Supporting Statement A for Paperwork Reduction Act Submissions
Medicare Enrollment Application
(CMS-855O, OMB 0938-1135)

BACKGROUND

The primary function of the CMS-855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services. The CMS-855O allows a physician or other eligible professional to enroll in Medicare without being approved for billingprivileges.

In CMS-5531-IFC (RIN 0938-AU32), applicable beginning on March 1, 2020, CMS gives individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the 2019 Novel Coronavirus (COVID-19). Recognizing the urgency of this situation, and understanding that some pre-existing Medicare payment rules may inhibit innovative uses of technology and capacity that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are amending several Medicare and Medicaid policies and regulations in response to the COVID-19 public health emergency (PHE) and recent legislation.

Section 3708 of the CARES Act amended sections 1814(a) and 1835(a) of the Act to allow NPs, CNSs, and PAs (as those terms are defined in section 1861(aa) of the Act), to order and certify patients for eligibility under the Medicare home health benefit. Additionally, section 3708 of the CARES Act amended sections 1814(a)(2)(C), 1835 (a)(2)(A)(ii), and 1861(m) of the Act to allow the home health plan of care to be established and periodically reviewed by a physician, Nurse Practitioner (NP), Clinical Nurse Specialist (CNS), or Physician Assistant (PA) where such services are or were furnished while the individual was under the care of a physician, NP, CNS or PA. The CARES Act also amended section 1861(o)(2) of the Act to allow NPs, CNSs or PAs to perform the role originally reserved for a physician in establishing HHA policies that govern the services (and supervision of such services) provided to patients under the Medicare home health benefit. Finally, section 3708 of the CARES Act amended section 1895(c) of the Act to allow payment for the furnishing of items and services under the home health prospective payment system (HH PPS) when these items and services are prescribed by a NP, CNS or PA.

In accordance with section 3708 of the CARES Act, these changes are required to take effect within 6 months of enactment of the law. We are addressing changes in the regulations in this IFC to ensure these requirements are issued within the timeframe required by statute. We also believe that enacting these provisions at this time will afford flexibility for providers seeking to order home health care services during the PHE for the COVID-19 pandemic. That is, NPs, CNSs and PAs would be able to practice to the top of their state licensure to certify eligibility for home health services, as well as to establish and periodically review the home health plan of care. This is imperative during the PHE for the COVID-19 pandemic as more beneficiaries may be considered “homebound”, either because a practitioner has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or

suspected diagnosis of COVID-19, or because a practitioner has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

In accordance with section 1861(aa)(5) of the Act, NPs, CNSs and PAs are required to practice in accordance with state law in the state in which the individual performs such services. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required. Home health agencies can consult specific practitioner association websites to ensure that practitioners are working within their scope of practice and prescriptive authority.[1] Section 1861(aa)(5) of the Act allows the Secretary regulatory discretion regarding the requirements for NPs, CNSs and PAs. As such, the regulations at §§ 410.74 through 410.76 outline in detail the qualifications and services for which these entities are responsible. We believe that we should align, for Medicare home health purposes, the definitions for such practitioners with the existing definitions in regulation at §§ 410.74 through 410.76 for consistency across the Medicare program and to ensure that Medicare home health beneficiaries are afforded the same standard of care. Therefore, we are amending the regulations at parts 409, 424, and 484 to define a nurse practitioner, a clinical nurse specialist, and a physician assistant (as such qualifications are defined at §§ 410.74 through 410.76) as an "allowed practitioner". This means that in addition to a physician, as defined at section 1861(r) of the Act, an "allowed practitioner" may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. We would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed provider type, as set out at § 424.22(a)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. We are soliciting comments on finalizing in perpetuity these conforming regulations text changes as required by section 3708 of the CARES Act, effective at the time of publication of CMS-5531-IFC.

No additional material data collection has been added in this revision.

A. JUSTIFICATION

1. Need and Legal Basis

Various sections of the Act and the Code of Federal Regulations require suppliers to furnish information concerning the identification of individuals who order and certify medical services to beneficiaries before payment can be made.

- Section 3708 of the CARES Act allows Nurse Practitioner (NP), Clinical Nurse Specialist (CNS), or Physician Assistant (PA) to order and certify patients for eligibility under the Medicare home health benefit, allows the home health plan of care to be established and

[1] https://nacns.org/ for Clinical Nurse Specialists; https://www.aapa.org/ for Physician Assistants; and https://www.aanp.org/ for Nurse Practitioners.

periodically reviewed by a physician, NPs, CNSs, or a PAs where such services are or were furnished while the individual was under the care of a physician, NP, CNS or PA, allows NPs, CNSs or PAs to perform the role originally reserved for a physician in establishing HHA policies that govern the services (and supervision of such services) provided to patients under the Medicare home health benefit, and allows payment for the furnishing of items and services under the home health prospective payment system (HH PPS) when these items and services are prescribed by a NP, CNS or PA.

