

Supporting Statement, A
Health Insurance Benefit Agreement and Supporting Regulations
CMS-1561 and -1561A

I. Background

Providers and Rural Health Clinics (RHCs) applying to participate in the Medicare program must agree to provide services in accordance with Federal requirements. Opioid treatment programs (OTPs) must also agree to provide services in accordance with Federal requirements, but only with respect to the furnishing of opioid use disorder treatment services.

The CMS-1561 and CMS-1561A forms are health insurance benefits agreements that are essential for the Centers for Medicare and Medicaid Services (CMS) to ensure that applicants to the Medicare program have made a binding commitment to comply with all applicable Federal requirements. This is a reinstatement of the information collection. The CMS-1561A form applies to RHCs and the CMS-1561 form applies to the following types of health care providers:

- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Community Mental Health Centers (CMHCs)
- Home Health Agencies (HHAs)
- Hospice
- Hospitals/Critical Access Hospitals (CAHs)
- Outpatient Physical Therapy/Outpatient Speech Therapy (OPT/OSP)
- Opioid Treatment Programs (OTPs)
- Rural Emergency Hospitals (REHs)
- Skilled Nursing Facilities (SNFs)

The CMS-1561 form requires health care providers to agree to the following: (1) to conform to the provisions of section of 1866 of the Social Security Act and applicable provisions in 42 CFR; (2) assurance of compliance with title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 as amended; and in the event of a transfer of ownership, the agreement will automatically be assigned to the new owner subject to the conditions specified in the agreement and 42 CFR 489, subject to existing plans of correction.

The CMS-1561A form requires an RHC to agree to do the following: (1) To maintain compliance with the conditions for certification set forth in part 491 of chapter IV, title 42 of the Code of Federal Regulations; (2) to report promptly to the Centers for Medicare & Medicaid Services any failure to do so; (3) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of part 405 of chapter IV, title 42 of the Code of Federal Regulations (or for which the beneficiary would have been entitled if the Rural Health Clinic had filed a request for payment in accordance with §410.165 of chapter IV), except for any deductible or coinsurance amounts for which the beneficiary is liable under §405.2410b; (4) To refund as promptly as possible any money incorrectly collected from a beneficiary or from someone on his or her behalf; (5) To accept beneficiaries for care and treatment without limitations, except as it may impose on all other persons; and (6) To accept any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

The collection is made only once during the applicant's participation in Medicare. The applicant and CMS enter into agreement at the beginning of the applicant's participation in Medicare by signing the completed CMS-1561 or CMS-1561A form (as applicable). The purpose of the agreement is to assure CMS that the provider or RHC will continue to meet all Federal requirements following their approval.

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The agreement remains in force so long as it is not terminated by either party.

II. Justification

1. Need and Legal Basis

a. Legal basis for CMS-1561 form:

In accordance with Section 1866 of the Social Security Act (the Act), Section 2475(d) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115-271, **October 24, 2018**) amends section 1866(e) of the Act by adding a new paragraph (3) which includes opioid treatment programs (but only with respect to the furnishing of opioid use disorder treatment services) 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.

In a proposed rule published on August 14, 2019 (84 FR 40482) (RIN 0938-AT72, CMS-1715-P) proposed to include OTPs as a provider and that the provider agreements apply to OTPs only to furnish Opioid use disorder (OUD) treatment services. In that regard, OTPs would be required to complete Provider Agreement CMS-1561.

On November 15, 2019, we finalized this proposal in our final rule titled ***Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2020***.

b. Need & Legal Basis for the CMS-1561A form:

CMS promulgated regulations at 42 CFR Part 405 Subpart X and 42 CFR Part 491 in accordance with Section 1861(aa)(2)(K)(ii) of the Act. These regulations require that for RHCs to participate in the Medicare program, all applicants must agree to comply with the requirements specified therein.

2. Information Users

This collection will be used to assure that each provider, OTP, 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. Providers and suppliers, including OTPs will sign the forms CMS-1561 or -1561A, known as provider agreements and submit to their respective Medicare Administrative Contractor (MAC) through electronic upload into the Provider Enrollment Chain and Ownership System (PECOS).

