

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 renewals 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 demonstration projects and report annually to Congress on the implementation of approved demonstration projects. This information collection request would establish requirements pertaining to the provisions required under Section 10201(i) of the Affordable Care Act.

A. Justification

1. Need and Legal Basis

The information required under this collection is necessary to ensure that State's comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects allowed under the Statute. States seeking waiver authority under Section 1115 of the Act are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. The legislative authority for these requirements is found in Section 1115 of the Social Security Act, as amended 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 information required is used by the Centers for Medicare and Medicaid Services (CMS) or its designee when evaluating demonstrations to determine compliance with statutory requirements set forth in Section 1115 of the Act.

3. Use of Information Technology

States are required to furnish the information required under §431.408(a) electronically.

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

There are no special circumstances associated with this collection.

7. Special Circumstances

N/A

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on December 12, 2014 (79 FR 73891). No comments were received.

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 publically 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 questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2013 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 the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage*	Fringe Benefit (at 100%)	Adjusted Hourly Wage
Medical and Health Services Managers	11-9111	54.41	54.41	109.02

*This is the most current data available as of February 2015; the publication of the 30-day Federal Register notice.

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. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

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 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).

The burden estimate associated with this requirement is the time and effort necessary to develop and publish notice with a comment period that complies with the aforementioned information requirements. We estimate that each of the **15 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 **1,200 hours** at a cost of **\$130,824/yr**.

5 initial applications +10 extension applications = 15 total applications per/yr
 15 total applications per/yr x 80 hr = 1,200 hr/yr
 1,200 hr x \$109.02/hr for 1 FTE = \$130,824/yr

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). We estimate that this requirement applies to 37 States however we estimate that no more than **15 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 **600 hours** at a cost of **\$65,412/yr.**

15 total applications x 40 hr = 600 hr/yr
600 hr/yr x \$109.02/hr for 1 FTE = \$65,412/yr

Application Procedures (§431.412)

Section 431.412(a) discusses the application process for Medicaid 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 **5 applications** annually. Similarly we estimate that it will take **400 hours** for a State to develop and submit a complete demonstration application. The total estimated annual burden associated with the requirements in §431.412(b) is **2,000 hours** at a cost of **\$218,040/yr.**

$$\begin{aligned} 5 \text{ initial applications} \times 400 \text{ hr} &= 2,000 \text{ hr/yr} \\ 2,000 \text{ hr} \times \$109.02/\text{hr for 1 FTE} &= \$218,040/\text{yr} \end{aligned}$$

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 **10 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 **3200 hours at a cost of \$348,864/yr.**

$$\begin{aligned} 10 \text{ extension applications} \times 320 \text{ hr} &= 3,200 \text{ hr/yr} \\ 3,200 \text{ hr} \times \$109.02/\text{hr for 1 FTE} &= \$348,864/\text{yr} \end{aligned}$$

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 **80 hours** annually to periodically review the demonstration's implementation. We also estimate that **15 States** must comply with this requirement. The total estimated annual burden associated with this requirement is **1,200 hours** at a cost of **\$130,824/yr.**

$$\begin{aligned} 15 \text{ total applications} \times 80 \text{ hr} &= 1,200 \text{ hr/yr} \\ 1,200 \text{ hr/yr} \times \$109.02/\text{hr for 1 FTE} &= \$130,824/\text{yr} \end{aligned}$$

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).

Evaluation Requirements (§431.424)

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 is the time and effort necessary to design an evaluation for a new demonstration. We estimate that it will take each State **160 hours** to develop an evaluation. Similarly, we estimate that **15 States** must comply with this requirement. We further estimate that the total estimated annual burden associated with this requirement is **2,400 hours** at a cost of **\$261,648/yr**.

$$\begin{aligned} 15 \text{ demonstration evaluations per/yr} \times 160 \text{ hr} &= 2,400 \text{ hr/yr} \\ 2,400 \text{ hr/yr} \times \$109.02/\text{hr for 1 FTE} &= \$261,648/\text{yr} \end{aligned}$$

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 **10 States** must comply with this requirement. We further estimate that the total estimated annual burden associated with this requirement is **1,600 hours** at a cost of **\$174,432/yr.**

10 interim evaluations per/yr x 160 hr = 1,600 hr/yr
1,600 hr/yr x \$109.02/hr for 1 FTE = \$174,432/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 **70 hours** for each State to comply with this disclosure requirement. We further estimate that **15 States** must comply with this provision. We further estimate that the total estimated annual burden associated with this requirement is **1,050 hours** at a cost of **\$114,471/yr.**

15 published evaluations per/yr x 70 hr= 1,050 hr/yr
1,050 hr/yr x \$109.02/hr for 1 FTE = \$114,471/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 **15 States** must comply with this requirement. We estimate that it will take **40 hours** for each State to comply with this reporting requirement. We further estimate that the total estimated annual burden associated with this requirement is **600 hours** at a cost of **\$65,412/yr.**

15 annual reports x 40 hr = 600 hr/yr
600 hr/yr x \$109.02/hr for 1 FTE = \$65,412/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 each of the **15 States** will require **4 hours** to comply with this requirement. The total estimated annual burden associated with this requirement is **60 hours at a cost of \$6,541/yr.**

15 published annual reports x 4 hr = 60 hr/yr
 60 hr x \$109.02/hr for 1 FTE = \$6,541/yr

Summary of Requirements and Burden Estimates

Regulation Section(s) under Title 42 of the CFR	Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
431.408(a)(1) and (a)(2)(i)	15	1	15	80	1,200	109.02	130,824
431.408(b)(1)	15	1	15	40	600	109.02	65,412
431.412(a)	5	1	5	400	2,000	109.02	218,040
431.412(c)	10	1	10	320	3,200	109.02	348,864
431.420(b)	15	1	15	80	1,200	109.02	130,824
431.424(c)(1)	15	1	15	160	2,400	109.02	261,648
431.424(d)	10	1	10	160	1,600	109.02	174,432
431.424(e)	15	1	15	70	1,050	109.02	114,471
431.428	15	1	15	40	600	109.02	65,412
431.428(b)(2)	15	1	15	4	60	109.02	6,541
Total	--	--	130	--	13,910	109.02	1,516,468

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

While there are no program changes, our cost estimates have been adjusted to account for the most recent BLS wage data.

16. Publication/Tabulation Dates

There are no specific publication dates associated with this collection.

17. Expiration Date

There are no forms involved in this collection that will have an expiration date; therefore, this item is not applicable.

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.