

**Supporting Statement for Paperwork Reduction Act Submissions**  
Medicare Enrollment Applications Package Extension  
CMS-855A/B/I, OMB 0938-0685

**BACKGROUND**

The primary function of the CMS-855 Medicare enrollment application is to gather information from a provider or supplier that tells us who it is, whether it meets certain qualifications to be a health care provider or supplier, where it practices or renders services, the identity of the owners of the enrolling entity, and other information necessary to establish correct claims payments. For reasons discussed below, CMS is revising the CMS-855 Medicare Enrollment Applications Package (OMB No. 0938-0685).

*1. General Enrollment Process*

a. Affordable Care Act Disclosure Provisions

On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (ACA), Public Law 111-148. The law established a number of important payment safeguard provisions involving the reporting of certain information by Medicare providers and suppliers. These provisions included section 6001, which requires Medicare hospitals to report whether they have any physician owners.

b. Additional CMS-855 Application Revisions

Besides the above-referenced CMS-855 application changes, CMS needs to make further revisions to the forms. Those that will require the provider/supplier to submit new or additional information will be discussed in section 12 below.

*2. Proposed Rule - CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1654-P)*

In the proposed rule titled “CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B” (CMS-1654-P), we proposed in new § 422.222 that providers and suppliers that are types of individuals or entities that can enroll in Medicare in accordance with § 1861 of the Social Security Act, must be enrolled in Medicare in an approved status in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an Medicare Advantage organization. The purpose of this proposal is to ensure that providers and suppliers that furnish MA services are qualified to do so and meet all applicable Medicare requirements.

As discussed in section 12(D), these providers and suppliers would complete the applicable Form CMS-855 application, thus increasing the total hour and cost burden associated with the CMS-855.

*4. Proposed Rule: Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics (CMS-6012-F)*

This proposed rule would implement certain provisions of section 1834(h)(1)(F) of the Act. It would establish the qualifications and requirements that must be met in order to be considered a qualified practitioner or a qualified supplier of prosthetics and custom-fabricated orthotics. The proposed rule would also amend the special payment rules for items furnished by DMEPOS suppliers set forth at 42 CFR § 424.57 and the accreditation organization requirements in 42 CFR § 424.58. Only qualified practitioners who furnish or fabricate prosthetics and custom-fabricated orthotics and qualified suppliers that fabricate or bill for prosthetics and custom-fabricated orthotics would be subject to these requirements.

As discussed in section 12(D), these individuals and entities would, as required, complete the Form CMS-855S application, thus increasing the total hour and cost burden associated with the CMS-855.

**A. JUSTIFICATION**

*1. Need and Legal Basis*

*a. General Enrollment Process*

Various sections of the Act and the Code of Federal Regulations 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.

- 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 physician 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 1842(u) of the Act requires us to deny billing privileges under Medicare to physicians and certain other health care professionals certified by a State Child Support Enforcement Agency as owing past-due child support.
- Section 1866(j)(1)(C) of the Act requires us to consult with providers and suppliers of services before making changes in provider 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.
  - The Social Security Act, section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, paragraph 1834(a)(20) requires us to collect additional information about accreditation of Advanced Diagnostic Imaging Suppliers.
  - 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 physicians, non-physician practitioners and Independent Diagnostic Testing Facilities, that furnish the technical component of advanced diagnostic imaging services.
  - The Tax Increase Prevention and Reconciliation Act of 2005 (TIPRA), section 511 requires us to collect information necessary to withhold 3% withholding tax from Medicare providers/suppliers.
  - 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.
  - Social Security Act, section 6401 - Provider Screening and Other Enrollment Requirements under Medicare, Medicaid, and CHIP.
  - 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.
  - We are authorized to collect information on the CMS-855 (Office of Management and Budget (OMB) approval number 0938-0685) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by Title XVIII of the Act.

The CMS-855 applications collect this information, including the information necessary to uniquely identify and enumerate the provider/supplier. Additional information necessary to process claims accurately and timely is also collected on the CMS-855 application.

#### b. CMS-1654-P

The enrollment provision in this proposed rule is needed to help ensure that providers and suppliers that furnish MA services are qualified to do so and meet all applicable Medicare requirements. The legal authorities for this provision are as follows:

- Section 1856(b) of the Act provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans “consistent with, and to carry

out, this part.” In addition, section 1856(b) states that these standards have superseded any state law or regulation (other than those related to licensing or plan solvency) for all MA organizations.

- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

c. CMS-6012-F

This proposed rule is needed to help ensure that (1) only qualified practitioners furnish or fabricate prosthetics and custom-fabricated orthotics and (2) only qualified suppliers fabricate or bill for prosthetics and custom-fabricated orthotics. The legal authorities for this rule include, but are not limited to, the following:

- Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) added section 1834(h)(1)(F) of the Act, which states that no payment shall be made for custom-fabricated orthotics or for an item of prosthetics unless furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets criteria the Secretary determines appropriate. Section 1834(h)(1)(F) of the Act describes custom-fabricated orthotics as individually fabricated for the patient over a positive model of the patient and also requires education, training, and experience to custom-fabricate. BIPA also requires that the item of prosthetics or custom-fabricated orthotics must be included in a list of items established by the Secretary, updated as appropriate.
- Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)(Pub. L. 108-173), which added a new paragraph (20) to section 1834(a) of the Act requiring the Secretary to establish and implement DMEPOS quality standards that suppliers must meet in order to furnish and bill for covered items and services described in new section 1834(a)(20)(D) of the Act, which includes prosthetics and orthotics. The new paragraph (20) also required the Secretary to designate and approve one or more independent accreditation organizations to apply the quality standards. In addition, the new section 1834(a)(20) of the Act required that to obtain or retain a Medicare Part B billing number DMEPOS suppliers must be accredited by one of the approved accreditation organizations.

*2. Purpose and users of the information - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

The CMS-855 is submitted at the time the applicant first requests a Medicare billing number. The application is used by Medicare contractors to collect data to ensure 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. It also gathers information that allows Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare program, or debarred,

suspended or excluded from any other Federal agency or program.

*3. Improved Information Techniques - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

This collection lends itself to electronic collection methods. The Provider Enrollment, Chain and Ownership System (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 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, transmit it to the Medicare contractor database for processing and then the data is transferred from the Medicare contractor processing database into PECOS by the Medicare contractor. 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.

PECOS began housing provider/supplier information in 2003 in compliance with the Government Paperwork Elimination Act. However, until CMS adopts an electronic signature standard, providers/suppliers will be required to submit a hard copy signature page of the applicable CMS-855 with an original signature.

