Supporting Statement Part A
Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services
(OMB#: 0938-1368; CMS-10711)

BACKGROUND

In the Calendar Year (CY) 2020 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Final rule (CMS-1717-FC), CMS established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Social Security Act (the Act), which allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services.[1]" The regulations governing the prior authorization process are located in Subpart I of 42 CFR Part 419, specifically at §§ 419.80 – 419.89. In finalizing the process, we initially identified first five service categories for which prior authorization was required: (i) blepharoplasty, (ii) botulinum toxin injections, (iii) panniculectomy, (iv) rhinoplasty, and (iv) vein ablation. As part of the CY 2021 OPPS/ASC Final Rule (CMS -1736-FC), CMS added two more service categories to the prior authorization process: (i) cervical fusion with disc removal and (ii) implanted spinal neurostimulators. Through the CY 2023 OPPS/ASC Final Rule (CMS-1772-FC), CMS added an eighth service category to the list of OPD services requiring prior authorization: facet joint interventions.

The final rules stated that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital OPD services requiring prior authorization to CMS or its contractor. The prior authorization request must be submitted before the service is rendered to the beneficiary and before the claim is submitted. The request should include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Claims submitted for services that require prior authorization that have not received a provisional affirmation will be denied unless the provider is exempt. The rules also stated that, even when a provisional affirmation has been received, a claim for services may be denied based upon either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information was not available at the time the prior authorization request is received.

While most prior authorization reviews will be decided within 10 days, providers have an opportunity to submit prior authorization requests for expedited review when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function.

If the request meets the applicable Medicare coverage, coding, and payment rules, CMS or its contractor will issue a provisional affirmation to the requesting provider. If the request does not meet the applicable Medicare coverage, coding, and payment rules, CMS or its contractor will issue a non-affirmation decision to the requesting provider. OPD prior authorization requests that are non-affirmed will not be considered an initial determination and, therefore, will not be appealable; however, the provider may resubmit a prior authorization request with any applicable additional relevant documentation provided the claim has not yet been submitted and denied. This

[1] See 84 FR 61142 issued November 12, 2019, and Correction Notice 85 FR 224 issued January 3, 2020.

includes the resubmission of requests for expedited reviews.

If a claim is submitted for the selected services without a provisional affirmation, it will be denied. CMS intends to deny claims associated with or related to a selected service that requires PA as a condition of payment when a provider either did not submit a prior authorization request, received non-affirmation decisions, and/or has denied claims.

Also, CMS may elect to exempt a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules, and that this exemption would remain in effect until CMS elects to withdraw the exemption. CMS may elect to exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during an annual assessment. In addition, CMS may withdraw an exemption if evidence becomes available based on a review of claims that such claims do not meet Medicare's billing, coding, or payment guidelines. Moreover, CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' website.

JUSTIFICATION

1. Need and Legal Basis

Section 1833(t)(2)(F) of the Act authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services. CMS believes the increases in volume associated with certain covered OPD services are unnecessary because the data show that the volume of utilization of these OPD service categories far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries. Therefore, CMS is using the authority under section 1833(t)(2)(F) of the Act to require prior authorization for certain covered OPD services as a condition of Medicare payment. The reviews conducted under the program help to reduce unnecessary utilization and payments for these services.

2. Information Users and Use

The information required for the prior authorization request includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Trained clinical reviewers at the Medicare Administrative Contractors (MACs) receive and review the information required for this collection. Review of that documentation is used to determine if the requested services are medically necessary and meet Medicare requirements in order to help reduce unnecessary increases for these services.

3. Improved Information Techniques

Some of this collection of information could involve the use of electronic or other forms of information technology at the discretion of the requester. Where available, requesters may submit their requests and/or other documentation through electronic means. CMS offers electronic

submission of medical documentation (esMD)[2], and the MACs provide electronic portals for providers to submit their documentation.

4. Duplication and Similar Information

The CMS as a whole does not collect the information in any existing format. With the exception of basic identifying information such as beneficiary name, address, etc., there is no standard form or location where this information can be gathered.

