

A. Background

This is a request for revision of form CMS-381 which is approved for collection under OMB Control number (0938-0273).

The CMS-381 form is currently required for initial certification, during the recertification surveys and when the OPT/OSLP requests any changes to its locations. CMS issued guidance consistent with this change via policy memorandum [QSO24-18-OPT](#).

CMS is implementing a program whereby CORF, RHC, OPT/OSLP providers and PXR suppliers may recertify every 6 years by self-attesting that they meet the CMS requirements instead of receiving a recertification survey by the State Survey Agencies (SAs). Because of this new program, we have changed the instructions to the CMS-381 form by deleting a reference to recertification surveys and replacing it with a reference to the “recertification attestation process.” (See page 2 of the instructions for the CMS-318 form).

After the start of the self-attestation program, the CMS-381 form will be completed when:

- (1) new OPT/OSLP providers enter the Medicare program (initial certification);
- (2) when existing OPT/OSLP providers delete or add a service, or close or add an extension location;
or
- (3) when existing OPT/OSLP providers are recertified by the State Survey Agency (SA) through survey or attestation every 6 years.

For deemed OPT/OSLP providers under a CMS-approved Accrediting Organization (AO), the CMS-381 will continue to be part of the reaccreditation surveys at least every 36 months.

The OPT/OSLP providers may render services on their already approved premises and the premises of other institutions (e.g., skilled nursing facilities) or on a premise owned/leased/rented by the OPT/OSLP. If the OPT/OSLP 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/OSLP. However, a patient’s home is not considered an extension location.

Extension locations are considered part of the OPT/OSLP provider’s primary location and are subject to the same approval policy as is applicable to the OPT/OSLP 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/OSLP provider agreement and are identified under the OPT/OSLP provider number.

Form CMS-381 is used by the SA, AO, 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 to ensure the appropriate monitoring of providers’ compliance with the Federal requirements.

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.

The CMS-381 form supports the initial certification process of a new OPT/OSLP consistent with the process of obtaining a decision as to whether the conditions of participation are met. The form is used by the State Agencies (SAs) to enter the new provider into the national surveyor database. The form is also used for recertification of the provider as well as when the provider makes any changes to its primary or extension locations. As defined in 42 CFR 485.703, an extension location is "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." The regulations at 42 CFR 485.703 have no restrictions 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.

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.

In short, the provider will use the CMS-381 upon 1) initial certification; 2) reporting any changes to operations (as needed); and 3) when existing OPT/OSLP providers are recertified by the SA through survey or attestation every 6 years. Deemed OPT/OSLPs will continue to report at least every 36 months upon survey from a CMS-approved AO.

2. Information Users

Form CMS-381 is used by the SAs, AOs and by the CMS Survey Operations Group to identify information about the OPT/OSLPs operation, including its extension locations where services are furnished by providers of outpatient physical therapy and speech-language pathology services. The Form ensures 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/OSLP providers, including primary and extension sites and the types of services provided at these sites. OPT/OSLP 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/OSLP 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. The OPT/OSLP will also complete the form upon a recertification at least every six years for SAs and at least every 36 months if deemed under a CMS AO.

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/OSLP 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/SLP 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 XXXX.

The 30-day Federal Register notice published on XXXX.

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)

a. Time and Cost Burdens Related to the Completion of the CMS-381 Forms By OPT/OSLP Providers for All Purposes.

The form CMS-381 is completed when the following circumstances occur:

- (1) When new OPT/OSLP providers enter the Medicare program;
- (2) When Existing OPT/OSLP providers:
 - a. delete a service,
 - b. add a service, or
 - c. close an extension location; or
 - d. add an extension location; or
- (3) When existing OPT/OSLP providers are recertified by the State Survey Agency through survey or attestation every 6 years or for deemed OPT/OSLPs at least every 36 months.

There are approximately 44 new OPT/OSLP providers each year. The average was calculated based on the last four years of data (62 new in FY 2023; 41 new in FY 2024, 28 new in FY 2025). There are currently 1,923 active OPT/OSLP providers as of November 2025.

We estimate that approximately 5% of or 96 existing OPT/OSLP providers would delete or add a service, or close or add an extension location each year. This equates to 96 OPT/OSLP providers that would be required to complete the form CMS-381 due to programmatic changes.

- $1,923 \text{ OPT/OSLP providers} \times .05 = 96$

Supporting Statement for Medicare Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSLP)
Provider Certification Requirements (CMS-381)

OPT/OSLP providers are recertified by the State Survey Agency every 6 years via survey or self-attestation. There are currently 1,923 existing OPT/OSLP providers. Of the total active OPTs/SLPs, 247 are deemed through a CMS approved AO.

