Supporting Statement – Part A

Regulation 6050-P: Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items (CMS-10524; OMB-0938-1293)

General Instructions

A. *Background*

The CMS has had longstanding concerns about the improper payments related to DMEPOS items. The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2017 Medicare FFS program improper payment rate for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) was 44.6%, accounting for over $3.7 billion in projected improper payments. The CMS has implemented several initiatives in recent years to address these issues, such as the DMEPOS Competitive Bidding Program, as well as heightened screening of suppliers, as authorized by the Affordable Care Act.

In addition to those actions, CMS is continuing the use of prior authorization in fee for service Medicare. Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before an item is rendered to a Medicare patient and before a claim is submitted for payment. Prior authorization helps make sure that applicable Medicare coverage, payment, and coding rules are met before item(s) are rendered. Prior to furnishing the item to the beneficiary and prior to submitting the claim forprocessing, a requester must submit a prior authorization request that includes evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the DMEPOS item likely meets Medicare's coverage, coding, and payment requirements. Suppliers who receive a non-affirmative decision have unlimited resubmission opportunities.

The prior authorization demonstration for power mobility devices (PMDs) began in 2012 in 7 states with high incidences of fraudulent claims and improper payments. In 2014, the demonstration was expanded to 12 additional states. The demonstration was extended in July 2015 and ended on August 31, 2018 for all 19 states.

Based on claims processed as of March 30, 2017, monthly expenditures for the PMD codes

included in the demonstration decreased from $12 million in September 2012 to $2.2 million in September 2016 in the original seven demonstration states, $10 million in September 2012 to $1.7 million in September 2016 in the 12 additional expansion states, and $10 million in September 2012 to $2.2 million in September 2016 in the non-demonstration states.

In addition, on December 30, 2015, CMS promulgated final rule (80 FR 81674) titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," which establishes a Master List of certain DMEPOS that the Secretary determined, on the basis of prior payment experience, are frequently subject to unnecessary utilization and by establishing a prior authorization process for these items. On December 21, 2016 CMS announced the selection of two items of durable medical equipment to be subject to required prior authorization in 4 states beginning on March 20, 2017. In July 2017 CMS began requiring prior authorization nationwide for those items. CMS added the addition of 31 Healthcare Common Procedure Coding System (HCPCS) codes to the Required Prior Authorization List nationwide on September 1, 2018.

B. Justification

1. Need and Legal Basis

Section 1834(a)(15) of the Social Security Act (the Act) authorizes the Secretary to develop and periodically update a list of DMEPOS that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Pursuant to this authority, CMS published final rule 6050-F titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies."

The Secretary's authority to request information supporting the prior authorization request was created by Section 1833(e) which states, in part, "no payment shall be made to any provider... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider."

The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2017 Medicare FFS program improper payment rate for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) was 44.6%, accounting for over $3.7 billion in projected improper payments.

Payment made when the item does not meet Medicare policy is an improper payment. It is important to keep in mind that all fraud is considered to be improper payment, but not all improper payments are fraud. Prior authorization is a tool utilized by private sector health care payers to prevent unnecessary utilization. CMS's prior authorization demonstration for power mobility devices has shown that prior authorization effectively prevents unnecessary

utilization for Medicare as well. Consequently, we believe prior authorization for items on the Required Prior Authorization List, a subset of the Master List, will prevent or reduce improper payments for those items as well.

2. Information Users

Information generated by the requirements of 1834(a)(5) is requested of the entity submitting the prior authorization request and sent to Medicare contractors in advance of the claim submission for processing. No new information or documentation requirements are created by this rule. Rather, the point at which the information is requested is earlier in the process.

3. Use of Information Technology

Automated, electronic, or other forms of information technology may be used at the discretion of the prior authorization submitter. CMS and its contractors are required to be compliant with all Electronic Health Record transmissions.
CMS offers electronic submission of medical documents (esMD) to many providers and suppliers who wish to explore this alternative for sending in medical documents. Additional information on esMD can be found at www.cms.gov/esMD.

4. Duplication and Similar Information

CMS published final rule 6050-F that requires prior authorization under the Medicare fee-for-service program for the list of items on the Required Prior Authorization List, a subset of the Master List. There are no new or duplicative documentation requirements created by this regulation.

