Indian Tribes. Established in 1787, this relationship is based on Article I, Section 8 of the U.S. Constitution and has been given form and substance by numerous treaties, laws, Supreme Court decisions, and Executive Orders. The IHS is the principal federal health care provider

and health care advocate for Indian people. The IHS provides a comprehensive health service delivery system for American Indians and Alaska Natives.

The IHS Strategic Plan, covering FY 2019–2023, includes a mission statement, a vision statement, and details on how the IHS will achieve its mission through three strategic goals: (1) To ensure that comprehensive, culturally appropriate personal and public health services are available and accessible to American Indian and Alaska Native people; (2) To promote excellence and quality through innovation of the Indian health system into an optimally performing organization; and (3) To strengthen IHS program management and operations. These strategic goals are supported by objectives that reflect the outcomes the IHS is working to achieve and strategies describe how the IHS plans to make progress toward the objectives.

Background

The IHS Strategic Plan reflects the feedback received from Tribes, Tribal organizations, urban Indian organizations, staff, and other stakeholders. The IHS used a process