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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 414

CMS-6050-F

RIN 0938-AR85

Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes a prior authorization program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items that are frequently subject to unnecessary utilization. This rule defines unnecessary utilization and creates a new requirement that claims for certain DMEPOS items must have an associated provisional affirmed prior authorization decision as a condition of payment. This rule also adds the review contractor's decision regarding prior authorization of coverage of DMEPOS items to the list of actions that are not initial determinations and therefore not appealable.

DATES: These regulations are effective [insert date 60 days after the date of publication in the **Federal Register]**.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

The purpose of this final rule is to implement a new prior authorization program aimed at reducing unnecessary utilization and aberrant billing of certain DMEPOS items.

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. This final rule implements that authority by interpreting "frequently subject to unnecessary utilization," by specifying a list of items that meet our criteria, and by establishing a prior authorization process.

2. Summary of the Major Provisions

The following provisions are addressed in this final rule:

- Establishment of a prior authorization process for DMEPOS items that are frequently subject to unnecessary utilization. We define "unnecessary utilization" as the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules. We believe a prior authorization process will ensure beneficiaries receive medically necessary care while minimizing the risk of improper payments, and will therefore protect both beneficiaries and the Medicare program.

● Creation of a Master List of certain DMEPOS items potentially subject to prior authorization. The final rule will create an initial Master List that 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.

We note that, in the proposed rule, this report was titled as stated in the previous sentence. However, for the purposes of this final rule, we are changing the name to the CERT Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report DME and/or DMEPOS Service Specific Report(s). The Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report DME and/or DMEPOS Service Specific Report(s) will hereafter be referred to as the CERT DME and/or DMEPOS Service Specific Report(s). We believe that changing the term to Report(s) (rather than Appendix) and removing the Overpayment Rate wording could limit possible future confusion if the CERT DME and/or DMEPOS Service Specific report(s) are reported in the narrative rather than the appendices or if the name of the report changes in future annual publications.

++ Have an average purchase fee of $1,000 or greater (adjusted annually for inflation) or an average monthly rental fee schedule of $100 or greater (adjusted annually for inflation). (These dollar amounts are referred to as the payment threshold).

● Maintenance of the Master List of certain DMEPOS items potentially subject to prior authorization is conducted based on the following:

++ The Master List is self-updating annually. That is, items on the DMEPOS Fee Schedule that meet the payment threshold are added to the list when the item is listed in a future OIG or GAO report of a national scope or listed in a future CERT DME and/or DMEPOS Service Specific Report(s).

++ Items remain on the Master List for 10 years from the date the item was added to the Master List.

++ Items are updated on the Master List when the Healthcare Common Procedure Coding System (HCPCS) codes representing an item have been discontinued and cross-walked to an equivalent item.

++ Items are removed from the list sooner than 10 years if the purchase amount drops below the payment threshold (currently an average purchase fee of $1,000 or greater or an average monthly rental fee schedule of $100 or greater).

++ Items that age off the Master List because they have been on the list for 10 years can remain on or be added back to the Master List if a subsequent GAO/OIG, or CERT DME and/or DMEPOS Service Specific Report(s) identifies the item to be frequently subject to unnecessary utilization.

++ Items already on the Master List that are identified by a GAO/OIG, or CERT DME and/or DMEPOS Service Specific Report(s) will remain on the list for 10 years from the publication date of the new report(s).

++ We will notify the public annually of any additions and deletions from the Master List by posting the notification in the **Federal Register** and on the CMS Prior Authorization website.

- The Required Prior Authorization List--Presence on the Master List will not automatically require prior authorization. In order to balance minimizing provider and supplier burden with our need to protect the Medicare program, we are initially implementing prior authorization for a subset of items on the Master List (hereafter referred to as "Required Prior Authorization List").

- The Prior Authorization Process--This provision requires that prior to furnishing the item and prior to submitting the claim for processing, a prior authorization requester must submit evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. 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. We will issue specific prior authorization guidance in subregulatory communications.

- A provisional affirmation prior authorization decision is a condition of payment. We are finalizing the provision to automatically deny payment for a claim for an item on the Required Prior Authorization List that is submitted without a provisional affirmation prior authorization decision.

- A prior authorization decision is not a payment decision, and thus a prior authorization decision is not appealable. We have added new section 405.926(t) to our regulations to specify that a review contractor's prior determination of coverage is not an initial determination.

3. Summary of Costs, Benefits, and Transfers

The overall economic cost of this final rule is approximately $1.3 million in the first year. The 5 year cost is approximately $57 million and the 10 year cost is approximately $212 million, mostly driven by the increased number of items subjected to prior authorization after the first year. Additional administrative paperwork costs to private sector providers and suppliers and an increase in Medicare spending to conduct reviews combine to create the financial impact. However, this impact is offset by some savings. We believe there are likely to be other benefits and cost savings that result from the DMEPOS prior authorization requirement. However, many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare FFS payments (note that not all improper payments are fraudulent).

The overall benefits of this final rule include a change in billing practices that also enhances the coordination and collaboration of care between the primary care provider and the supplier to provide the most appropriate DMEPOS item to meet the needs of the beneficiary. The provider and supplier community will benefit from the increased education and outreach that is planned during year 1 of the prior authorization program.

Savings, net of premium offsets, to the Medicare program due to reductions in payments to DMEPOS suppliers are estimated to be $10 million in 2016, potentially rising over time to between $10 million and $110 million in 2025, yielding a 10-year annualized amount of $10 to

$68.1 million with a 7 percent discount rate or $10 to $71.4 million with a 3 percent discount rate.

B. Background

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

The term "durable medical equipment (DME)" is defined in section 1861(n) of the Social Security Act (the Act). It is also referenced in the definition of "medical and other health services" in section 1861(s)(6) of the Act. Furthermore, the term is defined in 42 CFR 414.202 as equipment furnished by a supplier or a home health agency (HHA) that—

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to an individual in the absence of an illness or injury; and
- Is appropriate for use in the home.

Section 1861(s)(9) of the Act provides for the coverage of leg, arm, back, and neck braces; and artificial legs, arms, and eyes, including replacement if required because of a change in the patient's physical condition. As indicated by section 1834(h)(4)(C) of the Act, together with certain shoes described in section 1861(s)(12) of the Act, these items are often referred to as "orthotics and prosthetics." Under section 1834(h)(4)(B) of the Act, the term "prosthetic devices" does not include parenteral and enteral nutrition, supplies and equipment, and implantable items payable under section 1833(t) of the Act.

Examples of durable medical equipment include hospital beds, oxygen tents, and wheelchairs. Prosthetic devices are included in the definition of "medical and other health services" in section 1861(s)(8) of the Act. Prosthetic devices are defined as devices (other than dental) which replace all or part of an internal body organ, including replacement of such devices. Examples of prosthetic devices include cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves.

Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. These conditions of payment vary by item, but are specified in statute and in CMS regulations. They are further detailed in our manuals and in local and national coverage determinations. Among other things, there must be a valid order for the item obtained from a physician or, when permitted, an eligible professional.

Once Medicare coverage, coding, and payment rules are satisfied, the supplier dispenses the item to the beneficiary. In general, items are delivered directly to the beneficiary or to an authorized representative, delivered to the beneficiary by shipping or delivery service, or delivered to a nursing facility on behalf of the beneficiary. The supplier is required to maintain proof of delivery in its files in keeping with the supplier standards contained in 42 CFR 424.57(c). The claim is then submitted to the Medicare Administrative Contactor (MAC) for payment. If a claim is denied, the beneficiary or supplier may appeal the MAC's decision. Claims may also be selected for pre- or post-payment review. As discussed in the

following section, the prior authorization process will require applicable documentation to be submitted for review before an item is delivered to the beneficiary.

2. DMEPOS Payment Rules—Advance Determination of Coverage

Section 1834(a)(15) of the Act authorizes the Secretary to develop and periodically update a list of DMEPOS items 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.

This final rule implements that authority by interpreting "frequently subject to unnecessary utilization," specifying a list of items that meet our criteria, and establishing a prior authorization process.

3. Improper Payments for DMEPOS Items

Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, all required documentation elements outlined in Medicare policies must be present for the claim to be paid.

Payment made for the furnishing of an item that does not meet one or more of Medicare's coverage, coding, and payment rules is an improper payment. The CERT program measures improper payments in the Medicare FFS program. CERT is designed to comply with the Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111–204).

For the 2014 CERT reporting period, approximately 5.1 billion dollars was improperly paid for DMEPOS items. This represents a 53.1 percent improper payment rate for DMEPOS

and represents 10.4 percent of the overall improper payment rate.[1] Ninety-two percent of DMEPOS improper payments were due to insufficient documentation.[2]

Given that for the 2014 reporting period, 92 percent of the DMEPOS improper payment rate is attributed to insufficient documentation, we believe we must develop a mechanism for DMEPOS to have sufficient associated documentation before the item is furnished and before the claim is submitted for payment. We believe a prior authorization program can accomplish this by reviewing many of the required documentation elements outlined in applicable Medicare policies before the item is furnished and before the claim is submitted for payment.

Prior authorization has the added benefit of providing a supplier some assurance of payment for items receiving a provisional affirmation decision. (However, as described later in this section, certain requirements – such as proof of delivery – can only be evaluated after the claim has been submitted). In addition, beneficiaries will have information regarding coverage prior to receiving the item, and will benefit by knowing in advance of receiving an item, if they will incur financial liability for non-covered items. If a supplier does not submit all of the required documentation with its first prior authorization request, it will be notified of the missing documentation and may resubmit its request. We proposed that requesters be permitted to submit a prior authorization request an unlimited number of times.

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[1] The Medicare Fee-For-Service 2014 Improper Payments Report: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/Medicare-FeeforService-2014-Improper-Payments-Report.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending Accessed July 30, 2015.

[2] The Supplementary Appendices for the Medicare Fee-for-Service 2014 Improper Payment Report retrieved January 2015 from http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/Downloads/AppendicesMedicareFee-for-Service2014ImproperPaymentsReport.pdf?agree=yes&next=Accept

We note claims for which there is a provisional affirmation prior authorization decision will be afforded some protection from future audits, both pre- and post-payment. However, review contractors may audit claims if potential fraud, inappropriate utilization or changes in billing patterns are identified. In addition, IPERA requires all federal agencies to evaluate their programs for improper payments. The CMS CERT program reviews a stratified, random sample of claims annually to identify and measure improper payments. It is possible for a DMEPOS claim subject to prior authorization to fall within the sample. In this situation, the subject claim would not be protected from the CERT audit. While implementing a new prior authorization program will require suppliers to modify their processes, we believe suppliers can minimize disruption to their business processes by learning in advance what information or documentation is required for coverage of specific items. We will partner with the supplier, provider, and beneficiary community to make sure they have all the information about the new program needed to submit a prior authorization request. We believe that some assurance of payment and some protection from future audits may ultimately reduce burdens associated with denied claims and appeals.

4. Access to Care

Of the approximately 37 million beneficiaries enrolled in the Medicare FFS program in 2013, 11 million had a DMEPOS claim.[3] Beneficiaries utilized approximately 91,000 DME suppliers.[4] For 2014, there were approximately 37.5 million beneficiaries enrolled in the

3 CY 2013 Data from OnePI Business Objects, NCH DMEPOS claims, obtained January 16, 2015: All NCH DMEPOS Claims dated between January 1, 2013 to December 31, 2013: 10,680,646 unique beneficiaries.
4 CMS Fast Facts retrieved January 2015 from http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html .

Medicare FFS program and 10 million had a DMEPOS claim. Beneficiaries utilized approximately 90,000 DME suppliers.[5]

We have experience in implementing a prior authorization program that enables beneficiaries to receive a needed DME item, without access issues or barriers to care. We have monitored the beneficiary experience in The Medicare Prior Authorization of Power Mobility Devices (PMDs) Demonstration, which began in 2012. Prior to implementation, we spoke to numerous Medicare beneficiary groups that expressed support for the demonstration. Feedback from beneficiaries has been largely positive. We are not aware of any access issue or barriers to care created by the prior authorization process for PMDs.

The Medicare Prior Authorization of PMDs Demonstration was initially implemented in California, Illinois, Michigan, New York, North Carolina, Florida, and Texas. Since implementation, we have observed a decrease in expenditures for PMDs in the demonstration states and non-demonstration states. Based on claims processed from September 1, 2012 through November 14, 2014, monthly expenditures for the PMD codes included in the demonstration decreased from $12 million to $3 million in the demonstration states and from $20 million in September 2012 to $6 million in June 2014 in the non-demonstration states. Subsequently, we expanded the demonstration to 12 additional states on October 1, 2014, and on July 15, 2015, we extended the demonstration for all 19 states until August 31, 2018.[6] In 2013, there were approximately 91,000 national DMEPOS suppliers which may have adjusted their

5 CMS Fast Facts retrieved October 2015 from http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html and CY 2014 Data from OnePI Business Objects, NCH DMEPOS claims, obtained October 15, 2015: All NCH DMEPOS Claims dated between January 1, 2014 to December 31, 2014.

6 https://www.federalregister.gov/articles/2015/07/15/2015-17365/medicare-program-extension-of-medicare-prior-authorization-for-power-mobility-devices-pmds

billing practices nationwide as a result of the demonstration (not just in the demonstration states that included 16,000 suppliers). This may have led to the savings documented in both the demonstration and non-demonstration states. As stated previously, savings were realized in both the demonstration and non-demonstration states. The decrease in spending may be due only in part to the demonstration, as other changes in policies regulating the provision of DMEPOS also took effect during this time. In addition, suppliers may have also started complying with CMS policies based on their experiences with prior authorization in the demonstration states.[7]

We promote a high quality health care system by aiming for better care at lower costs and for improved health outcomes. Crucial to this is maintaining beneficiary access to quality care. We believe the Medicare Prior Authorization of PMDs Demonstration shows that by collaborating with beneficiaries and beneficiary advocacy groups, we can develop a prior authorization program that contributes to higher quality health care at lower costs without compromising access to care. This final rule creates a prior authorization program that supports our goals and makes sure beneficiaries are not hindered from accessing necessary DMEPOS items and services when they need them.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the May 28, 2014 **Federal Register** (79 FR 30511 through 30531), we published a proposed rule titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Items." In response to the publication of that proposed rule, we received 1,009 comments from the prosthetics and orthotics

7 Medicare Prior Authorization of Power Mobility Devices Demonstration Status Update retrieved January 2015 from http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/MedicalReview/Downloads/PMDDemoDecemberStatusupdate12302014.pdf

community, beneficiaries (including amputees) and beneficiary advocacy groups, professional and trade organizations, physicians and other clinicians, suppliers, and other interested parties.

In the following sections of this final rule, we include a summary of the provisions of the May 28, 2014 proposed rule, the public comments received, our responses, and our final decisions.

A. Proposed Prior Authorization for Certain DMEPOS Items

In § 414.234(a), we proposed that "prior authorization" be defined as a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing. We also proposed that "provisional affirmation" be defined as a preliminary finding that a future claim meets Medicare coverage, coding, and payment rules.