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those small businesses order and bill Medicare for DMEPOS items on the Required Prior Authorization List. The retention and submission of required information by suppliers and physicians are routine business practices. We do 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 work with providers to obtain the necessary medical documentation to support their claims.

6. Less Frequent Collection

Since this information is only collected when potential program vulnerability exists, less frequent collections of this information would be imprudent. CMS and its agents continue to refine their tools for identifying improper billing practices.

7. Special Circumstances

More often than quarterly - This information is collected on an as-needed basis. That is, information is requested only when an entity submits a request for prior authorization for an eligible item. CMS published final rule 6050-F, which created a prior authorization program for eligible DMEPOS items. The program is continuous. Improper Medicare payments caused by overutilization may increase if not mitigated by the requirement for prior authorization.

More than original and two copies - There is no requirement to submit more than 1 copy of the requested documentation.

Retain records more than three years - This estimate does not impose any new or additional record retention requirements beyond those requirements currently in place. Providers and suppliers are reminded that Medicare claims can be reopened for review at any time where fraud or improper payment is suspected, or within 4 years of an initial determination for good cause or within 1 year for any reason.

Conjunction with a statistical survey - This information collection is not associated with a statistical survey.

Use of statistical data classification - This collection does not require a statistical data classification.

Pledge of confidentiality - This collection does not require a pledge of confidentiality.

Confidential Information - The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows for the disclosure of health records for payment purposes. Medicare contractors are required to have procedures in place to ensure the protection of the health information provided.

8. Federal Register/Outside Consultation

The 60-day Federal Notice was published in the Federal Register on 10/23/2018.

No comments were received

The 30-day Federal Notice was published in the Federal Register on XXX.

No additional outside consultation was sought.

9. Payments/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 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 Estimates (Hours & Wages)

The burden associated with this demonstration is the time and effort necessary for the submitter to locate and obtain the supporting documentation for prior authorization request and to forward the materials to the MAC for review. CMS expects that this information will generally be maintained by providers as a normal course of business and that this information will be readily available. The documentation submitted must support medical necessity for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare benefit eligibility, and meet all other applicable Medicare statutory and regulatory requirements.

The process of submitting a prior authorization request for an expedited review is the same as for a standard review. The unit cost for CMS performing an expedited review is the same as for a standard review; however it is possible that a larger workforce requires to perform reviews within the established timeframes if many expedited requests are received. We believe most items on the Master List are not generally used in emergent situations, so we expect the use of expedited reviews to be relatively rare.

Providers have a number of methods to submit documentation quickly including fax, electronic portals, and esMD, so provider burden should not be affected by the method of submission. CMS anticipates clerical staff will collect the information from the medical record and prepare it to be submitted for review. CMS estimates that the average time for office clerical activities associated with this task to be 30

minutes. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics. Based on Bureau of Labor Statistics here all occupations/Miscellaneous Health care support occupations, information we estimate an average hourly rate of $16.00 with a loaded rate of $32.00.

We based the estimated number of responses for Year One on the number of beneficiaries who were billed for one of the following items on the Master List in 2017: power mobility devices, support surfaces, negative pressure wound therapy device, or respiratory assist device, which was 276,985. We assume that 95% of suppliers will submit an initial prior authorization request for these items (263,135.75). We assume that 20% of this subset (52,627) will receive a non-affirmative decision and submit a resubmitted request, 10% of this subset (10,525) will receive a non-affirmative decision and submit a second resubmitted request, and another 10% of this subset (2,105) will receive a non-affirmative decision and submit a third resubmitted request. The total number of submissions for year one is 321,551, which includes the total number of initial prior authorization request submissions plus resubmission(s), as described above.

Suppliers may use electronic submission of medical documentation (esMD) as an alternative to mail or fax for sending in medical documents. Additional information on esMD can be found here. The MACs may also offer electronic portals for suppliers to submit their documentation. The total esMD utilization rate was 21.5%, with 1% mail, and 77.5% fax submissions. We estimate the cost of mailing medical records to be $5 per request for prior authorization. The total mailing cost for year one is estimated to be $16,075. The total estimated burden for year one was $5,160,896.76, which includes the time associated with submitting the prior authorization requests plus the cost of mailing.

Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items – Year One

Activity	Responses Per Year (number of prior authorization requests submitted)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
DMEPOS - Fax and Electronic Submitted Requests	Initial Submissions - 260,504	0.5	130,252	$4,168,064
	Resubmissions - 57,832	0.5	28,916	$925,312

DMEPOS - Mail Requests	Initial Submissions – 2,631	0.5	1,315.68	$42,101.76
	Resubmissions - 584	0.5	292	$9,344
Mail Costs	Total Submissions - 3,215	$5	n/a	$16,075
DMEPOS Total	321,551	n/a	160,775.68	$5,160,896.76

We assume that in year two and three we will begin prior authorization on additional items from the Master List, such as lower limb prosthetics. Using the same assumptions as above regarding initial submissions and resubmission, we estimate the total burden in Years Two and Three to be $10,738,698.

Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items – Year Two & Three

Activity	Responses Per Year (number of prior authorization requests)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs per year using loaded rate
DMEPOS - Fax and Electronic Submitted Requests	Submissions - 264,956	0.5	132,478	$4,239,296
	Resubmissions - 66,239	0.5	33,119	$1,059,808
DMEPOS - Mail Requests	Submissions - 2,676	0.5	1,338	$42,816
	Resubmissions - 669	0.5	334.5	$10,704
Mail Costs	Total Submissions - 3,345	$5	n/a	$16,725
DMEPOS Total per Year	334,540	n/a	167,270	$5,369,349

Total Response per Years Two and Three	669,080	n/a	334,540	$10,738,698

Annual Total Burden

Year One	Year Two	Year Three
$5,160,896.76	$5,369,349	$5,369,349

13. Capital Costs

There are no capital costs associated with this collection. Providers and suppliers maintain these medical records and routinely submit them to various healthcare entities.

14. Cost to Federal Government

Consistent with Sections 1833(e), 1842(a)(2)(B), and 1862(a)(1) of the Social Security Act, the Centers for Medicare & Medicaid Services (CMS) is required to protect the Medicare Trust Fund against inappropriate payments and take corrective actions. To meet this requirement CMS contracts with Part A and Part B Medicare Administrative Contractors (A/B MACs), Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and others to perform analysis of fee-for-service (FFS) claim data to identify atypical billing patterns and perform medical review. These entities are referred to Medicare Contractors. Medical review is the collection of information and clinical review of medical records by Medicare Contractors to ensure that payment is made only for services that meet all Medicare coverage, coding, and medical necessity requirements. MACs also review the prior authorization requests when making prior authorization determinations.

The cost for DME MAC to review the number of prior authorization requests as described above, as well as CMS program oversight is $ 16,795,746 for year one and $17,458,975 per year for years two and three. CMS estimates that the costs associated with performing review and CMS oversight for DMEPOS under the revised demonstration would be approximately $51,713,696 over the 3-year demonstration period.

15. Changes to Burden

This is a revised collection. The overall average burden has increased from $1,575,000 to
$5,299,865. The previous FY 2015 estimate was completed as a proposed rule and the Master List had not been finalized. The average burden estimate was 157,500 cases per year in years one through three. It was projected that the average cost per year in years one through three was $1,575,000. CMS began prior authorization as a condition of payment in December 2016. At the conclusion of the Prior Authorization Demonstration for Power Mobility Devices (PMDs), CMS added the majority of those codes to the Required Prior Authorization List. These items were included under a separate information collection approval – OMB # 0938-1169. The FY 2019 President's Budget included an administrative proposal for CMS to expand prior authorization for DMEPOS and we expect to continue adding additional DMEPOS items to the Required Prior Authorization List in the coming years. Actual experience with the Prior Authorization process for Certain DMEPOS items, coupled with the scheduled end of the Prior Authorization Demonstration for PMDs, and our expectation that we will continue adding items to the Required Prior Authorization List result in an increased estimated burden under this collection. Our estimates are based on the number of beneficiaries who were billed for certain items on the Master List in 2017. Theaverage burden estimate is 330,210 cases per year in years one through three. The average projected cost per year in years one through three is $5,299,865.

16. Publication/Tabulation Dates

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

17. Expiration Date

    There is no collection data instrument used in the collection of this information. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date.

18. Certification Statement
    There are no exceptions to the certification statements.