*4. Duplication and Similar Information - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

There is no duplicative information collection instrument or process.

*5. Small Business*

*a. General Enrollment Process*

*The data collections described in section (A)(1) above will impact small businesses. However, because of the relative infrequency with which the information will need to be submitted and the minimal time involved in each data collection, we believe that the overall impact on small businesses will be extremely negligible. In addition, these businesses have been required to provide CMS with substantially the same information in order to enroll in the Medicare Program and for CMS to successfully process their claims. The removal of the CMS-855R from this package will not affect small businesses.*

*b. CMS-1654-P*

The enrollment requirement in this proposed rule would not have a significant economic impact on a substantial number of small businesses because the number of non-enrolled MA providers

and suppliers is small in comparison to the general nationwide population of providers and suppliers. Moreover, many MA providers and suppliers are already enrolled in Medicare and would therefore not be affected by this rule.

c. CMS-6012-F

This proposed rule would not have a significant economic impact on a substantial number of small businesses because the number of affected suppliers is small in comparison to the general nationwide population of providers and suppliers.

6. *Less Frequent Collections - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

This information is collected on an as needed basis. The information provided on the CMS-855 is necessary for 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 ensure that the provider/supplier meets all statutory and regulatory requirements necessary for enrollment and that claims are paid correctly.

In addition, to ensure uniform data submissions, CMS requires that all changes to previously submitted enrollment data be reported via the appropriate provider enrollment application.

7. *Special Circumstances - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

There are no special circumstances associated with this collection.

8. *Federal Register Notice/Outside Consultation*

The proposed rule published on July 15 2016 (81 FR 46162) and is serving as the 60-day Federal Register notice (CMS-1654-P, RIN 0938-AS81).

9. *Payment/Gift to Respondents - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

N/A.

10. *Confidentiality - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

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.

11. *Sensitive Questions - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

There are no sensitive questions associated with this collection.

12. *Burden Estimate (hours)*

a. General Enrollment Process

In calculating the cost, we used the following assumptions:

- The CMS-855I will likely be completed by administrative staff.
- The CMS-855A and CMS-855B will likely be completed by professional staff (attorney or accountant).
- The cost per respondent per form has been determined using the follow wages:
  - \$20.00 per hour (administrative wage)
  - \$150.00 per hour (professional wage)
- Our estimates below as to the number of providers and suppliers that will complete each form include initially enrolling and revalidating providers and suppliers, as well as those submitting a change of information involving the data element in question. We note, though, that these numbers are merely averages; the actual numbers will vary each year.

**CMS-855A**

*(1) Physician-Owned Hospital Checkbox*

We have added a checkbox to section 2A of the CMS-855A that will identify whether the hospital is a physician-owned hospital. We estimate that an average of 40,000 providers will complete this CMS-855A each year. Out of this total, we project that 2,000 providers will complete this checkbox. We believe it will take the provider 5 minutes to complete the checkbox, at a per hour labor cost of \$150. This results in a 167-hour burden (2,000 X .0833 hours) and a total annual cost of \$25,050 (167 X \$150).

*(2) Registration of Business*

To ensure compliance with § 511 of the Tax Increase Prevention and Reconciliation Act of 2005 (TIPRA), we will require the provider in section 2B1 of the application to identify how its business is registered with the Internal Revenue Service (IRS).

Using our earlier estimate of 40,000 providers that will complete this CMS-855A each year, we believe it will take each provider 5 minutes to furnish this information, at a per hour labor cost of \$150. This results in a 3,332-hour burden (40,000 X .0833 hours) and a total annual cost of \$499,800 (3,332 X \$150).

*(3) Indian Health Facilities*

To ensure that CMS-855A enrollment applications are routed to the correct Medicare contractor,

we will require the provider in section 2B1 of the application to answer the following question: “Is this provider an Indian Health Facility enrolling with Trailblazer Health Enterprises?”

We project that it will take the provider 5 minutes to furnish this information. Using our previous estimate of 40,000 providers, this results in a 3,332-hour burden (40,000 X .0833 hours), at a total annual cost of \$499,800 (3,332 X \$150 per hour).

#### *(4) Cost Report Date*

We are reinserting into section 2B of the CMS-855A a data element that asks for the provider’s year-end cost report date.

We estimate that it will take the provider 5 minutes to provide this information. Using our previous figure of 40,000 providers, results in a 3,332-hour burden (40,000 X .0833 hours) and a total annual cost of \$499,800 (3,332 X \$150 per hour).

#### *(5) Effective Dates of Ownership or Managerial Control*

We are reinserting into sections 5 and 6 of the CMS-855A a data element that requests the effective date of an entity/individual’s ownership/managerial interest in the provider. This is to help verify the entity/individual’s relationship with the provider.

We believe that it will take the provider 1 hour to disclose this information for all of its owners and managing employees. Using our earlier estimate of 40,000 providers, results in a 40,000-hour burden (40,000 X 1 hour) and a total annual cost of \$6,000,000 (40,000 X \$150 per hour).

#### *(6) Percentage of Direct and Indirect Ownership*

In sections 5 and 6 of the CMS-855A, we request information on the percentage of direct or indirect ownership a particular entity or individual has in the provider. This is to help verify the extent of the entity/individual’s ownership interest.

We estimate that it will take the provider 30 minutes to provide this information for all of its owners. Using our earlier estimate of 40,000 providers, results in a 20,000-hour burden (40,000 X .5 hours) and a total annual cost of \$3,000,000 (20,000 X \$150 per hour).

#### *(7) Purchase of Provider*

In Section 5 of the CMS-855A, we have inserted a checkbox for the provider to indicate whether the owning entity was created for the purpose of acquiring the provider. This is to help us determine whether the owner is a holding company.



We estimate that it will take the provider 15 minutes to provide this information for all of its organizational owners. Using our earlier estimate of 40,000 providers, this results in a 10,000-hour burden (10,000 X .25 hours), with a total annual cost of \$1,500,000 (10,000 X \$150 per hour).

#### *(8) Contractual Services*

In sections 5 and 6 of the CMS-855A, we request that the provider identify the type of contractual services (if any) that its managing organizations/employees furnish. This is to help verify the specific relationship the provider has with the managing entity/individual.

We estimate that it will take the provider 20 minutes to provide this information for all of its managing organizations/individuals that provide contractual services. Using our earlier estimate of 40,000 providers, results in a 13,333-hour burden (40,000 X .333 hours). The total annual cost would be \$1,999,950 (13,333 X \$150 per hour).