We also proposed in § 414.234(a) that "unnecessary utilization" be defined as the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules. In accordance with section 1834(a)(15)(A) of the Act, we proposed to use "prior payment experience" to establish which items are "frequently" subject to unnecessary utilization. The Government Accountability Office (GAO), the Department of Health and Human Services' (HHS) Office of Inspector General (OIG), and CMS through CERT reports publish analyses of prior payment data and identify Medicare DMEPOS items that have high improper payment rates. We proposed that since the findings in these reports are the result of analysis of prior payment experience, we would use these reports to establish which items are frequently subject to unnecessary utilization. We discuss the use of GAO, OIG, and CERT reports to establish Master List inclusion criteria in section II.B. of this final rule.

We strive in every case to pay the right amount to a legitimate provider, for covered, correctly coded, and correctly billed services provided to an eligible beneficiary. We believe that a prior authorization process for DMEPOS items frequently subject to unnecessary utilization can help suppliers comply with Medicare's coverage, coding, and payment rules by having the required information and documentation reviewed before the item is furnished and before the claim is submitted. In addition, claims for which there is a provisional affirmation prior authorization decision will be afforded some protection from future audits. The review contractors may continue to audit claims if potential fraud, inappropriate utilization or changes in billing patterns are identified. In addition, IPERA requires all federal agencies to evaluate their programs for improper payments. The CMS CERT program reviews a stratified, random sample of claims annually to identify and measure improper payments. It is possible for a DMEPOS claim subject to prior authorization to fall within the sample. In this situation, the subject claim would not be protected from the CERT audit. In addition, OIG's authority to audit claims is not impacted by the protection from future audits provided by the provisional affirmation prior authorization decision.

When unnecessary utilization (as defined by this final rule) of a covered Medicare service, item or device is identified, we have a responsibility to evaluate the errors and develop processes to mitigate or reduce the unnecessary utilization. This is sometimes difficult since we must not only safeguard the Medicare program, but we must also safeguard beneficiaries' full access to the covered care they need. We believe using a prior authorization process would help to make sure items frequently subject to unnecessary utilization are furnished in compliance with applicable Medicare coverage, coding, and payment rules before they are delivered. This would

safeguard against unnecessary utilization while also protecting beneficiaries' access to medically necessary items. We believe this is an effective way to reduce or prevent improper payments for unnecessary DMEPOS items while preserving beneficiary access to quality care and services.

The following summarizes comments on our proposed definitions of "prior authorization," "provisional affirmation," and "unnecessary utilization" at § 414.234(a).

Comment: While some commenters agreed with the proposed definition of "unnecessary utilization," the majority disagreed. We defined unnecessary utilization as the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules. We did not receive any suggestions for alternate definitions of unnecessary utilization. However, several commenters noted that unnecessary utilization is not a question of beneficiaries receiving unnecessary DMEPOS items but instead a lack of provider or supplier clarity on how to document medical necessity, and that the lack of documentation does not equal unnecessary utilization.

Response: We acknowledge "unnecessary utilization" may be interpreted from several perspectives. Our proposed definition is constructed for the purpose of implementing Medicare coverage and payment policies. A DMEPOS item may be medically necessary for a particular beneficiary, but without sufficient documentation to support compliance with Medicare coverage and payment policies, we cannot confirm whether Medicare payment for a particular item is appropriate. Furthermore, if the provider or supplier has not complied with Medicare coverage, coding or payment rules, we do not have authority to make payment. Accordingly, we interpret and define the phrase "unnecessary utilization" to mean the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules.

We are finalizing the definitions of "prior authorization," "provisional affirmation," and "unnecessary utilization" at § 414.234(a) as proposed. In addition, we are finalizing the use of GAO, OIG, and CERT reports to establish prior payment history. Public comments and our responses pertaining to the use of GAO, OIG, and CERT reports are described in section II.B. of this final rule.

B. Proposed Criteria for Inclusion on the Master List of DMEPOS Items Frequently Subject to Unnecessary Utilization (Master List)

1. Inclusion Criteria

In the May 28, 2014 proposed rule (79 FR 30516 through 30519), we proposed a Master List of initial items that, based on proposed criteria, are frequently subject to unnecessary utilization, hereafter referred to as the "Master List." We solicited public comments on the proposed inclusion criteria and the proposed Master List maintenance process. We proposed to include an item on the initial Master List if the item appears on the DMEPOS Fee Schedule list, meets one of the two criteria described later in this section, and has an average purchase fee of $1,000 or greater or an average rental fee schedule of $100 or greater. We refer to these dollar amounts as the payment threshold. We stated that having the payment threshold for DMEPOS items included on the Master List would allow us to focus our limited resources on items for which prior authorization will result in the largest potential savings for the Medicare program. The DMEPOS Fee Schedule is updated annually and lists Medicare allowable pricing for DMEPOS, including the full payment amount for capped rental items. For administrative simplicity, we proposed that we would not annually adjust the average purchase fee of $1,000 or greater or the average monthly rental fee schedule of $100 or greater threshold for inflation.

Under our proposal, any changes to this threshold would be proposed through notice and comment rulemaking.

In addition to the payment threshold, we proposed that the item must meet one of the two following criteria:

- The item is identified in a GAO or HHS OIG report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.
- The item is listed in the 2011 or later published CERT program's Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report Durable Medical Equipment (DME) Service Specific Overpayment Rate Appendix.

We proposed using reports dated from 2007 or later because the GAO and OIG do not always repeat analysis of specific items annually. We believed it necessary to look back a number of years to capture findings on a variety of DMEPOS items. The GAO audits agency operations to determine whether federal funds are being spent efficiently and effectively as well as identifies areas where Medicare may be vulnerable to fraud and improper payments. Section 1834(a)(15) of the Act directs the Secretary to use prior payment experience as a basis for identifying DMEPOS items frequently subject to unnecessary utilization. We believe utilizing GAO evaluations that identify DMEPOS items as having a high rate of fraud or unnecessary utilization accomplishes this directive because GAO's analysis includes an evaluation of paid claims history.

The OIG provides independent and objective oversight that promotes economy, efficiency, and effectiveness in the programs and operations of HHS. OIG's mission to protect the integrity of HHS programs is carried out through a network of audits, investigations, and

inspections. The OIG audits and evaluates the performance of HHS programs and their participants. In some cases, OIG reports disclose aberrant billing utilization data or high incidences of improper payments for particular items or services.

Because the CERT program reviews a representative random sample of claims each year, we are using the most recent published report at the time of the writing of this final rule which is the 2014 CERT Report. We believe limiting this criterion to items listed in the 2011 or later CERT DME and/or DMEPOS Service Specific Report(s) (and also meeting the payment threshold) accomplishes the directive of section 1834(a)(15) of the Act. Interested parties can access the CERT reports at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports.html

We proposed that nationwide findings by OIG or by GAO of potentially high rates of fraud, unnecessary utilization, or aberrant or improper billings, and CERT reports of the incidence and rates of improper payments are good indicators that an item is "frequently subject to unnecessary utilization" as set out in section 1834(a)(15) of the Act. The use of GAO, OIG, and CERT reports to establish which items are frequently subject to unnecessary utilization are discussed in detail in section II.B. of the proposed rule (79 FR 30513).

2. Maintenance of the Master List

In the May 28, 2014 proposed rule (79 FR 30514), we described the proposed Master List maintenance process. We proposed the following:

- The Master List is self-updating annually. That is, items on the DMEPOS Fee Schedule that meet the payment threshold are added to the list when the item is listed in a future

OIG or GAO report of a national scope or a future CERT DME and/or DMEPOS Service Specific Report(s).

- Items remain on the Master List for 10 years from the date the item was added to the Master List.
- Items are updated on the Master List when the Healthcare Common Procedure Coding System (HCPCS) code representing an item has been discontinued and cross-walked to an equivalent item.
- Items are removed from the list sooner than 10 years if the purchase amount drops below the payment threshold (an average purchase fee of $1,000 or greater or an average monthly rental fee schedule of $100 or greater).
- Items age off the Master List because they have been on the list for 10 years and can remain on or be added back to the Master List if a subsequent GAO/OIG or CERT DME and/or DMEPOS Service Specific Report(s) identifies the item to be frequently subject to unnecessary utilization.
- Items already on the Master List that are identified by a GAO/OIG, or CERT DME and/or DMEPOS Service Specific Report(s) will remain on the list for 10 years from the date of the new report.
- We notify the public annually of any additions and deletions from the Master List by posting the notification in the **Federal Register** and on the CMS Prior Authorization website.

In the proposed rule we stated that we selected a 10-year timeframe because we believe 10 years without a finding that the item has a potentially high rate of fraud, unnecessary utilization or aberrant or improper billing makes the original placement no longer current.

We received the following comments on the proposed Master List inclusion criteria and Master List maintenance process in section 414.234(b) and our responses follow:

Comment: A few commenters suggested we apply the Secretary's authority from section 1834(a)(15)(B) of the Act rather than apply the Secretary's authority from section 1834(a)(15)(A) of the Act, which is the basis for this final rule. Section 1834(a)(15)(B) of the Act allows the Secretary to develop a list of suppliers that have had a substantial number of claims denied on the basis of the application of section 1862(a)(1) or that have a pattern of overutilization resulting from the business practice of the supplier.

Response: We conducted an analysis of the improper payment rate for DMEPOS items listed on the CERT DME and/or DMEPOS Service Specific Report(s) as well as findings from 2007 or later GAO/OIG reports and found that the errors generally did not trend to specific suppliers. We found that the root cause of the improper payments was lack of appropriate documentation and the issue was widespread. The list of DMEPOS items focuses our efforts on the root cause of improper payments-- inadequate documentation. In addition, several suppliers have indicated they prefer some assurance of payment, which prior authorization affords. By focusing on items rather than aberrant suppliers, more suppliers will benefit from documentation education and some assurance of payment that prior authorization provides.

Comment: Some commenters stated that the proposed payment threshold was too low; other commenters stated that there should be a separate threshold for specific items on the proposed Master List. For example, several commenters suggested that the payment threshold should be 167 percent of the Medicare average purchase price for the proposed prosthetic codes on the proposed Master List. Other commenters expressed concerns regarding the threshold and

competitive bidding, stating that some DMEPOS items in some competitive bidding areas and in 19 of the largest states for traditional Medicare are under this $100 rental-rate threshold. Commenters requested that CMS clarify which geographical areas and fee schedules were used to calculate the proposed threshold. Commenters were also concerned that the proposed threshold may cause suppliers to deny Medicare beneficiaries their DMEPOS supplies. Several commenters were concerned that CMS proposed no annual adjustment in payment threshold for inflation. Commenters also suggested that any changes to the threshold should be done through public notice and comment.

Response: We conducted a return on investment analysis and found that we realize savings when items with an average rental price of $100 monthly or an average payment price of $1,000 are subject to prior authorization. If we went to higher thresholds, we noted that many of the DMEPOS items known to have an associated high improper payment rate would not be included. If we went to lower thresholds, we did not realize the expected savings to support implementation of a prior authorization. For example, applying a payment threshold of several thousand dollars would not capture many of the DMEPOS items known to have associated high improper payments such as continuous positive airway pressure (CPAP). While pricing for Competitive Bidding areas may differ, we did not use particular geographical areas to determine the payment and rental threshold. Instead, we selected the payment threshold after evaluating the average payment and rental fees for all the states on the Medicare DMEPOS fee schedule.[8] We calculated the average payment and rental fees by averaging the sum of all the states' fees and

8 Medicare DMEPOS Fee Schedule. Accessed 10/13/15: https://www.cms.gov/Medicare/Medicare-Fee-for-Service Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/DME15-A.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

then dividing the sum by the total number of states, including the District of Columbia, Puerto Rico, and the Virgin Islands.

We believed using the payment threshold as described would allow us to focus our limited resources on the more expensive DMEPOS items frequently subject to unnecessary utilization. However, we agree with the commenters who believed a fixed-payment threshold would not be appropriate in future years. While there were several price points suggested, we have decided that the best solution would be to keep the current payment threshold, but adjust it annually for inflation. The DMEPOS Fee Schedule is updated every year and announced in November with an effective date of January 1. In accordance with the statutory sections 1834(a)(14) and 1886(b)(3)(B)(xi)(II) of the Act, the DMEPOS fee schedule amounts are updated annually by the percentage increase in the consumer price index for all urban consumers (United States city average) or CPI-U for the 12-month period ending with June of the previous year, adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business multifactor productivity (MFP). For example, for CY 2015, the MFP adjustment is 0.6 percent and the CPI-U percentage increase is 2.1 percent. Thus, the 2.1 percentage increase in the CPI-U is reduced by the 0.6 percentage increase in the MFP resulting in a net increase of 1.5 percent for the update factor. For CY 2015, the update factor of 1.5 percent was applied to the applicable CY 2014 DMEPOS fee schedule amounts.

In response to public comment, we will make an annual inflation adjustment to the payment threshold. This adjustment will be the same percentage as the DMEPOS fee schedule annual adjustments. This adjustment will apply to the Master List maintenance process as well.

Specifically, items already on the Master List with an average rental price that drops below $100 (adjusted for inflation) or average purchase price that drops below $1,000 (adjusted for inflation) will be removed from the list.

We disagree with the commenter that stated that the payment threshold may cause suppliers to deny Medicare beneficiaries their DMEPOS items. The payment threshold does not establish a new price for the DMEPOS; rather it establishes the criteria to initiate a prior authorization process. The PMD demonstration has shown that unnecessary utilization has decreased while beneficiaries have continued to receive a PMD when medically necessary. [9] However, we do believe that the proposed prior authorization timelines, 10 business days for an initial prior authorization decision to be returned to the requester, may create some access or barriers to care. To address this, we are not finalizing the proposed prior authorization timelines. This is discussed further in section II.E. of this final rule. Finally, while the payment threshold would adjust annually for inflation, a change to the threshold base would require new rulemaking.

Comment: Some commenters disagreed with the use of the OIG/GAO reports as Master List inclusion criteria. For example, several commenters stated that the OIG/GAO reports are arbitrary and were not open for public comment. Other commenters expressed concern with the age of the OIG/GAO reports used. Many commenters believed that the OIG data analysis misrepresented utilization and Medicare spending for certain items on the list especially lower-limb prostheses.

9 https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/PMDDemoDecemberStatusupdate12302014.pdf. Accessed 10/13/15

Some commenters disagreed with the use of the CERT 2011 report or later as Master List inclusion criteria stating that some items on the 2011 do not appear on later reports, indicating that policy or other factors have already reduced the improper payment rate for those items. Others believed that the sample size for the CERT reports is too small to conclude improper payment rates. Several commenters recommended that CMS consider using more recent CERT reports as well as internal data sources. Other commenters stated that CMS should look into the reasons for the high error rates for the proposed Master list items, such as, overly complex regulations, a need for targeted education to medical professionals and suppliers, and the misapplication of policies by CERT personnel.

Response: The mission of the OIG and GAO is to protect the integrity and improve the efficiency of HHS programs, including Medicare. We disagree with the commenter who stated that the OIG/GAO report topics selected were arbitrary. For example, the OIG publishes their work plan annually. Some of their reports are statutorily required, while others are based on known program vulnerabilities. Some other reports are based on congressional requests which are sometimes made public. Disagreements with the findings of their reports are outside the scope of this final rule. We proposed using reports dated from 2007 or later because GAO/OIG do not always repeat an analysis of specific items annually and it is necessary to look back a number of years to capture findings on a variety of DMEPOS items.

