Supporting Statement Part A
Health Insurance Benefit Agreement and Supporting Regulations
CMS-1561 and -1561A, OMB 0938-0832

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. Opioid treatment programs, but only with respect to the furnishing of opioid use disorder treatment services (OTPs), are also 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.

The August 14, 2019 (84 FR 40482) NPRM (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 or CMS-1561A. On November 15, 2019, we finalized this proposal in our final rule: Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2020.

Note: OTPs are required to be certified by SAMHSA and accredited by an accrediting body approved by SAMHSA.

B. Justification

1. Need and Legal Basis

For the CMS-1561, in accordance with Section 1866 of the Social Security Act (the Act), Section 2005(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.

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, 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 and -1561A, known as provider agreements and submit to their respective Medicare Advantage Contractor (MAC) through electronic upload into the Provider Enrollment Chain and Ownership System (PECOS). .

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 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, 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 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/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 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 Notice/Outside Consultation

Serving as the 60-day notice, the proposed rule (RIN 0938-AT72, CMS-1715-P) published in the Federal Register on August 14, 2019 (84 FR 40482). The rule was filed for public inspection on July 29, 2019. No comments were received.

The final rule (CMS-1715-F) published in the Federal Register on November 15, 2019 (84 FR 62998, COI beginning on page 63105), and is effective on January 1, 2020.

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)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 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

mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Chief Executive	11-1011	96.22	96.22	192.44
Medical Secretaries	43-6013	17.83	17.83	35.66

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

Requirements and Associated Burden Estimates

There are approximately 2,454 new providers/Changes of Ownership (CHOWs) completing the CMS-1561 or CMS-1561A yearly. We generally estimate that there are about 1,700 already certified and accredited OTPs eligible for Medicare enrollment initially; and approximately 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year).

Annually, we estimate an average of 3,088 respondents (2,454 CHOWs + [(1,767 OPTs for year 1 + 67 OTPs for year 2 + 67 OTPs for year 3)/3 years].

Review Statutory and Regulatory Provisions

We estimate it would take the signer of the form (CMS-1561 or CMS-1561A), approximately 40 minutes to review the applicable law. This would likely be performed by the facility CEO at $192.44/hr. For CMS-1561, this includes Section 1866 of the Social Security Act and CMS regulations at 42 CFR part 489. For CMS-1561A, this 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 498.

The time required across all facilities to complete their review of the statutory and regulatory provisions is **2,059 hours** (40 min/60 x 3,088 facilities) at a cost of **$396,234** (2,059 hr x $192.44/hr).

Form Completion

We estimate it will take 10 minutes at $192.44/hr for the facility CEO to complete the CMS-1561/CMS-1561A form. Therefore, the time required across all facilities to review, complete, and sign the form is **515 hours** (10 min/60 x 3,088 facilities) at a cost of **$99,107** (515 hr x $192.44/hr).

Prepare Completed Form for Mailing

Upon completion of the form, the facility must mail one original copy to the State Survey Agency and the Medicare Administrative Contractor (MAC). We estimate that it will take 10 minutes at $35.66/hr for medical secretary to prepare these 2 original copies for mailing, that is: 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.

Therefore, the time required across all facilities to prepare the completed forms for mailing is **515 hours** (10 min/60 x 3,088 facilities) at a cost of **$18,365** (515 hr x $35.66/hr).

Summary of Requirements and Burden Estimates

A. Respondents
- 3,088 facilities

B. Burden to review statutory and regulatory provisions
- 40 min by the facility CEO at $192.44/hr
- 40 min/60 x 3,088 facilities = 2,059 hours (total)
- 2,059 hours x $192.44/hr = $396,234 (total)

C. Burden to complete the form
- 10 min by the facility CEO at $192.44/hr
- 10 min/60 x 3,088 facilities = 515 hours (total)
- 515 hours x $192.44/hr = $99,107 (total)

D. Burden to prepare completed forms for mailing
- 10 min by a medical secretary at $35.66/hr
- 10 min/60 x 3,088 facilities = 515 hours (total)
- 515 hours x $35.66/hr = $18,365

E. Total Burden
- 3,089 hours (2,059 hr + 515 hr +515 hr)
- $513,706 ($396,234 + $99,107 + $18,365)

13. Capital Costs

Although there are no capital costs associated with this collection, there are mailing costs.

Each facility 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 per facility. The cost across all facilities is $2,521 ($1.00/facility x 2,521 facilities = $2,521.