#### *(9) Billing Agent Date of Birth*

We are requesting the billing agent's date of birth in section 8 of the CMS-855A if the provider has a billing agent who is an individual. This is necessary for the verification of the agent's tax identification number (TIN) in the Provider Enrollment, Chain and Ownership System (PECOS) and to ensure consistency between the CMS-855A paper and electronic forms.

We project that of the aforementioned 40,000 providers, 4,000 will have an individual billing agent. We estimate that it will take the provider 10 minutes to furnish this information, resulting in a 667-hour burden (4,000 X .1666 hours) at a total annual cost of \$100,050 (667 X \$150 per hour).

#### *(10) IRS Determination Letter*

To ensure compliance with § 511 of TIRPA, we will require the provider to submit a copy of its "IRS Determination Letter" if it is registered with the IRS as a non-profit entity.

Of the aforementioned 40,000 providers, we estimate that 6,000 will provide this letter. We project that this requirement will take the provider 10 minutes to fulfill, resulting in a 1,000-hour burden (6,000 X .1666 hours) at a total annual cost of \$150,000 (1,000 X \$150 per hour).

#### *(11) Submission of Additional Documents*

We have added a statement to section 17 of the CMS-855A to the effect that the Medicare contractor may request from the provider additional documents not listed in section 17. This is to ensure that the provider is in compliance with all enrollment requirements.

Of the aforementioned 40,000 providers, we project that 8,000 will be requested to submit additional verifying documentation. We estimate that it will take the provider 10 minutes to produce this information. This results in a 1,333-hour burden (8,000 X .1666 hours) at a total annual cost of \$199,950 (1,333 X \$150 per hour).

*(12) Confirmation of LLC/Disregarded Entity Status*

In section 17 under the title "Mandatory, if Applicable," we have added a checkbox stating that "Written confirmation from the IRS confirming your Limited Liability Company (LLC) is automatically classified as a Disregarded Entity" may be required. This is to verify the provider's "disregarded entity" status.

Of the 40,000 aforementioned providers, we estimate that 2,000 will be requested to submit IRS documentation verifying the provider's "disregarded entity" status. We estimate that it will take the provider 10 minutes to produce this information. This results in a 333-hour burden (2,000 X .1666 hours) at a total annual cost of \$49,950 (333 X \$150).

Table 1 below outlines the burden costs associated with furnishing the CMS-855A information outlined above:

Table 1 – Burden of Producing Information for CMS-855A Changes

<b>Provision</b>	<b>OMB Control No.</b>	<b>Respondents</b>	<b>Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Hourly Labor Cost of Reporting (\$)</b>	<b>Total Cost (\$)</b>
Physician-Owned Hospital Checkbox	0938-0685	2,000	2,000	.0833	167	150	25,050
Registration of Business	0938-0685	40,000	40,000	.0833	3,332	150	499,800
Indian Health Facilities	0938-0685	40,000	40,000	.0833	3,332	150	499,800
Cost Report Dates	0938-0685	40,000	40,000	.0833	3,332	150	499,800
Effective Dates of Ownership	0938-0685	40,000	40,000	1	40,000	150	6,000,000
Percentage of Direct and Indirect Ownership	0938-0685	40,000	40,000	.5	20,000	150	3,000,000
Purchase of Provider	0938-0685	40,000	40,000	.25	10,000	150	1,500,000
Contractual Services	0938-0685	40,000	40,000	.3333	13,333	150	1,999,950
Billing Agent DOB	0938-0685	4,000	4,000	.1666	667	150	100,050

IRS Determination Letter	0938-0685	6,000	6,000	.1666	1,000	150	150,000
Submission of Additional Documents	0938-0685	8,000	8,000	.1666	1,333	150	199,950
Confirmation of LLC Status	0938-0685	2,000	2,000	.1666	333	150	49,950
<b>TOTAL</b>		<b>302,000</b>	<b>302,000</b>		<b>96,829</b>		<b>14,524,350</b>

### **CMS-855B**

#### *(1) Registration of Business*

To ensure compliance with § 511 of TIPRA, we will require the supplier to identify how its business is registered with the IRS.

We project that 120,000 suppliers will complete the CMS-855B annually and, in the process, disclose their business registration. We estimate that it will take the provider 5 minutes to furnish this information at a per hour labor cost of \$150. This results in a 10,000-hour burden (120,000 X .0833 hours) at a total annual cost of \$1,500,000 (10,000 X \$150).

#### *(2) Indian Health Facilities*

To ensure that CMS-855B enrollment applications are routed to the correct Medicare contractor, we will require the supplier in section 2 to respond to this question: “Is this provider an Indian Health Facility enrolling with Trailblazer Health Enterprises?”

We estimate that it will take the supplier 5 minutes to furnish this information. Using our estimate of 120,000 suppliers, we project a 10,000-hour burden (120,000 X .0833 hours) and a total annual cost of \$1,500,000 (10,000 X \$150 per hour).

#### *(3) Ambulatory Surgical Center Accreditation*

In Section 2 of the CMS-855B, we will require accredited ambulatory surgical centers (ASCs) to report the expiration date of their accreditation. This will help enable CMS to monitor the supplier’s accreditation status.

Of the 120,000 aforementioned suppliers, we project that 1,400 ASCs will furnish this data. The estimated time involved will be 10 minutes. We therefore project a 233-hour burden (1,400 X .1666 hours) at a total annual cost of \$34,950 (233 X \$150 per hour).

*(4) Advanced Diagnostic Imaging Information*

In Section 2 of the form, we will request information from advanced diagnostic imaging services (ADIs) suppliers regarding: (1) the services the supplier provides, and (2) whether the supplier is accredited.

Of the 120,000 aforementioned suppliers, we project that 20,000 ADI suppliers will furnish this data. The estimated time involved will be 15 minutes. We therefore project a 5,000-hour burden (20,000 X .25 hours) at a total annual cost of \$750,000 (5,000 X \$150 per hour).

*(5) Effective Dates of Ownership*

We are reinserting into sections 5 and 6 a data element that requests the effective date of an entity's or individual's ownership/managerial interest in the supplier. This is to help verify the organization's/person's relationship with the supplier.

We believe that it will take the provider 20 minutes to disclose this information for all of its owners and managing employees. Using our earlier estimate of 120,000 providers, results in a 40,000-hour burden (120,000 X .3333 hours) and a total annual cost of \$6,000,000 (40,000 X \$150 per hour).

*(6) Title of Section 6 Official*

We are reinserting into section 6 a data element that asks for the titles of the individuals listed in that section. This is to help verify the person's status within the organization.

We project that it will take the provider 5 minutes to furnish this information for all of its officials. Using our estimate of 120,000 suppliers, this results in a 10,000-hour burden (120,000 X .0833 hours) at a total annual cost of \$1,500,000 (10,000 X \$150).

