

Supporting Statement for Paperwork Reduction Act Submissions  
Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers Revision CMS-855B, OMB Control Number: 0938-1377

## **BACKGROUND**

The primary function of the CMS-855B Medicare enrollment application for suppliers/providers is to gather information from the supplier that tells us who the supplier is, whether the supplier/provider meets certain qualifications to be a Medicare health care provider or supplier, where the supplier/provider practices or renders services, and other information necessary to establish correct claims payments. The CMS-855B is one of several Medicare enrollment forms used to enroll providers and suppliers (e.g., hospitals, suppliers of durable medical equipment, physicians, etc.). The CMS-855B is specifically written for clinics, group practices, and certain other suppliers under a similar business structure.

The changes in this collection of information request are associated with our December 28, 2020 (85 FR 84472) final rule (CMS-1734-F, RIN 0938-AU10) regarding, “CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies.” This rule made revisions to the enrollment process for opioid treatment programs (OTPs). We are also proposing a correction that is not associated with the CMS-1734-F rule. Overall, we project a burden reduction of -1,290 respondents, -1,290 responses, and -3,870 hours. We are not proposing any changes to the CMS-855B form. See section 15 for details concerning the burden.

### **A. JUSTIFICATION**

#### **1. Need and Legal Basis**

Various sections of the Social Security Act (Act), the United States Code (U.S.C.), Internal Revenue Service Code (Code) and the Code of Federal Regulations (CFR) require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made.

- 42 CFR 424.500 state the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies.
- Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person.
- Section 1842(r) of the Act requires us to establish a system for furnishing a unique identifier for each provider/supplier who furnishes services for which payment may be made. In order to do so, we need to collect information unique to that provider or supplier.
- Section 1866(j)(1)(C) of the Act requires us to consult with providers and suppliers of services before making changes in provider/supplier enrollment forms.
- The Balanced Budget Act of 1997 (BBA) (Public Law 105-33) section 4313, amended sections 1124(a) (1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, as well as any managing employees. The Secretary of Health and Human Services (the Secretary) signed and sent to the Congress a “Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as Required by the Balanced Budget Act” on January 26, 1999, with mandatory collection of SSNs and EINs effective on or about April 26, 1999.
- Section 31001(I) of the Debt Collection Improvement Act of 1996 (DCIA) (Public Law 104-134) amended 31 U.S.C. 7701 by adding paragraph (c) to require that any person or entity doing business with

the Federal Government provide their Tax Identification Number (TIN).

- Section 1866(b)(2)(D) and 1842(h)(8) of the Act require denial of enrollment (directly or indirectly) of persons convicted of a felony for a period not less than 10 years from the date of conviction.
- Section 424.502, defines enrollment and enrollment related terms.
- Sections 1102 and 1871 of the Act, provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program
- The Internal Revenue (IRS) Code, section 3402(t) requires us to collect additional information about the proprietary/non-profit structure of a Medicare provider/supplier to allow exclusion of non-profit organization from the mandatory 3% tax withholding.
- The IRS section 501(c) requires each Medicare provider/supplier to report information about its proprietary/non-profit structure to the IRS for tax withholding determination.
- The Patient Protection and Affordable Care Act, section 3109(a) allows certain Medicare supplier types to be exempt from the accreditation requirement.
- Section 1866(j)(2)(A) of the Act requires the Secretary, in consultation with the Department of Health and Human Services' Office of the Inspector General, to establish procedures under which screening is conducted with respect to providers/suppliers of medical or other items or services and suppliers under Medicare, Medicaid, and CHIP.
- Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening to be conducted according to the risk of fraud, waste, and abuse with respect to the category of provider or supplier.
- Section 1848(k)(3)(B) defines covered professional services and eligible professionals.
- Section 3004(b)(1) of the Public Health Service Act (PHSA) requires the Secretary to adopt an initial set of standards, implementation guidance, and certification criteria and associated standards and implementation specifications will be used to test and certify complete EHRs and EHR modules in order to make it possible for eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology.
- The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), section 135(a) amended section 1834(e) of the Social Security Act and required the Secretary to designate organizations to accredit suppliers, including but not limited to suppliers, physicians, non-physician practitioners and Independent Diagnostic Testing Facilities, that furnish the technical component of advanced diagnostic imaging services.
- Section 2205 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act requires a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020.
- Section 6401(a) of the Affordable Care Act (ACA) requires the Secretary to impose a fee on each "institutional provider of medical or other items or services and suppliers." The fee is to be used by the Secretary to cover the cost of program integrity efforts including the cost of screening associated with provider/supplier enrollment processes, including those under section 1866(j) and section 1128J of the Social Security Act.
- Section 6201(c), of the Affordable Care Act (ACA) Subtitle C, requires DHHS to obtain state and national background checks on prospective employees, including national fingerprint-based criminal history record checks.
- Section 508 of the Rehabilitation Act of 1973, as incorporated with the Americans with Disabilities Act of 2005 requires all Federal electronic and information technology to be accessible to people with disabilities, including employees and members of the public.

