

Supporting Statement Part A
Health Insurance Benefit Agreement and Supporting Regulations–
(CMS Form 1561 and 1561A)

A. Background

Providers and rural health clinics applying to participate in the Medicare program are required to agree to provide services in accordance with Federal requirements. This health insurance benefits agreement is essential for the Centers for Medicare and Medicaid Services (CMS) to ensure that applicants to the Medicare program are aware of and have made a binding commitment to comply with all applicable Federal requirements. Applicants will be required to sign the completed form and provide operational information to CMS to assure they continue to meet all Federal requirements following their approval. The form is signed when the applicant and CMS enter into agreement at the beginning of the applicant's participation in Medicare. The agreement remains in force so long as it's not terminated by either party; thus the collection is made one time only during the course of the applicant's participation in Medicare.

B. Justification

1. Need and Legal Basis

For the CMS-1561, in accordance with Section 1866 of the Social Security Act (the Act) and the implementing regulations at 42 CFR Part 489, to participate in the Medicare program all applicants must agree to comply with the requirements specified therein.

For the CMS-1561A, in accordance with Section 1861(aa)(2)(K)(ii) of the Act and the implementing regulations at 42 CFR Part 405 Subpart X and 42 CFR Part 491, to participate in the Medicare program as a rural health clinic all applicants must agree to comply with the requirements specified therein.

2. Information Users

This collection will be used by CMS to assure that each provider or rural health clinic applicant seeking to participate in the Medicare program has made a binding commitment in writing to comply with the applicable provisions of Sections 1861 and 1866 of the Act and the applicable regulations in 42 CFR.

3. Improved Information Technology

This collection does not lend itself to electronic submission at this time.

4. Duplication of Similar Information

There is no duplication of similar information.

5. Small Businesses

These requirements do affect small businesses; however, the information collection is necessary for the business to participate in the Medicare program. These paperwork requirements are minimal and are necessary to meet the participation requirements of the law.

6. Less Frequent Collection

This information is collected one time only over the course of the duration of the agreement between CMS and the applicant. It is necessary to prevent fraud and abuse in the Medicare program and to assure that providers and rural health clinics understand they must comply with all applicable Federal requirements and make a binding commitment to compliance throughout their participation in the Medicare program. If the information were collected less frequently, CMS would not have a binding commitment on the part of providers or rural health clinics to comply with all applicable Medicare requirements. The presence of unsafe, fraudulent, or abusive entities in the Medicare program puts patients/residents at risk of harm and diverts resources from the Medicare Trust Funds that are needed to reimburse legitimate claims for medical care provided to Medicare beneficiaries.

7. Special Circumstances

There are no special circumstances pertaining to this collection.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on April 14, 2017 (82 FR 17997). There were no comments received.

The 30-day Federal Register notice published on June 26, 2017 (82 FR 28851). There were no comments received.

9. Payments/Gifts to Respondents

There will be no payment or gifts provided to respondents, except for reimbursement for covered services as provided for under the law via normal reimbursement procedures.

10. Confidentiality

We make no pledges of confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimate (Total Hours and Wages)

We estimate that it would take the facility 5 minutes to review, fill in the required information, and sign the CMS-1561 or CMS-1561A form. We have further estimated that it would take an additional 5 minutes to file the document when fully executed. This work would likely be performed by the facility CEO. This would equate to 10 minutes of time required to complete the CMS-1561 or CMS-1561A form.

There are approximately 2,454 new providers/Changes of Ownership (CHOWs) completing the CMS-1561 or CMS-1561A yearly.¹ (10 minutes x 2,454 = 409 hours spent across all new providers/CHOWs to complete the CMS-1561/CMS-1561A form.

Upon completion of the CMS-1561 or CMS-1561A form, the new provider/CHOW must mail one original copy to the State Survey Agency and the Medicare Administrative Contractor (MAC). We also estimate that it will take 10 minutes of time by a Medical Secretary to prepare these 2 original copies of the CMS-1561 or CMS-1561A for mailing (i.e. – preparing a mailing envelope, reviewing the form for completeness, folding the forms and inserting them into the envelopes, and putting the envelopes into the mail).

In the previous submissions of this PRA package, our burden estimate presumed the applicant has full knowledge of the Medicare program requirements in which they're requesting participations via completion of the Medicare application (CMS-855), one could also presume the likelihood of an individual not having such knowledge of these program requirements is probable.