*(7) Place of Birth of Section 6 Official*

We are inserting into section 6 a data element that asks for the birthplaces of the individuals listed in that section. This is to help verify the person's identity.

We project that it will take the provider 5 minutes to furnish this information. Using our estimate of 120,000 suppliers, this results in a 10,000-hour burden (120,000 X .0833 hours) at a total annual cost of \$1,500,000 (10,000 X \$150).

*(8) Billing Agent Date of Birth*

We are requesting the billing agent's date of birth if the supplier has a billing agent who is an individual. This is necessary for the verification of the agent's TIN in PECOS and to ensure consistency between the CMS-855B paper and electronic forms.

Of the 120,000 suppliers that will complete the CMS-855B each year, we project that 24,000 of them will have an individual billing agent. We estimate that it will take the supplier 5 minutes to furnish this information. This results in a 2,000-hour burden (24,000 X .0833 hours) at a total annual cost of \$300,000 (2,000 X \$150).

#### *(9) IRS Determination Letter*

To ensure compliance with § 511 of TIRPA, we will require the supplier to submit a copy of its "IRS Determination Letter" if it is registered with the IRS as a non-profit entity.

We estimate that 20,000 of the 120,000 aforementioned suppliers will provide this letter. We estimate that this requirement will take the provider 10 minutes to fulfill, resulting in a 3,333-hour burden (20,000 X .1666 hours) at a total annual cost of \$499,950 (3,333 X \$150 per hour).

#### *(10) Submission of Additional Documents*

We added a statement to section 17 to the effect that the Medicare contractor may request additional documents not listed in section 17 from the supplier. This is to ensure that the supplier is in compliance with all enrollment requirements.

Of the aforementioned 120,000 suppliers, we estimate that 20,000 will be requested to submit additional verifying documentation. We project that it will take the supplier 10 minutes to produce this information. This results in a 3,333-hour burden (20,000 X .1666 hours) at a total annual cost of \$499,950 (3,333 X \$150).

#### *(11) Confirmation of LLC/Disregarded Entity Status*

In section 17 under the title "Mandatory, if Applicable," we added a checkbox stating that "Written confirmation from the IRS confirming your Limited Liability Company (LLC) is automatically classified as a Disregarded Entity" may be required. This is to verify the supplier's "disregarded entity" status.

Of the estimated 120,000 suppliers that will annually complete the CMS-855B, we believe that 6,000 will be requested to submit IRS documentation verifying its LLC status. We project that it will take the supplier 10 minutes to produce this information. This results in a 1,000-hour burden (6,000 X .1666 hours) at a total annual cost of \$150,000 (1,000 X \$150).

#### *(12) Submission of TIN Documentation*

In section 17, we require the supplier to submit written confirmation from the IRS of the supplier TIN (e.g., CP-575) if the supplier is a professional corporation, professional association, or limited liability corporation, or is a sole proprietor using an EIN.

We believe that 20,000 suppliers will be required to submit this information. We project that it will take the supplier 10 minutes to do so. This results in a 3,333-hour burden (20,000 X .1666 hours) at a total annual cost of \$499,950 (3,333 X \$150).

Table 2 below outlines the burden costs associated with furnishing the CMS-855B information outlined above:

Table 2 – Burden of Producing Information for CMS-855B Changes

<b>Provision</b>	<b>OMB Control No.</b>	<b>Respondents</b>	<b>Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Hourly Labor Cost of Reporting (\$)</b>	<b>Total Cost (\$)</b>
Registration of Business	0938-0685	120,000	120,000	.0833	10,000	150	1,500,000
Indian Health Facilities	0938-0685	120,000	120,000	.0833	10,000	150	1,500,000
ASC Accreditation	0938-0685	1,400	1,400	.1666	233	150	34,950
ADIs Information	0938-0685	20,000	20,000	.25	5,000	150	750,000
Effective Dates of Ownership	0938-0685	120,000	120,000	.3333	40,000	150	6,000,000
Title of Section 6 Official	0938-0685	120,000	120,000	.0833	10,000	150	1,500,000
Birthplace of Section 6 Official	0938-0685	120,000	120,000	.0833	10,000	150	1,500,000
Billing Agent DOB	0938-0685	24,000	24,000	.0833	2000	150	300,000
IRS Determination Letter	0938-0685	20,000	20,000	.1666	3,333	150	499,950
Submission of Additional Documents	0938-0685	20,000	20,000	.1666	3,333	150	499,950
Confirmation of LLC Status	0938-0685	6,000	6,000	.1666	1,000	150	150,000
TIN Documentation	0938-0685	20,000	20,000	.1666	3,333	150	499,950

<b>TOTAL</b>		<b>711,400</b>	<b>711,400</b>		<b>98,232</b>		<b>14,734,800</b>

### **CMS-855I**

#### *(1) Acceptance of New Patients*

In section 2A, we have added the following question: “Do you accept new patients?” Medicare beneficiaries have requested that the “Medicare Physician and Healthcare Provider Directory” indicate whether physicians are accepting new patients.

We estimate that 220,000 physicians/practitioners will complete the CMS-855I each year and identify whether he/she accepts new patients. We estimate that it will take the supplier 5 minutes to furnish this information at a per hour labor cost of \$20 (administrative wage). This results in an 18,333-hour burden (220,000 X .0833 hours) and a total annual cost of \$366,660 (18,333 X \$20).

#### *(2) Employing Physician EIN*

In section 2, we are requesting the employer identification number (EIN) of a physician assistant’s employing physician. This is designed to reduce the time in which physician assistant enrollment applications are processed.

Of the estimated 220,000 individuals who will complete the CMS-855I each year, we believe that 12,000 will be physician assistants who will, in turn, submit the EIN of their employing physician. We estimate that it will take the supplier 5 minutes to furnish this information. This results in a 1,000-hour burden (12,000 X .0833) at a total annual cost of \$20,000 (1,000 X \$20 per hour).

#### *(3) Information on ADIs*

In Section 2, we will request information from ADI suppliers regarding the services they provide and whether they are accredited.

Of the 220,000 aforementioned suppliers, we estimate that 12,000 will furnish this data. The estimated time involved will be 15 minutes. We therefore project a 3,000-hour burden (12,000 X .25 hours) at a total annual cost of \$60,000 (3,000 X \$20 per hour).

#### *(4) Indian Health Facilities*

To ensure that CMS-855I enrollment applications are sent to the correct Medicare contractor, we will require the supplier in section 2 to indicate whether it is an Indian Health Facility that is enrolling with Trailblazer Health Enterprises.