We disagree with the commenter that stated the CERT sample was too small. The CERT sample is stratified so that the sample and its findings are representative of the universe of Medicare FFS claims; we believe using stratification provides greater precision and that using these tools provides validity to the criteria. In addition to these criteria, we may choose to take

current claims data into consideration when determining which Master List item(s) will be on the Required Prior Authorization List.

Items appearing on earlier CERT reports but not later ones will stay on the Master List for 10 years from their inclusion date. While some commenters believed an item no longer appearing in the CERT report should be dropped from the Master List, we believe the item should remain on the list to assure that the improved billing practice is sustained over time.

In response to the commenters who stated that we should look into the reasons for the high error rates for the proposed Master list items, such as: having overly complex regulations; lacking targeted education to medical professionals and suppliers; and misapplying policies, we conduct analyses on the root causes for high improper payment rates, including CMS policies, and auditor application of the policies to their reviews. Medicare review contractors undergo frequent education and inter-rater reliability assessments to assure consistency in review approaches. Inter-rater reliability assessment is a performance measurement tool used to assess the level of consistency among medical review staff and adherence to organizational standards. It is used to promote quality and consistency in reviews. Where findings indicate that the problem may be overly complex CMS policies, we initiate policy revision. A recent example is the substantially increased improper payment rate for home health services published in the 2013 Annual CERT report. In response, we published a final rule in November 2014 that simplified the home health service face-to-face documentation requirements because most of the increased errors were related to the face-to-face documentation.

We believe using both the CERT report and the OIG/GAO reports allow us to create safeguards for a broader category of items.

Comment: Some commenters disagreed with a self-updating Master List. Several commenters suggested that the public should have input regarding the Master List updates. Commenters also suggested that the Master List be updated more frequently (that is, quarterly). Some recommended that the 10-year timeframe for removal of items from the Master List is too long and arbitrary.

Response: We respectfully disagree. We believe an annual update aligns best with the annual publication of the fee schedule. A more frequent update would be administratively burdensome to suppliers, providers, and CMS. We are finalizing the Master List maintenance procedure; all new items that meet the inclusion criteria will be added to the Master List on an annual basis.

We recognize commenters requested public input on Master List updates. However, we respectfully disagree. We believe by the nature of the criteria, the Master List is inherently self-updating. We note that there will be no discretion about which items are added or updated because it will be based on the inclusion criteria about which the public provided comment. However, inclusion on the Master List does not mean that the item will automatically be subject to prior authorization. (Only a subset of the Master List items will be selected and added to the "Required Prior Authorization List." This is further discussed in section II.D. of this final rule.) We believe 10 years without a finding that the item has a potentially high rate of fraud, unnecessary utilization or aberrant or improper billing makes the original placement no longer current. We recognize some commenters believe 10 years is too long, but this timeframe will enable us to have a thorough and complete Master List. However, we may choose to take

current claims data into consideration when determining which items will be on the Required Prior Authorization List.

We are finalizing the Master List inclusion criteria and Master List maintenance process as proposed in section 414.234(b). Section 1834(a)(15)(A) of the Act requires us to use "prior payment history" when identifying DMEPOS items frequently subject to unnecessary utilization. We believe using past and future GAO and OIG reports as well as CERT DME data is a way to meet this requirement.

We are finalizing the Master List inclusion criteria and Master List maintenance process as proposed in section 414.234(b). In addition, we are finalizing the proposed payment threshold, but are including an annual adjustment for inflation as stated in revised section 414.234(b)(1). The adjusted payment threshold will apply to the inclusion criteria as well as the Master List maintenance process. We are also finalizing our proposal to notify the public annually of any additions and deletions from the Master List by posting the notification in the **Federal Register** and on the CMS Prior Authorization website, as stated in section 414.234(f)(2).

C. Proposed List of DMEPOS Items Frequently Subject to Unnecessary Utilization (Master List)

In the May 28, 2014 proposed rule (79 FR 30516 through 30519), we proposed a Master List of Items Frequently Subject to Unnecessary Utilization. There have been several reports that were national in scope and published by the HHS OIG since 2007 identifying DMEPOS items that meet the payment threshold and are frequently subject to unnecessary utilization. They are as follows:

• An August 2011 OIG report titled "Questionable Billing by Suppliers of Lower Limb Prostheses" found that between 2005 and 2009, Medicare spending for lower limb prostheses increased 27 percent, from $517 million to $655 million.[10] During the same time period, the number of Medicare beneficiaries receiving lower limb prostheses decreased by 2.5 percent, from almost 76,000 to about 74,000. The report cited several examples of unnecessary utilization.

One finding, billing for prostheses when the beneficiary had no claims from the referring physician, raised questions about whether the physician ever evaluated the beneficiary and whether the billed devices were medically necessary. Another finding related to billing for a high percentage of beneficiaries with no history of an amputation or missing limb also raised questions about medical necessity. These findings based on prior payment history indicate that certain lower limb prostheses are frequently subject to questionable utilization.

• A July 2011 OIG report titled "Most Power Wheelchairs in the Medicare Program Did Not Meet Medical Necessity Guidelines" found that 61 percent of power wheelchairs provided in the first half of 2007 were medically unnecessary or lacked sufficient documentation to determine medical necessity.[11] This 61 percent accounted for $95 million of the $189 million allowed DMEPOS claims in that period of time.

There were two previous OIG reports based on the same sample of claims that found noncompliance problems with documentation requirements and coding requirements ("Medicare

10 OIG, Questionable Billing By Suppliers Of Lower Limb Prostheses. OEI-02-10-00170, August 2011.
11 OIG, Most Power Wheelchairs In The Medicare Program Did Not Meet Medical Necessity Guidelines. OEI-04-09-00260, July 2011.

Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements"[12] and "Miscoded Claims for Power Wheelchairs in the Medicare Program."[13]). Across both reports, it was found that 80 percent of claims did not meet Medicare requirements for the sample period of 2007.

• An August 2009 OIG report titled "Inappropriate Medicare Payment for Pressure Reducing Support Surfaces," found that 86 percent of claims for group 2 pressure reducing support surfaces did not meet Medicare coverage criteria for the first half of 2007.[14] This amounted to an estimated $33 million in improper payments during that time.

• A June 2007 OIG report titled "Medicare Payments for Negative Pressure Wound Therapy Pumps in 2004" found that 24 percent of negative pressure wound therapy pumps did not meet Medicare coverage criteria in 2004.[15] This amounted to an estimated $21 million in improper payments. Furthermore, the report found that in 44 percent of the claims with medical records and supplier prepared statement, the information on the supplier prepared statement was not supported by the medical record.

In Tables 1 through 4, we provide the 2011 through 2014 Annual Medicare FFS Improper Payment Rate Report DME and/or DMEPOS Service Specific Reports. These tables illustrate the overpayment rates for specified DMEPOS items and the corresponding overpayment amounts. Items from these tables are included on the Master List if they meet the payment threshold. The listed DMEPOS items and the information in the "projected dollars

12 OIG, Medicare Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements.OEI-04-07-00401, December 2009
13 OIG, Miscoded Claims for Power Wheelchairs in the Medicare Program, OEI-04-07-00403, July 2009.
14 OIG, Inappropriate Medicare Payments for Pressure Reducing support Surfaces. OEI-02-07-00420, August 2009.
15 OIG, Medicare Payments for Negative Pressure Wound Therapy Pumps in 2004. OEI-02-05-00370, June 2007.

overpaid" column were provided by the CERT program. CERT includes DMEPOS items on this list if the items have 30 or more claims sampled and are in the top 20 services by descending projected overpayment amount. Any services that have less than 30 claims are wrapped up into the "Less than 30 Claims" line. Numbers are projected to the universe (or population) using a weighting system that accounts for both the volume of a stratified service and expenditures. Each claim is individually weighted based upon the strata it was sampled in and the jurisdiction it was processed in. Dollar amounts are then multiplied by this weight value.

TABLE 1: 2011 ANNUAL MEDICARE FFS IMPROPER PAYMENT RATE REPORT DME SERVICE SPECIFIC OVERPAYMENT RATE APPENDIX

Service Billed to DME (HCPCS)	Number of Claims in Sample	Number of Lines in Sample	Dollars Overpaid in Sample	Total Dollars Paid in Sample	Projected Dollars Overpaid	Overpayment Rate
All Codes With Less Than 30 Claims	1,769	2,742	$300,255	$531,107	$2,212,120,825	57.8%
Oxygen concentrator (E1390)	1,258	1,293	$148,631	$193,810	$1,133,180,723	77.7%
Blood glucose/reagent strips (A4253)	1,457	1,466	$126,344	$150,622	$929,031,554	84.4%
Hosp bed semi-electr w/ Matt (E0260)	227	232	$19,078	$21,779	$135,908,667	88.5%
Budesonide non-comp unit (J7626)	72	74	$13,555	$24,420	$106,061,471	57.9%
Tacrolimus oral per 1 MG (J7507)	68	72	$16,147	$31,803	$104,040,006	52.4%
Lancets per box (A4259)	852	858	$12,940	$15,323	$99,822,219	84.8%
Cont airway pressure device (E0601)	303	318	$12,665	$21,987	$98,014,011	60.1%
Portable gaseous 02 (E0431)	634	658	$12,774	$16,517	$97,194,278	77.4%
Diab shoe for density insert (A5500)	125	136	$11,949	$15,420	$88,965,667	78.2%
Multi den insert direct form (A5512)	78	84	$9,561	$11,631	$71,586,004	81.8%
Enteral feed supp pump per d (B4035)	67	68	$8,452	$14,853	$66,560,532	58.2%
RAD w/o backup non-inv Intfc (E0470)	68	75	$9,264	$13,079	$64,412,596	69.8%
CPAP full face mask (A7030)	81	81	$8,336	$12,774	$64,248,424	65.6%
Nasal application device (A7034)	145	145	$9,043	$14,366	$62,469,031	62.0%
High strength ltwt whlchr (K0004)	84	88	$7,870	$8,315	$61,980,799	94.9%
Disp fee inhal drugs/30 days (Q0513)	386	389	$7,590	$12,210	$57,749,018	62.0%
Multi den insert custom mold (A5513)	45	52	$7,333	$9,366	$54,355,934	80.5%
Lightweight wheelchair (K0003)	114	115	$6,995	$7,503	$52,201,255	92.6%
Mycophenolate mofetil oral (J7517)	43	43	$7,669	$12,566	$49,929,224	64.1%
All Other Codes	3,482	4,795	$125,245	$194,402	$943,311,918	65.9%
Combined	8,110	13,784	$881,693	$1,333,852	$6,553,144,155	67.4%

TABLE 2: 2012 ANNUAL MEDICARE FFS IMPROPER PAYMENT RATE REPORT DME SERVICE SPECIFIC OVERPAYMENT RATE APPENDIX

Service Billed to DME (HCPCS)	Number of Claims in Sample	Number of Lines in Sample	Dollars Overpaid in Sample	Total Dollars Paid in Sample	Projected Dollars Overpaid	Overpayment Rate
All Codes With Less Than 30 Claims	2,354	3,738	$1,256,083	$2,231,572	$1,536,420,429	51.9%
Oxygen concentrator (E1390)	1,286	1,317	$156,295	$194,294	$1,168,366,128	80.9%
PWC gp 2 std cap chair (K0823)	999	1,002	$513,426	$553,349	$201,693,896	97.3%
Hosp bed semi-electr w/ matt (E0260)	283	289	$23,544	$27,437	$137,852,967	87.2%
Lancets per box (A4259)	742	748	$10,761	$13,088	$98,992,634	83.1%
Tacrolimus oral per 1 MG (J7507)	58	63	$12,118	$23,120	$97,807,986	54.3%
Portable gaseous 02 (E0431)	590	608	$12,296	$15,203	$96,375,515	80.9%
Cont airway pressure device (E0601)	210	213	$7,914	$14,860	$80,812,581	50.0%
Budesonide non-comp unit (J7626)	100	105	$13,453	$24,905	$78,369,581	54.1%
Neg press wound therapy pump (E2402)	39	39	$17,464	$47,731	$72,189,807	51.0%
Enteral feed supp pump per d (B4035)	91	92	$10,283	$19,145	$70,291,185	54.8%
Nasal application device (A7034)	121	122	$8,030	$12,254	$70,244,578	65.3%
Diab shoe for density insert (A5500)	97	102	$8,271	$11,594	$68,920,996	73.2%
RAD w/o backup non-inv intfc (E0470)	68	75	$9,166	$13,213	$63,658,439	69.6%
Disp fee inhal drugs/30 days (Q0513)	413	413	$7,392	$13,068	$58,594,189	57.0%
CPAP full face mask (A7030)	75	75	$7,308	$11,524	$57,481,278	59.3%
High strength ltwt whlchr (K0004)	80	83	$7,826	$8,016	$56,257,539	97.7%
Lightweight wheelchair (K0003)	99	110	$6,250	$6,821	$55,809,106	94.2%
Multi den insert direct form (A5512)	61	63	$6,805	$8,548	$55,671,152	79.4%
All Other Codes	5,311	9,107	$1,735,735	$2,669,607	$1,380,908,350	64.4%
Combined	10,117	19,627	$3,933,943	$6,048,632	$6,412,968,806	66.0%

TABLE 3: 2013 ANNUAL MEDICARE FFS IMPROPER PAYMENT RATE REPORT DME SERVICE SPECIFIC OVERPAYMENT RATE APPENDIX

Service Billed to DME (HCPCS)	Number of Claims in Sample	Number of Lines in Sample	Dollars Overpaid in Sample	Total Dollars Paid in Sample	Projected Dollars Overpaid	Overpayment Rate
Oxygen concentrator (E1390)	1,212	1,262	$136,312	$181,075	$983,768,125	75.6%
All Codes With Less Than 30 Claims	2,147	3,235	$545,968	$1,053,401	$867,058,104	37.4%
Blood glucose/reagent strips (A4253)	1,131	1,148	$85,298	$114,282	$791,786,761	75.1%
PWC gp 2 std cap chair (K0823)	734	747	$181,940	$212,803	$201,643,982	85.4%
Hosp bed semi-electr w/ matt (E0260)	364	386	$28,235	$34,055	$137,106,877	84.1%
Tacrolimus oral per 1MG (J7507)	70	71	$11,920	$26,692	$88,099,443	43.4%
Cont airway pressure devce (E0601)	118	126	$4,255	$8,732	$84,740,816	48.8%
Lancets per box (A4259)	607	615	$8,409	$11,030	$82,958,405	76.3%
Portable gaseous 02 (E0431)	525	567	$9,876	$13,516	$78,011,911	73.2%
Enteral feed supp pump per d (B4035)	90	90	$11,685	$18,809	$69,222,164	61.7%
Diab shoe for density Insert (A5500)	82	90	$7,384	$9,580	$65,194,062	78.3%
Nasal application device (A7034)	78	79	$4,808	$8,022	$59,780,922	56.8%
Budesonide non-compUnit (J7626)	136	141	$13,136	$33,672	$59,537,844	39.0%
CPAP full face mask (A7030)	62	62	$5,982	$9,206	$53,974,803	66.0%
Lightweight wheelchair (K0003)	67	69	$4,291	$4,606	$53,344,568	95.5%
Standard wheelchair (K0001)	74	79	$2,736	$3,016	$52,628,676	92.5%

