

SUPPORTING STATEMENT

REQUEST FOR CERTIFICATION IN THE MEDICARE AND/OR MEDICAID PROGRAM TO PROVIDE OUTPATIENT PHYSICAL THERAPY (OPT) AND/OR SPEECH PATHOLOGY SERVICES (OSP)- INITIAL AND EXTENSION SITE REQUESTS (CMS-381)

A. BACKGROUND

This is a request for revision of form CMS-381 which is approved for collection under OMB Control number (0938-0273). Form CMS-381 was developed to ensure that each OPT/OSP extension location at which OPT/OSP providers furnish services, must be reported by the providers to the State Survey Agencies (SAs).

In addition to rendering services on their already approved premises, OPT/OSP providers may also render services on the premises of other institutions (e.g., skilled nursing facilities) or on a premise owned/leased/rented by the OPT/OSP. If the OPT/OSP bills the Medicare program for these services and renders these services in an area within the institution set aside for rehabilitation care, these premises are considered extension locations of the OPT/OSP. However, a patient's home is not considered an extension location.

Extension locations are considered part of the OPT/OSP provider's primary location and are subject to the same approval policy as is applicable to the OPT/OSP primary site. In addition to meeting applicable sections of the conditions of participation for all outpatient physical therapy/speech pathology providers, these extension locations fall under the OPT/OSP provider agreement and are identified under the OPT/OSP provider number.

Form CMS-381 is completed when: (1) new OPT/OSP providers enter the Medicare program; (2) when existing OPT/OPS providers delete or add a service, or close or add an extension location; or, (3) when existing OPT/OSP providers are recertified by the State Survey Agency every 6 years.

Form CMS-381 is used by the State survey agencies and by the CMS Survey Operations Group to identify extension locations where services are furnished by providers of outpatient physical therapy and speech-language pathology services. These locations must be known to surveyors in order to ensure the appropriate monitoring of providers' compliance with the Federal requirements.

In 2022, CMS transitioned some of the certification processes to the Center for Program Integrity (CPI) and the Medicare Administrative Contractor (MAC) (see [Admin Info 22-02](#)). Prior to the transition, the CMS Survey Operations Group was involved in the processing of the extension location requests. As a result of the new processing instructions, CMS is now reconciling the Form CMS-381 with updates to the instructions. Additionally, CMS has revised the Form CMS-381 to incorporate the initial enrollment of OPT/OSPs which was previously completed on the Form CMS-

1856. CMS has combined the forms into one form in order to further align with the transitioned processes and streamline the requests from the provider community. This change will decrease the burden on both the provider community as well as CMS. Furthermore, this change will also allow for OPTs who wish to initially enroll in the Medicare program to submit an extension location request with the initial enrollment. The State Survey Agency or Accrediting Organization (for those OPTs requesting deemed status) will survey the extension location during the initial survey to verify compliance with the Medicare conditions.

B. JUSTIFICATION

1. Need and Legal Basis

In accordance with Title XVIII of the Social Security Act, Section 1861(p), the collection of this information is authorized by 42 CFR Part 485.701-485.729 pursuant to Sections 1864 and 1875 of the Social Security Act requiring that providers and suppliers of services to Medicare beneficiaries meet such requirements as the Secretary finds necessary to ensure the health and safety of individuals who are furnished such services. For Medicare purposes, certification is based on the State survey agency's reporting of a provider's or supplier's compliance or noncompliance with the health and safety requirements published in federal regulations. To determine compliance with these requirements, the Secretary has authorized CMS to contract with State Survey Agencies to conduct surveys of providers and suppliers.

Previously, the Form CMS-1856, *Request for Certification in the Medicare/Medicaid Program to Provide Outpatient Physical Therapy and/or Speech-Language Pathology*, was utilized as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare/Medicaid programs. This form initiated the process of obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy and/or speech-language pathology services. The form was used by the State Agencies (SAs) to enter the new prospective provider into the national surveyor database. The form is also used for recertification of the provider.

42 CFR 485.703 defines extension location as "a location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency." Collection of this information is used in conjunction with Conditions of Participation at 42 CFR §485.701 through §485.729 governing the operation of providers of outpatient physical therapy and speech-language pathology services. The provider uses form CMS-381 to report to the State survey agency extension locations that it has added since the date of last report. The

collection occurs annually.

