Supporting Statement Part A
Section 1115 Demonstration Projects Regulations at
42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428
CMS-10341, OMB 0938-1162

Background

Section 10201(i) of the Affordable Care Act amended section 1115 of the Social Security Act (the Act) to require the Secretary of the Department of Health and Human Services (HHS) to establish requirements relating to applications for and extensions of any experimental, pilot and demonstration project allowed under section 1115 of the Act. The Secretary is required to establish a process for public notice to ensure a meaningful level of public input at the state and federal level and provide guidelines for public notice and comment after an application for a demonstration project is received by the Secretary. In addition, the Secretary must implement reporting requirements for states, establish a process for the periodic evaluation of approved state demonstration projects, and report annually to Congress on the implementation of approved demonstration projects. This information collection request establishes requirements pertaining to the provisions required under section 10201(i) of the Affordable Care Act.

This 2024 iteration seeks to extend the expiration date for another three years without change.

This collection of information request does not include any collection of information instruments. Instead, all requirements are set out in the CFR.

A. Justification

1. Need and Legal Basis

The information required under this collection is necessary to ensure that states comply with statutory and regulatory requirements related to the application, implementation, monitoring, and evaluation of demonstration projects allowed under section 1115 of the Act. States seeking authority under section 1115 of the Act are required to meet certain requirements for public notice, monitoring, and evaluation of demonstration projects. CMS is also required to use this information to report to the Secretary on the implementation of approved demonstrations. The legislative authority for these requirements is found in section 1115(d) of the Act, as added by section 10201(i) of the Affordable Care Act. This information collection reflects the Affordable Care Act requirements provided in the final rule published on February 27, 2012 (77 FR 11677).

2. Information Users

The respondents to all of the requirements (specified in section 3 and 12) that comprise this information collection are states (specifically Medicaid and Children's Health Insurance Program (CHIP) state agencies) who submit applications for demonstration projects to be implemented under section 1115 authority to the Centers for Medicare and Medicaid Services (CMS). The information required is used by CMS or its designee to determine whether a state's application submission should be approved in accordance with statutory and regulatory requirements and

also to monitor and evaluate approved demonstrations to determine whether they are operating in compliance with statutory and regulatory requirements.

3. Use of Information Technology

States are required to furnish the information for the following list of requirements which are explained in more detail in section 12.

i. State Public Notice Process (§431.408) – States are required to provide a public notice and comment period regarding applications for a new demonstration project, or extensions of existing demonstration projects the states intend to submit to CMS for review and approval.
ii. Application Procedures (§431.412) – States are required to submit applications for new demonstrations or extensions of existing demonstrations with certain information in order for the applications to be accepted as "complete" by CMS for the purpose of initiating federal review.
iii. Monitoring and Compliance (§431.420) – States are required to periodically perform reviews of the implementation of their demonstrations and report progress to CMS.
iv. Evaluation Requirements (§431.424) – States are required to submit for CMS approval designs (i.e., plans) for evaluations of their demonstrations. Evaluations measure the effectiveness and usefulness of demonstration projects as models to help shape policy.
v. Reporting Requirements (§431.428) – States are required to specifically submit annual reports to CMS documenting their demonstration implementation activities completed in the past year of the project; including identifying any challenges or issues that arose and how they were addressed by the state.

4. Duplication of Efforts

This information collection does not duplicate any current information collection. It contains information required by statute which supplements previous requirements.

5. Small Businesses

This information collection does not impact small businesses or other small entities.

6. Less Frequent Collection

The frequency of required response to this information collection by states is quarterly, annually or a one-time submission depending on the requirement.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on October 30, 2024 (89 FR 86340). We did not receive any public comments.

The 30-day notice displayed at the Federal Register on January 30, 2025, and is scheduled for publication on February 3, 2025. A copy of the display notice is attached to this submission.

9. Payments/Gifts to Respondents

There is no payment or gift to respondents.

10. Confidentiality

We make no pledges of confidentiality. The information received by CMS is not confidential and will be made publicly available, in whole or in part, in order to comply with statutory requirements designed to promote transparency in the review and approval of section 1115 demonstration projects.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates

(http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage along with our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary) and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Medical and Health Services Managers	11-9111	64.64	64.64	129.28

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

The basis of new subpart G under 42 Code of Federal Regulations (CFR) Part 431 is to implement the provisions of section 1115(d) of the Act that outlines requirements for:

- the development of state demonstration applications;
- public notice for states and the Department;
- Department monitoring, compliance, and evaluation of demonstration projects; and
- the Departments' submission of reports to the Secretary.