This means that the State Survey Agency would recertify approximately 279 non-deemed OPT/OSLP providers each year. Meaning, the OPT/OSLP would complete the Form CMS-381 along with their self-attestation statement.

- $1,676 \text{ non-deemed OPT/OSLP providers} \div 6 \text{ years} = 279$

For deemed OPTs/SLPs, this means that the AO would recertify approximately 82 non-deemed OPT/OSLP providers each year. Meaning, the OPT/OSLP would complete the Form CMS-381 at least every 36 months upon reaccreditation survey.

- $247 \text{ deemed OPT/OSLP providers} \div 3 \text{ years} = 82$

Based on the above-stated information, we estimate that a total of 457 OPT/OSLP providers would complete the form CMS-381 each year.

- $96 \text{ (5\% updates)} + 279 \text{ (non-deemed)} + 82 \text{ (deemed)} = 457$

We estimate that it would take the OPT/OSLP providers approximately 30 minutes to complete Form CMS-381. There is no increased time 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/OSLP facility.

We estimate that the total annual time burden for the completion of all 457 form CMS-381 forms annually would be 229 hours.

- $457 \text{ form CMS-381 annually} \times 30 \text{ minutes per each form} = 13,719 \text{ minutes}$
- $13,719 \text{ minutes} \div 60 \text{ minutes per hour} = 229 \text{ hours}$

We believe that the person at the OPT/OSLP 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.

- $\$32.04 \text{ per hour} \times 0.5 \text{ hour} = \16.02

We further estimate that the total annual cost burden across all CMS-381 forms would be \$7,337.

- $\$32.04 \text{ per hour} \times 229 \text{ hours annually} = \$7,337$

b. Summary of Time and Cost Burdens Associated With The CMS-381 Form.

Task	Number of Annual Responses	Time Per Response	Annual Hour Burden Across All Providers	Cost Per Each Response	Annual Cost Burden Across all Providers
Completion of the CMS-381 form for addition or deletion of a service; or add or close an extension	96	0.5 hours	48 hours	\$16.02	\$1,538
Completion of CMS-381 forms for recertification of non-deemed OPT/OSLP providers	279	0.5 hours	140 hours	\$16.02	\$4,485
Completion of CMS-381 forms for recertification of non-deemed OPT/OSLP providers	82	0.5 hours	41 hours	\$16.02	\$1,314
TOTAL TIME & COST BURDENS RELATED TO THE CMS-381 FORM	457 responses	0.5 hours	229 hours	\$16.02	\$7,337

13. Capital Costs

There are no capital costs.

14. Federal Cost Estimates

CMS pays all states \$397 million per year to conduct surveys of all providers. This amount is appropriated by Congress each year and is intended to cover the costs associated with surveying providers, including completing/reviewing the CMS 381 form.

15. Burden Changes/Program Changes

The table below compares the time and cost burden in the current PRA package to that which was approved in the previous PRA package, and shows what, if any, change in burden has occurred.

Supporting Statement for Medicare Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSLP)
Provider Certification Requirements (CMS-381)

Description	Amount Requested In Current PRA Package	Amount Approved in Previous PRA Package	Change in Burden
Number of new OPT/OSLP providers that complete the CMS-381 form when submitting their initial application for participation in the Medicare program	44 respondents	78 respondents	-34 respondents
Number of annual respondents who use the CMS-381 form to delete or add a service, or close or add an extension location	96 respondents	99 respondents	-3 respondents
Number of annual respondents <i>deemed</i> respondents (accredited by an AO) who would submit the CMS-381 form at the time of recertification	82 respondents	0 respondents	+82 respondents
Number of <i>non-deemed</i> annual respondents who submit the CMS-381 form at the time of recertification	279 respondents	329 respondents	-50 respondents
Annual time burden related to the CMS-381 form across all OPT/OSLP providers	229 hours	253 hours	-24 hours
Annual cost burden related to the CMS-381 form across all OPT/OSLP providers	\$7,337	\$8,106	-\$769
Total Annual Number of Respondents	501 respondents	506 respondents	-5 respondents
Annual Time Burden Across All OPT/OSLPs	229 hours	253 hours	-24 hours
Annual Total Cost Across OPT/OSLPs	\$7,337	\$ 8,106	-\$769

As the above table shows, the number of respondents has decreased by 5, the total annual time burden has decreased by 24 hours, and the total annual cost burden has decreased by \$769.

These changes are minimal and can be attributed to the decrease in the number of respondents.

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.

C. Collections Of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.