The CMS-855 applications collect this information, including the data necessary to uniquely identify and enumerate the provider/supplier. Additional information needed to ensure that providers and suppliers meet all applicable Medicare requirements and to process claims accurately and timely are also collected on the CMS-855 applications. This information also ensures that the data collected allows CMS to make correct

payments to providers and suppliers under the Medicare program as established by Title XVIII of the Act.

## 2. Purpose and users of the information

Section 424.500 et seq. states the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies. Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person.

The CMS-855B is submitted by an applicant to the Medicare Administrative Contractors (MACs) to initially apply for Medicare billing privileges. It is thereafter submitted in order to, among other things: (1) revalidate Medicare enrollment; (2) reactivate Medicare enrollment; (3) enroll with another MAC in a different geographic location; (4) report a change to current Medicare enrollment information; and (5) voluntarily terminate the supplier's or provider's Medicare enrollment, as applicable. It is used by new applicants as well as suppliers/providers that are already enrolled in Medicare but need to submit the form for a reason other than initial enrollment into the Medicare program. A medical practice, group/clinic, or certain other suppliers/providers that will bill for Medicare Part B services (e.g., group practices, clinics, independent laboratories, opioid treatment programs, portable x-ray suppliers) complete this form for the submittal reasons above.

The MAC establishes Medicare Identification Numbers. The MACs store these numbers and information in CMS' Provider Enrollment, Chain and Ownership System (PECOS). The application is used by the CMS' contractors to collect data that ensures that the applicant has the necessary information for unique identification. The license numbers that come through paper applications are validated against state licensing websites. All the license numbers are captured and stored in PECOS. Social Security Numbers (SSNs) are validated against the Social Security Administration database (SSA) and only the valid entries are allowed to proceed in the process of getting a Medicare billing number. International Tax Identification Numbers (ITINs) are not validated. However, if a user enters an ITIN, additional forms of identification may be required. Both ITINs and SSNs are captured in PECOS. Mailing addresses, practice location addresses, and contact information are captured to contact the supplier. Specialty type is captured to identify the specialty of the supplier. The information obtained is to help prevent fraud by allowing vetting of the suppliers as well as to ensure that a supplier is not illegitimately attempting to enroll in Medicare. In addition, the information collected allows CMS and the MACs to determine relationships among those enrolled in Medicare; under § 424.500 et seq., certain relationships could result in the denial or revocation of the supplier's enrollment.

The collection and verification of this information defends and protects our beneficiaries from illegitimate suppliers. These procedures also protect the Medicare Trust Funds against fraud. It gathers information that allow Medicare contractors to ensure that the supplier is not excluded or debarred from Medicare, Medicaid, and/or any other Federal agency or program. The data collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare, including information that allows the Medicare contractor to correctly price, process and pay the applicant's claims. This is sole instrument implemented for this purpose.