The requirements apply uniformly to all Medicaid and Children's Health Insurance Program (CHIP) section 1115 applications and approved demonstration projects with the purpose of promoting transparency in the review and approval of section 1115 demonstrations.

This information collection request governs the burden associated with completing the requirements of part 431, which are not subject to specific reporting/information collection instruments. States determine the format and structure of documents developed and submitted to CMS for establishing compliance with part 431 requirements. While CMS has published guidance to help states meet various part 431 requirements, this guidance does not direct states to use any specific reporting/information collection instruments.

There may be instances where CMS determines that certain part 431 requirements or types of section 1115 demonstrations require use of specific reporting/information collection instruments in order to support Medicaid/CHIP program objectives. To the extent that CMS develops such instruments, we have sought or will seek separate PRA approval for the use of such instruments[1]; noting that the reporting requirement itself is governed and approved under this information collection for part 431 requirements.

[1] See for example, approved information collection #10 and #51 (CMS-10398/OMB 0938-1148) for the Section 1115 Demonstration and Waiver Application Template and FAST TRACK Federal Review Process for Section 1115 Medicaid and CHIP Demonstration Extensions. These collections approve the use of specific templates for states to use to meet application requirements outlined in 42 CFR 431.412.

State Public Notice Process (§431.408)

Section §431.408 provides for a state to provide a public notice and comment period regarding applications for a new demonstration project, or an extension of an existing demonstration project the state intends to submit to CMS for review and consideration. Section 431.408(a)(1) specifies that prior to submitting an application to CMS for a new demonstration project or an extension of a previously approved demonstration project, the state must provide public notice with a comment period of at least 30 days. The public notice must address the information requirements listed at §431.408(a)(1)(i) through (iv) as detailed below. The below burden estimate includes the burden associated with these sub-requirements:

- §431.408(a)(1)(i) A comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to ensure meaningful input from the public, including:
  (A) The program description, goals, and objectives to be implemented or extended under the demonstration project, including a description of the current or new beneficiaries who will be impacted by the demonstration.
  (B) To the extent applicable, the proposed health care delivery system and the eligibility requirements, benefit coverage and cost sharing (premiums, co-payments, and deductibles) required of individuals that will be impacted by the demonstration, and how such provisions vary from the State's current program features.
  (C) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable. This includes a financial analysis of any changes to the demonstration requested by the State in its extension request.
  (D) The hypothesis and evaluation parameters of the demonstration.
  (E) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

The burden estimate associated with this requirement is the time and effort necessary to develop and publish separate public notice materials accompanied with a minimum 30-day comment period; along with a proposed application that complies with the below mentioned information requirements of §431.412. We estimate that each of the 27 states submitting applications for new demonstration projects or an extension of a previously approved demonstration project will require 80 hours to comply with the requirements in this section. The estimated annual burden associated with this section is 2,160 hours at a cost of $279,245/yr.

Annual Responses:	7 initial applications + 20 extension applications = **27 applications/yr**
Time:	27 applications/yr x 80 hr/application = **2,160 hr/yr**
Cost:	**2,160** hr/yr x $129.28/hr = **$279,245yr**

Section 431.408(a)(2)(i) provides that states establish and maintain a readily identifiable link to a demonstration web page on the public web site of the state agency responsible for making applications for demonstrations. The state public notice must appear in a prominent location on

the demonstration web page of the state's public web site throughout the entire review process; and the public notice must appear in at least one of the publications listed at §431.408(a)(2)(ii) and (iii).

The burden associated with this is the time and effort necessary to develop a notice and to publish it both on the web site for the state agency responsible for submitting demonstration applications and in at least one of the publications listed at §431.408(a)(2)(ii) and (iii). While these requirements are subject to the PRA, we believe we addressed the burden estimates in our discussion of §431.408(a)(1).

