Supporting Statement – Part A

Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items
Supporting Statement For Paperwork Reduction Act Submissions (CMS-10524)

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.

The Master List includes items that meet the following criteria:

++ Appear on the DMEPOS Fee Schedule list.

++ Meet either of the following criteria:

--- Identified in a General Accountability Office (GAO) or Department of Health and Human Services Office of Inspector General (OIG) report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.

--- Listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program's Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report Durable Medical Equipment (DME) Report's Service Specific Overpayment Rate Appendix.

Presence of an item(s) on the Master List does not automatically result in that item being subject to prior authorization. This subset of items is called the Required Prior Authorization List. The rule does not specify the item(s) that are included on the Required Prior Authorization List. We will inform the public of the item(s) selected for inclusion on the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation.

For purposes of this final 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 final 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 (adjusted annually for inflation).

This final rule would not change documentation requirements specified in policy or who originates the documentation. However, we believe it will initially increase the time burden associated with collecting and submitting said documentation. Required information to support a 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.

A. 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 2014, the total utilization for all items listed in the Master List was nearly $1.6 billion[1]. 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. A recent CMS demonstration pilot for power mobility devices may have led to a decrease in spending on such devices[2]. Consequently, we believe prior authorization for items on the Required Prior Authorization List, a subset of the Master List, will reduce unnecessary utilization of those items.

3. Information Users

Information generated by the requirements of 1834(a)(5) is sent to Medicare contractors in advance of the claim submission for processing. No new information or documentation requirements are created by this rule however more information will be reviewed by Medicare contractors than before.

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1 CY 2014 Medicare Claims Utilization.

2 http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/PADemo.html

4. Use of Information Technology

Many providers and suppliers elect to submit medical documents electronically. CMS currently offers electronic submission of medical documents (esMD) to many providers and suppliers who wish to explore this alternative for sending in medical documents. During this process, a pdf version of the medical documents is submitted to the review contractor. Medical documents containing signatures that are submitted using esMD, are accepted. Additional information on the process of using esMD as an alternative for sending in medical documents can be found at www.cms.gov/esMD

CMS notes that automated, electronic, or other forms of information technology including paper and fax may be used at the discretion of the prior authorization submitter. At this time, CMS does not have the capability to collect and store digital certificates that are necessary to authenticate electronic signature and thus cannot accept electronic signatures. Providers and suppliers who choose to submit medical documents via electronic means, other than esMD, will need to take the extra step to authenticate signatures usually through the submission of a paper medical record with the signature.

We are aware that there are Health Insurance Portability and Accountability Act (HIPAA) compliance standards specific to electronic transmission of prior authorization. This standard is often referred to as the electronic data interchange (EDI) 278 standard. We expect to have the ability to process electronic 278 standard transmissions and will notify the public when electronic 278 transmissions can be accepted.

CMS notes that other means of electronic submission of medical documents may be available in the future. Any other means would be voluntary to the provider and supplier and the provider and supplier communities would be given advance notice of their availability.

5. Duplication of Efforts

This final rule 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. Currently, CMS is conducting a 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.[3] This regulation does not affect the current Prior Authorization of PMD Demonstration.

There are no new or duplicative documentation requirements created by this rule. Prior to finalization of this rule, suppliers participating in the Medicare program are expected to maintain documentation that supports the medical necessity of and coverage criteria for the DMEPOS item for which a prior authorization and payment are sought. Medicare Administrative Contractors (MACs) are also already authorized to request this information to help make payment determination. Generally, MACs do not make this request for 100% of DMEPOS claims. This rule will require that for items on the Required Prior Authorization

3 http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/PADemo.html

List, the supplier must submit the associated documentation for the item on the Required Prior Authorization List for each beneficiary being furnished the item.

6. 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 of required information by suppliers and physicians are routine business practices.

7. 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 to minimize burden CMS will examine items before placing them on the Required Prior Authorization List to ensure that the burden of providing requested information is outweighed by the benefit of reduced improper billing.

8. 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 for select items created by this proposed rule.

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.

9. Federal Register/Outside Consultation

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

10. 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.

11. Confidentiality

Medicare contractors have the duty to safeguard all protected health information collected under applicable security and privacy authorities.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

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 fewer 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 derive our primary estimate (see Table 1) by averaging the low and high estimate of potential claims affected. Based on the 2014 CERT data, there were over 200,000 Medicare payments made for the top 14 Master List DMEPOS items with the highest average improper payment dollars per line. If we avoid 100 percent of improper payments for the top 14 Master List DMEPOS items with the highest improper payment dollars per line, we realize a moderate gain on investment. Subjecting 14 items to prior authorization results in moderate programmatic activity, thus we used 253,750 as our primary estimate of affected claims for years 8 through 10 in our projections (CYs 2023 through 2025 (see Table 6)). We believe the primary estimates accounts for Medicare growth as well as the potential variability in ranking the highest improper payment rates of Master List DMEPOS items which may result in higher than 200,000 claim counts.