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 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 $108,899, and which equates to an average hourly salary of $52.18.[1] **(30** min x **$52.18** per hour = **$25.67** per each CMS-1561/CMS-1561A form received by the RO) and **($26.06** x **2,521** CMS-1561/ CMS-1561A form/year = **$65,773** for all CMS-1561/CMS-1561A forms received per year). However, the first year an additional cost of **$44,302** would be applied for the 1,700 already certified OTPs requiring to enroll (**30** min x **$52.18** per hour = **$25.67** per each CMS-1561/CMS-1561A form received by the RO) and **($26.06** x **2,521** CMS-1561/ CMS-1561A form/year = **$44,302** for all CMS-1561/CMS-1561A forms received the first year).

Table 2: Federal Government Processing Costs

Year 1* Total Cost for Regional Office	**Annual after Year one Total Cost**	**Average (over 3 years)**
$110,075 ($65,773 + $44,302)	$65,773	$80,540

*Year 1 includes the annual number of 2,521 providers/OTPs/CHOW + 1,700 initial OTP enrollees.

We note, that for OTPs, the CMS-1561/CMS-1561A would be processed through the pre-approved process in which the OTP would complete the form and submit the form directly to the MACs. In the event of termination of the CMS-1561/CMS-1561A, these CMS Regional Office procedures would apply, therefore the cost remains as stated.

15. Changes in Program/Burden

Our November 15, 2019 final rule (RIN 0938-AT72, CMS-1715-F) amended 42 CFR part 489 to include OTPs as a provider as required by section 1866(e)(3) of the Act. We are proposing that the requirements under part 489, which include limitation of charges to beneficiaries, would apply to OTPs. Specifically, we are proposing to add OTPs to the list of providers in § 489.2 and that the provider agreements apply to OTPs only to furnish OUD treatment services. In that regard OTPs would be required to complete Provider Agreement CMS-1561 or CMS-1561A in order to enroll in Medicare.

The burden for reporting and completing the Provider Agreement is based on SAMHSA statistics. We generally estimate that there are about 1,700 already certified and accredited OTPs

[1] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/PHL_h.pdf

eligible for Medicare enrollment initially; and approximately 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year).

Annually, we estimate an average of 635 additional respondents ([1,767 OPTs for year 1 + 67 OTPs for year 2 + 67 OTPs for year 3)/3 years]).

We anticipate would take the OPT 10 minutes at $192.44/hr for a Chief Executive to complete the form and an additional 10 minutes at $35.66/hr for a Medical Secretary to mail/file the document when fully executed.

The 40 minute burden for OTPs to review statutory and regulatory provisions was also excluded.
- 40 min by the facility CEO at $192.44/hr
- 423 hours (40 min/60 x 635 OTP facilities) a cost of $81,402 (423 hr x $192.44/hr)

Each OTP facility that completes a CMS-1561/CMS-1561A form 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 per facility. The cost across all facilities is $634 ($1.00/facility x 634 facilities on average per year).

Summary of Changes

A. Respondents
- 635 facilities

B. Burden to review statutory and regulatory provisions
- 40 min by the facility CEO at $192.44/hr
- 40 min/60 x 635 facilities = 423 hours (total)
- 423 hours x $192.44/hr = $81,402 (total)

C. Burden to complete the form
- 10 min by the facility CEO at $192.44/hr
- 10 min/60 x 635 facilities = 106 hours (total)
- 106 hours x $192.44/hr = $20,399 (total)

D. Burden to prepare completed forms for mailing
- 10 min by a medical secretary at $35.66/hr
- 10 min/60 x 635 facilities = 106 hours (total)
- 106 hours x $35.66/hr = $3,780

E. Total Burden
- 635 hours (423 hr + 106 hr + 106 hr)
- $106,215 ($81,402 + $20,399 + $3,780 +$634)

Reconciliation of Active and Proposed Burden

	#	#	Burden	Total

	Respondents	responses	per response (hours)	Annual Time (hours)
Currently Approved (Active) Burden	2,454	2,454	1	2,454
Changes (CMS-1715-F)	+635	+635	No Change	+635
TOTAL (see Summary of Requirements and Burden Estimates)	3,088	3,088	1	3,088*

16. Publication and Tabulation Dates

There are no publication and/or tabulation dates.A public list of Medicare enrolled OTPs is available at data.cms.gov.

17. Expiration Date

CMS will display the expiration date on the forms.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.