Section 431.408(a)(3) specifies that at least 20 days prior to submitting an application for a new demonstration project, or an extension of a previously approved demonstration project to CMS for review, the state must have conducted at least two public hearings regarding the state's demonstration application using at least two of the following public forums contained in this section. The state must use telephonic and/or web conference capabilities for at least one of the two required public hearings in order to ensure statewide accessibility to the public hearing unless it can document it has afforded the public throughout the state the opportunity to provide comment. The burden associated with this requirement is the time and effort necessary for a state to conduct at least two public hearings 20 days prior to submitting an application for a demonstration. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(4). Facts or opinions submitted in response to general solicitations of comments from the public, published in the Federal Register or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment are not subject to the PRA.

Section 431.408(b)(1) requires states with Federally recognized Indian tribes, Indian health programs, Urban Indian Organizations or all three of the aforementioned entities, to consult with the Indian tribes, Indian Health programs and Urban Indian Organizations in the state, before submitting a demonstration application. Section 431.408(b)(2) specifies that consultation activities must be conducted in a manner consistent with the state approved consultation process outlined in the state's Medicaid State Plan. Section 431.408(b)(3) explains that documentation of the state's consultation activities must be included in the demonstration application, such as, the date and location of the consultation and must include issues raised and the potential resolution for such issues.

The burden associated with these requirements is both the time and effort necessary for a state to conduct its tribal consultations and the time and effort necessary to notify CMS of the state's compliance with §431.408(b)(3). This requirement applies to 35 states that have tribal entities recognized by the United States Bureau of Indian Affairs as published in the January 29, 2021 Federal Register. However, we estimate that an average 22 states would be subject to this requirement in a given year. We further estimate that it will take each state a total of 40 hours to both conduct its tribal consultations, notify the Indian Tribes in writing of its intent to submit an application for a new demonstration project or an extension of an existing demonstration project

and to submit the aforementioned evidence to CMS. The estimated annual burden associated with these requirements is 880 hours at a cost of $113,766/yr.

Time: 22 total applications x 40 hr = **880 hr/yr**
Cost: 880 hr/yr x $129.28/hr for 1 FTE = **$113,766/yr**

Application Procedures (§431.412)

Section 431.412(a) discusses the application process for Medicaid/CHIP demonstration projects. A state's application for approval of a new demonstration project or an extension of an existing demonstration project must be submitted to CMS as both printed and electronic documents. Section 431.412(b) explains that applications for the initial approval of a demonstration will not be considered complete if they do not comply with the requirements contained at §431.412(b) and §431.408.

The burden associated with the requirements in §431.412 is the time and effort necessary for a state to develop and submit a complete initial application for a demonstration. We estimate we will receive 7 initial demonstration applications annually. Similarly, we estimate that it will take 400 hours for a state to develop and submit a complete demonstration application for a new demonstration project. The total estimated annual burden associated with the requirements in §431.412(b) is 2,800 hours at a cost of $361,984/yr.

Time: 7 initial applications x 400 hr = **2,800 hr/yr**
Cost: 2,800 hr x $129.28/hr for 1 FTE = **$361,984/yr**

Section 431.412(c) specifies that a state must submit a request to extend an existing demonstration under sections 1115(e) of the Act at least 12 months prior to the expiration date of the demonstration, or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f) of the Act. An extension application, including an extension for the purpose of phasing-out a demonstration, must be sent from the Governor of the State to the Secretary. Section 431.412(c)(2) further specifies that an application to extend an existing demonstration will be considered complete when the state provides the required information listed at §431.412(c)(2)(i) through (vii). The burden associated with the requirements in §431.412(c) is the time and effort necessary for a state to develop and submit a demonstration extension application. CMS estimates that 20 states will apply for extensions annually. We further estimate that it will take each state approximately 320 hours to develop and submit a demonstration extension application. The total estimated annual burden is 6,400 hours at a cost of $827,392/yr.

Time: 20 extension applications x 320 hr = **6,400 hr/yr**
Cost: 6,400 hr x $129.28/hr for 1 FTE = **$827,392/yr**

Monitoring and Compliance (§431.420)

According to §431.420(b) states will periodically perform reviews of the implementation of the demonstration. We estimate that it will take each state 70 hours annually, per demonstration, to periodically review a demonstration's implementation progress. We also estimate that 48 states

must comply with this requirement for the 77 approved section 1115 demonstration projects as of April 30, 2021. Because monitoring and compliance requirements apply to each approved section 1115 demonstration project and some states have more than one approved section demonstration project, this annual burden estimate factors the number of approved section 1115 projects rather than number of states. The total estimated annual burden associated with this requirement is 5,390 hours at a cost of $696,819/yr.