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those hospital outpatient departments that qualify as small businesses bill Medicare for the services that require prior authorization. Providers, regardless of size, must maintain and submit the necessary documentation to support their claims.

6. Less Frequent Collections

Under prior authorization, a request is submitted for a service prior to the service being rendered and the claim being submitted. As the reviews under this program help reduce unnecessary increases in utilization for these services, less frequent collection of information would be imprudent and undermine that goal. However, CMS has a process for less frequent collections for those providers who demonstrate compliance with Medicare rules after an initial assessment period. CMS may elect to exempt a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules by achieving a prior authorization provisional affirmation threshold of at least 90 percent during an annual assessment. An exemption may be withdrawn if a provider's rate of non-payable claims submitted becomes higher than 10 percent during an annual assessment.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice

The 60-day notice was published on XX, XXXX.

No additional outside consultation was sought.

9. Payments or Gifts to respondents

No payments or gifts will be given to respondents to encourage their response to any request for information under this control number.

[2] http://www.cms.gov/esMD

10. Confidentiality

Medicare contractors have procedures in place to ensure the protection of the health information provided. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows for the disclosure of health records for payment purposes. The MACs will safeguard all protected health information collected in accordance with HIPAA and Privacy Act standards as applicable.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimate

The information collection requirements associated with prior authorization requests for these covered outpatient department services are the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted for processing. The burden associated with this process is the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation.

CMS expects that this information would generally be maintained by providers and that the average time for office clerical activities associated with this task would be 30 minutes, which is equivalent to that for normal prepayment or postpayment medical review. CMS anticipates that most prior authorization requests would be sent by means other than mail. However, CMS estimates a cost of $5 per request for mailing medical records. CMS estimates that annually, at a minimum, there would be 127,397 initial requests mailed during a year. In addition, CMS estimates there would be 41,806 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $846,015 (169,203 mailed requests x $5). We estimate that an additional 3 hours would be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS) and based on the 2022 median rate for Miscellaneous Healthcare Support Occupations[3]. Based on the BLS information, CMS estimates an average clerical hourly rate of $18.53 with a loaded rate of $37.06. The prior authorization program does not create any new documentation or administrative requirements. Instead, it would just require the currently needed documents to be submitted earlier in the claim process. Therefore, CMS continues to use the clerical rate since we do not believe that clinical staff would need to spend more time completing the documentation than needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. CMS estimates that the total annual number of submissions would be 564,010 (394,808 submissions through fax or electronic means + 169,203 mailed submissions). The annual burden hours, allotted across all providers, would be

[3] https://www.bls.gov/oes/current/oes_nat.htm

316,412 hours (.5 hours x 564,010 submissions plus 3 hours x 11,469 providers for education). The annual burden cost would be $12,572,244 (316,412 hours x $37.06 plus $846,015 for mailing costs). For the total burden and associated costs for eight service categories, CMS estimates the annual burden to be 316,412 hours and $12,572,244 million. The ICR approved under OMB control number 0938-1368 will be submitted to OMB for approval of this extension.

Annual Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests- Initial Submissions	297,261	0.5	148,630	$5,508,239
Fax and Electronic Submitted Requests- Resubmissions	97,546	0.5	48,773	$1,807,535
Mailed in Requests- Initial Submissions	127,397	0.5	63,699	$2,360,674
Mailed in Requests- Resubmissions	41,806	0.5	20,903	$774,658
Mailing Costs	169,203	5		$846,015
Provider Demonstration- Education	11,469	3	34,407	$1,275,123
Total			316,412	$12,572,244

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to Federal Government

The average annual cost associated with performing reviews for eight service categories is $25.3 million.

15. Changes in Burden

There is a one-hour change in the burden hours, from 316,413 to 316,412, however this is likely due to rounding up in the previous year calculations. The burden costs have increased from $11,561,950 to $12,572,244 due to an increase in the clerical hourly rate.

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected due to this information being confidential. CMS periodically publish summary level information on the demonstration such as the number of prior authorization requests submitted, number of requests affirmed, number of requests non-affirmed, etc.

17. Expiration Date

There are no instruments for this PRA package. The expiration date can be found on the OMB website here.