## 3. Improved Information Techniques

This collection lends itself to electronic collection methods and is currently available through the CMS website. PECOS is a secure, intelligent and interactive national data storage system maintained and housed within the CMS Data Center with limited user access through strict CMS systems access protocols. Access to the data maintained in PECOS is limited to CMS and Medicare contractor employees responsible for provider/supplier enrollment activities. The supplier has access to its own records. PECOS is an electronic Medicare enrollment system through which providers and suppliers can: (1) submit Medicare enrollment applications; (2) view and print enrollment information; (3) update enrollment information; (4) complete the enrollment revalidation process; (5) voluntarily withdraw from the Medicare program; and (6) track the status of a submitted Medicare enrollment application.

The data stored in PECOS mirrors the data collected on the CMS-855s (Medicare Enrollment Applications) and is maintained indefinitely as both historical and current information. CMS also supports an Internet-based provider/supplier CMS-855 enrollment platform which allows the provider/supplier to complete an online CMS-855 enrollment application and transmit it to the Medicare contractor database for processing. The data is transferred from the Medicare contractor processing database into PECOS by the Medicare contractor. CMS also has the ability to allow suppliers to upload supporting documentation (required for enrollment) electronically. Furthermore, CMS has also adopted an electronic signature standard; however, suppliers will have the choice to e-sign via the CMS website or to submit a hard copy of the CMS-855B certification page with an original signature. Periodically, CMS will require adjustment to the format of the CMS-855 form (either paper, electronic or both) for clarity or to improve form design. These adjustments do not alter the current OMB data collection approval. Currently, approximately 36% of individual provider/suppliers use the electronic method of enrolling in the Medicare program via the PECOS system.

#### 4. Duplication and Similar Information

There is no duplicative information collection instrument or process. CMS revised this form in July 2020 to ensure there was no duplication for the supplier completing the form.

For example, CMS:

- Added a checkbox above the Remittance Notice/Special Payments address, "Check here if your Remittance Notice/Special Payments should be mailed to your Correspondence Address in section 2A4 and skip this section." The checkbox will be used to reduce possible duplication of reporting the same correspondence address twice.
- Deleted subsection "New Enrollees and Those with a New Tax ID Number." This information is included in the subsection "Who Should Complete This Application."
- Deleted subsection "Enrolled Medicare Suppliers" because the definitions were redundant. There is a definition section at the beginning of the form. Duplicating the definitions in this subsection would require the supplier to read the definitions twice.
- Removed middle column of the table for Final Adverse Legal Actions. The middle column was, "Billing Number Information." CMS can derive the billing number information from the next section in the application and therefore the collection would be redundant.
- Deleted the question, "Is this technician employed by a hospital?" with yes/no checkboxes and "If yes, provide the name of the hospital here:" with a line space for the answer. CMS can derive and add this information to enrollment records independent of a self-reporting requirement.

#### 5. Small Business

A Medicare billing number is required of all health care suppliers/providers who wish to submit claims for payment to the Medicare Trust Funds. This thus affects small businesses that wish to have a Medicare billing number. However, these businesses have always been required to provide CMS with the same information in order to enroll in the Medicare program to submit information for CMS to ensure the

suppliers are legitimate and to collect information to successfully process their Medicare claims.

#### 6. Less Frequent Collections

This information is collected on an as needed basis. The information provided on this form is necessary for initial enrollment in the Medicare program. It is essential to collect this information the first time a provider/supplier enrolls with a Medicare contractor so that CMS' contractors can: (1) uniquely identify the provider/supplier; (2) ensure the provider's/supplier's eligibility and legitimacy; (3) determine if the provider/supplier meets all statutory and regulatory requirements; (4) ascertain whether the provider/supplier is properly credentialed in their specialty (if applicable); and (5) collect relevant information to process the provider's/supplier's claims in a timely and accurate manner.

After the initial enrollment and approval, the information is collected less frequently and often initiated by the supplier for reasons such as a change of information, enrollment within another MACs jurisdiction, and to voluntarily withdraw from the Medicare program. It will be collected to complete the enrollment revalidation process every five years. In addition, to ensure uniform data submissions, CMS requires that all changes to previously submitted enrollment data be reported via this enrollment application.