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4. Duplication of Similar Information

There is no duplication of similar information. The CMS-1561 and -1561A forms are Provider Agreements which are CMS requirements. SAMHSA will collect documentation related to the OTPs health and safety standards for OTPs only. Other providers and suppliers will follow the existing process for their provider agreements and Medicare oversight.

5. Small Businesses

These requirements do affect small businesses; however, the information collection is necessary for the business to participate in the Medicare program.

6. Less Frequent Collection

This information is collected one time 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, OTPs, 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 to be collected less frequently, CMS would not have a binding commitment on the part of providers, OTPs, 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 or residents at risk of harm and diverts resources from the Medicare Trust Funds used to reimburse legitimate claims for medical care provided to Medicare beneficiaries.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on September 29, 2023 (88 FR 67300). There were no public comments received.

The 30-day Federal Register notice published on December 6, 2023 (88 FR 84820).

9. Payments/Gifts to Respondents

There will be no payment or gifts to any parties in connection with the use of the CMS- 1561 and CMS-1561A forms.

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10. Confidentiality

We make no pledges of confidentiality; however, the information will be kept private to the extent allowed by law.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimate

a. Burden Related to the CMS-1561 form.

The requirement to submit the completed and signed CMS-1561 form occurs at the time the provider or OTP is approved for participation in the Medicare program. This is a one-time requirement for new providers and OTPs because the agreement remains in force so long as it's not terminated by either party.

Type of Provider	Number of New Providers in 2020	Number of New Providers in 2021	Number of New Providers in 2022
CAHs	6	6	6
CMHCs	9	2	9
CORFs	0	4	1
HHA's	453	247	539
Hospices	430	795	650
Hospitals/	272	120	30
OPT/OSP	92	77	41
IRF Hospitals	18	20	20
IRF Units	0	3	1
OTPs	704	124	76
Psychiatric Hospitals	17	19	13
Psychiatric Units	2	2	0
REHs	0	0	0
SNFs	99	85	34
TOTAL¹	2,102	1,504	1,420

¹ This information was obtained from the CMS Survey & Certification Quality, Certification & Quality Reports (S&C QCOR Reports) and the CMS IQIES system.

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As shown in the table below, the 3-year average number of new providers each year (including those providers that enter the Medicare program through the changes of ownership (CHOWs) process) that would be required to complete and submit the CMS-1561 form yearly is 1,675.

- $2,102 + 1,504 + 1,420 = 5,026$
- $5,026 \text{ divided by } 3 = 1,675$

i. **Review of the Statutory & Regulatory Law Associated with the CMS-1561 form.**

We estimate that before completing and signing the CMS-1561 form, the facility CEO want to take time to research the statutory and regulatory law related to this form, including Section 1866 of the Social Security Act and CMS regulations at 42 CFR part 489. According to the May 2022 U.S. Bureau of Labor Statistics, the mean hourly wage for a CEO is \$102.41². This wage, adjusted for the employers overhead and fringe benefits would be \$204.82³.

We estimate that this task would take 40 minutes to complete. We further estimate that this task would take **1,117 hours across all** new providers and OTPs.

- $40 \text{ minutes} \times 1,675 \text{ new providers} = 67,000 \text{ minutes}$
- $67,000 \text{ minutes divided by } 60 \text{ minutes per hour} = 1,117 \text{ hours}$

We estimate the cost to **each** provider to perform this research to be **\$136.54**.

- $\$204.82 \text{ divided by } 60 \text{ min per hour} = \$3.4136 \text{ per minute}$
- $\$3.4136 \text{ per min} \times 40 \text{ minutes} = \136.54

We further estimate that the total annual cost **across all** new healthcare providers and OTPs would be **\$228,784**.

- $1,117 \text{ hours} \times \$204.82 \text{ per hour} = \$228,783.94$

ii. **Completion of the CMS-1561 form.**

We estimate that it takes **10 minutes** to complete **each** CMS-1561 form.

We further estimate that the total annual time burden **across all** new providers and OTPs for completion of all CMS-1561 forms is **279 hours**.