Service Billed to DME (HCPCS)	Number of Claims in Sample	Number of Lines in Sample	Dollars Overpaid in Sample	Total Dollars Paid in Sample	Projected Dollars Overpaid	Overpayment Rate
High strength ltwt whlchr (K0004)	80	91	$7,419	$9,046	$51,690,372	90.9%
LSO sag-coro rigid frame pre (L0631)	62	62	$28,990	$48,450	$51,310,493	60.4%
Multi den insert direct form (A5512)	45	48	$5,649	$6,623	$49,722,593	86.0%
Disp fee inhal drugs/30 Days (Q0513)	424	426	$7,062	$13,398	$47,738,353	53.1%
All Other Codes	7,274	13,747	$3,982,290	$7,804,614	$1,736,897,848	55.4%
Combined	11,204	23,141	$5,093,646	$9,624,629	$5,666,217,120	58.2%

TABLE 4: 2014 ANNUAL MEDICARE FFS IMPROPER PAYMENT RATE REPORT DMEPOS SERVICE SPECIFIC OVERPAYMENT RATE APPENDIX

Service Billed to DME (HCPCS)	Number of Claims in Sample	Number of Lines in Sample	Dollars Overpaid in Sample	Total Dollars Paid in Sample	Projected Dollars Overpaid	Overpayment Rate
All Codes W Less Than 30 Claims	2,451	3,594	$669,407	$1,753,102	$933,768,888	51.9%
Oxygen concentrator (E1390)	1,044	1,081	$93,657	$152,154	$783,718,989	61.2%
Blood glucose/reagent strips	962	979	$52,086	$91,761	$569,440,653	57.1%
PWC gp 2 std cap chair (K0823)	581	587	$124,754	$155,463	$154,185,886	80.6%
Hosp bed semi-electr w/matt (E0260)	228	232	$16,834	$19,626	$117,275,279	83.4%
Cont airway pressure device (E0601)	104	111	$2,875	$8,197	$75,196,567	34.3%
Enteral feed supp pump per d (B4035)	79	82	$11,389	$17,282	$69,895,164	64.3%
CPAP full face mask (A7030)	66	66	$6,083	$10,595	$63,826,897	51.8%
Portable gaseous 02 (E0431)	446	463	$6,527	$10,981	$59,862,194	59.3%
Lancets per box (A4259)	518	523	$4,937	$8,633	$59,652,076	57.8%
Nasal application device (A7034)	73	73	$3,971	$6,814	$58,848,469	57.1%
NDC 00004-1101-51 Capecitabi (WW093)	38	38	$19,149	$86,881	$56,535,421	22.8%
Arformoterol non-compunit (J7605)	71	72	$8,132	$21,217	$53,572,352	48.8%
Diab shoe for density insert (A5500)	77	85	$6,203	$8,790	$52,941,678	68.0%
EF spec metabolic noninherit (B4154)	53	56	$13,512	$18,333	$52,564,481	78.2%
RAD w/o backup non-inv intfc (E0470)	54	56	$5,612	$9,227	$51,504,678	58.9%
Lightweight wheelchair (K0003)	61	61	$3,704	$3,852	$50,812,414	97.3%
Budesonide non-comp unit (J7626)	101	103	$7,748	$27,022	$50,266,076	27.8%
High strength ltwt whlchr (K0004)	60	60	$5,400	$5,543	$46,672,538	96.5%
Standard wheelchair (K0001)	70	72	$2,228	$2,497	$46,021,996	87.1%
All Other Codes	7,286	19,766	$5,123,515	$14,266,388	$1,686,721,479	48.1%
Combined	10,979	28,170	$6,187,724	$16,684,357	$5,093,284,175	53.1%

We received the following comments with regard to items that were included on the

proposed Master List and our responses follow.

Comment: Several commenters recommended that any DMEPOS items needed for chronic/lifelong conditions should not require prior authorization (for example, missing a limb). Many commenters stated lower-limb prosthetic(s) (LLP) or items used in the prosthesis process (that is, gel liners) should be exempt from the Master List due to concerns regarding complex functional criteria documentation requirements and because of possible numerous changes in the beneficiary's functional capabilities throughout their lifetime.

Some commenters noted that certain contractor local coverage determinations are based, in part, on the pricing, data analysis, and coding (PDAC) contractor assignment of functional levels for specific prosthetics and their components. Commenters went on to state that there are no studies showing that specific prosthetic components are inappropriate for any functional level. With this, some commenters expressed concern that even if the beneficiary had the appropriate functional level, he or she may still be denied prior authorization thus, they state, LLPs should not be included on the Master List.

Several commenters were concerned because prostheses can change frequently when the beneficiary changes (for example, weight changes) and many prostheses are customized. Commenters were concerned that with the advent of the prior authorization program, subsequent limbs would not receive a provisional affirmative decision.

Many commenters expressed concerns that including LLPs on the proposed Master List would cause a delay in care, increased complications, comorbidities, higher out-of-pocket costs, and poor clinical outcomes. Some commenters recommended a private insurance company handle the prior authorization of all LLPs on the proposed Master List.

Some commenters noted that success of the prior authorization of PMD demonstration should not be applied to the prior authorization developed by this final rule since PMDs are "commodities" while many other DMEPOS items (such as LLPs) are not.

Response: Timely beneficiary access to care is of utmost concern to us. Regarding the comment that prior authorization of the PMD demonstration should not influence how or why we apply prior authorization to other DMEPOS items, we want to assure the public that we understand that clinical considerations differ with each DMEPOS item. For example, we realize some LLPs are required soon after surgery and we do not want to delay care or rehabilitation. Prior authorization is not meant to be a barrier to care; it is a process to make sure products and services provided meet applicable Medicare coverage, coding, and payment rules prior to the service being furnished.

We disagree with the suggestion that any item needed for chronic or life-long conditions be exempt from the Master List. Most of the Master List items are used for chronic or life-long medical conditions and documentation requirements for these items remains unchanged. We believe we can address access issues by designing a prior authorization process that is nimble and efficient when an item is needed quickly. In section II.E. of this final rule, we discuss in more detail the proposed timelines for the prior authorization process and our final decision regarding timelines.

Regarding some commenters' concern that a beneficiary may not receive the appropriate LLP because of functional requirements criteria or because the beneficiary's functional capabilities have changed, we again reassure commenters that we support a beneficiary's access to the appropriate prosthetic. The submitted medical documentation must support the request for

payment of the subject LLP. As noted previously, we will issue specific guidance regarding the prior authorization timelines in subregulatory guidance. One reason for this is to create timelines/processes that are logical for each DMEPOS item selected for prior authorization. For example, timelines and contractor processes for prior authorization of LLPs may be uniquely different than for other DMEPOS items. We disagree with the commenter who suggested that we use a private insurance company to process prior authorizations for LLPs. Any entity doing work on behalf of the government is an agent of the government and must abide by all applicable Medicare coverage, coding, and payment rules when making payment determinations. We recognize that the Pricing, Data Analysis, and Coding (PDAC) contractor developed the functional levels of LLPs. However, longstanding documentation requirements based on PDAC assignment have not changed and will also apply to documentation requirements for the prior authorization process.

Finally, we do not understand how a prior authorization program could increase beneficiary out-of-pocket expenses for LLPs. The same coverage, coding, and payment rules apply. A beneficiary will still have access to medically necessary LLPs and his or her costs should not change due to prior authorization processes.

Comment: Several commenters recommended using a clinical threshold to identify when an expedited review request is justified for respiratory and oxygen items on the Master List. Suggested examples included when a patient's respiratory disturbance index is greater than 20, the oxygen saturation falls below 80 percent or complex cardiac arrhythmias accompany obstructive episodes. If clinical laboratories and studies show less severe obstructive sleep apnea, the recommendation was that the standard prior authorization process, not the expedited

process, should be used.

Some commenters requested that we include all oxygen and respiratory devices, while many commenters requested that we exclude all of them. Commenters recommended that CMS exclude respiratory assistive devices from the prior authorization requirement because of the administrative burden to furnish medical documentation before the device is given to the beneficiary. Specifically, a commenter expressed concern regarding the impact of a prior authorization process on the commercial driver community. Commenters noted that those commercial drivers who have a diagnosis of obstructive sleep apnea must undergo a clearance process that requires the beneficiary to utilize a respiratory assistive device prior to obtaining commercial driver clearance. Commenters were concerned that the proposed prior authorization process would prolong the process of obtaining the clearance necessary to perform their job duties. Other commenters believe that the proposed prior authorization timeline would give beneficiaries the impression that respiratory therapy is not mandatory; which would then lead to more costly treatment(s) of obstructive sleep apnea.

Response: We disagree with the suggestion to exclude all oxygen and respiratory devices, and we have included respiratory devices that meet the inclusion criteria on the finalized Master List. Again, not all items on the Master List will require prior authorization. We recognize that the original proposed prior authorization process timeframes may have caused some commenters to suggest excluding all oxygen and respiratory devices. The original proposed prior authorization process timeframes, as discussed in section II.E. of this final rule, may have presented a barrier to timely care in certain circumstances. We will take these comments into consideration when developing the prior authorization timeframes. We will issue

the timeframes in subregulatory guidance. We believe that by doing so, we create flexibility to quickly modify the timeframes if issues are identified. For more information on the prior authorization processes, including timeframes, see section II.E. of this final rule.

Comment: Several commenters were concerned that for some Master List items, the proposed prior authorization program would discourage suppliers from working with Medicare beneficiaries. These commenters believed that this would leave beneficiaries unable to find suppliers, resulting in a potential for increased beneficiary liability and out-of-pocket expenses.

Some commenters recommended that the beneficiary should be liable if a supplier did not obtain a prior authorization. Other commenters recommended that CMS use its authority to suspend or cease any prior authorization program if patient access is jeopardized. In addition, commenters requested that CMS clarify the Advance Beneficiary Notice of Non-Coverage (ABN) process and the proposed prior authorization process.

Response: We appreciate the concerns about access but disagree that the Master List creates access issues or barriers to care. Since we are not finalizing the proposed prior authorization process timeframes as discussed in section II.E. of this final rule, we believe we can address beneficiary access and care delivery issues by creating a prior authorization process that safeguards beneficiary access to care and avoids creating any barriers for beneficiaries and suppliers. We will issue the timeframes in subregulatory guidance, as discussed in section II.E. of this final rule. Additionally, we are finalizing our authority to suspend or cease prior authorization for the entire list or individual items at any time, as discussed at the end of this section.

In the May 28, 2014 proposed rule, we included a discussion of Medicare's ABN and liability policies. This discussion can be found under section II.F. of this final rule. However, interested persons can find more information regarding Medicare's ABN process at this site: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/abn_booklet_icn006266.pdf.

Comment: Some commenters recommended adding more items to the proposed Master List, including, but not limited to, oxygen and all oxygen equipment, enteral and parenteral nutrients and supplies, all manual wheelchairs, all hospital beds, all bi-level respiratory devices and ventilators, and knee and back braces. Some commenters recommended including items on the proposed Master List regardless of the payment threshold for which there is proven disregard for medical necessity requirements or do not have associated LCDs or NCDs. Other commenters suggested narrowing the criteria for the proposed Master List.

Response: We are finalizing the items on the Master List as proposed with two modifications, discussed at the end of this section. The statutory basis and definition of DMEPOS items for this final rule, combined with our analysis, require us to include only those items that, based on prior payment experience, are subject to frequent overutilization. We believe this will allow us to focus finite resources on the higher cost items more frequently subject to over utilization.

Comment: Some commenters believe that all items on the Master List will be subject to the prior authorization requirements. A commenter stated that the HCPCS codes on the proposed Master List had errors, but did not list which HCPCS code(s) were in error.

Response: The criteria discussed previously determine inclusion on the Master List. As such, we have updated the Master List from what was published in the May 28, 2014 proposed rule to reflect the most current application of these criteria. As discussed earlier, updating the Master List for this final rule required us to review the 2015 DMEPOS fee schedule as well as OIG/GAO/CERT reports published after the proposed rule was published. Consequently, we added one item to the Master List: E1390: oxygen concentrator (mistakenly left off the proposed Master List). Aside from the omission of HCPCS code E1390, we did not find additional errors in the listed HCPCS codes in the proposed Master List.

Regarding the commenters who believe that all items on the Master List will be subject to the prior authorization requirements, we would like to clarify that only a subset of the Master List items will be selected and added to the "Required Prior Authorization List." This is further discussed in section II.D. of this final rule.

We are finalizing the Master List as proposed with two modifications. First, we are adding oxygen concentrator (E1390) since it meets the criteria and should have been added to the proposed Master List. The addition is bolded and italicized for easy reference on the Master List (Table 5). Second, we are removing five proposed items from the list that did not meet the 2015 DMEPOS Fee Schedule list criteria of $1,000 or greater average purchase fee schedule or an average rental fee schedule of $100 or greater. These items include the following:

- Custom shaped protective cover, above knee (L5705).
- Custom shaped protective cover, knee disarticulation (L5706).
- Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control (L5718).

• Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control (L5722).

• Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock (L5816).

DMEPOS items meeting the proposed criteria are listed in the Final Master List, which is found in Table 5.

TABLE 5: FINAL MASTER LIST OF DMEPOS ITEMS SUBJECT TO FREQUENT UNNECESSARY UTILIZATION FOR PRIOR AUTHORIZATION

(Items added to the proposed Master List are bolded and Italicized)

HCPCS	Description
E0193	Powered air flotation bed (low air loss therapy)
E0260	Hosp bed semi-electr w/ matt
E0277	Powered pres-redu air mattrs
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width
E0373	Nonpowered advanced pressure reducing mattress
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e. g. , nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0601	Continuous Airway Pressure (CPAP) Device
E1390	***Oxygen Concentrator***
E2402	Negative pressure wound therapy electrical pump, stationary or portable
K0004	High strength, lightweight wheelchair
K0813	Power wheelchair, group 1 standard, portable, sling/solid seat and back, patient weight capacity up to and including 300 pounds
K0814	Power wheelchair, group 1 standard, portable, captains chair, patient weight capacity up to and including 300 pounds
K0815	Power wheelchair, group 1 standard, sling/solid seat and back, patient weight capacity up to and including 300 pounds
K0816	Power wheelchair, group 1 standard, captains chair, patient weight capacity up to and including 300 pounds
K0820	Power wheelchair, group 2 standard, portable, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0821	Power wheelchair, group 2 standard, portable, captains chair, patient weight capacity up to and including 300 pounds

HCPCS	Description
K0822	Power wheelchair, group 2 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0823	Power wheelchair, group 2 standard, captains chair, patient weight capacity up to and including 300 pounds
K0824	Power wheelchair, group 2 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0825	Power wheelchair, group 2 heavy duty, captains chair, patient weight capacity 301 to 450 pounds
K0826	Power wheelchair, group 2 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0827	Power wheelchair, group 2 very heavy duty, captains chair, patient weight capacity 451 to 600 pounds
K0828	Power wheelchair, group 2 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more
K0829	Power wheelchair, group 2 extra heavy duty, captains chair, patient weight 601 pounds or more
K0835	Power wheelchair, group 2 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0836	Power wheelchair, group 2 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds
K0837	Power wheelchair, group 2 heavy duty, single power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0838	Power wheelchair, group 2 heavy duty, single power option, captains chair, patient weight capacity 301 to 450 pounds
K0839	Power wheelchair, group 2 very heavy duty, single power option sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0840	Power wheelchair, group 2 extra heavy duty, single power option, sling/solid seat/back, patient weight capacity 601 pounds or more
K0841	Power wheelchair, group 2 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0842	Power wheelchair, group 2 standard, multiple power option, captains chair, patient weight capacity up to and including 300 pounds
K0843	Power wheelchair, group 2 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0848	Power wheelchair, group 3 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0849	Power wheelchair, group 3 standard, captains chair, patient weight capacity up to and including 300 pounds
K0850	Power wheelchair, group 3 heavy duty, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0851	Power wheelchair, group 3 heavy duty, captains chair, patient weight capacity 301 to 450 pounds

