

Supporting Statement Part A
Prior Authorization Demonstration for Certain Ambulatory Surgical Center (ASC)
Services
CMS-10884 (OMB Control Number: 0938-NEW)

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) intends to use the Section 402(a)(1)(J) demonstration authority to implement a 5-year demonstration project for the prior authorization of certain services provided in Ambulatory Surgical Centers (ASC) for a limited number of demonstration states¹. The service categories targeted by the demonstration are blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation procedures. The Calendar Year 2020 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Final Rule (CMS -1717-FC) established a nationwide prior authorization process and requirements for certain hospital outpatient department (OPD) services, which are blepharoplasty, botulinum toxin injections, rhinoplasty, panniculectomy, and vein ablation. These targeted services can potentially be provided as cosmetic procedures, rather than medically necessary procedures, resulting in improper or fraudulent payments.

Data from 2019 to 2021 shows these services have experienced significant increases in utilization in the ASC setting. There is considerable concern about unnecessary utilization of these services in the OPD moving to the ASC as the OPD prior authorization program continues and services are scrutinized in the OPD setting. Implementing prior authorization requirements in the ASC setting would help prevent that shift in unnecessary utilization and potential fraud, waste, and abuse. CMS selected the targeted services for inclusion in this demonstration, based upon problematic events, data, trends, and potential billing behavior impacts of the OPD Prior Authorization Program which requires prior authorization as a condition of payment for these services.

The proposed demonstration will help ensure eligible treating providers in ASCs are only performing the targeted services for beneficiaries in accordance with Medicare guidelines, by requiring them to submit a prior authorization request and obtain a provisional affirmation before providing a service or be subject to prepayment review and potentially be denied payment if services are deemed ineligible. We see the demonstration as another step in our overall approach to enhancing our ability to separate problematic providers from those providers proactively working to comply with our coverage and documentation requirements, thus helping prevent fraud, waste, and abuse.

TARGETING FRAUD and IMPROPER PAYMENTS

In addition to improving methods for the investigation and prosecution of fraud, we believe a demonstration may facilitate a reduction in the overall improper payment rate for the targeted services by requiring providers to provide documentation prior to providing a service or be subject to prepayment review. We identified the targeted services for the demonstration by reviewing payment data for trends that could indicate a potential increase in fraudulent billing behavior from some providers in ASCs. We also considered known healthcare fraud schemes, state and federal healthcare fraud indictments, and

¹ The states included in this demonstration are California, Florida, Texas, Arizona, Ohio, Tennessee, Pennsylvania, Maryland, Georgia, and New York.

behavior impacts from the OPD Prior Authorization Program.

Spending for the selected services in the OPD setting was over \$79.7 million before implementing prior authorization and then dropped by 28% to approximately \$57.3 million. This represents a savings of over \$22.4 million and we expect similar results in the ASC setting. Additionally, there have been several recent law enforcement actions for each of the selected services. These cases demonstrate the need for greater oversight to help prevent fraudulent behavior. Implementing prior authorization requirements for these same services in the ASC setting would help prevent and reverse that shift in potentially fraudulent behavior.

Demonstration Design

CMS proposes requiring prior authorization requests for ASC services prior to furnishing those services. The proposed demonstration does not change Medicare benefit or coverage requirements, nor does it create new documentation requirements. Instead, regularly required documentation must be submitted earlier in the process. The prior authorization process will test methods to improve the investigation and prosecution of fraud and will also help ensure that payments for ambulatory surgical services meet Medicare requirements prior to providers submitting claims for payment, thereby helping to prevent improper payments, including payments representing potential fraud, waste, or abuse.

This demonstration will include ASC providers that submit claims with place of service 24 (Ambulatory Surgical Center), perform certain ASC services in the 10-demonstration states, and submit claims to Medicare fee-for-service. If a provider does not obtain prior authorization and the service is furnished, the claim will be subject to prepayment review. Prepayment review means that the Medicare Administrative Contractor (MAC) will make a claim determination before claim payment, using the standard Medicare prepayment review process.

Providers that forgo prior authorization could incur financial losses on services that are provided and found ineligible for payment during prepayment review and would be unable to legally pass these costs onto their patients, unless the patient signed an Advanced Beneficiary Notice of Non-coverage in advance. The ASC provider will submit the prior authorization requests to their local MAC jurisdiction. The MAC will review the information submitted and issue the decision (provisional affirmation, non-affirmation, or partial affirmation) to the provider.

A provisional affirmation is a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules. Consistent with existing CMS prior authorization program processes, a claim with a provisional affirmation may nevertheless be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or based on information not available at the time the MAC receives the prior authorization request. A non-affirmation prior authorization decision is a preliminary finding that, if a future claim is submitted to Medicare for the requested service, it does not meet Medicare's coverage, coding, and payment requirements. A provisional partial affirmation prior authorization decision means that one or more service(s) on the prior authorization request received a provisional affirmation decision and one or more service(s) received a non-affirmation decision. While most

prior authorization reviews will be decided within 7-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. A decision will be rendered within the expedited review timeframe of 2 business days for requests that are deemed valid for expedited review.