Time: 77 total approved section 1115 demonstrations x 70 hr = **5,390 hr/yr**
Cost: 5,390 hr/yr x $129.28/hr for 1 FTE = **$696,819/yr**

Section 431.420(c) further specifies that at least 6 months after the implementation date of the demonstration and annually thereafter, the state must hold a public forum to solicit comments on the progress of a demonstration project. Section 431.420(c)(3)(i) through (ii) explains that the public forum to solicit feedback on the progress of a demonstration project must occur using a Medical Care Advisory Committee meeting in accordance with §431.408, or a commission, or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about and comment on the demonstration's progress. Additionally, as stated in §431.420(c)(3)(iii) the state must publish the date, time, and location of the public forum in a prominent location on the state's public web site, at least 30 days prior to the date of the planned public forum.

The burden associated with these provisions includes the time and effort necessary to conduct the public meeting and the time and effort necessary for a state to publish the date, time, and location of the public forum in a prominent location on the state's public web site, at least 30 days prior to the date of the planned public forum. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA. As discussed previously in this collection, facts or opinions submitted in response to general solicitations of comments from the public, published in the Federal Register or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment are not subject to the PRA. Therefore, the burden associated with the annual public hearing requirement is exempt. Similarly, we believe the time and effort necessary for a state to publish the date, time, and location of the public forum in a prominent location on the state's public web site is a burden that would be incurred in the course of usual and customary state business practices and is therefore exempt from the PRA under 5 CFR 1320.3(b)(3).

<u>Evaluation Requirements (§431.424)</u>

As required in §431.424(c)(1), the state must receive CMS approval of a design for an evaluation of the demonstration project and publish this document to the state's public web site. The draft evaluation must include information established in §431.424(c)(2). The burden associated with this requirement comprises the time and effort necessary to: (A) design an evaluation for a new demonstration or update an evaluation design for an extended demonstration and (B) develop a final report on findings from evaluation activities conducted under the evaluation plan for the complete approval period for submission to CMS.

- Sub-requirement (A) – We estimate that it will take each state 160 hours to develop or update an evaluation design. Similarly, we estimate that 24 states must comply with this requirement annually. We further estimate that the total estimated annual burden associated with this requirement is 3,840 hours at a cost of $496,435/yr.

  Time: 24 demonstration evaluation design plans per/yr x 160 hr = **3,840 hr/yr**
  Cost: 3,840 hr/yr x $129.28/hr for 1 FTE=$**496,435/yr**

- Sub-requirement (B) – We estimate that it will take each state 160 hours to develop a final report on findings from evaluation activities conducted under the evaluation plan for the complete approval period for submission to CMS (§431.424(c)(2)(v)). CMS's refers to this requirement as the "summative report" in the Special Terms and Conditions (STCs) of approval. Similarly, we estimate that 24 states must comply with this requirement annually. We further estimate that the total estimated annual burden associated with this requirement is 3,840 hours at a cost of $496,435/yr.

  Time: 24 demonstration final (summative) evaluation reports per/yr x 160 hr = **3,840 hr/yr**
  Cost: 3,840 hr/yr x $129.28/hr for 1 FTE=$**496,435/yr**

The aggregate total of the estimated annual burden associated with this requirement is 7,680 hours at a cost of $996,870/yr.

Section 431.424(d) specifies that in the event that the state requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the state must submit an interim evaluation report as part of the state's request for a subsequent extension of the demonstration. The burden associated with this is the time and effort necessary for a state to develop and submit an interim evaluation report. We estimate that each state will require 160 hours to comply with this requirement. Similarly, we estimate that 24 states must comply with this requirement annually. We further estimate that the total estimated annual burden associated with this requirement is 3,840 hours at a cost of $496,435/yr.

Time: 24 interim evaluations per/yr x 160 hr = **3,840 hr/yr**
Cost: 3,840 hr/yr x $125.28/hr for 1 FTE = **$496,435/yr**

Section 431.424(e) established that states will publish CMS-approved demonstration evaluation designs on their state public web site within 30 days of submission to CMS. We estimate that it will take 4 hours for each state to comply with this disclosure requirement. We further estimate that 24 states must comply with this provision annually. We further estimate that the total estimated annual burden associated with this requirement is 96 hours at a cost of $12,411/yr.