- $10 \text{ minutes} \times 1,675 \text{ providers \& OTPs} = 16,750 \text{ minutes}$

² See <https://www.bls.gov/oes/current/oes111011.htm>

³ We adjust the employee hourly wage estimates by a factor of 100 percent to reflect the employer's additional costs for overhead, benefits and fringe benefits. 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.

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Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

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- 16,750 min. divided by 60 min per hour = 279 hours

We believe that the person at the facility or OTP that would be responsible for completing and signing the CMS-1561 form would be the Chief Executive Officer (CEO). According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a CEO is \$102.41⁴. This wage, adjusted for the employers overhead and fringe benefits would be \$204.82⁵.

We estimate that the cost burden per *each* CMS-1561 form would be **\$34.14**.

- \$204.82 divided by 60 min per hour = \$3.414 per minute
- \$3.414 per min x 10 minutes = \$34.14

We further estimate that the total annual cost burden *across all* new providers and OTPs for completion of *all* CMS-1561 forms per year would be **\$57,145**.

- 279 hours x \$204.82 per hour = \$57,144.78

iii. Time & Cost Burden for Submission of the Completed CMS-1561 form.

Upon completion of the CMS-1561 form, the provider must submit a copy to the State Survey Agency or CMS Location (for CAHs, REHs, and RHCs) and the Medicare Administrative Contractor (MAC).

We estimate that it will take **10 minutes by each** OTP or provider to prepare these forms for submission.

We further estimate that the total annual time burden *across all* new providers and OTPs for this task would be **279 hours**.

- 10 minutes x 1,675 providers & OTPs = 16,750 minutes
- 16,750 min. divided by 60 min per hour = 279.166 hours

We believe that the person at the facility who would perform this task would be a Medical Secretary. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Secretary is \$18.01⁶. This wage adjusted for the employer's fringe benefits and overhead would be **\$36.02**.

⁴ See <https://www.bls.gov/oes/current/oes111011.htm>

⁵ We adjust the employee hourly wage estimates by a factor of 100 percent to reflect the employer's additional costs for overhead, benefits and fringe benefits. 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, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

⁶ See <https://www.bls.gov/Oes/current/oes436013.htm>.

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We estimate that the cost burden to *each* provider or OTP for preparing the CMS- 1561 form for submission (electronic or mail) would be **\$6.00**.

- \$36.02 divided by 60 min per hour = \$0.60 per minute
- \$0.60 per min x 10 minutes = \$6.00

We further estimate that the total annual cost burden across all providers and OTPs for this task would be **\$10,050**.

- 279 hours x \$36.02 = \$10,049.58

b. Burden Related to the CMS-1561A form

The requirement for the completion and submission of the CMS-1561A form applies only to new RHCs. Also, this is a one-time burden to these RHCs.

Number of New RHCs By Year		
2020	2021	2022
415	393	317

The 3-year average of new RHCs established each year is 375².

$$415 + 393 + 317 = 1,125$$

$$1,125 \text{ divided by } 3 = 375$$

i. Time & Cost Burden for Review of the Statutory & Regulatory Law Associated with the CMS-1561A form.

We estimate that before completing and signing the CMS-1561 form, the facility CEO would need to take time to research the statutory and regulatory law related to this form, including section 1861(aa)(2)(K)(ii) of the Act and the implementing regulations at 42 CFR part 405 subpart X and 42 CFR part 498.

We estimate that this task would take **40 minutes per each new RHC** to complete this task.

⁷ This information was obtained from the CMS Survey & Certification Quality, Certification & Quality Reports (S&C QCOR Reports).

² This information was obtained from the CMS Survey & Certification Quality, Certification & Quality Reports (S&C QCOR Reports).

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We further estimate that the total annual time burden for this task **across all new** RHCs per year would be **250 hours**.

- 40 minutes x 375 new RHCs per year = 15,000 minutes
- 15,000 minutes divided by 60 min./hour = 250 hours

We believe that the person at the RHC who would research the applicable regulatory and statutory law and complete the CMS-1561A form would be the facility CEO. As stated above, the adjusted hourly wage for a facility CEO is **\$204.82**.