Of the 220,000 suppliers that will complete the CMS-855I each year, we estimate that 60,000 will complete section 2 as a solely-owned corporation or LLC. We project that it will take the supplier 5 minutes to furnish this information. This results in a 5,000-hour burden (60,000 X .0833 hours) at a total annual cost of \$100,000 (5,000 X \$20 per hour).

#### *(5) Registration of Business*

To ensure compliance with § 511 of TIPRA, the supplier will need to identify his/her business registration in section 2.

Of the 220,000 aforementioned suppliers, we estimate that 60,000 will complete section 2 as a solely-owned corporation or LLC. We project that it will take the supplier 5 minutes to furnish data about its business registration. This results in a 5,000-hour burden (60,000 X .0833 hours), with a total annual cost of \$100,000 (5,000 X \$20 per hour).

#### *(6) Effective Dates of Individuals in Section 6*

We are inserting into section 6 a data element that asks for the effective date of an individual's managing control of the business. This is to help verify the individual's relationship with the practice.

We estimate that of the 220,000 suppliers that will complete the CMS-855I each year, 80,000 will have at least one managing employee. We project that it will take the supplier 10 minutes to furnish this information on the individual(s). This results in a 13,333-hour burden (80,000 X .1666 hours) and a total annual cost of \$266,660 (13,333 X \$20 per hour).

#### *(7) Places of Birth of Section 6 Officials*

We are inserting into section 6 a data element that requests the birthplace of each person listed therein. This is to help verify the individual's identity.

Using the 80,000-supplier and 10-minute figures mentioned in the previous data element, we project a 13,333-hour burden (80,000 X .1666 hours) at a total annual cost of \$266,660 (13,333 X \$20 per hour).

#### *(8) Billing Agent Date of Birth*

For reasons already stated, we are requesting the billing agent's date of birth if the supplier has a



billing agent who is an individual.

Of the aforementioned 220,000 suppliers, we project that 44,000 of them will have an individual billing agent. We estimate that it will take the provider 10 minutes to furnish this information. This results in a 7,333-hour burden ( $44,000 \times .1666$  hours) at a total annual cost of \$146,660 ( $7,333 \times \$20$  hour).

#### *(9) Submission of Additional Documents*

We are adding a statement to section 17 to the effect that the supplier may be required to submit additional documents not listed in section 17.

We estimate that 40,000 of the estimated 220,000 suppliers completing the CMS-855I each year will be required to submit this documentation. We project that it will take the supplier 10 minutes to produce this information. This results in a 6,667-hour burden ( $40,000 \times .1666$  hours) at a total annual cost of \$133,340 ( $6,667 \times \$20$ ).

#### *(10) Confirmation of LLC/Disregarded Entity Status*

In section 17, we will require the supplier to, if applicable, confirm its status as a disregarded entity.

Of the above-referenced 220,000 suppliers, we project that 12,000 will furnish this information. We estimate that it will take the supplier 10 minutes to produce this data. This results in a 2,000-hour burden ( $12,000 \times .1666$  hours) at a total annual cost of \$40,000 ( $2,000 \times \$20$  per hour).

#### *(12) IRS Determination Letter*

In section 17, we will require non-profit entities to submit a copy of their IRS-501(c) form.

We estimate that 8,000 of the aforementioned 220,000 suppliers will need to submit this information. We estimate that it will take the provider 10 minutes to do so. This results in a 1,333-hour burden ( $8,000 \times .1666$  hours) at a total annual cost of \$26,660 ( $1,333 \times \$20$  per hour).

#### *(13) Submission of TIN Documentation*

In section 17, we will require certain suppliers to submit a copy of their CP-575 form. This is necessary to verify the business's EIN.

We estimate that of the 220,000 suppliers that will annually complete the CMS-855I, 60,000 will

submit this information. We estimate that it will take the supplier 10 minutes to do so. This results in a 10,000-hour burden (60,000 X .1666 hours), with a total annual cost of \$200,000 (10,000 X \$20 per hour).

*(13) Information about Advanced Diagnostic Imaging Suppliers*

We will be adding an attachment to the CMS-855I that captures information on any ADIS services the supplier performs.

Of the aforementioned 220,000 suppliers, we estimate that 32,000 will complete this attachment and that it will take 15 minutes to do so. This results in an 8,000-hour burden (32,000 X .25 hours) at a total annual cost of \$160,000 (8,000 X \$20 per hour).

Table 3 below outlines the burden costs associated with furnishing the CMS-855I information outlined above:

<b>Provision</b>	<b>OMB Control No.</b>	<b>Respondents</b>	<b>Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Hourly Labor Cost of Reporting (\$)</b>	<b>Total Cost (\$)</b>
Acceptance of New Patients	0938-0685	220,000	220,000	.0833	18,333	20	366,660
Employing Physician EIN	0938-0685	12,000	12,000	.0833	1,000	20	20,000
ADI Information – Section 2	0938-0685	12,000	12,000	.25	3,000	20	60,000
Indian Health Facility Information	0938-0685	60,000	60,000	.0833	5,000	20	100,000
Registration of Business	0938-0685	60,000	60,000	.0833	5,000	20	100,000
Effective Date of Section 6 Individual	0938-0685	80,000	80,000	.1666	13,333	20	266,660
Birthplace of Section 6 Individual	0938-0685	80,000	80,000	.1666	13,333	20	266,660
Billing Agent Date of Birth	0938-0685	44,000	44,000	.1666	7,333	20	146,660
Submission of Additional Documents	0938-0685	40,000	40,000	.1666	6,667	20	133,340

Confirmation of LLC Status	0938-0685	12,000	12,000	.1666	2,000	20	40,000
IRS Determination Letter	0938-0685	8,000	8,000	.1666	1,333	20	26,660
Verification of EIN	0938-0685	60,000	60,000	.1666	10,000	20	200,000
Additional ADI Information	0938-0685	32,000	32,000	.25	8,000	20	160,000
<b>TOTAL</b>		<b>720,000</b>	<b>720,000</b>		<b>94,332</b>		<b>\$1,886,640</b>

b. CMS-1654-P

We made the following estimates in CMS-1654-P:

- 64,000 MA providers and suppliers would be required to enroll under § 422.222. Of this figure:
  - 32,000 would be individuals (16,000 would be physicians; 16,000 would be non-physician practitioners).
  - 32,000 would be organizations
- According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2015 (see [http://www.bls.gov/oes/current/oes\\_nat.htm#29-0000](http://www.bls.gov/oes/current/oes_nat.htm#29-0000)), the mean hourly wage for the general category of "Physicians and Surgeons" is \$97.33, and the mean hourly wage for the general BLS category of "Health Diagnosing and Treating Practitioners, All Other" is \$46.65. With fringe benefits and overhead, the respective per hour rates are \$194.66 and \$93.30. Since, based on our experience, administrative staff typically complete the applicable Form CMS-855 enrollment form for unenrolled organizations, we used the most recent BLS mean hourly wage estimate for the general category of "Office and Administrative Support Occupations," or \$17.47 per hour; the rate is \$34.94 with fringe benefits and overhead.
- Consistent with previous estimates, we projected that it would take:
  - Physicians and non-physician practitioners three (3) hours to complete the Form CMS-855I.
  - Administrative staff six (6) hours to complete the Form CMS-855A, Form CMS-855B, or Form CMS-855S.