Time: 24 published evaluations per/yr x 4 hr = **96 hr/yr**
Cost: 96 hr/yr x $129.28/hr for 1 FTE = **$12,411/yr**

Reporting Requirements (§431.428)

Section 431.428 establishes that states will submit annual reports to CMS documenting the

information listed in §431.428(a)(1) through (11). As part of the submission process, §431.428(b) requires states to submit draft annual reports to CMS no later than 90 days after the end of each demonstration year, and that the state must publish its draft annual report on its public website within 30 days of submission to CMS. The burden associated with this reporting requirement is the time and effort necessary to submit draft annual reports to CMS. We estimate that 48 states must comply with this requirement for the 77 approved section 1115 demonstration projects as of April 30, 2021. Because annual reporting requirements apply to each approved section 1115 demonstration project and some states have more than one approved section demonstration project, this annual burden estimate factors the number of approved section 1115 projects rather than number of states). We estimate that it will take states 160 hours, per demonstration, to comply with this reporting requirement. We further estimate that the total estimated annual burden associated with this requirement is 12,320 hours at a cost of $1,592,730/yr.

Time: 77 annual reports x160 hr = **12,320 hr/yr**
Cost: 12,320 hr/yr x $129.28/hr = **$1,592,730/yr**

§431.428(b)(1) establishes that within 60 days of receipt of comments from CMS, the state must submit to CMS the final annual report for the demonstration year. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(9). Facts or opinions obtained or solicited through non-standardized follow-up questions designed to clarify responses to approved collections of information are not subject to the PRA.

Section 431.428(b)(2) states that the final annual report must be published on the state's public web site within 30 days of approval by CMS. The burden associated with this is the time and effort required for a state to post the aforementioned information on the state's public web site. We estimate that it will require states 4 hours to comply with this requirement for each approved section 1115 demonstration project. Forty-eight states will have to meet this requirement for the 77 approved section 1115 demonstration projects as of April 30, 2021. Because annual reporting requirements apply to each approved section 1115 demonstration project and some states have more than one approved section demonstration project, this annual burden estimate factors the number of approved section 1115 projects rather than number of states. The total estimated annual burden associated with this requirement is 308 hours at a cost of $39,818/yr.

Time: 77 published annual reports x 4 hr = **308 hr/yr**
Cost: 308 hr x $129.28/hr = **$39,818/yr**

Summary of Requirements and Burden Estimates

Regulation Section(s) under Title 42 of the CFR	Respondents	Responses per Respondent	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost ($/hr)	Total Cost ($)
431.408(a) State Public	27	1	27	80	2,160	129.28	279,245
Regulation Section(s) under Title 42 of the		Responses per	Total	Time per Response	Total Time	Labor Cost	Total Cost

CFR	Respondents	Respondent	Responses	(hours)	(hours)	($/hr)	($)
Notice Process							
431.408(b) State Public Notice Process (for Tribes)	22	1	22	40	880	129.28	113,766
431.412(a) Application Procedures	7	1	7	400	2,800	129.28	361,984
431.412(c) Application Procedures	20	1	20	320	6,400	129.28	827,392
431.420(b) Monitoring and Compliance	77	1	77	70	5,390	129.28	696,819
431.424(c)(1) Evaluation Requirements	24	1	24	160	3,840	129.28	496,435
431.424(c)(2)(v) Summative Report	24	1	24	160	3,840	129.28	496,435
431.424(d) Evaluation Requirements	24	1	24	160	3,840	129.28	496,435
431.424(e) Evaluation Requirements	24	1	24	4	96	129.28	12,411
431.428 Reporting Requirements	77	1	77	160	12,320	129.28	1,592,730
431.428(b)(2) Reporting Requirements	77	1	77	4	308	129.28	39,818
Total	**77**	**1**	**403**	**Varies**	**41,874**	**129.28**	**5,413,470**

Collection of Information Instruments and Instruction/Guidance Documents

Not applicable. As indicated, requirements are set out in the CFR.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

There is no cost to the Federal government.

15. Changes to Burden

This 2024 iteration seeks to extend the expiration date for another three years without change. The costs have been adjusted to reflect the most recent BLS data.

16. Publication/Tabulation Dates

There are no specific publication dates associated with this collection.

17. Expiration Date

The expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.