#### 7. Special Circumstances

The collected information is necessary for initial enrollment in the Medicare program. After the initial enrollment and approval, the information is collected less frequently and often initiated by the supplier for reasons such as a change of information, enrollment within another MACs jurisdiction, and to voluntarily withdraw from the Medicare program. It will be collected as part of the enrollment revalidation process every five years. Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- 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 (1) is not supported by authority established in statute or regulation, (2) is not supported by disclosure and data security policies consistent with the pledge, or (3) 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

##### *Federal Register Notice*

Serving as the 60-day notice, the proposed rule (CMS-1734-P, RIN 0938-AU10) published in the Federal Register on August 17, 2020 (85 FR 50074). We did not receive any PRA-related comments.

The final rule (CMS-1734-F, RIN 0938-AU10) published in the Federal Register on December 28, 2020 (85 FR 84472).

##### *Outside Consultation*

No outside consultation was sought.

#### 9. Payment/Gift to Respondents

The function of the CMS-855B form is to collect and verify data that proves the legitimacy of the enrolling supplier and to collect information for correct claims payment. Once completed, submitted, processed, and accepted, the respondent will be able to receive payment for medical procedures and/or services rendered to Medicare beneficiaries in accordance with the Medicare claims payment system.

#### 10. Confidentiality

CMS will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

The data will be provided from CMS' database of enrolled Medicare providers and suppliers. The SORN title is Provider Enrollment, Chain and Ownership System (PECOS), number 09-70-0532 (July 31, 2019; 84 FR 37393).

#### 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

CMS is basing the burden on data compiled from PECOS and the Medicare Administrative Contractors (MACs).

##### A. Requirements and Associated Burden Estimates

The burden is calculated based on the following assumptions:

- MACs currently process approximately 107,965 CMS-855B applications per year (107,332 applications + 633 applications from the Support Act pursuant to our November 15, 2019 Physician Fee Schedule final rule (CMS-1715-F; RIN 0938-AT72) (84 FR 62567) that permitted OTPs to enroll in Medicare) (see Tables 1 and 3).
- As explained in section 15 (below) our currently approved burden had inadvertently set out 1,900 applications per year. Given that 1,900 is the total number of newly enrolling OTPs over a 3 year period, we are now correcting that figure by dividing it by 3 years. In this regard we are now estimating 633 applicants (1,900 newly enrolling applicants/3 years).
- The time for completing the CMS-855B application depends on the reason for submittal.
- To derive average costs, CMS used data from the U.S. Bureau of Labor Statistics' (BLS) May 2020 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). For the purposes of this application, CMS used the wages under the general categories of "Medical Secretaries," and "Health Diagnosing and Treating Practitioners." We have adjusted the employee hourly wage estimates by a factor of 100 percent. This is necessarily an estimated 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, CMS believes that doubling the hourly wage to estimate total cost

is an accurate estimation method that has been used successfully in previous burden calculations.

- o The application will likely be completed by administrative staff (BLS occupation title: medical secretaries; BLS occupation code: 43-6013; Mean Wage: \$18.75/hr; Adjusted Wage: \$37.50/hr),
- o The recordkeeping burden is included in the burden for medical secretaries to complete the application, and
- o The CMS-855B application is reviewed and signed by the enrolling or enrolled supplier (BLS occupation title: healthcare diagnosing and treating practitioners; BLS occupation code: 29-1000; Mean Wage: \$50.58/hr; Adjusted Wage: \$101.16/hr).

**Table 1 – Number of CMS-855B Applications Processed per Year by Reason for Submittal**

<b>Reason for Submittal</b>	<b>Number of CMS-855Bs Processed per Year</b>
Initial Enrollment	15,187*
Initial Enrollment (Support Act)	633* (corrected, see section 15 for details)
Initial Enrollment (CMS-1734-F)	-23**
<i>1-Subtotal Initial Enrollment</i>	<i>15,797</i>
2-Enrolling with Another MAC	37*
3-Revalidation	31,211*
4-Reactivation	1,316*
5-Reporting a Change of Medicare Enrollment Information	55,650*
6-Voluntary Termination of Medicare Enrollment	3,931*
<b>TOTAL</b>	<b>107,942***</b>

\*The estimates for completing the CMS-855B Medicare enrollment application are the actual number of applications processed for calendar year 2018.