HCPCS	Description
K0852	Power wheelchair, group 3 very heavy duty, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0853	Power wheelchair, group 3 very heavy duty, captains chair, patient weight capacity 451 to 600 pounds
K0854	Power wheelchair, group 3 extra heavy duty, sling/solid seat/back, patient weight capacity 601 pounds or more
K0855	Power wheelchair, group 3 extra heavy duty, captains chair, patient weight capacity 601 pounds or more
K0856	Power wheelchair, group 3 standard, single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0857	Power wheelchair, group 3 standard, single power option, captains chair, patient weight capacity up to and including 300 pounds
K0858	Power wheelchair, group 3 heavy duty, single power option, sling/solid seat/back, patient weight 301 to 450 pounds
K0859	Power wheelchair, group 3 heavy duty, single power option, captains chair, patient weight capacity 301 to 450 pounds
K0860	Power wheelchair, group 3 very heavy duty, single power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0861	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0862	Power wheelchair, group 3 heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 301 to 450 pounds
K0863	Power wheelchair, group 3 very heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 451 to 600 pounds
K0864	Power wheelchair, group 3 extra heavy duty, multiple power option, sling/solid seat/back, patient weight capacity 601 pounds or more
L5010	Partial foot, molded socket, ankle height, with toe filler
L5020	Partial foot, molded socket, tibial tubercle height, with toe filler
L5050	Ankle, symes, molded socket, sach foot
L5060	Ankle, symes, metal frame, molded leather socket, articulated ankle/foot
L5100	Below knee, molded socket, shin, sach foot
L5105	Below knee, plastic socket, joints and thigh lacer, sach foot
L5150	Knee disarticulation (or through knee), molded socket, external knee joints, shin, sach foot
L5160	Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee joints, shin, sach foot
L5200	Above knee, molded socket, single axis constant friction knee, shin, sach foot
L5210	Above knee, short prosthesis, no knee joint ('stubbies'), with foot blocks, no ankle joints, each
L5220	Above knee, short prosthesis, no knee joint ('stubbies'), with articulated ankle/foot, dynamically aligned, each

HCPCS	Description
L5230	Above knee, for proximal femoral focal deficiency, constant friction knee, shin, sach foot
L5250	Hip disarticulation, canadian type; molded socket, hip joint, single axis constant friction knee, shin, sach foot
L5270	Hip disarticulation, tilt table type; molded socket, locking hip joint, single axis constant friction knee, shin, sach foot
L5280	Hemipelvectomy, canadian type; molded socket, hip joint, single axis constant friction knee, shin, sach foot
L5301	Below knee, molded socket, shin, sach foot, endoskeletal system
L5312	Knee disarticulation (or through knee), molded socket, single axis knee, pylon, sach foot, endoskeletal system
L5321	Above knee, molded socket, open end, sach foot, endoskeletal system, single axis knee
L5331	Hip disarticulation, canadian type, molded socket, endoskeletal system, hip joint, single axis knee, sach foot
L5341	Hemipelvectomy, canadian type, molded socket, endoskeletal system, hip joint, single axis knee, sach foot
L5400	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment, suspension, and one cast change, below knee
L5420	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast change 'ak' or knee disarticulation
L5500	Initial, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, plaster socket, direct formed
L5505	Initial, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, plaster socket, direct formed
L5510	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, plaster socket, molded to model
L5520	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, direct formed
L5530	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, molded to model
L5535	Preparatory, below knee 'ptb' type socket, non-alignable system, no cover, sach foot, prefabricated, adjustable open end socket
L5540	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, laminated socket, molded to model
L5560	Preparatory, above knee- knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, plaster socket, molded to model

HCPCS	Description
L5570	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, direct formed
L5580	Preparatory, above knee - knee disarticulation ischial level socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, molded to model
L5585	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, prefabricated adjustable open end socket
L5590	Preparatory, above knee - knee disarticulation ischial level socket, non-alignable system, pylon no cover, sach foot, laminated socket, molded to model
L5595	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, sach foot, thermoplastic or equal, molded to patient model
L5600	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, sach foot, laminated socket, molded to patient model
L5610	Addition to lower extremity, endoskeletal system, above knee, hydracadence system
L5611	Addition to lower extremity, endoskeletal system, above knee - knee disarticulation, 4 bar linkage, with friction swing phase control
L5613	Addition to lower extremity, endoskeletal system, above knee-knee disarticulation, 4 bar linkage, with hydraulic swing phase control
L5614	Addition to lower extremity, exoskeletal system, above knee-knee disarticulation, 4 bar linkage, with pneumatic swing phase control
L5616	Addition to lower extremity, endoskeletal system, above knee, universal multiplex system, friction swing phase control
L5639	Addition to lower extremity, below knee, wood socket
L5643	Addition to lower extremity, hip disarticulation, flexible inner socket, external frame
L5649	Addition to lower extremity, ischial containment/narrow m-l socket
L5651	Addition to lower extremity, above knee, flexible inner socket, external frame
L5681	Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code l5673 or l5679)
L5683	Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code l5673 or l5679)
L5700	Replacement, socket, below knee, molded to patient model
L5701	Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model

HCPCS	Description
L5702	Replacement, socket, hip disarticulation, including hip joint, molded to patient model
L5703	Ankle, symes, molded to patient model, socket without solid ankle cushion heel (sach) foot, replacement only
L5707	Custom shaped protective cover, hip disarticulation
L5724	Addition, exoskeletal knee-shin system, single axis, fluid swing phase control
L5726	Addition, exoskeletal knee-shin system, single axis, external joints fluid swing phase control
L5728	Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5780	Addition, exoskeletal knee-shin system, single axis, pneumatic/hydra pneumatic swing phase control
L5781	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system
L5782	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy duty
L5795	Addition, exoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5814	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock
L5818	Addition, endoskeletal knee-shin system, polycentric, friction swing, and stance phase control
L5822	Addition, endoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5824	Addition, endoskeletal knee-shin system, single axis, fluid swing phase control
L5826	Addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5830	Addition, endoskeletal knee-shin system, single axis, pneumatic/ swing phase control
L5840	Addition, endoskeletal knee/shin system, 4-bar linkage or multiaxial, pneumatic swing phase control
L5845	Addition, endoskeletal, knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type

HCPCS	Description
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5930	Addition, endoskeletal system, high activity knee control frame
L5960	Addition, endoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5964	Addition, endoskeletal system, above knee, flexible protective outer surface covering system
L5966	Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system
L5968	Addition to lower limb prosthesis, multiaxial ankle with swing phase active dorsiflexion feature
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source
L5979	All lower extremity prosthesis, multi-axial ankle, dynamic response foot, one piece system
L5980	All lower extremity prostheses, flex foot system
L5981	All lower extremity prostheses, flex-walk system or equal
L5987	All lower extremity prosthesis, shank foot system with vertical loading pylon
L5988	Addition to lower limb prosthesis, vertical shock reducing pylon feature
L5990	Addition to lower extremity prosthesis, user adjustable heel height

In addition, we are finalizing our proposal to notify the public annually of any additions and deletions from the Master List by posting the notification in the **Federal Register** and on the CMS Prior Authorization website as described in § 414.234(b)(2). We are also finalizing our proposal to suspend or cease prior authorization for the entire list or individual items at any time as described in § 414.234(f)(1).

D. Process for Selecting Items from the Master List to be Subject to the Prior Authorization Program

In the May 28, 2014 proposed rule (79 FR 30519), we stated that an item's presence on the Master List would not automatically require prior authorization. We proposed implementing

the prior authorization program by limiting the number of items from the Master List that would be subject to prior authorization. We stated that by implementing prior authorization for a subset of Master List items, we would minimize provider and supplier burden while safeguarding the Medicare program. This subset of Master List items is hereafter referred to as the "Required Prior Authorization List" as described in § 414.234 (c). We proposed that we would inform the public of the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation.

Additionally, we proposed a prior authorization program for eligible items that may be implemented nationally or locally. For example, we noted that OIG and GAO reports and the CERT DME and/or DMEPOS Service Specific Report(s) often include regional data, and we proposed that we could elect to limit the prior authorization requirement to a particular region of the country if claims data show that unnecessary utilization of the selected item(s) is concentrated in a particular region. Alternately, we proposed that we may elect to implement prior authorization nationally if claims data show that unnecessary utilization of the selected item(s) is widespread and occurring across multiple geographic areas.

We also proposed to have the authority to suspend or cease the prior authorization program generally, or for a particular item or items at any time, without undertaking a separate rulemaking. An example of when we may elect to exercise this authority, described in the proposed rule, is suspending or ceasing the prior authorization program due to new payment policies, which may render the prior authorization requirement obsolete or remove the item from Medicare coverage. If we suspend or cease the prior authorization requirement, we proposed we

would post notification of the suspension on the CMS Prior Authorization website, contractor websites, publications, and bulletins and include the date of suspension.

The proposed rule did not announce the first items on the Required Prior Authorization List. In the proposed rule, we requested public comment on the: (1) number of items selected for initial implementation; (2) number of future items selected for implementation; and (3) frequency in which we would select the items.

We noted in the May 28, 2014 proposed rule (79 FR 30520) that the proposed Master List contains DMEPOS items currently included in the CMS Prior Authorization of PMD Demonstration, and that we would not require prior authorization for PMDs under this rule, at least until the demonstration was complete. We proposed that the finalized rule would not affect the current Prior Authorization of PMD Demonstration.

In the following discussion, we summarize the comments and our responses for section II.D. of this final rule along with our final decision applicable to this section.

Comment: Commenters requested clarification regarding the definition of implementing a prior authorization program locally and nationally.

Response: Locally is a geographical area such as a state or jurisdiction; nationally is nationwide, as in all states/jurisdictions. As such, we may elect to establish a prior authorization program for a certain Master List item for a particular state, or a particular MAC jurisdiction, or nationally, as authorized by section 1834(a)(15) of the Social Security Act and as stated in new § 414.234(c)(1)(ii) of our regulations.

Comment: A commenter recommended that CMS implement prior authorization for all items on the proposed Master List at the same time with a nationwide rollout. Others suggested

that CMS implement a pilot for select items locally, in a small region. Some commenters expressed their objection to CMS's decision to not identify in the proposed rule which Master List item(s) would initially be subject to prior authorization. Another commenter believed the Required Prior Authorization List process should include a notice for public input in the **Federal Register**. Others believed the proposed **Federal Register** 60-day public notice of items selected for the Required Prior Authorization List was not a long enough notice for suppliers to accommodate a change in their business practice. Commenters did not provide specific recommendations on the number of items to move from the Master List to the Required Prior Authorization List for initial implementation or in the future. Most commenters wanted the least amount of burden possible, but did not indicate what number of items would minimize the burden. A commenter suggested adding an undetermined number of items to the Required Prior Authorization List quarterly. Some commenters expressed concern that undue burden may be created if too many Master List items are added to the Required Prior Authorization List at once. Other commenters found having two lists, the Master List and the Required Prior Authorization List, confusing.

Response: We appreciate commenters' suggestion that we pilot prior authorization in a small region before fully implementing the program and we will take it under advisement. We do not agree with the suggestion to initially implement all Master List items nationally or to add items to the Required Prior Authorization List on a regular quarterly basis. We believe doing so may create undue burden for suppliers and beneficiaries. For instance, if we update the Required Prior Authorization List in January and we quickly learn that the proposed timeline for an item newly added to the list is problematic, we would want to change that as quickly as possible.

Waiting until the next quarter would be potentially harmful to beneficiaries. However, we also recognize that it may be difficult for suppliers and beneficiaries to keep up with changes if there are frequent additions to the list.

We point out that the public commented on the Master List items, which we published as part of the proposed rule. Thus we disagree with the commenters that believed the Required Prior Authorization List (a subset of the Master List) process should include another public comment. We are finalizing our proposal to implement the prior authorization program locally or nationally or to suspend or cease the prior authorization requirement program generally or for a particular item or items at any time without undertaking a separate rulemaking. Providing subregulatory guidance will allow us to implement the prior authorization program in such a way that if we encounter problems, we can quickly halt the program as a whole, or for a particular item.

We are aware that some suppliers believe they need more than 60-day notice to prepare for prior authorization of a selected item on the Required Prior Authorization List. However, while the notice in the **Federal Register** will be published 60 days before the start of prior authorization for a particular item, CMS will be communicating to the community in a variety of ways before posting the 60-day notice. For example, we may conduct Open Door Forum calls or the MACs may host informational webinars. We believe that through education and community interaction before the 60-day notice, suppliers will be well informed of the upcoming prior authorization program requirements and can be ready 60 days after the official posting of the public notice.

We agree with commenters who believed initially implementing prior authorization for all items on the Master List creates undue burden for suppliers and physicians. In response to commenters that expressed their objections to CMS's decision to not identify in the proposed rule which Master List item(s) would initially be subject to prior authorization, we believe a number of factors will guide our selection. For example, CMS may consider factors such as geographic location, item utilization or cost, system capabilities, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis. Therefore, we may initially elect to require prior authorization on only one item in a small region and quickly suspend the requirement if we find there are unintended effects.

In response to a commenter who believed having two lists was too confusing, we believe having two lists is necessary. The Required Prior Authorization List is selected from the Master List of Items Frequently Subject to Unnecessary Utilization. The Required Prior Authorization List is defined as a subset of Master List items subject to prior authorization.

We believe having the two lists minimizes burdens associated with implementation of prior authorization. For example, CMS may elect to implement prior authorization a limited number of items. Having only one list would require us to implement prior authorization on all items on the list. As we mentioned previously, we believe implementing prior authorization for the entire list would create undue burden for suppliers, physicians, and beneficiaries. In addition, it would create administrative burden for the review contractor. We believe implementing prior authorization on a subset of the items on the Master List allows us to closely monitor the prior authorization program for each selected item and make changes, if needed.

Comment: Public comments were solicited on the number of items selected for initial implementation of the prior authorization requirement and potential impact on the burden to the DMEPOS community. However, commenters did not provide a recommendation for a certain number of items. Instead, commenters expressed their concerns in more general terms. For example, most commenters recommended the least amount of burden possible, but did not indicate what number of items would minimize the burden. Other commenters believe that the public should be given the opportunity to comment on each item we select from the Master List and move to the Required Prior Authorization List. A commenter suggested adding an undetermined number of items to the Required Prior Authorization List quarterly. Some commenters believe that CMS should "pilot" the program in a small area before going national. Commenters believe that by doing so, CMS could identify and address any unforeseen challenges before implementing nationally.

Response: Earlier in this final rule, we reminded commenters that both the final rule and the Act gives us the authority to select the item, implement the prior authorization requirement for that item locally or nationally, and suspend or cease the prior authorization process generally or for a particular item. We believe that this authority allows us to be quickly responsive to any general implementation issue(s) that may surface, or issues related to the prior authorization implementation for a specific item.