Table 4 – Burden of Compliance with Requirement to Enroll in § 422.222

	<b>OMB Control No.</b>	<b>Respondents</b>	<b>Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Hourly Labor Cost of Reporting (\$)</b>	<b>Total Cost (\$)</b>
Physicians (CMS-855I)	0938-0685	16,000	16,000	3	48,000	194.66	9,343,680
Non-Physician Practitioners (CMS-855I)	0938-0685	16,000	16,000	3	48,000	93.30	4,478,400
Organizations (CMS-855A, CMS-855B, CMS-855S)	0938-0685 (CMS-855A; CMS-855B); 0938-1056 (CMS-855S)	32,000	32,000	6	192,000	34.94	6,708,480
<b>TOTAL</b>		64,000	64,000		288,000		20,530,560

Three years is the maximum length of an OMB approval. Therefore, we must average the totals in Table 4 over a 3-year period. This results in annual figures of (1) 21,333 respondents; (2) 96,000 hours; and (3) \$6,843,520 in total costs.

c. CMS-6012-F

*(1) Accreditation as a Prerequisite for Enrollment*

(i) Enrolled Physicians and Practitioners Pursuing Accreditation

Under 42 CFR § 424.57(c)(22), DMEPOS suppliers that furnish, fabricate and bill for prosthetics or custom-fabricated orthotics must meet all accreditation requirements specified in these provisions, and be licensed in orthotics, pedorthics, or prosthetics in the state in which its practice is located (if the state requires such licensure). Table 5 identifies categories and approximate numbers of individuals who: (1) are enrolled in Medicare as DMEPOS suppliers; (2) have billed Medicare for prosthetic devices; and (3) are certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) or the Board for Orthotist/Prosthetist Certification International, Incorporated (BOC). This data is based on internal CMS statistics. These individuals have met all applicable state licensure requirements (for example, for furnishing prosthetics).

**Table 5 - Prosthetics**

<b>Category</b>	<b>Number Enrolled as DMEPOS Suppliers</b>	<b>Number Who Are ABC or BOC Certified</b>
Prosthetists	8,000	5,000
Physicians	5,000	3,000
Physical and Occupational Therapists	1,000	500
Ocularists	400	200

Orthotists	1,500	800
Pedorthists	900	500
<b>Total</b>	<b>16,800</b>	<b>10,000</b>

The 10,000 physicians and practitioners in Table 5 who are enrolled as DMEPOS suppliers and are accredited would meet the requirements of proposed § 424.57(c)(22). The remaining 6,800 would need to obtain ABC or BOC accreditation in order to bill Medicare for prosthetics.

Table 6 identifies categories and approximate numbers of individuals who (1) are enrolled in Medicare as DMEPOS suppliers; (2) have billed Medicare for custom-fabricated orthotics; and (3) are ABC or BOC certified. This data, too, is based on internal CMS statistics. All of these persons have met the applicable state licensure requirements (for example, for furnishing custom-fabricated orthotics).

**Table 6: Custom-Fabricated Orthotics**

<b>Category</b>	<b>Number Enrolled as DMEPOS Suppliers</b>	<b>Number Who Are ABC or BOC Certified</b>
Prosthetists	4,000	2,000
Physicians	3,000	1,500
Physical and Occupational Therapists	1,000	500
Ocularists	300	200
Orthotists	4,000	2,500
Pedorthists	700	400
<b>Total</b>	<b>13,000</b>	<b>7,100</b>

The 7,100 physicians and practitioners in Table 6 who are currently enrolled as DMEPOS suppliers and are accredited would meet the requirements of proposed § 424.57(c)(22). The remaining 5,900 would need to obtain ABC or BOC accreditation in order to bill Medicare for custom-fabricated orthotics.

Although it is highly likely that some of the individuals in Tables 5 and 6 provide both prosthetics and custom-fabricated orthotics, CMS-6012-F assumed that the tables reflect unduplicated counts of physicians and practitioners.

We projected in CMS-6012-F that-- (1) all prosthetists, orthotists, ocularists, and pedorthists would pursue accreditation; and (2) 90 percent of physicians, physical therapists, and occupational therapists would seek accreditation. This results in a base figure of 12,250 physicians and practitioners.

**Table 7: Number of Physicians and Practitioners Pursuing Accreditation**

<b>Category</b>	<b>Approximate Percentage of Universe*</b>	<b>Number</b>
Prosthetists	40.8	5,000
Physicians	25.7	3,150
Physical and Occupational Therapists	7.3	900
Ocularists	2.5	300
Orthotists	18.0	2,200
Pedorthists	5.7	700

<b>Total</b>		<b>12,250</b>
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\* Rounded to nearest tenth

Table 8 identifies the mean hourly wages for the BLS categories that most appropriately apply to the physician and practitioner types mentioned previously. The data is from May 2015, the most recent month for which information is available; see

[http://www.bls.gov/oes/current/oes\\_nat.htm#43-0000](http://www.bls.gov/oes/current/oes_nat.htm#43-0000). As there are no specific BLS categories for ocularists and pedorthists, we included them within the larger category of orthotists and prosthetists.

Table 8: BLS Mean Hourly Wages

<b>BLS Category</b>	<b>BLS Mean Hourly Wage (\$)</b>	<b>Hourly Wage with Fringe Benefits and Overhead (\$)</b>
Orthotists and Prosthetists*	33.63	67.26
Physicians and Surgeons	97.33	194.66
Physical Therapists	41.25	82.50 **
Occupational Therapists	39.27	78.54 **

\*Includes ocularists and pedorthists.

\*\*The average mean hourly wage for physical and occupational therapists combined, which we will use in our analysis, is \$80.52 (or (\$82.50 + \$78.54)/2).

Table 9 identifies the total hour and cost burdens for enrolled physicians and practitioners seeking accreditation. The cost burdens, reflected in CMS-6012-F, are based on the wage estimates in Table 8.

