Supporting Statement Part A
Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services
CMS-10711

BACKGROUND

The Center Program Integrity (CPI) developed a new prior authorization process and requirements for Hospital Outpatient Department (OPD) Services. This process is under the authority of §1833(t)(2)(F) which authorizes the Secretary 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 services far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries. CPI established a List of Outpatient Department Services Requiring Prior Authorization and is focusing on five groups of OPD services – Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, Vein Ablation, and their related services.

The final rule states that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital outpatient department services requiring prior authorization to CMS that meets the requirements; namely, that the prior authorization request includes all 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 rendered to the beneficiary and before the claim is submitted. Claims submitted for services that require prior authorization that have not received a provisional affirmation of coverage from CMS or its contractors will be denied, unless the provider is exempt. Moreover, the rule states 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 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 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. Any claims associated with or related to a selected service for which a claim denial is issued will be denied as well, since these services would be unnecessary if the selected service had not been provided. The associated claims will be denied whether a non-affirmation was received for a selected service or the provider did not request a prior authorization request.

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 a semiannual assessment. In addition, CMS may withdraw an exemption if evidence becomes available based on a review of claims that the provider has begun to submit claims that are not payable based on Medicare's billing, coding or payment requirements. 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' webpage.

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 described above are unnecessary because the data show that the volume of utilization of these services 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 will 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) 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 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)[i] 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 will 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 a semiannual assessment. An exemption may be withdrawn if a provider's rate of non-payable claims submitted becomes higher than 10 percent during a biannual assessment.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice

The CY 2020 Outpatient Prospective Payment System and Ambulatory Surgical Center final rule published on November 12, 2019 (84 FR 61142).

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.

10. Confidentiality

The MACs will safeguard all protected health information collected in accordance with HIPAA and Privacy Act standards as applicable.

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.

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 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. 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 to 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. Due to a July start date, the first year of the prior authorization program will include only six months. Based on calendar year 2018 data, CMS estimates that for those first six months at a minimum there will be 15,191 initial requests mailed during a year. In addition, CMS estimates there will be 4,987 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost is estimated to be $100,890 (20,178 mailed requests x $5 per request). Based on calendar year 2018 data, CMS estimates that annually at a minimum there will be 30,381 initial requests mailed during a year. In addition, CMS estimates there will be 9,971 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost is estimated to be $201,762 (40,352 mailed requests x $5 per request). CMS also estimates that an additional 3 hours would be required for attending educational meetings and reviewing training documents. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, CMS is unable to quantify that burden.

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. Based on the Bureau of Labor Statistics information, CMS estimates an average hourly rate of $16.63 with a loaded rate of $33.26. The prior authorization program does not create any new documents or administrative requirements. Instead, it just requires the currently needed documents to be submitted earlier in the claim process. Therefore, the estimate uses 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. Therefore, CMS estimates that the total burden for the first year (six months), allotted across all providers, would be 50,826 hours (.5 hours x 67,260 submissions plus 3 hours x 5,732 providers for education). The burden cost for the first year (6 months) is $1,791,363 (50,826 hours x $33.26 plus $100,890 for mailing costs). In addition, CMS estimates that the total annual burden hours, allotted across all providers, would be 84,450 hours (.5 hours x 134,508 submissions plus 3 hours x 5,732 providers for education). The annual burden cost would be $3,010,569 (84,450 hours x $33.26 plus $201,762 for mailing costs). For the total burden and associated costs, we estimate the annualized burden to be 73,242 hours and $2,604,167 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden.

Year 1 (6 Month) 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	35,446	0.5	17,723	$589,465
Fax and Electronic Submitted Requests-Resubmissions	11,636	0.5	5,818	$193,508
Mailed in Requests-Initial Submissions	15,191	0.5	7,596	$252,628
Mailed in Requests-Resubmissions	4,987	0.5	2,493	$82,932
Mailing Costs	20,178	5		$100,890
Provider Demonstration-Education	5,732	3	17,196	$571,939
Total			50,826	$1,791,363

Annual (12 Month) 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	70,890	0.5	35,445	$1,178,896
Fax and Electronic Submitted Requests-Resubmissions	23,266	0.5	11,633	$386,912
Mailed in Requests-Initial Submissions	30,381	0.5	15,191	$505,241
Mailed in Requests-Resubmissions	9,971	0.5	4,986	$165,819
Mailing Costs	40,352	5		$201,762
Provider Demonstration-Education	5,732	3	17,196	$571,939
Total			84,450	$3,010,569

13. Capital Costs

There are no capital cost associated with this collection.

14. Costs to Federal Government

The CMS estimates that the costs associated with performing reviews would be approximately $3.9 million for the first year which includes six months and $7.4 million annually for a full year. The average annual cost estimate is $6.2 million.

15. Changes in Burden

The annualized burden hours have decreased from 108,044 stated in the proposed rule to 73,242 hours in the final rule. The annualized burden cost has decreased from $3,851,504 stated in the proposed rule to $2,604,167 in the final rule. In the proposed rule, the hour/cost burden was calculated using historical claims data, which included all claims lines billed on the claim and inaccurately inflated the burden. For the final rule, CMS used historical data to calculate at the revenue line level, which allowed for a more specific estimate as it ensures that only the claim lines that included the selected codes are included in the estimate. Additionally, based on the comments received on our proposal, CMS included two additional HCPCS codes to the list of codes that require prior authorization. Coupled with the change in methodology in our claim line calculations, these changes resulted in a net decrease in burden hours and costs.

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected.

17. Expiration Date

There are no instruments for this PRA package. The expiration date can be found at: https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-initiatives/prior-authorization-certain-hospital-outpatient-department-opd-services.

[i] www.cms.gov/esMD