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

BACKGROUND

The Center Program Integrity (CPI) is developing a new prior authorization process and requirements for Hospital Outpatient Department (OPD) Services. This process will be 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 will establish a List of Outpatient Department Services Requiring Prior Authorization and will focus on five groups of OPD services – Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, Vein Ablation, and their related services.

The CMS is proposing 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 would be denied, unless the provider is exempt. Moreover, CMS is proposing 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.

The CMS also is proposing that 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 would 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 would issue a non-affirmation decision to the requesting provider. OPD prior authorization requests that are non-affirmed would not be considered an initial determination and, therefore, would 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 would include 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 also is proposing that 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 would be denied whether a non-affirmation was received for a selected service or the provider did not request a prior authorization request.

Also, we are proposing that 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 would exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. In addition, CMS might 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 is proposing that it 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 proposing to use 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 small businesses bill Medicare in a manner that triggers review. CMS does not have the number of small business that will be impacted. This collection will only impact small business and all respondents in that they must maintain and submit the necessary medical 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 the that goal. However, CMS has proposed 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 proposed rule published on August 9, 2019 (84 FR 39398) .

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 would be the required documentation submitted by providers. CMS is proposing that a 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 furnished to the beneficiary and before the claim is submitted for processing. The burden associated with this proposed 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 2017 data, CMS estimates that for those first six months at a minimum there will be 23,309 initial requests mailed during a year. In addition, CMS estimates there will be 7,650 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost is estimated to be $154,799 (30,960 mailed requests x $5 per request). Based on calendar year 2017 data, CMS estimates that annually at a minimum there will be 46,618 initial requests mailed during a year. In addition, CMS estimates there will be 15,299 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost is estimated to be $309,584 (61,917 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. Therefore, CMS estimates that the total burden for the first year (six months), allotted across all providers, would be 73,647 hours (.5 hours x 103,199 submissions plus 3 hours x 7,349 providers for education). The burden cost for the first year (6 months) is $2,604,281 (73,647 hours x $33.26 plus $154,799 for mailing costs). In addition, CMS estimates that the total annual burden hours, allotted across all providers, would be 125,242 hours (.5 hours x 206,389 submissions plus 3 hours x 7,349 providers for education). The annual burden cost would be $4,475,116 (125,242 hours x $33.26 plus $309,584 for mailing costs). For the total burden and associated costs, we estimate the annualized burden to be 108,044 hours and $3,851,504 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 Proposed 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-Submissions	54,389	0.5	27,194	$904,482
Fax and Electronic Submitted Requests-Resubmissions	17,851	0.5	8,925	$296,857
Mailed in Requests-Submissions	23,309	0.5	11,655	$ 387,635
Mailed in Requests-Resubmissions	7,650	0.5	3,825	$127,224
Mailing Costs-Total Submissions	30,960	$5		$154,799

Provider Demonstration-Education	Providers 7,349	3	22,047	$733,283
Total			73,647	$2,604,281

Annual (12 Month) Estimated Burden and Cost Table for the Proposed 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-Submissions	108,775	0.5	54,388	$1,808,930
Fax and Electronic Submitted Requests-Resubmissions	35,697	0.5	17,849	$593,644
Mailed in Requests-Submissions	46,618	0.5	23,309	$775,256
Mailed in Requests-Resubmissions	15,299	0.5	7,650	$254,419
Mailing Costs-Total Submissions	61,917	$5		$309,584
Provider Demonstration-Education	Providers 7,349	3	22,047	$733,283
Total			125,242	$4,475,116

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 $5.8 million for the first year which includes six months and $11.6 million annually for a full year. The average annual cost estimate is $9.7 million.

15. Changes in Burden

This is a new collection.

16. Publication or Tabulation

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

17. Expiration Date

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

[i] www.cms.gov/esMD