The regulations at 42 CFR 485.703 have no restriction which require that an organization wishing to participate in the Medicare program to have a CMS-approved primary site prior to a request for an extension location. Prior to this revision, the provider community was required to submit a Form CMS-1856 for initial enrollment and recertification. If an OPT wished to add an extension location, it was required to submit the CMS-381 after initial approval of a primary site.

Additionally, in 2022, CMS transitioned certain certification activities to CPI and the MAC. Specifically, an organization wishing to participate in the Medicare program will continue to submit a CMS-855 enrollment application to the MAC. Once the enrollment application has been recommended by the MAC for approval to the State Survey Agency (SA) or a CMS-approved Accrediting Organization (AO), the SA or AO will conduct the survey and recommend approval to CPI and the MACs, who will assign the CMS Certification Number (CCN) and notify the OPT. For extension locations, the provider must also submit a CMS-855 to the MAC requesting the change.

By combining the previous Form CMS-1856 and the Form CMS-381, the burden to the provider community decreases as only one form is required to be submitted with the CMS-855 to the MAC. The combining of the two forms allows for more streamlining to the enrollment and certification process and will allow for OPTs to submit an initial request and extension location request at the same time.

2. Information Users

Form CMS-381 is used by the State survey agencies and by the CMS Survey Operations Group to identify extension locations where services are furnished by providers of outpatient physical therapy and speech-language pathology services. These extension locations must be known to the State surveyors in order to ensure the appropriate monitoring of providers' compliance with the Federal requirements.

3. Improved Information Technology

This form does not request anything other than identifying data for the OPT/OSP providers primary and extension sites and the types of services provided at these sites. OPT/OSP providers can complete form CMS-381 using a pdf form filler software program such as Adobe Acrobat Pro or hand write their responses on the form. OPT/OSP provider will send the revised Form CMS-381 to the MAC with the initial request for participation (e.g. CMS-855 application) and when the OPT is requesting a new extension location or closing an extension location.

4. Duplication

Form CMS-381 does not duplicate existing data collection. No forms exist that are similar or that collect this data.

5. Small Business

Form CMS-381 will affect large and small business OPT/OSP providers alike. However, the burden associated with the completion of the form CMS-381 is very minimal and would not place undue stress on small business OPT/OSP providers. Also, this data is not available from any other source.

6. Less Frequent Collection

Collection of this information coincides with the certification survey. If the information was collected less frequently than annually, it would result in surveys not being completed in projected timeframes and inefficient use of survey personnel.

7. Special Circumstances

No special circumstances exist for this information collection.

8. Federal Register and Outside Consultation

The 60-day Federal Register notice published on March 25, 2024 (89 FR 20658). There were no public comments received.

The 30-day Federal Register notice published on June 11, 2024 (89 FR 49178).

CMS discussed these form changes with stakeholders and CMS components prior to establishing the combined form.

9. Payments or Gifts

There are no payments/gifts to respondents.

10. Confidentiality

CMS does not assure confidentiality.

11. Sensitive Questions

There are no sensitive questions on this form.

12. Estimate of Burden (Hours and Wages)

The form CMS-381 is completed when: (1) new OPT/OSP providers enter the Medicare program; (2) when existing OPT/OSP providers delete or add a service, or close or add an extension location; or, (3) when existing OPT/OSP providers are recertified by the State Survey Agency every 6 years. The revised form CMS-381 will also be used when a new organization wishes to enroll as an OPT/OSP in the Medicare program.

- There are approximately 78 new OPT/OSP providers each year. The average was calculated based on the last four years of data (91 new in 2019; 94 in 2020; 79 in 2021; 48 in 2022).
- There are currently 1,976 active OPT/OSPs as of February 2023.
- We estimate that approximately 5% of the existing OPT/OSP providers would delete or add a service, or close or add an extension location each year. This equates to 98 OPT/OSP providers that would be required to complete the form CMS-381 due to programmatic changes.
 - $1,976 \text{ OPT/OPS providers} \times .05 = 99$
- OPT/OSP providers are surveyed by the State Survey Agency every 6 years. There are currently 1,976 existing OPT/OSP providers. This means that the State Survey Agency would survey approximately 329 OPT/OSP providers each year.
 - $1,976 \text{ OPT/OSP providers} \div 6 \text{ years} = 329$

Based on the above-stated information, we estimate that a total of 506 OPT/OPS provider would complete the form CMS-381 each year.

- $78 + 99 + 329 = 506$

We estimate that it would take the OPT/OPS providers approximately 30 minutes to complete form CMS-381. This increased time by 15 minutes from the previous iteration of the form reflects the changes to the form. We believe that the information required to respond to each question would be easily accessible in the OPT/OSP facility.