Therefore, we agree that since both the form CMS-1561 and CMS-1561A are based on certain statutes and regulatory law, the burden estimate for each form should also include the estimated time it takes for the signer of the form to read the applicable statutory and regulatory language. For the CMS-1561, this statutory and regulatory law includes Section 1866 of the Social Security Act and CMS regulations at 42 CFR 489. For the CMS-1561A, this statutory and regulatory law includes section 1861(aa)(2)(K) (ii) of the Act and the implementing regulations at 42 CFR Part 405 Subpart X and 42 CFR Part 49142.

¹ This number is based on 2016 statistics obtained from the CMS Survey & Certification OCQR Database

Thus we have revised our burden estimate to consider that it would take the signer of the CMS-1561 or CMS-1561(A) form, who is unfamiliar or minimally familiar with this statutory and regulatory language, approximately **40 minutes** to review the applicable law. This would likely be performed by the facility CEO.

We estimate that the time required by the CEO at each new provider/CHOW to review statutory and regulatory law associated with the CMS-1561 and CMS-1561A forms is **40 minutes** per facility. There are approximately **2,454** new facilities per year. Therefore time required across all new facilities to complete a review of the relevant statutory and regulatory language associated with the CMS-1561 / CMS 1561A is **1,636** hours (**40 min. x 2,454 = 98,160 minutes / 98,160** divided by **60 min/hour = 1,636** hours)

The estimated amount of time that would be spent by the CEO of each new provider/CHOW to fill in the required information on the CMS-1561 / CMS-1561A form, sign the form, make a copy and file in their records is **10 minutes**. The estimated time it would take across all new facilities to perform these tasks is **409** hours (**10 minutes x 2,454 CHOWS = 24,540 minutes per all CHOWS / 24,540 minutes divides by 60 min/hour = 409** hours per year across all facilities).

The estimated time required for a Medical Secretary to prepare two (2) original, signed copies of the CMS-1561 / CMS-1561A forms for mailing to the State Survey Agency and the Medicare Administrative Contractor (MAC), prepare the forms for mailing by creating mailing envelopes, putting these forms into the envelopes and sealing and putting the envelopes into the mail is **10 minutes**. The total time across all new facilities to perform the above-stated activities is estimated to be **409** hours ((**10 minutes x 2,454 CHOWS = 24,540 minutes per all CHOWS / 24,540 minutes divides by 60 min/hour = 409** hours per year across all facilities).

The labor related costs to each facility associated with this Information Request are as follows:

Cost for time associated with review of the statutory and regulatory language associated with the CMS-1561 and CMS-1561

As noted above, we estimate that it will take approximately 40 minutes for the CEO of a new provider/CHOW to review the applicable statutory and regulatory law. According to the U.S. Bureau of Labor Statistics, the mean average hourly salary of a CEO is **\$93.44**.² The total costs for each new provider/CHOW associated with review the applicable law by the CEO is **\$62.40**. (**\$93.44** divided by **60 minutes = \$1.56 per minute**) and (**\$1.56 per min. x 40 min. = \$62.40** per 40 min.).

² The wages for a facility CEO can be found on the U.S. Bureau of Labor Statistics website at <https://www.bls.gov/oes/current/oes111011.htm>

The total cost across all new facilities/CHOW would be **\$153,130** (**\$62.40** per **40** minutes x **2,454** new facilities = **\$153,130**).

Cost Required to Fill In and Sign the CMS-1561/CMS-1561A Form

We have estimated that it will take approximately 10 minutes of time by a facility CEO to fill in and sign the CMS-1561/ CMS-1561. According to the U.S. Bureau of Labor Statistics, the mean average hourly salary of a CEO is **\$93.44**. Therefore, the total costs to each new provider/CHOW associated with completion and signature of the CMS-1561/CMS-1561A by the CEO is **\$15.60** (**\$93.44** divided by **60** minutes = **\$1.56**) and (**\$1.56** x **10** min = **\$15.60**).

The total annualized cost across all new facilities would be **\$38,282** (**\$15.60** x **2,454** = **\$38,282**).