Table 9: Enrolled Physicians and Practitioners Pursuing Accreditation

<b>Category</b>	<b>Number of Physicians and Practitioners</b>	<b>Hour Burden Per Submission</b>	<b>Total Hour Burden</b>	<b>Hourly Wage (\$)</b>	<b>Total Cost Burden (\$)</b>
Prosthetists	5,000	10	50,000	67.26	3,363,000
Physicians	3,150	10	31,500	194.66	6,131,790
Physical and Occupational Therapists	900	10	9,000	80.52	724,680
Ocularists	300	10	3,000	67.26	201,780
Orthotists	2,200	10	22,000	67.26	1,479,720
Pedorthists	700	10	7,000	67.26	470,820
<b>Total</b>	<b>12,250</b>		<b>122,500</b>		<b>12,371,790</b>

Although this burden would be incurred in the first year of our proposed requirement, three years is the maximum length of an OMB approval. Therefore, we averaged the totals in Table 9 over a 3-year period. This results in the following average annual figures of: (1) 4,083 affected physicians and practitioners; (2) 40,830 ICR burden hours; and (3) \$4,123,930 in ICR burden costs.

## (ii) Accreditation for Newly Enrolling Physicians and Practitioners

Table 10 outlines the annual number of physicians and practitioners who, based on historical CMS data, would-- (1) seek accreditation in accordance with § 424.57(c)(22); (2) enroll in Medicare as DMEPOS suppliers; and (3) bill Medicare for prosthetics or custom-fabricated orthotics.

Table 10: Annual Number of Physicians and other Practitioners Seeking Accreditation, Enrolling in Medicare as DMEPOS Suppliers, and Billing for Prosthetics or Custom-Fabricated Orthotics

Category	Number of Enrollees
Prosthetists	400
Physicians	250
Physical and Occupational Therapists	100
Ocularists	40
Orthotists	400
Pedorthists	100
<b>Total</b>	<b>1,290</b>

Table 11 outlines the annual hour and cost burdens for newly enrolling physicians and practitioners. The table applies the 10-hour and BLS wage estimates mentioned previously.

Table 11: Annual Newly Enrolling Physicians and Practitioners Pursuing Accreditation

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	400	10	4,000	67.26	269,040
Physicians	250	10	2,500	194.66	486,650
Physical and Occupational Therapists	100	10	1,000	80.52	80,520
Ocularists	40	10	400	67.26	26,904
Orthotists	400	10	4,000	67.26	269,040
Pedorthists	100	10	1,000	67.26	67,260
<b>Total</b>	<b>1,290</b>		<b>12,900</b>		<b>1,199,414</b>

These figures are reflected in CMS-6012-F.

*(2) Reporting Accreditation via the CMS-855S (Medicare Enrollment Application: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers)*

(i) Enrolled Physicians and Practitioners

Upon becoming accredited, physicians and practitioners would need to report the accreditation to CMS via a CMS-855S change of information request. We estimated in CMS-6012-F that it would take physicians and practitioners 30 minutes to complete and submit this change request. Table 12 outlines the total hour and cost burdens of this requirement.

Table 12: Enrolled Physicians and Practitioners Reporting Accreditation via CMS-855S

<b>Category</b>	<b>Number of Physicians and Practitioners</b>	<b>Hour Burden Per Submission</b>	<b>Total Hour Burden</b>	<b>Hourly Wage (\$)</b>	<b>Total Cost Burden (\$)</b>
Prosthetists	5,000	0.5	2,500	67.26	168,150
Physicians	3,150	0.5	1,575	194.66	306,590
Physical and Occupational Therapists	900	0.5	450	80.52	36,234
Ocularists	300	0.5	150	67.26	10,089
Orthotists	2,200	0.5	1,100	67.26	73,986
Pedorthists	700	0.5	350	67.26	23,541
<b>Total</b>	<b>12,250</b>		<b>6,125</b>		<b>618,590</b>

Although this burden would be incurred in the first year of our proposed requirement, we must average the totals in Table 12 over a 3-year period. This results in: (1) 4,083 affected physicians and practitioners; (2) 2,042 ICR burden hours; and (3) \$206,197 in ICR burden costs. These figures are reflected in CMS-6012-F.

(ii) Newly Enrolling Physicians and Practitioners

When completing the CMS-855S initial enrollment application, physicians and practitioners would have to furnish accreditation information on the form. We estimated in CMS-6012-F that this would take 30 minutes per application. Table 13 outlines the total annual hour and cost burdens.

Table 13: Newly Enrolling Physicians and Practitioners Reporting  
Accreditation via CMS-855S

<b>Category</b>	<b>Number of Physicians and Practitioners</b>	<b>Hour Burden Per Submission</b>	<b>Total Hour Burden</b>	<b>Hourly Wage (\$)</b>	<b>Total Cost Burden (\$)</b>
Prosthetists	400	0.5	200	67.26	13,452
Physicians	250	0.5	125	194.66	24,333
Physical and Occupational Therapists	100	0.5	50	80.52	4,026
Ocularists	40	0.5	20	67.26	1,345
Orthotists	400	0.5	200	67.26	13,452
Pedorthists	100	0.5	50	67.26	4,026
<b>Total</b>	<b>1,290</b>		<b>645</b>		<b>60,634</b>

These figures are reflected in CMS-6012-F.

(3) *Requirements for Becoming a Qualified Practitioner*

Under § 424.57(d)(3), all eligible professionals who wish to become qualified practitioners, to provide prosthetics or custom-fabricated orthotics, and who are not enrolled in Medicare as



DMEPOS suppliers (and therefore do not bill Medicare for these items) must—

- Be licensed in orthotics, pedorthics, or prosthetics in the state in which his or her practice is located if the state requires such licensure; or
- If the state does not require such licensure—
- Be specifically trained and educated to provide and manage the provision of pedorthics, prosthetics, or orthotics; and
- Meet the certification requirements specified in § 424.57(d)(3)(ii)(B).

This section 12(c)(3) discusses the hour and cost burdens for physicians and practitioners who are-- (1) not enrolled in Medicare as DMEPOS suppliers; (2) located in a state that does not require licensure in orthotics, pedorthics, and prosthetics; and (3) must obtain certification under § 424.57(d)(3).

For purposes of this burden estimate, and solely to establish a rough figure on which commenters could submit feedback to us, we projected in CMS-6012-F that approximately 5,000 physicians and practitioners would seek certification within the first year following the implementation of § 424.57(d)(3). We estimated that 500 physicians and practitioners would seek certification under § 424.57(d)(3) each year thereafter. Using the aforementioned the wage estimates and the 10-hour projection, we estimated in CMS-6012-F the following Year 1 hour and cost burdens associated with § 424.57(d)(3).