We estimate that the cost burden for **each new** RHC for researching the regulatory and statutory law related to the CMS-1561A form would be **\$136.54**.

- \$204.82 divided by 60 min per hour = \$3.4136 per minute
- \$3.4136 per min x 40 minutes = \$136.54

We further estimate that the total annual cost **across all** new RHCs for the performance of this task would be **\$51,205**.

- 250 hours x \$204.82 per hour = \$51,205

ii. Time & Cost Burden for Completion of the CMS-1561A form.

We estimate that it would take **10 minutes** for **each new RHC** to complete the CMS-1561A form.

We further estimate that the total annual time burden **across all new** RHCs for completion of all CMS-1561A forms is **62.5 hours**.

- 10 minutes x 375 new RHCs = 3,750 minutes
- 3,750 min. divided by 60 min per hour = 62.5 hours

We estimate that the cost burden to **each** RHC for the completion of each CMS- 1561A form would be **\$34.14**.

- \$204.82 divided by 60 min per hour = \$3.4136 per minute
- \$3.4136 per min x 10 minutes = \$34.14

We further estimate that the total annual cost burden **across all** new RHCs for completion of all CMS-1561A forms per year would be **\$12,801**.

- 62.5 hours x \$204.82 per hour = \$12,801

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iii. Time & Cost Burden for Submission of the Completed CMS-1561A form

Upon completion of the CMS-1561A form, the facility must submit a copy to the CMS SOG Location and the Medicare Administrative Contractor (MAC).

We estimate that it would take *each* new RHC **10 minutes** to prepare these forms for submission to the CMS SOG Location and the Medicare Administrative Contractor (MAC).

We further estimate that the total annual time burden *across all* new RHCs for this task would be **62.5 hours**.

- 10 minutes x 375 new RHCs = 3,750 minutes
- 3,750 min. divided by 60 min per hour = 62.5 hours

We believe that the person at the facility who would perform this task would be a Medical Secretary. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Secretary is \$18.01⁸. This wage adjusted for the employer's fringe benefits and overhead would be **\$36.02**.

We estimate that the cost burden to prepare each CMS-1561A form for submission (electronic or mail) would be **\$6.00**.

- \$36.02 divided by 60 min per hour = \$0.60 per minute
- \$0.60 per min x 10 minutes = \$6.00

We further estimate that the total annual cost burden for the performance of this task across all new RHCs would be **\$2,251**.

- 62.5 hours x \$36.02 = \$2,251

c. Summary of Time and Cost Burdens

Time Burden Per Each Provider or RHC CMS-1561 form:

Time to review statutory & regulatory law (CMS-1561)	40 min
Time to complete & sign CMS-1561	10 min.
Time for submission of CMS-1561 form	<u>10 min.</u>
TOTAL	60 min.

⁸ See <https://www.bls.gov/Oes/current/oes436013.htm>

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CMS-1561A form:

Time to review statutory & regulatory law (CMS-1561A)	40 min
Time to complete & sign CMS-1561A	10 min.
Time for submission of completed CMS-1561A form	10 min
TOTAL	60 min.

Time Burden Across All Providers or RHCs

CMS-1561 form:

Time to review statutory & regulatory law (CMS-1561)	1,117 hrs.
Time to complete & sign CMS-1561	279 hrs.
Time for submission of completed CMS-1561 form	279 hrs.
TOTAL	1,675 hrs.

CMS-1561A form:

Time to review statutory & regulatory law (CMS-1561A)	250.0 hrs.
Time to complete & sign CMS-1561A	62.5 hrs.
Time for submission of completed CMS-1561A form	62.5 hrs.
TOTAL	375.0 hrs.