- Sections l 124(a)(l) and 1124A of the Act 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.
- 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, including the identity of the ordering or certifying physician.
- Section 1866(j)(l)(C) of the Act requires us to consult with providers and suppliers of services before making changes in provider enrollment forms.
- 31 U.S.C. section 7701(c) requires that any person or entity doing business with the federal government must provide their Tax Identification Number (TIN).
- Section 1866(i)(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 of medical or other items or services and suppliers under Medicare, Medicaid, and CHIP.
- Section 1866(i)(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.
- The Patient Protection and Affordable Care Act (PPACA), section 6405 - "Physicians Who Order Items or Services Required to be Medicare Enrolled Physicians or Eligible Professionals" contains a requirement for certain physicians and other eligible professionals to enroll in the Medicare program for the sole purpose of ordering or certifying items or services for Medicare beneficiaries.
- 42 CFR 424.507 uses the term "certify" as opposed to "refer." "Certify" is the appropriate term to use when referring to such services.
- Under 42 CFR 424.502, the definition of "enrollment" includes the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.
- Section 1848(k)(3)(B) defines the terms "eligible professionals."
- 42 CFR 413.75(b) defines licensed residents.
- Section 3004(b)(l) 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.

- Federal law 5 U.S.C. 522(b)(4) requires privileged or confidential commercial or financial information protection from public disclosure.
- Executive Order 12600 requires the pre-disclosure of notification procedures for confidentialcommercial information.
- 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.

This Medicare Enrollment Application collects information necessary to help CMS determine whether a physician or other eligible professional meets certain qualifications to be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services, including the information necessary to uniquely identify and enumerate the provider/supplier.

2. Purpose and users of the information

Physicians and practitioners complete the Form CMS-855O (Medicare Enrollment Application - Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners) if they are enrolling in Medicare not to obtain Medicare billing privileges but strictly to order, refer, or certify certain Medicare items and services. It is used by Medicare contractors to collect data to help ensure that the applicant has the necessary credentials to order and certify certain Medicare items and services.

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 ensures that the applicant has the necessary information for unique identification. The license numbers are validated against state licensing websites. All the license numbers are captured and stored in the MAC database. 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. Mailing address, practice location address and contact information is captured to contact the supplier.

The collection and verification of this information defends and protects our beneficiaries from illegitimate suppliers. These procedures also protect the Medicare Trust Fund against fraud. It gathers information that allow Medicare contractors to ensure that the physician or eligible professional is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. The data collected also ensures that the applicant has the necessary credentials to order and certify health care services. 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. 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 and transmit it to the Medicare contractor database for processing. Then the data is transferred from the Medicare contractor processing database into PECOS by the Medicare contractor. CMS now has the ability to allow suppliers to upload supporting documentation electronically. CMS has also adopted an electronic signature standard; however, practitioners will have the choice to e-sign via the CMS website or to submit a hard copy of the CMS-855O 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 50% 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.

5. Small Business

The CMS-855O is not completed by small businesses and therefore will not affect small businesses.

6. Less Frequent Collections

After initial enrollment, this information is collected on an as needed basis. The information provided on the CMS-855O is necessary for identification of certain physician and other eligible professionals in the Medicare program. It is essential to collect this information for all ordering/certifying physicians and other eligible professionals to ensure each applicant has the necessary credentials to order and certify certain Medicare items and services. In addition, Medicare contractors must ensure that the ordering/certifying physicians or other eligible professionals meet all statutory and regulatory requirements and are properly credentialed.

After the initial enrollment and approval, the information collected is less frequent and often initialized by the individual for either a change of information or to opt out of the Medicare program to solely order and certify. To ensure uniform data submissions, CMS requires that

all changes to previously submitted enrollment data be reported via this enrollment application.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation

We sought comment on_____, as part of a notice of proposed rulemaking, (Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-5531-IFC)), providing the public an opportunity to comment on these ICRs.

9. Payment/Giftto Respondents

There are no payments or gifts to respondents as the respondents are ordering or certifying services or items for Medicare beneficiaries to receive from Medicare enrolled physicians or other professionals. The respondents are ordering or certifying the need for such services or items only.

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.

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 (time and cost)

According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019 (see https://www.bls.gov/oes/current/oes_nat.htm).), the mean hourly wage for the general category of ‘‘Health Diagnosing and Treating Practitioners, All Others’’ is $49.26. With fringe benefits and overhead, the per hour rate are $98.52. We also project that, on average, it takes individuals approximately .5 hours to complete and submit the Form CMS–855O or an opt-out affidavit.