We are finalizing our proposal to select an item(s) from the Master List and include it on the Required Prior Authorization List, to implement the prior authorization program locally or nationally, and to suspend or cease the prior authorization requirement program generally, or for a particular item without undertaking a separate rulemaking. We are also finalizing our authority

to determine the number of item(s) selected upon initial implementation, determine the number of items selected for future implementation, and determine the frequency with which we would select the item(s).

Lastly, we are finalizing the proposal that we inform the public of the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation.

Comment: Some commenters suggested each item selected for prior authorization be time limited (a beginning and ending date) for the prior authorization requirements; other commenters suggested that items be subject to prior authorization for the duration of the capped rental period.

Response: We will take these comments into consideration. The length of time a prior authorization requirement is valid for a particular item may be dependent on the item chosen for prior authorization. We believe these operational logistics are more appropriately addressed in CMS guidance.

Comment: Some commenters stated that the proposed rule fails to outline factors or any methodology that CMS will use when selecting Master List items for the Required Prior Authorization List. Other commenters stated that no limits are placed on the number of items to move from the Master List to the Required Prior Authorization List. Commenters stated that without this information, the decision-making process is unclear and fails to provide adequate notice for physicians and other stakeholders.

Response: We solicited comments on the number of items we should implement initially and in the future, as well as the frequency in which we move the items from the Master List to the Required Prior Authorization list. We did not receive specific recommendations on the

number of items to move from the Master List to the Required Prior Authorization List for initial implementation or in the future, except for a few commenters who recommended we implement all of the items at the same time. In addition to the inclusion criteria discussed previously, future policies, regulations or response to stakeholder needs may be factored into the Master List item selection(s). While we are not finalizing any methodology or criteria for selection of items to be included on the Required Prior Authorization List, CMS may consider factors such as geographic location, item utilization or cost, system capabilities, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis. Such exemplary factors are not being provided to create a definitive list or set of pre-determined considerations, nor to indicate whether such factors could be reviewed in singular or aggregate, nor to indicate the level of priority to be applied to a specific item(s). Rather, they are cited for the limited purpose of notifying stakeholders of the types of factors CMS may take into consideration to create the Required Prior Authorization List.

We note that all provisions finalized in this rule apply in competitive bidding areas because CMS conditions of payment apply under the Medicare DMEPOS Competitive bidding Program.

E. The Proposed Prior Authorization Process

As described in the May 28, 2014 proposed rule (79 FR 30520), the proposed prior authorization process would not create new or change existing clinical documentation requirements. As proposed, it would require the same information necessary to support Medicare payment, just earlier in the process. This process allows the review contractor to confirm, to the extent possible, that all relevant coverage, coding, and clinical documentation

requirements are met before the item is furnished to the beneficiary and before the claim is submitted for payment.

We proposed that prior to furnishing the item and prior to submitting the claim for processing, a prior authorization requester would submit evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Information regarding Medicare coverage, coding, and payment rules for DMEPOS items is found in the Act, our regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCD), CMS manuals and transmittals, as well as Durable Medical Equipment Medicare Administrative Contractors' (DME MAC) websites. All Medicare coverage, coding, and payment rules would apply. Medicare coverage, coding, and payment rules applicable to items on the Required Prior Authorization List would also be posted on the CMS Prior Authorization website. Furthermore, we proposed we would not change existing requirements regarding the entity responsible for creating required clinical documentation. For example, clinical documentation that is required to be created by a practitioner would still be required to be created by the practitioner. Similarly, documentation requiring supplier origination (for example, product description) would still be generated by the supplier.

We stated in the proposed rule that CMS or its review contractors would review the prior authorization request to determine whether the item ordered for the beneficiary complies with applicable Medicare coverage, coding, and payment rules. After receipt of all applicable required Medicare documentation, CMS or its review contractors would conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. We proposed that a provisional affirmation is a preliminary finding that a future claim meets

Medicare's coverage, coding, and payment rules. Claims receiving a provisional affirmation may still be denied based on technical requirements that can only be evaluated after the claim has been submitted for formal processing. For example, a finding that a claim is a duplicate claim can only be made after the claim has been submitted for formal processing. Claims receiving a provisional affirmation may also be denied based on information not available at the time of a prior authorization request (that is, proof of delivery). A prior authorization request that is non-affirmed under section 1834(a)(15) of the Act is not an initial determination on a claim for payment for items furnished, and therefore, would not be appealable. We proposed making this distinction clear by adding a new paragraph (t) to § 405.926 stating that a review contractor's prior determination of coverage is not an initial determination.

In the May 28, 2014 proposed rule (79 FR 30520), we stated that claims associated with a non-affirmation decision, as well as claims for items subject to prior authorization but for which no prior authorization was requested, would be denied if submitted for processing. A requester who submits a claim for which there was a non-affirmation decision or for which no prior authorization request was obtained would be afforded full appeal rights on the claim.

We proposed that CMS or its review contractors would make reasonable efforts to communicate the decision within 10 days of receipt of all applicable information. However, we stated that final timelines for communicating a provisionally affirmed or non-affirmed decision to the requester would be described in CMS guidance and posted on the CMS Prior Authorization website. We proposed allowing unlimited resubmissions of prior authorization requests.

To address circumstances where applying the standard timeframe for making a prior

authorization decision could seriously jeopardize the life or health of the beneficiary, we proposed a mechanism for an expedited review. We proposed that if CMS or its review contractors agree that using the standard timeframes for review places the beneficiary at risk as previously described, then we would allow an expedited review of the prior authorization request and communicate an expedited decision. In these situations, we stated that CMS or its review contractors would make reasonable efforts to communicate the decision within 2 business days of receipt of all applicable Medicare required documentation. We stated this process would be further defined in CMS guidance and posted on the CMS Prior Authorization website. We proposed that a prior authorization request for an expedited review would include documentation that shows that applying the standard timeframe for making a decision could seriously jeopardize the life or health of the beneficiary. For example, documentation could include medical records, supplier documentation, home health documentation or any other documentation deemed to support the necessity of an expedited review. We solicited public comment on whether the proposed process would meet our objective of maintaining beneficiary access to care and protecting the Medicare program without placing undue burden on practitioners and suppliers.

We proposed to permit a requester to resubmit a prior authorization request if the initial request was non-affirmed. Prior authorization requests would be reviewed, and a decision of a provisional affirmation or a non-affirmation would be communicated to the affected parties in the same manner as an initial request. We stated we would consider a request for the same beneficiary for the same HCPCS code in a 6-month period of time to be a resubmission. We proposed that a request outside of those parameters would be treated as a new initial request. We sought public comment on the number of resubmitted prior authorization requests allowed.

In the May 28, 2014 proposed rule, we suggested that Medicare or its review contractors make a reasonable effort to render a provisional affirmation or a non-affirmation decision within 10 days of receiving the initial request, 2 days for an expedited request or 20 days for a resubmission. We also sought public comment on suggested timeframes for provisional affirmation or non-affirmation decisions on resubmitted prior authorization requests. Furthermore, in the proposed rule, we stated additional information about timeframes for all decisions would be described in CMS guidance to its contractors. In the May 28, 2014 proposed rule, we included the following illustrations of possible prior authorization scenarios:

Scenario 1: A requester submits to CMS (or its review contractors) a prior authorization request along with all required documentation. CMS (or its review contractors) finds that the request meets all applicable Medicare requirements. CMS (or its review contractors) would communicate a provisional affirmation decision to the affected parties. The supplier would submit the claim following receipt of a provisional affirmation decision, and the claim would be paid, as long as all other requirements were met.

In the preceding example, the granted affirmation decision is provisional because payment decisions can only be made after all requirements are evaluated. For example, a claim could have received a provisional affirmation prior authorization decision. However, after submission, the claim could be denied due to technical payment reasons, such as the claim was a duplicate claim or the claim was for a deceased beneficiary. In addition, certain documentation needed in support of the claim, such as proof of delivery, are unavailable for review on a prior authorization request.

Scenario 2: A requester submits to CMS (or its review contractors) a prior authorization request. CMS (or its review contractors) conducts a medical review of submitted documentation and determines that the request and submitted documentation does not comply with one or more applicable Medicare coverage, coding, and payment rules. CMS (or its review contractors) communicates a decision that non-affirms the request. A non-affirmation is a preliminary finding that a future claim associated with the submitted documentation and prior authorization request would be denied if submitted because the associated request and submitted documentation did not meet one or more of Medicare's coverage, coding, and payment rules. The communication to the affected parties would identify which Medicare coverage, coding or payment rule(s) was not supported in the request and submitted documentation and thus served as the basis for the non-affirmation decision. The requester could resubmit the prior authorization request. If the claim is submitted for payment without a provisional affirmation decision, it would be automatically denied. The supplier would assume liability if the item was furnished after receiving a non-affirmation decision, unless conditions for assigning liability to the beneficiary or Medicare are met. (For more information, see section 1879(h)(2) of the Act for assigned claims, section 1834(j)(4) of the Act for non-assigned claims, and our discussion in section II.F. of this final rule). A prior authorization request that is non-affirmed under section 1834(a)(15) of the Act is not an initial decision on a claim for payment for items furnished, and therefore would not be appealable. However, a claim for which a non-affirmation prior authorization decision was received, submitted, and subsequently denied could be appealed.

Scenario 3: A claim is submitted without a prior authorization decision. The claim would be denied because there was no prior authorization request, which is a condition of

payment. The supplier is liable unless the conditions for assigning liability to the beneficiary or Medicare are met. (For more information, see section 1879(h)(2) of the Act for assigned claims, section 1834(j)(4) of the Act for non-assigned claims, and our discussion in section II.F. of this final rule).

We proposed to automatically deny payment for a claim for an item on the Required Prior Authorization List that is submitted without a provisional affirmation prior authorization decision. We believe that section 1834(a)(15) of the Act established an advanced determination process (that is, a prior authorization process) as a condition of payment for items on the list developed by the Secretary. We stated in the May 28, 2014 proposed rule that absent this potential penalty for noncompliance with the prior authorization process, section 1834(a)(15) of the Act would be rendered moot, as suppliers would not be required to seek an advance decision of coverage for these items. A mandatory prior authorization process for these items best ensures that CMS effectuates its goal of reducing unnecessary utilization for the items identified by the Secretary in accordance with section 1834(a)(15)(A) of the Act.

We proposed in § 414.234(c) that we would require, as a condition of payment for certain DMEPOS items frequently subject to unnecessary utilization, that a prior authorization request be submitted prior to the submission of a claim. We stated that the new requirement would reduce the unnecessary utilization and the resulting overpayment for certain DMEPOS items.

In addition, we proposed adding a new paragraph (t) to § 405.926 stating that a review contractor's prior determination of coverage is not an initial determination and is thus not appealable because the prior authorization decision is not an initial determination with respect to a claim for benefits under Part A or Part B. Section 405.926 contains the list of actions that are

not initial determinations and thus not appealable. However, we noted that a requester who submits a claim for which there was a non-affirmation decision or for which no prior authorization request was obtained would be afforded appeal rights.

We believe that a prior authorization process is an effective way to address unnecessary utilization, particularly since most items frequently subject to unnecessary utilization are identified as such because of insufficient supporting documentation. Inherent in a prior authorization process is a review of supportive evidence for the medical necessity of the item. Traditionally, this review has involved the beneficiary's medical record.

In summary, we proposed the following prior authorization process:

- Prior to furnishing the item and prior to submitting the claim for processing, a prior authorization requester would submit evidence that the item complies with all coverage, coding, and payment rules.
- CMS or its review contractors would review the prior authorization request and accompanying documentation to determine whether the item ordered for the beneficiary complies with applicable Medicare coverage, coding, and payment rules.
- After receipt of all applicable required Medicare documentation, CMS or its review contractors would conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request.
- For the initial prior authorization request, CMS or its review contractors would make reasonable efforts to communicate a provisionally affirmed or a non-affirmed decision within 10 business days of receipt of all applicable information.

- A requester may resubmit a prior authorization request if the initial request was non-affirmed. Unlimited resubmissions are permitted.
- For each resubmitted prior authorization request, CMS or its review contractors would make reasonable efforts to communicate a provisionally affirmed or a non-affirmed decision within 20 business days of receipt of all applicable information.
- For circumstances where applying the standard timeframe for making a prior authorization decision could seriously jeopardize the life or health of the beneficiary, an expedited review could be requested. For expedited reviews, CMS or its review contractors would expect the submitted documentation to include evidence that applying the standard timeframe for making a decision could seriously jeopardize the life or health of the beneficiary. If CMS or its review contractors agreed that applying the standard timeframe would jeopardize the life or health of the beneficiary, then CMS or its review contractors would make reasonable efforts to communicate a provisionally affirmed or a non-affirmed decision within 2 business days of receipt of all applicable information.

In the proposed rule, we specifically solicited public comment on the following:

- The number of resubmitted prior authorization requests allowed.
- The suggested timeframes for provisional affirmation or non-affirmation decisions on resubmitted prior authorization requests.
- Whether the proposed process would meet our objective of maintaining beneficiary access to care and protecting the Medicare program without placing undue burden on practitioners and suppliers.

Comment: Commenters stated that some items on the Master List were needed sooner than the proposed prior authorization process could permit. For example, commenters stated that electric hospital beds (E0260 on the Master List) were often ordered for beneficiaries the day they are discharged from the hospital. Commenters stated that the proposed expedited review process was still too long for a beneficiary being discharged from the inpatient setting and who required an electric bed to be in their home upon arrival. For example, the proposed expedited process timeframe was 2 business days. If the 2 business days were split by a weekend or a holiday, it could take up to 5 days for the review contractor to render a prior authorization decision. The vast majority of commenters stated that the suggested timeframes would create delays in care or access issues for beneficiaries. Some commenters believed the proposed timeframe created undue burden for suppliers and ordering physicians as well. Several commenters submitted detailed suggestions on creating a prior authorization process that would more quickly return a prior authorization decision to the requester. For example, we received several suggestions to use forms rather than medical records to evidence the need for the requested item. There were suggestions to create a 24-hour, 7-days-a-week call-in service that could give a prior authorization decision after verbal conversation between the prior authorization requester and the call-in service personnel.

Response: We agree that additional flexibility beyond the proposed timeframes may be necessary under particular circumstances to ensure adequate beneficiary access to DMEPOS on the Required Prior Authorization List. In the interest of promoting beneficiary access to care and protecting the Medicare program without placing undue burden on practitioners and suppliers, we are not finalizing the proposed prior authorization timeframes. Therefore, prior authorization

timeframe requirements will be made available to stakeholders and the public in subregulatory guidance, which allows for greater flexibility in the event timeline modifications are warranted. We note the prior authorization timeframe(s) detailed in subregulatory guidance will not exceed the timeframes described in the proposed rule.

We will take the comments regarding alternate processes that afford more expedient responses to the requestor (for example, the 24-hour 7-day a week model) into consideration when developing the prior authorization timeframes.

Comment: Many commenters were confused about actions that are afforded appeal rights. Commenters understood that denied claims can be appealed, but also wanted appeal rights for non-affirmation prior authorization decisions.

Response: We remind commenters that a request for prior authorization is not a claim for benefits, and a non-affirmation prior authorization decision is not an initial determination. See, section 1869(a) of the Act, and 42 CFR 405.904(a)(2), 405.920, and 405.924(b) of the regulations. Rather, a non-affirmation prior authorization decision is a finding by the review contractor that the prior authorization request and accompanying documentation had at least one error or omission of an applicable Medicare coverage, coding or payment rules. If the error remains uncorrected but the claim is still submitted for processing, the claim would be denied.