Cost Burden Per Each Providers or RHCs

CMS-1561 form:

Cost to review statutory & regulatory law (CMS-1561)	\$136.54
Cost to complete & sign CMS-1561	\$ 34.14
Cost for submission of completed CMS-1561 form	\$ 6.00
TOTAL	\$176.68

CMS-1561A form:

Cost to review statutory & regulatory law (CMS-1561A)	\$136.54
Cost to complete & sign CMS-1561A	\$ 34.14
Cost for submission of completed CMS-1561A form	\$ 6.00
TOTAL	\$176.68

Cost Burden Across All Providers or RHCs

CMS-1561 form:

Cost to review statutory & regulatory law (CMS-1561)	\$228,784
Cost to complete & sign CMS-1561	\$ 57,145
Cost for submission of completed CMS-1561 form	\$ 10,050
TOTAL	\$295,979

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CMS-1561A form:

Cost to review statutory & regulatory law (CMS-1561A)	\$51,205
Cost to complete & sign CMS-1561A	\$12,801
<u>Cost for submission of completed CMS-1561A form</u>	<u>\$ 2,251</u>
TOTAL	\$66,257

The total burden hours for both forms are 2,050. The total cost is \$362,236.

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to the Federal Government

CMS is responsible for accepting the CMS-1561 or CMS-1561A forms (as applicable) submitted by each provider, OTP or RHC. Following a review of the file, an authorized CMS staff person will approve and sign the form.

We estimate that it would take a CMS reviewer **30 minutes** to review and file each CMS- 1561/CMS-1561A form. We further estimate that the total annual time expended by CMS reviewers for this task would be **1,025 hours**.

- 30 min. x 1,675 providers, OTPs & RHCs = 50,250 min.
- 50,250 min divided by 60 min per hour = 837.5 hours

- 30 min. x 375 new RHCs = 11,250 min.
- 11,250 min. divided by 60 min per hour = 187.5 hours

- 837.5 hrs. for providers OTPS & + 187.5 hours for RHCs = **1,025 hours**

We believe that the person at CMS who would perform this task would have the job title of “Reviewer.” We further believe that this person would be a GS-13, step 5. Such a person in the Pennsylvania region would have an annual salary of \$116,459, and which equates to an average hourly pay of \$55.99.⁹

We estimate that the cost associated with the receipt, review and filing of **each** CMS- 1561/CMS-1561A form by CMS would be **\$27.99**.

- \$55.99 divided by 60 min. per hour = \$0.933 per min
- \$0.933 per min. x 30 min. = \$27.99

⁹ https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/PHL_h.pdf

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We further estimate that the cost for the review of all CMS-1561/CMS-1561A forms submitted per year would be **\$57,389.75**.

- 1,025 hours x \$55.99 hours = \$57,390

15. Changes in Program/Burden

Combined Time & Cost Burdens for the CMS-1561 and CMS-1561A Forms			
Description of Burden	Time Burden	Burden Stated in Previous PRA Package	Change in Burden
Number of respondents for CMS-1561 form	1,675 responses	3,088 responses	-1,413 responses
Number of respondents for CMS-1561A form	375 responses	0 responses	+375 responses
Time Burden for CMS-1561 form	1,675 hrs.	3,088 hrs.	-1,413 hrs.
Time Burden for CMS-1561A form	375 hrs.	0 hrs.	+ 375 hrs.
Cost Burden for CMS-1561 form	\$295,979	\$513,706	-\$217,727
Cost Burden for CMS-1561A form	\$66,257	\$0	+\$66,257
Total Number of Respondents for Both Forms	2,050 respondent s	3,088 respondents	-1,038 respondents
Total Time Burden for Both Forms	2,050 hrs.	3,088 hrs.	- 1,038 hrs.
Total Cost Burden for Both Forms	\$362,236	\$513,706	-\$151,470

As the above table shows, the combined total annual time burden for both the CMS- 1561 and CMS-1561A forms has decreased by 1,038 hours. The total annual cost burden for both forms has decreased by \$151,470. This decrease can be explained by the decrease in the number of annual respondents, which has decreased by an average of 1,038 respondents per year since the last PRA package was submitted.

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16. Publication and Tabulation Dates

There are no publication and/or tabulation dates.

17. Expiration Date

CMS will display the OMB approval expiration date on the CMS-1561 and CMS-1561A forms.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.