We estimate that the total annual time burden for the completion of all 506 form CMS-381's annually would be 253 hours.

- $506 \text{ form CMS-381 annually} \times 30 \text{ minutes per each form} = 15,180 \text{ minutes}$
- $15,180 \text{ minutes} \div 60 \text{ minutes per hour} = 253 \text{ hours}$

We believe that the person at the OPT/OPS facility that would complete the CMS-381 would be a Healthcare Support Staff . According to the U.S. Bureau of Labor

Statistics, the mean average hourly wage for Healthcare Support positions is \$32.04 (<https://www.bls.gov/oes/current/oes310000.htm>)

We estimate that the total cost burden associated with the completion of each form CMS-381 would be \$16.02.

- \$ 32.04per hour x 0.5 hour = \$16.02

We further estimate that the total annual cost burden across all CMS-381 forms would be \$ \$8,106.

- \$ 32.04per hour x 253hours annually = \$ 8,106

Summary of Time and Cost Burdens

Time Burden per each new CMS-381 Form:	0.5 hours
Annual Time Burden Across OPTs:	253 hours
Cost Burden per each CMS-381 form:	\$ 16.02
Annual Total Cost Across OPTs:	\$ 8,106

13. Capital Costs

There are no capital costs.

14. Federal Cost Estimates

While the form is electronic and there is no printing cost associated with the form, the CMS Survey and Operations Group (SOG) Locations and Center of Program Integrity (CPI) are responsible for the review of this form.

We estimate that it would take **30 minutes** of time by a CMS reviewer to review and send the form to the State Agency or Accrediting Organization for further processing of the OPT provider's request for initial certification and/or request for extension locations.

These costs were calculated using the annual salary of a GS-13, step 1 reviewer in the Washington D.C./Baltimore/Pennsylvania area, which is \$112,015 and which equates to an average hourly salary of \$53.67. The burden hours would be 253 (.5 hours X 506 forms). The total cost to the Federal Government would be \$13,579 (253 hours X 53.67).

15. Burden Changes/Program Changes

While the burden for this data collection appears to have increased from the previous collection, we note that as a result of this revision, form CMS-1856 will be discontinued for use. The form CMS-1856 was required for all prospective OPT providers to be completed for initial enrollment. Given the information above, 78 new OPT providers would have needed to complete the CMS-1856 form by the equivalent of a Healthcare Support Staff (Healthcare Support Occupations).

The support staff with a mean hourly wage of \$16.02 which is \$32.04, including fringe benefits, based on the Bureau of Labor Statistics National Occupational Employment and Wage Estimates (<https://www.bls.gov/oes/current/oes310000.htm>). Therefore, previously had a total annual cost would be \$624.78 for all new prospective OPT providers to complete this form upon initial enrollment.

Since CMS has combined content of form CMS-1856 with this new revised form CMS-381 has increased the time for completion by 15 minutes, however has omitted the annual cost of \$624.78.

The revised CMS-381 would be at an annual cost of \$8,106. If taking the saving of \$624.78, the cost would be \$3,415.22, which is a minor increase reflective of annual inflation and therefore could be considered a saving.

For the revised CMS-381, we have increased the time burden for this data collection from 111 hours to 253 hours. This is a 142 hour increase in the time burden. We have also increased the cost burden associated with this data collection from \$3,116.60 to \$8,106. This is as a result of the combined forms.

Total Cost Burden and Comparison

Description	New Time/Cost	Previous Time/Cost CMS-381	Previous Time/Cost CMS-1856	Change with combined	Justification
Time Burden per each new CMS-381 Form	0.5 hours	0.25 hours	0.25 hours	None	N/A
Annual Time Burden Across OPTs	253 hours	110.75 hours	49 hours	+93.25	More OPTs completing the new form annually

Description	New Time/Cost	Previous Time/Cost CMS-381	Previous Time/Cost CMS-1856	Change with combined	Justification
Cost Burden per each CMS-381 form	\$ 32.04	\$28.14	\$31.00	- 27.10	Hourly cost reduced as only one form is completed
Annual Total Cost Across OPTs	\$ 8,106.00	\$3,116.50	\$1,519.00	+3,470.50	More OPTs completing the new form annually

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS will display the expiration date on collection instrument.

18. Certification Statement

There are no exceptions to the certification statement.