We believe that permitting resubmissions of non-affirmation prior authorization decisions allows the requester to be educated about what is missing in the initial prior authorization request before the claim is submitted. The review contractor will list the specific information that is missing for any prior authorization request receiving a non-affirmation prior authorization decision. For example, a requester who received a non-affirmation prior authorization decision

because medical necessity documentation was missing can resubmit the request and include the required documentation previously missing. If all applicable Medicare coverage, coding, and payment rules are satisfied with the resubmitted prior authorization request, the formerly non-affirmation prior authorization decision would be changed to a provisional affirmation decision. If the requester disagreed with the review contractor's non-affirmation decision and believed that the prior authorization request met all requirements, the requester could submit the claim for payment. The supplier would receive a payment denial. After receiving the payment denial, the supplier may appeal the claim. The beneficiary may also appeal the denied claim.

We remind readers that an affirmation prior authorization decision is provisional because other information that is only available after the claim is submitted may result in a denial. For example, there may be technical issues, such as a duplicate claim, or an absent or improperly listed proof of delivery date that can be known only after the claim is submitted. However, we believe that reviewing the documentation and information in advance of submitting the claims does provide some assurance that the claim is likely to be paid. We believe that suppliers and beneficiaries prefer to have some assurance that their claim is likely to be paid because all the required information was provided in advance of submitting the claim and furnishing the item to the beneficiary.

Comment: Some suppliers stated that providing documentation before the claim is submitted is less burdensome than having to submit the documentation after the claim is submitted and after the item is furnished. Some believed that prior authorization would reduce their need to access the appeals process, which they state is costly and burdensome.

Response: We agree that prior authorization may reduce a supplier's need to access the appeals process because a requester may resubmit a prior authorization request an unlimited number of times. We believe that allowing requesters to resubmit an unlimited number of times allows the requester multiple opportunities to understand documentation or other requirements of payment, correct the omission before the claim is submitted, and thereby avoid having the subject claim denied. We agree that a prior authorization process is less burdensome than accessing and preparing an appeal request.

Comment: Many commenters expressed a general concern that the proposed prior authorization process would create an overall delay in care, possibly resulting in poor beneficiary health outcomes. For example, several commenters stated that the review timeframes for negative pressure wound therapy items would create a delay in care and result in poor outcomes. They stated that poor outcomes could include a delay in healing which would increase hospital readmissions and poor patient satisfaction. Commenters also stated that a delay in outpatient negative pressure wound therapy would delay beneficiary discharges, extend hospital stays, and increase inpatient costs. Similarly, commenters stated that requiring prior authorization for pressure reducing support surfaces could also delay beneficiary discharges and extend hospital stays.

Response: We understand commenters' concerns and agree that requiring a lengthy prior authorization process for negative pressure wound therapy devices, pressure reducing support surfaces, and perhaps other Master List items, could potentially delay care and lead to negative outcomes. We will take these comments as well as other similar comments into consideration as we develop the timeframes for the prior authorization process. We will issue the timeframes in

subregulatory guidance because we believe that this will create the flexibility to quickly modify the timeframes as needed, if issues are identified.

Comment: Some commenters recommended that CMS compare and contrast the private insurance industry's prior authorization programs with the proposed prior authorization program and recommended that CMS mirror the private insurance industry as much as possible.

Response: We understand many commenters would like to see the Medicare Prior Authorization program mirror the private sector programs as much as possible. Due to the differences in how the private sector and Medicare do business with providers and suppliers, having the same process is not entirely possible. However, in the development of the prior authorization process timeframes, we plan to reach out to the private industry, whenever possible, for examples and best practices that we can adopt.

Comment: Commenters expressed concern about varying aspects of the required prior authorization medical record documentation. For example, many commenters from the prosthetics and orthotics community stated that the prosthetists' notes and records should be considered part of the medical record. Several commenters stated that LCD and NCD medical record documentation requirements will increase the review time, delay the time the beneficiary receives the equipment, and decrease clinician productivity. Some commenters stated individual documentation requirements for certain items on the proposed Master List are more burdensome than others (that is, the monthly documentation requirement for negative pressure wound therapy and physician orders for respiratory assistive devices). Other commenters recommended eliminating some required documentation like date stamps and face-to-face encounters. A

commenter recommended synchronizing the medical record documentation requirements of this rule with the medical record documentation requirements of the face-to-face encounter rule.

Response: As discussed previously, prior authorization does not create new or change any existing documentation requirements. This final rule does not change or create new Medicare medical necessity, coverage, coding or payment rules. As a long-standing expectation, all of the following requirements must be met to receive an affirmation prior authorization decision--

- Coverage and other requirements of NCDs/LCDs;
- Technical requirements (for example, date stamps);
- Statutory requirements (for example, face-to-face encounter documentation); and
- All other requirements.

We will provide education specific to each item subject to prior authorization so that suppliers are informed of specific documentation requirements.

In response to commenters that requested that the prosthetists' notes and records stand alone in fulfilling medical necessity documentation requirements for a beneficiary's prostheses, we note that the expertise of prosthetists is very important and contributes to beneficiaries' recovery. However, a prosthetist's records alone do not illustrate the comprehensive clinical picture of the beneficiary. For example, a physician order alone does not satisfy Medicare's medical necessity criteria. Rather, it is the documentation of multiple healthcare team members working on behalf of the beneficiary that conveys the complete picture of the beneficiary's medical need and appropriate delivery of care. As a principle, when reviewing any claim for

medical necessity, we look for corroboration between all entries (including physician's orders) in a beneficiary's medical record.

Comment: Commenters requested that CMS provide clear guidance regarding required documentation. Other commenters suggested that CMS develop a form or questionnaire for the requester to complete in place of submitting beneficiaries' medical records.

Response: We strive to continually educate providers on required documentation. As always, we expect that any request for Medicare payment is supported in the beneficiary's medical record. Suppliers are permitted to create forms or questionnaires for ordering physicians. However, templates and forms are subject to corroboration with information in the medical record.

Comment: Some commenters questioned who is held responsible for providing the review contractor with the required medical documentation: the primary care provider, the ordering physician or the supplier. Other commenters recommended holding the ordering physicians accountable for lack of documentation and not the supplier. Other commenters recommended that CMS be responsible and accountable for obtaining missing documentation from the ordering physician, not the requester (supplier).

Response: The entity requesting payment for a Medicare-covered item or service is responsible for meeting all Medicare coverage, coding, and payment rules. That responsibility cannot be delegated. We understand obtaining medical records from the beneficiary's other healthcare providers can be challenging for suppliers. However, Medicare's long-standing expectation is that no DMEPOS item(s) should be furnished by a supplier unless the supplier has in its possession or can easily obtain the required medical documentation. This is not unique to

DMEPOS suppliers. Other health care entities providing services to Medicare beneficiaries who were referred to them by other practitioners have an obligation to obtain all the pertinent medical documentation from the referring practitioner. This may require more collaboration among the beneficiary's health care providers, but this collaboration is needed. Research shows that the lack of collaboration between the beneficiary's treatment team can result in the beneficiary's readmission to the inpatient setting or in the beneficiary not receiving other needed care.[16]

Comment: A commenter recommended that we provide information on lower cost alternatives in cases when the review contractor returns a non-affirmation prior authorization decision to the requester.

Response: We expect providers to order and suppliers to provide the medically necessary item for a beneficiary, regardless of cost. If the review contractor determines that a prior authorization request does not meet all applicable Medicare coverage, coding, and payment rules based on the documentation received, it will be non-affirmed. The requester has the option of resubmitting the request with the required documentation an unlimited number of times. Receiving a non-affirmation prior authorization decision does not authorize the supplier to submit a claim for a similar but less costly item. All DMEPOS claims must have an associated physician's order submitted. That is, suppliers may not substitute DMEPOS items that are not ordered by the physician. A physician determines what DMEPOS item is medically necessary for the beneficiary.

16 The Revolving Door: A Report on U.S. Hospital Readmissions. Robert Wood Johnson Foundation, February 2013. Retrieved on February 2, 2015 from http://www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf404178.

Comment: Some commenters recommended using the tax ID and not the Provider Transactions Access Number (PTAN) in the prior authorization process. This way, commenters stated, the prior authorization is transferrable to new suppliers if the beneficiary relocates.

Response: We are developing the system capabilities to attach a prior authorization request to a claim. We will issue claims processing instructions in CMS guidance.

Comment: Several commenters recommended that suppliers be able to deliver the item to the beneficiary before a prior authorization decision is made.

Response: We recognize that some commenters' concerns about providing timely care to the beneficiary included a suggestion to allow suppliers to deliver the item to the beneficiary before a prior authorization decision is made, thus preventing any access issue. We proposed using a 10 business day timeline for initial prior authorization requests, 20 business days for resubmitted prior authorization request and 2 business days for request for expedited reviews. Many commenters believed that these timeframes could create barriers to care for beneficiaries. In response to the concern, we will not finalize the proposed timelines. As mentioned previously, creating a prior authorization process in subregulatory guidance that is customized for the DMEPOS item subject to prior authorization provides flexibility to develop a process that involves fewer days, as may be appropriate. We believe this flexibility allows us to safeguard beneficiary access to care and avoid creating any barriers for beneficiaries and suppliers. Rather, under particular circumstances, we may develop a prior authorization timelines for certain items that permits fewer days than the proposed 10 or 20 business days. At any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program.

Comment: Some commenters recommended that if the review contractor does not provide a prior authorization decision within the proposed timeframe, an automatic approval should be given. Several commenters believed that the review contractor should guarantee payment if they issue an affirmation prior authorization decision since the submitted documentation established medical necessity, even if technical errors are found after the claim is processed.

Response: We respectfully disagree with these suggestions. In order for a prior authorization request to receive an affirmation prior authorization decision, all Medicare coverage, coding, and payment rules must be met, including technical requirements. If medical necessity criteria are met with the initial prior authorization documentation, an affirmed prior authorization would be issued. If a prior authorization request receives an affirmation prior authorization decision, there is an assurance that the claim will not be denied on the basis of medical necessity. However, it is possible the claim could be denied because it did not meet a coding or billing requirement.

We expect that the review contractor will provide a prior authorization decision within the timeframes established in subregulatory guidance. We conduct day-to-day oversight, as well as formal annual performance evaluations of Medicare contractors, to make sure that they are meeting the requirements of their contract. We may require action plans for standards that are not met and also consider documented past performance for future contract awards.

Comment: Some commenters recommended that suppliers receiving a non-affirmation prior authorization decision for an advanced LLP should be allowed to submit another request after 30 days if the beneficiary's functional potential improves after 30 days.

Response: Prior authorization does not create or eliminate documentation requirements. Therefore, in the case of prostheses being subject to prior authorization, improved functional potential after 30 days does not take the place of documentation and medical necessity requirements evidencing this improvement. Provisionally affirmed prior authorizations are based on the submitted documentation. If the beneficiary's functional potential improves and the original prior authorization decision was a non-affirmation, the supplier would need to submit another prior authorization request with the change in beneficiary status in the clinical documentation and all of Medicare's coverage, coding, and payment rules must again be met. A prior authorization request can be submitted at any time and there are an unlimited number of resubmissions. However, if a new DMEPOS item is needed because the status of the beneficiary changes, then a new prior authorization request must be submitted.

Comment: A commenter suggested that the review contractor be fined 100 percent of the allowable amount for an item if one supplier receives a non-affirmation prior authorization for a particular item, for a particular beneficiary, but another supplier receives an affirmation decision for the same item, for the same beneficiary.

Response: A prior authorization request must meet all Medicare coverage, coding, and payment rules. Therefore, if one supplier did not provide all the required documentation or information, but another supplier did, the second supplier would receive a provisional affirmation prior authorization decision while the first one would not. In this situation, two suppliers submitted a prior authorization request at different times for the same item and same beneficiary, but only one supplier furnished the item. Our claims processing system will track

prior authorization requests and we will conduct frequent monitoring. Thus, we can avoid situations when a beneficiary receives two of the same items from two different suppliers.

Beneficiaries and suppliers may file a complaint in cases where they believe access to a DMEPOS item or a supplier was improperly denied or if they believe a prior authorization request was not handled properly. More information on ways to file a complaint is available at https://www.medicare.gov/claims-and-appeals/file-a-complaint/durable-medical-equipment/complaints-about-dme.html. One of the described processes is through the Competitive Acquisition Ombudsman (CAO). The CAO position was established by the Congress and operates within CMS' Office of Hearings and Inquiries. The CAO plays a vital role in ensuring that Agency processes respond effectively to inquiries and complaints about the Program. The CAO notifies Agency leadership about potential systemic issues that may affect beneficiaries' access to quality DMEPOS items and services.

Federal procurement regulations effectively prohibit issuing fines or similar financial penalties to Medicare Administrative Contractors for not meeting performance standards. We provide incentives to contractors for exceeding the requirements in their contracts. This is done through a formal award fee process. Contractors are awarded extra fees for exemplary accuracy in their medical review determinations. We conduct quality checks of the prior authorization decisions through a sample of random claims. Findings from this quality check are communicated to CMS' Medicare Contractor Management Group (MCMG) and are used to determine if a contractor is eligible for an award fee. We also perform annual performance evaluations of MACs to ensure that they are meeting all requirements of their contract. We may require action plans for standards that are not met and also consider documented past

performance for future MAC contract awards. In situations where two suppliers in the same contractor jurisdiction submit identical documentation to support medical necessity and receive two different determinations, we would refer the incident to MCMG for review.

In addition, we conduct day-to-day contractor oversight by, among other things, frequent communication with the contractor medical review components. In these communications, we receive status updates about the different types of medical review decisions. For example, we monitor contractors' pre- and post-pay medical review strategies. Upon implementation, we will also monitor contractors' prior authorization processes, including the decisions they render and the timeframes in which the decisions are rendered.

As noted earlier, prior authorization timeframe requirements will be made available to stakeholders and the public in subregulatory guidance, which allows for greater flexibility in the event timeline modifications are warranted. We remind commenters that both the final rule and the Act gives us the authority to implement the prior authorization requirement for a DMEPOS item locally or nationally, and suspend or cease the prior authorization process generally or for a particular item. We note the prior authorization timeframe(s) detailed in subregulatory guidance will not exceed the timeframes described in the May 28, 2014 proposed rule (79 FR 30521). We believe that this authority allows us to be quickly responsive to any general implementation issue(s) that may surface, including any unforeseen beneficiary access issues.

Comment: Some commenters questioned if receiving a non-affirmation prior authorization request is curable. For example, commenters sought clarification on whether a requestor could submit the prior authorization request multiple times until the requestor receives a provisional affirmative prior authorization decision.

Response: If a prior authorization request receives a non-affirmation decision, the prior authorization request can be resubmitted an unlimited number of times. If on subsequent submission(s) the requester provides information previously missing, and the resubmitted request complies with all applicable Medicare coverage, coding, and payment rules, the non-affirmation decision will be changed to a provisional affirmation decision.

We are finalizing prior authorization as a condition of payment. As such, if a claim subject to prior authorization is received without an associated affirmed prior authorization request, it will be denied. Once the claim is denied, standard appeal rights apply.