\*\*See section 15 of this Supporting Statement for details.

\*\*\*Excludes Home Infusion Therapy – Supplier Enrollment which added 700 applications on (November 4, 2020; 85 FR 70298) as a result of CMS-1730-F (RIN 0938-AU06).

**Table 2 – Per Response Burden for Completing CMS-855B per Reason for Submittal (Excluding Home Infusion Therapy – Supplier Enrollment)**

<b>Reason for Submittal</b>	<b>Time for Completion by Medical Secretaries (hours)</b>	<b>Time for a Health Diagnosing and Treating Practitioner to Review and Sign (hours)</b>	<b>Total Time for Completion (per Response) (hours)*</b>	<b>Cost for Completion by Medical Secretaries (at \$37.50/hr)</b>	<b>Cost for Review and Signature by a Health Diagnosing and Treating Practitioner (at \$101.16/hr)</b>	<b>Total Cost of Completion (per Response)*</b>
Initial Enrollment	2.5	0.5	3	\$93.75 (2.5 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$144.33
Enrolling with Another MAC	1.5	0.5	2	\$56.25 (1.5 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$106.83
Revalidation	1.5	0.5	2	\$56.25 (1.5 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$106.83
Reactivation	1.5	0.5	2	\$56.25 (1.5 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$106.83
Reporting a Change of Medicare Enrollment Information	0.75	0.25	1	\$28.13(0.75 hr x \$37.50/hr)	\$25.29 (0.5 hr x \$101.16/hr)	\$53.42
Voluntary Termination of Medicare Enrollment	0.42	0.08	0.5	\$15.75 (0.42 hr x \$37.50/hr)	\$8.09 (0.5 hr x \$101.16/hr)	\$23.84

\*Our per response time estimates are unchanged.

\*\*Our per response cost estimates have been revised by using current (May 2020) BLS wage data.

**Home Infusion Therapy Supplier Enrollment**

CMS added 700 suppliers to the initial enrollment count to accommodate the 21<sup>st</sup> Century Cures Act. Section 5012 of the 21<sup>st</sup> Century Cures Act established a new home infusion therapy (HIT) benefit, which using existing accreditation statistics and our internal data, we generally estimate that: (1) there are about 600 home infusion therapy suppliers that would be eligible for Medicare enrollment under our proposed provisions, all of whom would enroll in the initial year of our requirements; and (2) 50 home infusion therapy suppliers would annually enroll in year 2 and in year 3. This results in a total of 700 home infusion therapy suppliers enrolling over the next 3 years. CMS contacted Medicare Administrative Contractors (MACs), both through conference calls and through focus groups to determine how the application was typically completed (by medical secretaries and reviewed and signed by the health diagnosing and treating practitioners).

We estimate it would take each home infusion therapy supplier an average of 2.5 hours to obtain and furnish the information on the Form CMS- 855B. Per our experience, the home infusion therapy supplier’s medical secretary would be responsible for securing and reporting data on the Form CMS-855B and that this task takes approximately 2 hours. Additionally, the form would be reviewed and signed by a health diagnosing and treating practitioner of the home infusion therapy supplier, a process we estimate takes 30 minutes.



Therefore, we project a first-year burden of 1,500 hours (600 suppliers x 2.5 hr) at a cost of \$75,348 (600 suppliers x ((2 hr x \$37.50/hr) + (0.5 hr x \$101.16/hr)), a second-year burden of 125 hours (50 suppliers x 2.5 hr) at a cost of \$15,698 (50 suppliers x ((2 hr x \$37.50/hr) + (0.5 hr x \$101.16/hr)), and a third-year burden of 125 hours (50 suppliers x 2.5 hr) at a cost of \$15,698 (50 suppliers x ((2 hr x \$37.50/hr) + (0.5 hr x \$101.16/hr)). In aggregate, we estimate a burden of 1,750 hours at a cost of \$106,744.