Cost Associated with Preparation and Mailing of the CMS-1561/CMS-1561A Form

The cost to each new provider/CHOW associated with the task of preparing the two original CMS-1561/CMS-1561A forms for mailing to the State Survey Agency and the Medicare Administrative Contractor (MAC) and putting them into the mail, is **\$2.70**. (**10** minutes of time by a Secretary of Office Clerk as an hourly salary of **\$16.22** per hour³) and (**\$16.22** divided by **60** min. = **\$0.27**) and (**\$0.27** x **10** min = **\$2.70**).

The total annualized costs across all new facilities for these tasks would be **\$6,626** (**\$2.70** x **2,454** = **\$6,626**).

Total Labor Costs

The total annual labor costs across all new facilities is **\$198,038** (**\$153,130** + **\$38,282** + **\$6,626** = **\$198,038**).

Fringe Benefits

We estimate that there will be fringe benefits incurred on the wages stated above at a rate of 100% of the gross wages. Therefore, we have added the amount of **\$198,038** to our burden estimate for fringe benefits.

Non-Labor Related Costs

Each new provider/CHOW that completes a CMS-1561/CMS-1561A must mail an original copy of the CMS-1561 / CMS-1561 to the State Survey Agency and the Medicare Administrative Contractor (MAC). This will require the facilities will incur costs for two first class postage stamps or postage marks which cost **\$0.50** each for a total of **\$1.00**.in costs per each new provider/CHOW.

³ The wages for a Medical Secretary can be found on the U.S. Bureau of Labor Statistics website at <https://www.bls.gov/oes/current/oes436013.htm>.

The costs across all new facilities is **\$2,454**
(**\$1.00** per each new provider/CHOW x **2,454** new facilities = **\$2,454**)

The total annualized burden costs are estimated to be **\$398,530**.

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to the Federal Government

The CMS Regional Offices are responsible for approving the CMS-1561/CMS-1561A. Accepting these forms on behalf of the Secretary, counter-signing and issuing them follows a review of the file for a new Medicare provider applicant or for a CHOW. We estimate that it would take 30 minutes of time by a Regional Office (RO) reviewer to review and file each CMS-1561/CMS-1561A form.

We estimate that the cost associated with the receipt, review and filing of each CMS-1561/CMS-1561A form by the CMS Regional Office would be **\$25.67**. We further estimate that the cost for these tasks for all CMS-1561/CMS-1561A form submitted per year would be **\$62,994**.

These costs were calculated using the annual salary of a GS-13, step 5 RO reviewer in the Pennsylvania region, which is \$106,789, and which equates to an average hourly salary of \$51.34.⁴ (**30 min x \$51.34 per hour = \$25.67 per each CMS-1561/CMS-1561A form received by the RO**) and (**\$25.67 x 2,454 CMS-1561/ CMS-1561A form/year = \$62,994 for all CMS-1561/CMS-1561A forms received per year**).

15. Changes in Program/Burden

The number of new providers/CHOW stated in the previous PRA package (submitted in 2015) was 3,000. For calendar year 2015 the number of new providers/CHOWs was 2,400 and in CY 2016 the figure was 2,454. This demonstrates that, while there was a significant decrease in the number of new providers/CHOWs in CY 2014, this number was relatively stable from the beginning of CY 2015 through the end of CY 2016.

The decrease in the number of new providers/CHOWs to 2,454 in 2016 from 3,000 new providers/CHOWs (as stated in the 2015 PRA packages) accounts for a slight decrease in the burden related to the preparation and submission of the CMS-1561/CMS-1561A. However, this decrease in burden is offset by an additional 40 minutes we have added to our burden estimate. This time was added to allow for the facility CEO to review and become familiar with the

⁴ <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/PHL.pdf>

applicable statutory and regulatory language before signing the CMS-1561/CMS-1561A form.

For the CMS-1561, this statutory and regulatory law includes Section 1866 of the Social Security Act and CMS regulations at 42 CFR 489. For the CMS-1561A, this statutory and regulatory law includes section 1861(aa)(2)(K)(ii) of the Act and the implementing regulations at 42 CFR Part 405 Subpart X and 42 CFR Part 49142.

We have added this additional time to our burden estimate because we believe it is necessary for the person signing the CMS-1561/CMS-1561A form to have knowledge of the statutory and regulatory law related to CMS provider agreements and we cannot assume that the signer has such familiarity with these statutes and regulations.

16. Publication and Tabulation Dates

There are no publication and/or tabulation dates.

17. Expiration Date

CMS will display the expiration date on the forms.