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

National Occupational Employment and Wage Estimates

BLS Occupation Title	Occupation Code	Mean Hourly Wage ($/hour)	Fringe Benefits and Overhead ($/hour)	Adjusted Hourly Wage ($/hour)
Health Diagnosing and Treating Practitioners, All Others'	43-9199	49.26	49.26	98.52

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

The annual average of new enrollments and applications for opting out of the Medicare program to solely order and certify for the three specialties of NPs, CNS', and PAs is approximately 1,600. This number is based on averaging enrollment data from the PECOS system from 2017 through 2019. For the first year of this new benefit, CMS estimates approximately four times the average completion of new CMS-855O application by these three non-physician practitioner (NPP) types as this would require these NPPs to be enrolled in or opted-out of Medicare to certify and/or supervise such services. After the first year, CMS estimates approximately 65% additional NPs, CNS', and PAs to enroll or opt out solely to certify and/or supervise the need for home health services, and/or to furnish items and services under this new Medicare home health benefit.

The CMS-855O form is completed by the individuals in the general category of health diagnosing and treating practitioners. Respondent burden is calculated based on the following assumptions:

- Completion of the CMS-855O takes 0.5 hours for initial enrollments, changes of enrollment information, and reporting voluntary withdrawals of enrollment information from the Medicareprogram.
- Record keeping time is included in the total of 0.5 hours for completion of the CMS- 855O.

CMS is requesting approval of our revised burden estimates as follows:

<u>Completing the Initial Enrollment Application</u>

Based on the expansion of home health services under section 3708 of the CARES Act, we estimate a first-year burden of 3,000 hours (0.5 hour x (5,000 + 1,000)) at a cost of $295,560. The annual burden in Year 2 and in Year 3 is 500 hours (0.5 hour x 1,000) is $49,260. This results in a total burden of 4,000 hours at a cost of $394,080. When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 1,333 hours (4,000 hour/3) at a cost of $131,360 ($394,080/3).

CMS is requesting the addition of 6,000 respondents for the first year, and 1,000 additional respondents for years 2 and 3 to the currently approved burden for this collection, pursuant to section 3708 of the CARES Act.

Annual Burden Summary

Requirements	Respondents	Responses	Time (hours)	Cost ($)
Initial Enrollment Application	28,000	28,000	14,000	875,830
Changes of Enrollment Information No burden change.	11,200	11,200	5,600	350,299
Reporting a Voluntary Withdrawal No burden change.	56,000	56,000	14,000	1,266,589
New Burden CMS-5531-IFC – Initial Enrollment Application	**6000**	**6000**	**3000**	**295,560**
Initial Enrollment Application (Year 2)	**1,000**	**1,000**	**500**	**49,260**
Initial Enrollment Application (Year 3)	**1,000**	**1,000**	**500**	**49,260**
Existing Totals	95,200	95,200	33,600	2,492,718
New Burden CMS-5531-IFC	**8,000**	**8,000**	**4,000**	**394,080**
Cumulative Totals	**103,200**	**103,200**	**37,600**	**2,886,798**

13. Cost to Respondents (Capital)

There are no capital costs associated with this collection.

14. Cost to Federal Government

Medicare contractors currently finalize approximately 1.3 million provider/supplier enrollment applications a year. The cost to Medicare contractors is built into their Medicare contracts.

15. Changes in Burden/Program Changes

As previously explained, under section 3708 of the CARES Act, we are expanding § 424.507(b)(1) to allow NPs, CNSs, and PAs to certify the need for home health services. This will require the completion of the CMS-855O application.

The burden hour and cost changes are shown in the table below.

As demonstrated in the following table, the number of respondents associated with initial enrollment application requirements has increased by 8,000 respondents (from 28,000 to 36,000 NPPs). Therefore, the burden hours have increased. No revisions have been made to the Changes of Enrollment Information and Reporting of Voluntary Withdrawal requirements.

Requirements	Currently Approved	New Estimates	ICF Revision	Currently Approved	New Estimates	IFC Revision
	Respondents/Responses			Time (hours)		
(NEW) Initial Enrollment Application	**28,000**	**36,000**	**+8,000**	**14,000**	**18,000**	**+4,000**
Changes of Enrollment Information	11,200	11,200	0 (no change)	5,600	5,600	0 (no change)
Reporting a Voluntary Withdrawal	56,000	56,000	0 (no change)	14,000	14,000	0 (no change)
TOTAL	**95,200**	**103,200**	**+8,000**	**33,600**	**37,600**	**+4,000**

16. Publication/Tabulation

The results from this data collection will not be published.

17. Expiration Date

We display the expiration date in the upper right hand corner of the first page of the application.

18. Certification Statement

There are no exceptions to item 19 of OMB Form 83-1.