Table 14: Hour and Cost Burdens of § 424.57(d)(3) in Year 1

<b>Category</b>	<b>Number of Physicians and Practitioners*</b>	<b>Hour Burden Per Submission</b>	<b>Total Hour Burden</b>	<b>Hourly Wage (\$)</b>	<b>Total Cost Burden (\$)</b>
Prosthetists	2,040	10	20,400	67.26	1,372,104
Physicians	1,285	10	12,850	194.66	2,501,381
Physical and Occupational Therapists	365	10	3,650	80.52	293,898
Ocularists	125	10	1,250	67.26	84,075
Orthotists	900	10	9,000	67.26	605,340
Pedorthists	285	10	2,850	67.26	191,691
<b>Total</b>	<b>5,000</b>		<b>50,000</b>		<b>5,048,489</b>

Table 15 reflects the annual hour and cost burdens in Year 2 and each year thereafter. The figures are based on the 500-individual universe.

Table 15: Annual Hour and Cost Burdens of § 424.57(d)(3) in Year 2 and Subsequent Years

Category	Number of Physicians and Practitioners*	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	204	10	2,040	67.26	137,210
Physicians	128	10	1,280	194.66	249,165
Physical and Occupational Therapists	36	10	360	80.52	28,987
Ocularists	13	10	130	67.26	8,744
Orthotists	90	10	900	67.26	60,534
Pedorthists	29	10	290	67.26	19,505
<b>Total</b>	<b>500</b>		<b>5,000</b>		<b>504,145</b>

We averaged the totals in Tables 14 and 15 over a 3-year period. This resulted in the following annual figures of: (1) 2,000 affected physicians and practitioners; (2) 20,000 burden hours; and (3) \$2,018,926. These figures are reflected in CMS-6012-F.

#### (4) Final ICR Hour and Cost Burdens

We estimated in CMS-6012-F the following total ICR burdens associated with our proposed CMS-6012 provisions in each of the first three years of this rule.

**Table 16: Summary of Annual Information Collection Burdens**

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost (\$)	Total Labor Cost (\$)	Total Cost (\$)
§424.57(c)(22) – Enrolled seeking accreditation	0938-New	4,083	4,083	10	40,830	†	4,123,930	4,123,930
§424.57(c)(22) – Newly enrolling seeking accreditation	0938-New	1,290	1,290	10	12,290	††	1,199,414	1,199,414
§424.57(c)(22) – Enrolled reporting accreditation via 855S	0938-1056	4,083	4,083	.5	2,042	†††	206,197	206,197
§§424.57(c)(22) – Newly enrolling reporting accreditation via 855S	0938-1056	1,290	1,290	.5	645	††††	60,634	60,634
§ 424.57(d)(3)**	0938-New	2,000	2,000	10	20,000	†††††	2,018,926	2,018,926

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost (\$)	Total Labor Cost (\$)	Total Cost (\$)
<b>Total</b>		12,476	12,476		75,807			7,609,101

† See the values listed in Table 9.

†† See the values listed in Table 11.

††† See the values listed in Table 12.

†††† See the values listed in Table 13.

\*\*\*The values are based on the 3-year average of the values listed in tables 14 and 15. Three years is the maximum length of an OMB approval.

††††† See the values listed in Tables 14 and 15.

#### d. Final Estimates

Table 17 summarizes the total hour and burden costs of this information collection:

Table 17 – Burden of Information Collection

Form	Respondents	Annual Burden Hours	Total Cost
CMS-855A	304,400	97,629	\$14,644,350
CMS-855B	711,400	98,232	\$14,734,800
CMS-855I	720,000	94,332	\$1,886,640
Enrollment Requirement under § 422.222	21,333	96,000	\$6,843,520
Requirements Pursuant to CMS-6012-F	12,476	75,807	\$7,609,101
<b>TOTAL</b>	<b>1,769,609</b>	<b>462,000</b>	<b>45,718,411</b>

#### 13. Cost to Respondents (Capital) - General Enrollment Process, CMS-1654-P, and CMS-6012-F

There are no capital costs associated with this collection.

#### 14. Cost to Federal Government - General Enrollment Process, CMS-1654-P, and CMS-6012-F

There is no additional cost to the Federal government. Applications will be processed in the normal course of Federal duties.

#### 15. Changes in Burden/Program Changes

##### a. General Enrollment Process

CMS is removing the CMS-855R application from the CMS-855 Medicare Enrollment Applications Package (OMB No. 0938-0685). On May 22, 2013, in accordance with the Paperwork Reduction Act, OMB approved a reinstatement without change of a previously approved collection of the Medicare enrollment applications (specifically, the CMS-855A, CMS-855B, CMS-855I and CMS-855R Medicare enrollment application bundle, OMB number 0938-0685, ICR reference number 201210-0938-009). This was necessary in order to allow the CMS-855A, CMS-855B and CMS-855I to remain active. That collection expires on May 31, 2016. While the CMS-855R enrollment form is included in that collection, it is not active and not being used by the public as CMS now uses the revised CMS-855R, OMB number 0938-1179, approved by OMB on November 1, 2012 (ICR reference number 201206-0938-007). The CMS-855R application under OMB number 0938-0685 is now being removed from the Medicare application bundle collection. There is no duplication of CMS-855R Medicare application forms as only the CMS-855R Medicare application form under OMB approval number 0938-1179 is active. Therefore, CMS is seeking to redefine the CMS-855 Medicare Enrollment Applications Package (OMB No. 0938-0685) to include only the CMS-855A, CMS-855B, and CMS-855I enrollment applications.

The adjustments to the total burden (number 12, Table 4) reflect the removal of the CMS-855R from this CMS-855 enrollment package. The total respondents were reduced by 5,000, making the new total 1,735,800. The annual burden hours were reduced by 835, making the new total 289,774 hours.

b. CMS-1654-P

CMS-1654-P adds an annual 96,000 hour burden and a \$6,843,520 cost burden to the CMS-855 information collection.

c. CMS-6012

CMS-6012-F:

- Establishes a 53,120 hour burden and \$5,323,344 cost burden for accreditation for prosthetics or custom-fabricated orthotics.
- Adds a 1,287 hour burden and \$266,831 cost burden to the CMS-855S information collection.
- Establishes a 20,000 hour burden and \$2,018,926 cost burden for § 424.57(d)(3).

16. *Publication/Tabulation - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

N/A.

17. *Expiration Date - General Enrollment Process, CMS-1654-P, and CMS-6012-F*

We are planning on displaying the expiration date.