As is standard with our prior authorization processes, a unique tracking number (UTN) will be assigned to each prior authorization request. The MAC will send decision letters with the UTN to the requester using the method the prior authorization request was received postmarked within 7-days for standard review and 2 business days for expedited review. Providers must place the UTN received on the claim submitted.

CMS will implement an exemption process for those providers who continually show compliance with meeting coverage requirements, and those providers will not need to request prior authorization for the selected services. This exemption will 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% 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 ASC prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' website.

CMS will implement the demonstration in one phase, and it will last 5-years. CMS does not anticipate beginning the demonstration earlier than 2025. In this demonstration, the MACs will be utilizing a similar review process for these services as they do for the OPD prior authorization program. The documentation requirements that MACs already have for the services in the OPD program, including local coverage determinations (LCDs), are applicable to these ASC services as well. Since MACs already have a foundation for reviewing prior authorization requests for these services, we believe that phasing in this demonstration is not necessary, and it can begin in all the demonstration states simultaneously.

JUSTIFICATION

1. Need and Legal Basis

Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." Pursuant to this authority, the CMS seeks to develop and implement a revised Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring in ambulatory surgical centers providing services to Medicare beneficiaries.

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 MACs will receive and review the information required for this collection. Review of that documentation will be used to determine if the requested services are medically necessary and meet Medicare requirements. The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors will request the information from ASC providers submitting claims for payment from the Medicare program in advance to determine appropriate payment.

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

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 ambulatory surgical centers 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 and fraud, 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% during an annual assessment. An exemption may be withdrawn if a provider's rate of non-payable claims submitted becomes higher than 10% during an annual assessment.

² <http://www.cms.gov/esMD>

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice

A 60-day Federal Register notice published on February 16, 2024 (89 FR 12350). Responses to comments received are included in Attachment A.

No 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.

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 ASC services is 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. If a provider does not obtain prior authorization and the service is furnished, the claim will be subject to prepayment review. Prepayment review means that the MAC will make a claim determination before claim payment, using the standard Medicare prepayment review process. 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 will generally be maintained by providers within the normal

course of business and that this information will be readily available. CMS estimates that the average time for office clerical activities associated with this task is 30-minutes, which is equivalent to normal prepayment or postpayment medical review.

Based on calendar year 2021 claims data from the demonstration states for the services selected (75,744 claims), CMS estimates that 95% will be submitted for prior authorization for a total of 71,959 initial prior authorization requests annually. CMS estimates that 25% of initial submissions will be resubmitted, 25% of first resubmissions will be resubmitted a second time, and 25% of second resubmissions will be submitted for a third time for a total of 23,620 resubmissions annually. Overall, this equates to 95,579 total prior authorization requests to be submitted annually.

CMS expects 97% of requests to be submitted by fax or electronically and 3% to be submitted by mail, based on submission data from the OPD prior authorization program. Based on these percentages CMS estimates there would be 92,712 total prior authorization requests submitted by fax or electronically and 2,867 submitted by mail annually. CMS estimates a cost of \$5 per request for mailing medical records, for a total estimated mailing cost of \$14,337 (2,867 total mailed requests x \$5 per request).

CMS also estimates that an additional 3 hours would be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, CMS was unable to quantify that burden.

The average labor costs (including 100% fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS 2023Fo rate for Miscellaneous Healthcare Support Occupations for Outpatient Care Centers, CMS estimated a median hourly rate of \$22.28 with a loaded rate of \$40.81.³ This prior authorization demonstration does not create any new documents or administrative requirements. Instead, it only requires the currently needed documents to be submitted earlier in the claim process. Therefore, the estimate used the clerical rate as CMS does not feel that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the demonstration. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. Based on the total estimated number of submissions annually (95,579; 92,712 submissions through fax or electronic means + 2,867 mailed submissions), CMS estimates that the total burden annually, allotted across all providers, would be 59,904 hours (.5 hours x 95,579 submissions plus 3 hours x 4,038 providers for education). The annual burden cost is \$2,459,019 (59,904 hours x \$40.81 plus \$14,337 for mailing costs).

³ <https://www.bls.gov/oes/tables.htm>

Annual (12-Month) Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain ASC Services- Five Service Categories

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	69,800	0.5	34,900	\$1,424,269
Fax and Electronic Submitted Requests- Resubmissions	22,911	0.5	11,456	\$467,519
Mailed in Requests- Initial Submissions	2,159	0.5	1,079	\$44,034
Mailed in Requests- Resubmissions	709	0.5	354	\$14,443
Mailing Costs	2,867	5		\$14,337
Provider Demonstration- Education	4,038	3	12,114	\$494,372
Total			59,904	\$2,459,019

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to Federal Government

The estimated yearly costs associated with operating this demonstration is approximately \$4.6 million. The cost estimate is based on review of the anticipated number of prior authorization requests, both initial and resubmissions, that would be submitted, the number of claims skipping prior authorization that would be medically reviewed through the prepayment medical record review process, the number of potential appeals, and the cost of outreach and education to providers practicing in the demonstration states.

15. Changes in Burden

This is a new collection of information.

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected due to this information being confidential. CMS will 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.⁴

17. Expiration Date

Each instrument displays the expiration date and OMB control number on the first page, top right corner.

⁴ <https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives> - Downloads Section - “Prior Authorization and Pre-Claim Review Program Statistics”