**Table 3 Home Infusion Therapy Supplier Enrollment Burden Projection**

<b>Explanation</b>	<b>Number of Respondents</b>	<b>Total Number of Responses</b>	<b>Hours per Completion of Form CMS- 855B</b>	<b>Total Hours</b>	<b>Cost for Completion by Medical Secretaries (at \$37.50/hr)</b>	<b>Cost for Review and Signature by a Health Diagnosing and Treating Practitioner (at \$101.16/hr)</b>	<b>Total Cost of Completion per CMS-855B</b>
Home Infusion Therapy Enrollment (Year 1)	600	600	2.5	1,500	\$75.00 (2 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$75,348 (600 responses x [\$75.00 + \$50.58])
Home Infusion Therapy Enrollment (Year 2)	50	50	2.5	125	\$75.00 (2 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$15,698 (50 responses x [\$75.00 + \$50.58])
Home Infusion Therapy Enrollment (Year 3)	50	50	2.5	125	\$75.00 (2 hr x \$37.50/hr)	\$50.58 (0.5 hr x \$101.16/hr)	\$15,698 (50 responses x [\$75.00 + \$50.58])
<b>Total</b>	<b>700</b>	<b>700</b>	<b>2.5</b>	<b>1,750</b>	<b>\$75.00</b>	<b>\$50.58</b>	<b>\$106,744</b>

**B. Summary**

A summary of our burden estimates is reflected in Table 3 (below).

For burden changes, please see section 15 (below) for details.

**Table 4 – Summary of Annual Burden Estimates**

<b>Reason for Submittal</b>	<b>Number of Respondents</b>	<b>Total Number of Responses</b>	<b>Time per Response (hours)</b>	<b>Total Annual Time (hours)</b>	<b>Labor Cost (\$/response)</b>	<b>Total Annual Cost (\$)</b>
Initial Enrollments	15,797	15,797	3	47,391	144.33 (see Table 2)	2,283,301 (\$144.33/response x 15,797 responses)
Enrolling with another Medicare Administrative Contractor (MAC)	37	37	2	74	106.83 (see Table 2)	3,953 (\$106.83/response x 37 responses)
Revalidation	31,211	31,211	2	62,422	106.83 (see Table 2)	3,334,271 (\$106.83/response x 31,211 responses)
Reactivation	1,316	1,316	2	2,632	106.83 (see Table 2)	140,588 (\$106.83/response x 1,316 responses)

Reporting a Change of Information	55,650	55,650	1	55,650	53.42 (see Table 2)	2,972,823 (\$53.42/response x 55,650 responses)
Voluntarily Withdrawing from Medicare	3,931	3,931	0.5	1,966	23.84 (see Table 2)	93,715 (\$23.84/response x 3,931 responses)
Home Infusion Therapy– Supplier Enrollment	700	700	7.5	1,750	125.58 (see Table 3)	87,906 (\$125.58/response x 700 responses)
<b>TOTAL</b>	<b>108,642</b>	<b>108,642</b>	<b>Varies</b>	<b>171,885</b>	<b>Varies</b>	<b>8,916,557</b>

*Reporting Instruments and Instruction/Guidance Documents*

Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B) (No changes)

13. Cost to Respondents (Capital)

There are no capital costs associated with this collection.

14. Cost to Federal Government

The application form revisions will not result in any additional cost to the federal government because the application revisions are designed for better flow and to reduce the burden on the supplier and the contractor. Medicare contractors currently finalize approximately 1.3 million provider/supplier enrollment applications a year. The CMS-855B form changes will not result in any additional cost to the federal government because Medicare contractors are already processing applications from suppliers who are enrolling or enrolled in the Medicare program. Applications will continue to be processed in the normal course of Federal duties.

