

guidance discussed FDA's views and recommendations on when an ingredient intended for use in a dietary supplement is an NDI, when the requirement to submit an NDIN to FDA applies, the types of data and information that manufacturers and distributors should consider when they evaluate the safety of a dietary supplement containing an NDI, what to include in an NDIN (including recommendations about identity and safety information), and the procedures for submitting an NDIN. We received significant comments and decided to issue a revised draft guidance.

In the **Federal Register** of August 12, 2016 (81 FR 53486), we announced the availability of a revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry" to replace the July 2011 draft guidance. We gave interested parties an opportunity to submit comments on the 2016 revised draft guidance by October 11, 2016. On October 4, 2016, we extended the comment period for the revised draft guidance to December 12, 2016 (81 FR 68434).

The final guidance, whose availability we are announcing through this document, finalizes in a stand-alone document the identity and safety recommendations that had been in sections VI.A, "Identity Information about the NDI and the Dietary Supplement," VI.B, "History of Use or Other Evidence of Safety," and VI.C, "Summary of the Basis for Your Conclusion of Safety," of the 2016 draft guidance. To help alleviate the burden of submitting separate documents regarding the safety data submitted in an NDIN, we eliminated the references to a "comprehensive safety profile" and, instead, recommend use of a single "safety narrative" for all NDINs. We made changes to provide additional clarity and description regarding what should be included in the NDIN safety narrative, when additional evidence of safety should be submitted, and what types of studies are recommended to support an NDIN. Finally, the guidance contains editorial changes to improve clarity.

FDA has also updated the 2016 revised draft guidance to indicate which portions have been finalized and which portions remain in draft status (see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notifications-and-related-issues>).

FDA considered the applicability of Executive Order 14192 and finds this

action to be neither an E.O. 14192 regulatory action nor an E.O. 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 190.6 and found in the guidance have been approved under OMB control number 0910–0330.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Program Forms—OMB No. 0915–0285—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 19, 2026.

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 Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program Forms, OMB No. 0915–0285—Revision

Abstract: The Health Center Program, administered by HRSA, is authorized under Section 330 of the Public Health Service Act (42 U.S.C. 254b). Health centers are patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients and adjust fees based on income and family size. More than 1,400 health centers operate nearly 17,000 service delivery sites that provide primary health care to more than 32 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA uses forms for new and existing health centers and other entities to apply for various grant and non-grant opportunities, renew grant and non-grant designations, report progress, and change their scopes of project.

A 60-day notice published in the **Federal Register** on July 30, 2026, Vol. 91, No.145, pp. 48170–72. There were no public comments.

Need and Proposed Use of the Information: The information HRSA collects from health centers via the Health Center Program-specific forms is necessary for the agency's oversight of Health Center Program awards. HRSA uses the information for program monitoring and for evaluating award recipients' compliance with Health Center Program statutory and regulatory requirements. These forms were approved by OMB on May 31, 2026, following 60- and 30-day public comment periods. Eight forms that were previously approved are being updated and three forms are being added to facilitate monitoring, improve scope of project documentation and oversight, increase the efficiency of the change in scope process, and enhance the accuracy of change in scope requests.

HRSA will modify the following forms to update and clarify data currently being collected:

Forms proposed to be modified: No./name	Description of modifications
Form 5A: Services Provided	Update labels and categories of services.
Form 5B: Sites	Modify fields collecting site information.
Checklist for Form 5A Scope Adjustments	Revise checklist statements and questions.
Checklist for Form 5B Scope Adjustments	Revise checklist statements and questions.
Checklist for Deleting a Service Site from Scope <i>Previously: Checklist for Deleting Existing Service Delivery Site.</i>	Revise checklist statements and questions.
Checklist for Adding a Service Site to Scope <i>Previously: Checklist for Adding a New Service Delivery Site.</i>	Revise checklist statements and questions.
Checklist for Adding a Service to Scope <i>Previously Checklist for adding a new service.</i>	Revise checklist statements and questions.
Checklist for Deleting a Service from Scope <i>Previously: Checklist for deleting existing service.</i>	Revise checklist statements and questions.

HRSA will add the following forms necessary for data collection and change in scope requests to simplify the process:

- Checklist for Replacing a Service Site in Scope: Checklist for updating a health center's scope to replace a service site.

- Quality Improvement Fund (QIF) Final Report: Collects data on the award recipient's QIF project progress as directed by the notice of funding opportunity.

- Loan Guarantee Progress Report: Used to monitor the status of the loan after the guarantee is issued to ensure the health center is compliant in meeting the terms and payment of the loan in the post monitoring phase of the program.

Likely Respondents: Health Center Program award recipients (those funded under section 330 of the Public Health

Service Act) and Health Center Program look-alikes.

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.

