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

## BACKGROUND

In the CY 2020 OPPS/ASC final rule, the Centers for Medicare & Medicaid Services (CMS) established a prior authorization process for certain Hospital Outpatient Department (OPD) services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. See 84 FR 61142 (November 12, 2019).[1] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89. The regulations also listed the initial five groups of OPD services – Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, Vein Ablation, and their related services for which CMS determined that the increases in volume are unnecessary because the data shows 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.

The final rule 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. The request should show that the service 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. The rule also 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

[1] See also Correction Notice issued January 3, 2020 (85 FR 224).

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.

As part of the CY 2021 OPPS/ASC final rule, CMS added two new service categories to the list of OPD services requiring prior authorization at § 419.83(a): Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, beginning for dates of service on or after July 1, 2021. Data analysis for these codes showed a claim volume increase above what would be expected based on the growth rate for OPD services. The process associated with prior authorization for these new covered outpatient department services will be the same as the initial five services.

## 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 both the initial five services and the two new 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. In addition, CMS is using the authority under paragraph (b) of 42 CFR 419.83 to add two additional services. 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)[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 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 semiannual assessment.

7. Special Circumstances

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

There are no special circumstances.

8. Federal Register Notice

The CY 2021 Outpatient Prospective Payment System and Ambulatory Surgical Center final rule published on December 29, 2020 (85 FR 85866).

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 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.

**Initial Five Service Categories (Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, and Vein Ablation):**
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 estimated that for those first six months at a minimum there would be 15,191 initial requests mailed during a year. In addition, CMS estimated there would be 4,987 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost was estimated to be $100,890 (20,178 mailed requests x $5 per request). Based on calendar year 2018 data, CMS estimated that annually at a minimum there would be 30,381 initial requests mailed during a year. In addition, CMS estimated there would be 9,971 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost was estimated to be $201,762 (40,352 mailed requests x $5 per request). CMS also estimated 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 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 estimated 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 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. Therefore, CMS estimated 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) was $1,791,363 (50,826 hours x $33.26 plus $100,890 for mailing costs). In addition, CMS estimated 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 estimated the annualized burden to be 73,242 hours and $2,604,167 million. The annualized burden was 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 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 Education | 5,732 | 3 | 17,196 | $571,939 |

| Total | | | 84,450 | $3,010,569 |
|---|---|---|---|---|

**Two New Service Categories (Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators):**

As with the initial five service categories, the burden associated with the prior authorization process for the two new categories, Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, would be 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. As stated above, we expect 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 post payment medical review. We again anticipate that most prior authorization requests would be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the July 1, 2021 start date, the first year of the prior authorization for the two new service categories would only include 6 months. Based on CY 2018 data, we estimate that for those first 6 months at a minimum there would be 6,808 initial requests mailed during the year. In addition, we estimate there would be 2,234 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $45,210 (9,042 mailed requests x $5). Based on CY 2018 data for the two new service categories, we estimate that annually at a minimum there would be 13,615 initial requests mailed during a year. In addition, we estimate there would be 4,468 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $90,415 (18,083 mailed requests x $5). We also estimate that an additional 3 hours would be required for attending educational meetings and reviewing training documents.

As noted above, 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). Based on the BLS information, we estimate an average clerical hourly rate of $16.63 with a loaded rate of $33.26. The prior authorization program for these two service categories would also 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, the estimate continues to use the clerical rate since we do not believe that clinical staff would need to spend more time on completing the documentation than would be 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. We estimate that the total number of submissions for the first year (6 months) would be 30,140 (21,098 submissions through fax or electronic means + 9,042 mailed submissions). Therefore, we estimate that the total burden for the first year (6 months) for the two new service categories, allotted across all providers, would be 24,820 hours (.5 hours x 30,140 submissions plus 3 hours x 3,250 providers for education). The burden cost for the first year (6 months) is $870,723 (24,820 hours x $33.26 plus $45,210 for mailing costs). In addition, we estimate that the total annual number of submissions would be 60,277 (42,194 submissions through fax or electronic means + 18,083 mailed submissions). The annual burden hours for the two new service categories, allotted across all providers, would be 39,889 hours (.5 hours x 60,277 submissions plus 3 hours x 3,250 providers for education). The annual burden cost would be $1,417,107 (39,889 hours x $33.26 plus $90,416 for mailing costs). For the total burden and associated costs for the two new service categories, we estimate the annualized burden to be 34,866 hours and $1,234,979 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- Two New 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 | 15,884 | 0.5 | 7,942 | $264,158 |
| Fax and Electronic Submitted Requests- Resubmissions | 5,214 | 0.5 | 2,607 | $86,702 |
| Mailed in Requests- Initial Submissions | 6,808 | 0.5 | 3,404 | $113,210 |
| Mailed in Requests- Resubmissions | 2,234 | 0.5 | 1,117 | $37,158 |
| Mailing Costs | 9,042 | 5 | | $45,210 |
| Provider Education | 3,250 | 3 | 9,750 | $324,285 |
| Total | | | 24,820 | $870,723 |

Annual (12 Month) Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services- Two New 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 | 31,768 | 0.5 | 15,884 | $528,304 |

| | | | | |
|---|---|---|---|---|
| Fax and Electronic Submitted Requests-Resubmissions | 10,426 | 0.5 | 5,213 | $173,381 |
| Mailed in Requests-Initial Submissions | 13,615 | 0.5 | 6,807 | $226,416 |
| Mailed in Requests-Resubmissions | 4,468 | 0.5 | 2,234 | $74,306 |
| Mailing Costs | 18,083 | 5 | | $90,416 |
| Provider Education | 3,250 | 3 | 9,750 | $324,285 |
| Total | | | 39,889 | $1,417,107 |

The total annual burden hours for this package is 108,108 (73,242 hours + 34,866 hours).

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 for the initial five service categories 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. The estimate for the costs associated with performing reviews for the two new service categories would be approximately $2 million for the first year which includes six months and $3.6 million annually for a full year. The average annual cost estimate is $3.1 million. The total annual cost is $9.3 million ($6.2 million + $3.1 million).

15. Changes in Burden

The annualize burden hours and costs have increased due to the addition of the two new service categories. The annualized burden hours have increased from 73,242 hours stated in the CY 2020 OPPS/ASC final rule to 108,108 with the addition of the two new service categories. The annualized burden cost has increased from $ $2,604,167 for the initial five service categories to $3,839,146 with the inclusion of the two new service categories.

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 on the PRA website here.