15. Changes in Burden/Program Changes

The changes in this collection of information request are associated with our December 28, 2020 (85 FR 84472)

final rule (CMS-1734-F, RIN 0938-AU10) regarding, “CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies.” This rule made revisions to the enrollment process for opioid treatment programs (OTPs). We are also proposing a correction that is not associated with the CMS-1734-F rule. Overall, we project a burden reduction of -1,290 respondents, -1,290 responses, and -3,870 hours. We are not proposing any changes to the CMS-855B form.

*Initial Enrollment: Modifications to OTP Enrollment Process (§ 424.67) (See 85 FR 84958 – 84960)*

Existing § 424.67 outlines a number of enrollment requirements for OTPs. One requirement, addressed in § 424.67(b)(1), is that OTPs must complete the Form CMS-855B application to enroll in Medicare. The reference to the Form CMS-855B in § 424.67(b)(1) was predicated in part on the assumption (which we made in the aforementioned November 15, 2019 final rule) that OTPs would generally submit the CMS-1500 claim form (Health Insurance Claim Form; OMB Control Number: 0938-1197) to receive payment for their services. However, we have received requests to allow OTPs to bill for services on an institutional claim form (specifically, the 837I). To do so, these OTPs would have to enroll in Medicare via the Form CMS-855A (Medicare Enrollment Application for Institutional Providers (OMB Control Number: 0938-0685)).

To account for circumstances where an OTP wishes to pursue Form CMS-855A enrollment for the reason stated above, we have finalized these changes. Additionally, and for purposes of this collection of information request, we foresee two main implications associated with these changes to § 424.67. First, newly enrolling OTPs would be able to complete and submit a Form CMS-855A (Medicare Enrollment Application - Institutional Providers) instead of a Form CMS-855B. This will represent a reduction in the number of OTPs that we previously estimated would complete the Form CMS-855B as an initial enrollment. That is, these OTPs will not, contrary to our prior estimates, enroll via the CMS-855B but will instead enroll via the CMS-855A. Second, we believe that some OTPs that enroll using the Form CMS-855A would later change their enrollment to a Form CMS-855B, thus increasing the total number of initial enrollments via this latter form. This results in a net reduction of burden for CMS-855B initial enrollments: specifically, a reduction of 23 responses and 89 hours.

Please note that the final rule had inadvertently set out a reduction of 89 hours when it should have been a reduction of 69 hours (23 responses x 3 hr/response).

	# Respondents	Total Annual Responses	Time (per response)	Total Annual Time
Currently Approved	17,087	17,087	3 hr	51,261
CMS-1734-F	-23	-23	3 hr	-89
CMS-1734-F (Correction)	n/a	n/a	n/a	+20
Balance	17,064	17,064	No Change	51,192

*Initial Enrollments (Non-Rulemaking Correction)*

Our currently approved burden had inadvertently set out 1,900 applications per year. Given that 1,900 is the total number of newly enrolling OTPs over a 3 year period, we are now correcting that figure by dividing it by 3 years. In this regard we are now estimating 633 applicants (1,900 newly enrolling applicants/3 years).

	# Respondents	Total Annual Responses	Time (per response)	Total Annual Time
Currently Approved	17,087 (15,187 +	17,087 (15,187 +	3 hr	51,261

	1,900)	1,900)		
Correction	15,820 (15,187 + 633)	15,820 (15,187 + 633)	3 hr	47,460
Difference	-1,267	-1,267	No Change	-3,801

*Summary of Annual Requirement/Burden Changes*

Initial Enrollment	# Respondents	Total Annual Responses	Time (per response)	Total Annual Time
CMS-1734-F	-23	-23	3 hr	-89
CMS-1734-F (Correction)	n/a	n/a	n/a	+20
Non-Rulemaking Correction	-1,267	-1,267	n/a	-3,801
Total Change	-1,290	-1,290	n/a	-3,870

16. Publication/Tabulation

A list of participating providers/suppliers can be accessed at <https://www.medicare.gov/physiciancompare/>. However, this list is not based on this information collection. It is based on 0938-0373 (Medicare Participating Physician or Supplier Agreement - CMS-460).

17. Expiration Date

The expiration date is displayed on the top, right-hand corner of page 1 of the CMS-855B application.