These updates will reduce the estimated annual burden by 1,621 hours based on the underlying unrounded burden calculations for the currently approved collection. The reduction reflects modifications to existing forms and the correction of the burden table to exclude *Form 5C: Other Activities/ Locations*. Form 5C was removed from the package during revisions completed earlier in 2026 and was inadvertently retained in the published 60-day **Federal Register** notice burden table. Compared with the 60-day notice, excluding Form 5C reduces the totals by 550 respondents, 550 responses, and 137.50 burden hours. In the burden table below, new forms are indicated through bold text, and revised forms are indicated through italicized text. Except for the correction regarding Form 5C described above, all other forms are unchanged.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form title	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Form 5A: Services Provided	1,400	1	1400	0.25	350.00
Form 5B: Sites	1,400	1	1400	0.25	350.00
Checklist for Form 5A Scope Adjustments	1,000	1	1000	1.00	1,000.00
Checklist for Form 5B Scope Adjustments	2,000	1	2000	1.00	2,000.00
Checklist for Deleting a Service Site from Scope Previously: Checklist for Deleting Existing Service Delivery Site	500	1	500	1.00	500.00
Checklist for Adding a Service Site to Scope Previously: Checklist for Adding a New Service Delivery Site	1,250	1	1250	1.50	1,875.00
Checklist for Adding a Service to Scope Previously: Checklist for adding a new service	450	1	450	1.00	450.00
Checklist for Deleting a Service from Scope Previously: Checklist for deleting existing service	500	1	500	1.00	500.00
Checklist for Replacing a Service Site in Scope	250	1	250	0.75	187.50
QIF Final Report	25	1	25	3.00	75.00
Loan Guarantee Progress Report	22	4	88	1.00	88.00
Capital Semi-Annual Progress Report	500	2	1,000	1.00	1,000.00
Equipment List	130	1	130	0.50	65.00
Federal Object Class Categories Form	500	1	500	0.25	125.00
Loan Guarantee Program Financial Performance Indicators	5	1	5	1.00	5.00

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form title	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Form 1A: General Information Worksheet	1,370	1	1,370	0.75	1,027.50
Form 1B: Funding Request Summary	900	1	900	0.75	675.00
Form 1C: Documents on File	1,460	1	1,460	0.50	730.00
Form 2: Staffing Profile	1,370	1	1,370	1.00	1,370.00
Form 3: Income Analysis	1,370	1	1,370	1.00	1,370.00
Form 6A: Current Board Member Characteristics	1,370	1	1,370	1.00	1,370.00
Form 6B: Request for Waiver of Board Member Requirements	1,370	1	1,370	1.00	1,370.00
Form 8: Health Center Agreements	1,370	1	1,370	1.00	1,370.00
Form 12: Organization Contacts	970	1	970	0.50	485.00
Funding Sources	130	1	130	0.50	65.00
FY 2022 Accelerating Cancer Screening Progress Report	29	1	29	1.50	43.50
Grant Number Form	400	1	400	0.25	100.00
Health Center Controlled Network Progress Report	50	1	50	0.50	25.00
Health Center Program Progress Report	130	1	130	1.00	130.00
HRSA Loan Guarantee Program Application	5	1	5	1.00	5.00
Impact Form	400	1	400	1.00	400.00
Native Hawaiian Health Care Improvement Act (NHHCIA) Non-Competing Continuation (NCC) Clinical Performance Measures	5	1	5	1.50	7.50
NHHCIA NCC Financial Performance Measures	5	1	5	0.50	2.50
NHHCIA NCC Income Analysis Form	5	1	5	0.15	0.75
NHHCIA Sample Project Work Plan	2	1	2	0.15	0.30
Native Hawaiian-NCC Project Work Plan Update	5	1	5	1.00	5.00
Operational Plan	350	1	350	2.00	700.00
Other Requirements for Sites	130	1	130	0.50	65.00
Participating Health Centers List	90	1	90	1.00	90.00
Project Cover Page	130	1	130	1.00	130.00
Project Narrative Update	1,325	1	1,325	4.00	5,300.00
Project Overview Form	500	1	500	1.00	500.00
Project Qualification Criteria	130	1	130	0.50	65.00
Project Work Plan	508	1	508	4.00	2,032.00
Proposal Cover Page	130	1	130	1.00	130.00
QIF Evaluative Measures Report	25	2	50	1.50	75.00
QIF Progress Report	25	12	300	1.50	450.00
QIF Transitions in Care for Justice-Involved Populations Evaluative Measures Report	54	10	540	1.50	810.00
QIF Transitions in Care for Justice-Involved Populations Progress Report	54	10	540	1.50	810.00
QIF Project Plan Form	100	1	100	1.00	100.00
Summary Page (New Access Point)	500	1	500	1.00	500.00
Summary Page (Service Area Competition)	360	1	360	0.50	180.00
Look-Alike Cover page	110	1	110	0.50	55.00
Checklist for Adding a Transitional Care in a Carceral Setting Site to Scope	50	1	50	1.00	50.00
Totals	27,219.00		29,057.00		31,164.55

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be partially open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or

other reasonable accommodation, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The intramural programs and projects and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the intramural programs and projects,