Supporting Statement – Part A

Regulation 6050-P: Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items Supporting Statement For Paperwork Reduction Act Submissions

A. Background

A revision is being made to §414.234 to require, as a condition for payment, a provisional prior authorization decision for certain items of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). A claim submitted for processing the certain DMEPOS item with a provisional affirmative prior authorization will be paid as long as all other requirements are met. A claim submitted for processing with a non-affirmative decision or without a decision will be denied.

Subsequent to codification of section 414.234(c), a new condition of payment for items on a Master List of DMEPOS items frequently subject to unnecessary utilization is created. The new condition of payment is that a prior authorization request be submitted for select items on the Master List prior to the submission of a claim. The proposed rule also creates the Master List.

Presence of an item(s) on the Master List does not automatically result in that item being subject to prior authorization. In order to balance provider burden and our need to protect the Trust Funds, we propose to initially implement prior authorization for a subset of items on the Master List. This subset of items will be called the Required Prior Authorization List. The proposed rule does not create the Required Prior Authorization List. We propose that we inform the public of the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation.

For purposes of this proposed rule, we are defining unnecessary utilization as "the furnishing of items or services that do not comply with one or more of Medicare's clinical documentation, coverage, payment and coding rules, as applicable." In addition, we are defining items frequently subject to unnecessary utilization and thus meeting the Master List inclusion criteria as those identified by evaluation of past payment experience. Specifically, and for the purpose of this proposed rule, Master List inclusion criteria are DMEPOS items that are:

- subject to high incidence of fraud, improper payments or unnecessary utilization as described in 2007 or later GAO or OIG reports, **or**
- reported in the appendix of the 2011 or later CERT report listing DMEPOS items with the highest improper payments, **and**
- priced with an average purchase fee of $1,000 or greater or an average rental fee schedule of $100 or greater and is listed on the DMEPOS fee schedule.

This proposed rule would not change documentation requirements specified in policy or who originates the documentation. Rather, required information to support Medicare provisional prior authorization determination is provided earlier in the process, before the item is delivered. This would ensure that all relevant clinical and/or medical documentation requirements are met before the item is delivered to the beneficiary and before the claim is submitted for payment. A prior

authorization request would include evidence that the request for payment complies with all Medicare clinical documentation, coverage, payment and coding rules.

B. Justification

1 . Legal Basis

Section 1834(a)(15) of 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. 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."

2. Need

In 2012, the total utilization for all items listed in the Master List was nearly $1.3 billion. 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. A recent CMS demonstration pilot 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 unnecessary utilization of those items.

3. 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.

4. 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. There are signature requirements, and at this time CMS does not accept electronic signatures.

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.

5. Duplication of Efforts

If enacted, the rule would require 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.

Currently there is CMS's Prior Authorization of Power Mobility Device (PMD) Demonstration. Under this proposed rule, PMD are excluded since there are prior authorization requirement under the demonstration. However, PMDs may be subject to prior authorization under this rule when the current demonstration is completed. This regulation does not affect the current Prior Authorization of PMD Demonstration. There are no new or duplicative documentation requirements created by the proposed 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.

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. The rule, if enacted, creates a prior authorization program for eligible DMEPOS items. The program is continuous. Improper Medicare payments may increase if not mitigated by the requirement for prior authorization created by this proposed rule.

Response within 30 days – The prior authorization requests are self-paced. That is, supporting documentation is required for each request for payment of DMEPOS items subject to the prior authorization requirement.

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 Privacy Rule allows for the disclosure of health records for payment purposes. Medicare contractors have procedures in place to assure the protection of the health information provided.

8. Federal Register/Outside Consultation

The notice of proposed rulemaking (CMS-6050-P) served as the 60-day Federal Register notice (79 FR 30511-30531).

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.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

Given the funding uncertainty, it is not possible to specify the number of items on the Required List in advance. Similarly, it is not possible to specify the resulting numbers of affected claims and medical reviews in advance. Consequently, CMS is proposing a range of estimates to capture various possible funding allocations. For the purpose of this prior authorization package we will make our estimations for cost and burden based on our high estimate of affected claims.

With significant funding, the high estimated affected claims in years two and three will be 100,000. In year one, we expect to do less claims because we will be conducting education and other activities to ramp up the program. We believe it is reasonable to expect that in year one the high estimate of affected claims will be 10 percent of the estimated high number of affected claims in years two and three. Therefore our first year high estimate of potentially affected claims is 10,000. This number would need to be adjusted to account for resubmissions which could be as high as 22,500 cases in the first year if unlimited resubmissions are allowed for the prior authorization request and 225,000 cases in years two and three. We are using the term case to refer to initial and resubmitted requests. The average burden estimate is 157,500 cases per year in years one through three.

We estimate that the per-case burden associated with this type of review is equivalent to that for submitting documentation for prepayment reviews (that is 30 minutes), initial submissions, and expedited requests and resubmissions. The total estimated time burden for the first year is 11,250 hours and the total estimated time burden per year for years two and three is 112,500 hours.

We estimate that the average time associated with office clerical activities relating to submission of the prior authorization request and the required documentation is 30 minutes. Based on Bureau of Labor Statistics information, we estimate an average hourly rate of $17.86 with a loaded rate of $35.36. This equates to a cost of $397,800 for the first year based on the 22,500 cases. The total estimated cost per year for years two and three is $3, 978,000. The average annual cost would be $2,784,600 in years one through three based on 157,500 average cases (years 1-3 averaged). This impact is allocated across providers and suppliers nationwide.

We also estimate the cost of mailing medical records to be $5 per request for prior authorization. We now offer electronic submission of medical documentation (esMD) to providers and suppliers who wish to use a less expensive alternative for sending in medical documents. Additional information on esMD can be found at www.cms.gov/esMD. In instances when the supplier must first obtain the medical records from a health care provider, we estimate that the mailing costs are doubled, as records are transferred from provider to supplier, and then CMS or its contractors. We estimate that there are 22,500 cases for which the mailing costs are doubled in the first year. In sum, we estimate the costs are $225,000 for the first year. The total estimated cost per year for years two and three is $2,250,000. We project that the average estimate cost per year in years one through three is $1,575,000.

We believe that the requirements expressed in this proposed rule meet the utility and clarity standards. We welcome comment on this assumption and on ways to minimize the burden on affected parties.

Summary Table: Year 1 Burden Estimate & Cost

	Claims Affected	**Time Per Response (minutes)**	**Total Time (hour)**	**Year 1**
Submitting a Prior Authorization Request	22,500	30	11,250	$397,800
Mailing medical records	22,500			$225,000
Total Cost				$622,800

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

CMS estimates that costs associated with prior authorization is $1,125,000 million in year one and $11,250,000 in years two and three. The average cost over the three year OMB approval period is $7,875,000

15. Changes to Burden

This is a request to collect the same required information just earlier in the process before the claim is submitted.

16. Publication/Tabulation Dates

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

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statements.