We provide the preceding discussion to explain how we arrived at the estimated number of potential claims affected. However, we note that other factors may contribute to the number of claims ultimately affected. For example, future policies, regulations or response to stakeholder needs may be factored into the Master List item selection(s) and consequently impact the number of claims ultimately affected.

Table 1 lists our estimated range of potentially affected claims.

TABLE 1: RANGE OF ESTIMATES OF POTENTIALLY AFFECTED CLAIMS

	NUMBER OF POTENTIALLY AFFECTED CLAIMS									
ESTIMATE	**CY 2016**	**CY 2017**	**CY 2018**	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**	**CY 2025**

Low	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500
Primary	8,750	53,750	53,750	128,750	128,750	128,750	128,750	253,750	253,750	253,750
High	10,000	100,000	100,000	250,000	250,000	250,000	250,000	500,000	500,000	500,000

To account for the possibility of unlimited resubmissions, we multiplied the low, primary, and high estimates of potentially affected claims in Table 1 by 2.25. We selected 2.25 as the multiplier based on preliminary analysis of resubmitted prior authorization requests in the CMS Prior Authorization of PMD Demonstration. We divided the total number of resubmissions by the total number of initial submissions and arrived at an average of 2.25. Once we multiplied the low, primary, and high estimates of potentially affected claims by 2.25, the value no longer reflects estimated individual affected claims. Rather, the value represents the estimated number of potential cases (potential claims plus resubmission(s) of associated prior authorization requests).

We note that it is a long standing expectation that supportive documentation be kept on file by affected providers/suppliers prior to furnishing a DMEPOS item. While it cannot be considered a usual and customary business practice as defined in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that the burden associated with maintaining the documentation represents a negligible increase above what is currently required for compliance with the base medical review information collection requirements approved under OMB control number 0938-0969. We also recognize that there will be an associated cost to the affected providers/suppliers when requiring full compliance with this expectation. This associated cost is incurred with the unlimited resubmission of prior authorization requests that this rule provides and the costs associated with documentation collection and submission during the prior authorization resubmission process. We believe this cost is justified in the case of unlimited resubmissions as the process affords the supplier more than one opportunity to receive a provisional affirmative prior authorization determination that ultimately could result in claim payment. In addition, the resubmission process allows for supplier education about the documentation requirements. We anticipate that as the supplier becomes more familiar with those requirements, the amount of resubmissions would decrease over time for that particular item or service as would the associated costs of documentation collection and submission. We further note, that by allowing an unlimited number of resubmissions, we ultimately reduce supplier burden as we expect that a fewer number of appeals will be pursued. We believe that the resubmission process would provide the supplier with an increased opportunity for claims to be paid; however, no data exists to validate this assertion so it is not assumed in the associated burden calculations.

Table 2 provides low, primary, and high estimates of potentially affected cases (claims and resubmissions of associated prior authorization requests). The average of the high estimate of potentially affected cases in years 1 through 3 is 157,500 ((22,500+225,000+225,000)/ 3) cases per year for the first 3 years.

TABLE 2: RANGE OF POTENTIALLY AFFECTED CASES (POTENTIAL CLAIMS AND RESUBMISSIONS OF ASSOCIATED PRIOR AUTHORIZATION REQUESTS)

	NUMBER OF POTENTIALLY AFFECTED CLAIMS									
ESTIMATE	**CY 2016**	**CY 2017**	**CY 2018**	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**	**CY 2025**
Low	16,875	16,875	16,875	16,875	16,875	16,875	16,875	16,875	16,875	16,875
Primary	19,688	120,938	120,938	289,688	289,688	289,688	289,688	570,938	570,938	570,938

High	22,500	225,000	225,000	562,500	562,500	562,500	562,500	1,125,000	1,125,000	1,125,000

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request is equivalent to that of submitting documentation and clerical activities associated for prepayment review, which is 0.5 hours per submission. We apply this time burden estimate to initial submissions, resubmissions, and expedited requests (that is, affected cases). The total high estimated burden for the first year is 11,250 hours (22,500 X 0.5 hours) and the total high estimated burden per year for years 2 and 3 is 112,500 hours (225,000 X 0.5 hours). Table 3 lists the low, primary, and high estimated time burden associated with potentially affected cases.

TABLE 3: RANGE ESTIMATE OF INFORMATION COLLECTION TIME BURDEN IN HOURS

ESTIMATE	NUMBER OF HOURS									
	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025
Low	8,437.50	8,437.50	8,437.50	8,437.50	8,437.50	8,437.50	8,437.50	8,437.50	8,437.50	8,437.50
Primary	9,843.75	60,468.75	60,468.75	144,843.75	144,843.75	144,843.75	144,843.75	285,468.75	285,468.75	285,468.75
High	11,250.00	112,500.00	112,500.00	281,250.00	281,250.00	281,250.00	281,250.00	562,500.00	562,500.00	562,500.00

Then, we multiply the time burden estimate to an average loaded hourly rate of $35.36 (mean hourly rate of $18.13 + fringe benefits) for the Medical Record and Health Information Technician classification [4] to equate the burden in dollars. The high time burden for the first year is 11,250 hours and multiplied by the hourly rate of $35.36, we arrive at a high cost estimate of $397,800. Using the same approach, the total estimated high cost per year for years 2 and 3 is $3,978,000. The average of the high estimate annual cost for years 1 through 3 is $2.8 million. Table 4, lists the range estimate of PRA burden in dollars. This impact is allocated across providers and suppliers nationwide.

TABLE 4: RANGE ESTIMATE OF INFORMATION COLLECTION BURDEN IN DOLLARS

ESTIMATE	PRA BURDEN (in dollars)									
	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025
Low	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350
Primary	348,075	2,138,175	2,138,175	5,121,675	5,121,675	5,121,675	5,121,675	10,094,175	10,094,175	10,094,175
High	397,800	3,978,000	3,978,000	3,978,000	9,945,000	9,945,000	9,945,000	19,890,000	19,890,000	19,890,000

We also estimate the cost of mailing medical records to be $5 per request for prior authorization. Some commenters questioned how we arrived at the $5 estimate cost for mailing medical records. Our estimation is based on the mailing costs of medical records for prepay review. However, many of the records are received via fax machines which have lower associated

4 Bureau of Labor Statistics. Accessed February 20, 2015 at http://www.bls.gov/oes/current/oes292071.htm

costs than traditional mail. Additionally, we offer methods of electronic submission of medical documentation to providers and suppliers who wish to use a less expensive alternative for sending in medical documents. Additional information is available on Medicare review contractor websites.

In instances when the supplier must first obtain the medical records from a health care provider, we estimate that the mailing costs are doubled ($10), as records are transferred from provider to supplier, and then to CMS or its contractors. We estimate that there are 22,500 cases (high estimate cases, see Table 2) for which the mailing costs could be doubled in the first year. Based on CMS' experience within the agency and Medicare medical review contractor feedback, it is reasonable to believe that less than half (11,250) of the medical records are mailed in. Therefore, we estimate the costs are $112,500 (11,250 x $10) for the first year. The total high estimated mailing cost for years 2 and 3 is $4,500,000, or $2,250,000 per year. Mailing costs for the CYs 2016 through 2018 average $3,037,500.

To summarize, based on the average of the high estimate of potentially affected claims for CYs 2016 through 2018 (Table 1), the information collection requirements discussed earlier in this section will affect an average of 70,000 claims in CYs 2016 through 2018. Please note that while we have provided data for 10 calendar years, our estimates are based off of the 3-year average of CYs 2016 through 2018. Three years is the maximum term of an OMB approval period for an information collection request. We estimate that the average 70,000 claims will have an associated prior authorization request submission 2.25 times resulting in an average of 157,500 cases. The total estimated average annual time burden for CYs 2016 through 18 is 78,750 hours per year at a cost of $2.8 million per year. After adding CYs 2016-2018 average mailing costs, the burden rises to $5.8 million per year.

The process of submitting a prior authorization request for an expedited review would be the same as for a standard review. Providers have a number of methods to submit documentation quickly including fax, electronic portals, and esMD, so provider burden should not be affected. The unit cost for CMS performing an expedited review would be the same as for a standard review; however it is possible that a larger workforce would be required to perform reviews within the established timeframes if many expedited requests are received. We believe items on the Master List are not commonly used in emergent situations, so we expect the use of expedited reviews to be relatively rare.

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.

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.[5]

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS plans to develop sub regulatory guidance for each prior authorization process as items are selected from the Master List and move to the Required Prior Authorization List. We will reference the approved information collection requests (ICR), valid OMB control numbers and the ICRs expiration dates, where applicable in the sub regulatory guidance documents.

18. Certification Statement

There are no exceptions to the certification statements.

5 https://www.federalregister.gov/articles/2014/05/28/2014-12245/medicare-program-prior-authorization-process-for-certain-durable-medical-equipment-prosthetics#h-22