Comment: Several commenters expressed concern that there is no process to appeal a non-affirmation determination on an initial request. Some commenters recommended that after two non-affirmation decisions, the supplier should have an option for appeal. Several commenters stated that an appeals backlog would occur. Some commenters recommended that the contractors be subject to a fine for every denial that is overturned by appeal in the amount of 25 percent of the allowable amount for the claim.

Response: We are finalizing prior authorization as a condition of payment. As such, lack of an affirmed prior authorization request in cases where a prior authorization is required will result in a claim denial. Once the claim is denied, standard appeal rights apply. As previously clarified, a non-affirmed prior authorization is not an initial determination of payment and therefore not appealable. The prior authorization process does not change traditional appeal rights once a claim is submitted and denied. Claims appeals processes are outside the scope of this rule.

Additionally we believe that permitting unlimited resubmissions gives the requester multiple opportunities to make a prior authorization request with all of the required documentation and receive a provisional affirmation decision. As such, we expect fewer denials because a significant percentage of denials have been due to insufficient documentation. With fewer denials, we expect fewer appeals.

Comment: Several commenters recommended that the prior authorization process should be tailored to each individual item on the proposed Master List. For example, some commenters suggested we use diagnosis codes in electronic health records to demonstrate medical necessity because coding is based upon the assumption that all devices within a code are equivalent in ability to provide medically necessary performance.

Response: We believe these operational logistics of the prior authorization process are more appropriately addressed in subregulatory guidance. Issuing subregulatory guidance will give us the ability to continually improve upon the process going forward and tailor it to individual items, if necessary. Typically, a diagnosis code alone is not sufficient to demonstrate medical necessity. We expect diagnosis codes to be backed up with evidence in the medical record.

Comment: Some commenters requested that CMS clarify circumstances where a "technical requirement" not met for a claim that has an associated affirmed prior authorization could result in a payment denial.

Response: Examples of not meeting a "technical requirement" include situations where a claim is a duplicate claim or where the claim is coded improperly. A claim reporting a HCPCS code for a DMEPOS item that differs from the DMEPOS item associated with the issued

provisional affirmation prior authorization decision is an example of a claim that is coded improperly. A claim with an associated affirmation prior authorization decision would be denied if these types of technical requirements were not met.

Comment: Several commenters recommended that CMS have a way of tracking and reporting the contractors' response times and inbound and outbound documentation submitted. Several commenters recommended that CMS make statistics of the prior authorization programs available to the public.

Response: We will take these comments into consideration as we implement the prior authorization process. We will meet regularly with our review contractors and will keep them informed on all aspects of the prior authorization program.

Comment: Some commenters recommended that after three non-affirmation prior authorization decisions, the suppliers should be allowed to talk directly to the review contractor's medical director. Some commenters recommended that there should be a verbal determination process, while others recommended that we create a central website where physicians can order DMEPOS and provide required information by answering a few questions, and that the website can provide an affirmed prior authorization approval in real time.

Response: We expect to create a process through subregulatory guidance that provides requesters with an efficient experience and takes into consideration public recommendations. For example, our review contractor will document specific requirements that were not met when issuing a non-affirmation decision. We believe that with knowledge of the applicable Medicare coverage, coding, and payment rules and communication from the review contractor, a supplier can receive a provisional affirmation decision for covered medically necessary items. In

addition, we believe that timelines for the prior authorization process may need to be different for some DMEPOS items. For example, the prior authorization timeline for PMDs would likely differ from the prior authorization timelines for oxygen concentrator. We believe these operational logistics and the commenters' suggestions are more appropriately addressed in subregulatory guidance. This gives us the greatest flexibility for making improvements in the process in the future.

Comment: Some commenters recommended that CMS begin vigorous outreach and education on existing documentation requirements and prioritize providers for this education.

Response: We agree that outreach and education are extremely important. We will take these comments into consideration as we implement the prior authorization process.

We are finalizing the following proposed provisions summarized in section II.E. of this final rule:

- Create prior authorization as a condition of payment for items on the Required Prior Authorization List, as proposed in § 414.234(c)(1). Claims receiving a non-affirmation decision, as well as claims for items subject to prior authorization but for which no prior authorization was requested, will be denied if submitted for processing.

- Add a new paragraph (t) to § 405.926 stating that a contractor's prior determination of coverage is not an initial determination. Section 405.926 contains the list of actions that are not initial determinations and thus not appealable.

- Define a "provisional affirmation" prior authorization request decision, as proposed in § 414.234(a).

• Require all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules be submitted before the item is furnished to the beneficiary and before the claims is submitted for processing, as proposed in § 414.234(d)(1).

• Permit unlimited resubmissions of the prior authorization request, as proposed in § 414.234(e)(3)(ii).

• Include an expedited review option and process, as proposed in § 414.234(e)(4).

F. Other

We received several comments that were outside the scope of the proposed rule. Other comments were related to the proposed prior authorization rule, but did not address any of the topics discussed in this final rule. In the following discussion, we summarize and respond to these comments.

Comment: Several commenters believe section 1834(a)(15) of the Act requires that the prior authorization process be fully electronic and use a valid ASC x12 278 transaction.

Response: We are aware of the need to be HIPAA compliant. We expect to have the ability to accept electronic 278 transmissions and will notify the public when electronic 278 transmissions can be accepted.

Comment: Several commenters recommended that the prior authorization decision should be communicated to both physician/practitioner and the supplier.

Response: We will take this comment under advisement as we develop operational guidance for this rule.

Comment: Commenters suggested that CMS continue to study the long-term impact of the PMD demonstration. Other commenters recommended that CMS should discontinue the PMD demonstration when finalizing this rule.

Response: The prior authorization of PMD demonstration will continue to its scheduled completion at which time we may choose to move any PMD codes on the Master List to the Required Prior Authorization List.

Comment: Several commenters recommended enforcing section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

Response: Section 427 of BIPA regarding enforcement is outside the scope of this final rule.

Comment: Several commenters recommended that claims for serial items subject to prior authorization be exempt from future audits. For example, commenters recommended that claims for first month rental as well as future months be exempt from future audits.

Response: As noted previously, in response to public concern that a supplier may be subject to audits even after meeting the documentation requirements for a prior authorization request, paid claims for which there is an associated affirmed prior authorization decision will be afforded some protection from future audits. However, when the subject claim falls within the CERT annual sample or when a supplier's billing patterns signal potential fraud, inappropriate utilization or changes in billing patterns, the claim may be subject to an audit. Claims for subsequent and serial rental items will be covered under the initial prior authorization decision for time periods stated in NCDs, LCDs, statutes, regulations, and CMS issued manuals and publication. For example, if a policy for the subject DMEPOS item requires medical necessity

documentation to be updated annually, the initial prior authorization decision will cover the claims for the subject DMEPOS item for 12 months.

Comment: Some commenters recommended we create an exception to the Stark Law.

Response: Exceptions to the Stark Law are outside the scope of this final rule.

Comment: A commenter recommended that Stage 1 meaningful use and 2013 Clinical Quality Measures (CQM's) should be allowed to qualify for meaningful use and incentive payments for 2014 because there is not enough time for the community to be able to successfully attest for 2014 meaningful use.

Response: Meaningful use incentive payments are outside of the scope of this final rule.

Comment: Several commenters gave alternate options to implement, instead of prior authorization. For example, rather than imposing prior authorization on suppliers, some commenters suggested that CMS recoup improper payments made by review contractors by having review contractors reimburse Medicare for the improper payments they made. Some commenters recommended that CMS continue to pay an incentive payment and to waiver temporary devices.

Response: We agree with commenters that CMS should avoid improper payments. In part, this is the reason we are implementing prior authorization for DMEPOS items subject to frequent unnecessary utilization that meet the inclusion criteria. We believe that a prior authorization request that meets the necessary requirements helps review contractors avoid making and suppliers avoid receiving improper payments. However, when an improper payment is identified, we must recoup the payment from the entity receiving it. Incentive payments and temporary device waivers are outside the scope of this final rule.

Comment: Some commenters stated that prior authorization will cost more than it will save and that the care of the beneficiaries, not cost, is most important.

Response: We agree that the care of beneficiaries is of utmost importance. We believe cost should not be the only consideration. There are likely to be other benefits that result from the DMEPOS prior authorization requirement. However, many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare FFS payments (note that not all improper payments are fraudulent). We believe we must make sure that beneficiaries are receiving medically necessary care, items, and drugs when needed and can make informed financial decisions prior to receiving items and services that are not covered under the Medicare program. We believe providers and suppliers participating in the Medicare program have a responsibility to make sure their documentation evidences that the care/item/drug they provide is medically necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (section 1862(a)(1)(A) of the Act).

Comment: A commenter expressed concern about claims for dually-eligible beneficiaries. They questioned whether a supplier would be allowed to use a provisional non-affirmation prior authorization decision to submit a request for payment to a Medicaid program. Other commenters recommended creating an exception for suppliers to submit eligible claims without a prior authorization if there was a coordination of benefits error.

Response: Clarifying Medicaid requirements for coverage of DME is outside of the scope of this final rule, though we stated that we do not consider such a prior authorization decision on its own to be a Medicare payment decision. However, we are aware that there are

opportunities to better align the two programs' coverage of DME, and note that we received comments on this opportunity in response to our May 16, 2011 Notice for Comment (76 FR 28196) in which we launched the Alignment Initiative. We will continue to work internally across components to find solutions to better serve dually-eligible beneficiaries.

Comment: Clarification was requested by some commenters whether the average cost of purchasing or renting an item would influence how long a contractor may have to reply to a request for prior authorization.

Response: Currently we do not believe purchase price or rental fee will impact the timeframe. We will issue the timeframes for making prior authorization decisions in subregulatory guidance. We believe that by doing so we create flexibility to quickly modify the timeframes if issues are identified.

Comment: Some commenters recommended that the requirement for physicians to co-sign and bill for the items should be removed. Some commenters requested clarification regarding the physician co-signature requirements.

Response: This final rule does not change any physician co-signature requirements. Physician co-signature requirements are outside the scope of this final rule.

Comment: A commenter recommended that CMS provide reimbursement for home care agencies to let medical social workers conduct visits with the sole intent of completing an updated advance directive and Physician Orders for Life-Sustaining Treatment (POLST).

Response: Home care reimbursements are outside the scope of this final rule.

Comment: Some commenters expressed concern regarding bundled items and that not all individual codes on the proposed Master List over $1,000 are standalone items and that they are

used in combination with an entire multi-coded device.

Response: We recognize that some items on the Master List could be ordered together. Our prior authorization process will accommodate this circumstance. For example, a requester could list all related items on their prior authorization request and receive one prior authorization decision that covers all the items listed in the request. Specific instructions will be given in subregulatory guidance.

G. Liability

In the May 28, 2014 proposed rule (79 FR 30520), we discussed how CMS' liability policies apply to the prior authorization process. A request for prior authorization must be submitted prior to furnishing the item to the beneficiary and prior to submitting the claim for processing. When a claim for an item on the Required Prior Authorization List is submitted and denied, the contractor determines liability for the denied item based on sections 1834(j)(4) of the Act for non-assigned claims and 1879(h)(2)of the Act for assigned claims. Under these sections, any expenses incurred for the denied item or service are the responsibility of the supplier unless liability is transferred to the beneficiary in instances where beneficiaries are given an ABN, Form CMS–R–131, because the beneficiary knows or could be expected to know that payment would not be made. Sections 1834(j)(4) and 1879(h)(2) of the Act, both of which reference the refund procedures in section 1834(a)(18)(A) of the Act, address liability decisions made after assessing actual or expected knowledge, based on all the relevant facts pertaining to each particular denial.

The limitation on liability provision in section 1879 of the Act establishes a process for determining financial liability for certain denials of items or services. In the case of assigned

DME that is subject to the prior authorization requirement established in this final rule, under section 1879(h) of the Act, a supplier is presumed to be financially liable for a claim denied if there is no prior authorization affirmation. The same holds true for non-assigned DME under section 1834(j)(4) of the Act. If the supplier collected any monies from the beneficiary for such denied items, the supplier is required to refund such monies. Under section 1879(a) of the Act, the determination of financial liability for certain categories of denied claims is based on actual or constructive knowledge that Medicare is not expected to cover or make payment for such denied items or services. In general, the supplier is held financially liable under section 1879 of the Act because it is expected to be familiar with Medicare coverage and payment requirements. However, as explained later in this section, under sections 1879(h) and 1834(a)(18) of the Act, liability may be shifted from the supplier to the beneficiary if the supplier delivers a valid ABN, Form CMS–R–131, to the beneficiary. Similarly, under section 1879(a) of the Act, if the supplier believes, for example, that an item may not be considered medically reasonable and necessary under section 1862(a)(1)(A) of the Act, the supplier may shift financial liability to the beneficiary by delivering a valid ABN to the beneficiary.

After promulgation of the prior authorization requirement through this final rule, CMS or its review contractors would presume that the supplier knew that Medicare would automatically deny the claim for which the supplier failed to request a prior authorization, per section 1834(a)(15) of the Act. However, CMS or its review contractors would generally presume that the Medicare beneficiary does not know, and cannot reasonably be expected to know, that Medicare will deny, or has denied, payment in advance under section 1834(a)(15) of the Act.

Under sections 1834(j)(4) and 1879(h)(2) of the Act, when a beneficiary receives an item or service and does not know that CMS or its review contractors may deny the claim based on an unmet prior authorization requirement, the supplier is financially liable for the denied claim and is obligated to refund any payments received from the beneficiary. In cases where the beneficiary insists on getting the item without the prior authorization decision or while the decision is pending, or in cases where the prior authorization decision is non-affirmed, the supplier must issue a valid ABN to the beneficiary, in order to shift liability to the beneficiary. If the beneficiary agrees to pay for the item when signing the ABN, liability rests with the beneficiary if Medicare does, in fact, deny the claim. The ABN notifies the beneficiary that an item usually covered by Medicare may not be paid for in this instance. When completing the ABN, the supplier must provide a clear reason why Medicare may deny payment. The ABN must not be used to bypass the prior authorization process, and existing policy prohibits routine ABN issuance. In order for the ABN to be considered valid, the ABN must be issued to the beneficiary before the beneficiary receives the item or services.

Detailed requirements for valid ABN issuance can be found in Chapter 30 of the Medicare Claims Processing Manual (Internet Only Manual (IOM) Pub 100–04):

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf .

This section will be updated to provide standard language that suppliers must include on ABNs issued for items requiring prior authorization. If an ABN is not given to the beneficiary in the manner described in CMS' claims processing manual, financial liability for the denied claim will not be shifted to the beneficiary.

We did not receive any comments on this discussion of how CMS's liability policies apply to the prior authorization process and we are not making any changes.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In compliance with the PRA we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). We note to readers that CMS is in compliance with the requirements of the PRA with respect to information collection requirements associated with the day-to-day medical review activities. The information collection requirements associated with day-to-day medical review activities are currently approved under OMB control number 0938-0969 and have an expiration date of July 31, 2018.

The base medical review information collection requirements assess the burden associated with the time and effort necessary for the provider and/or supplier of services to locate and obtain the supporting documentation for the Medicare claim and to forward the materials to the Medicare contractor for the medical review process. We note that the burden analysis for the prior authorization process proposed by this rule only addresses additional burdens created in excess of the standard medical review process utilized by CMS contractors and addressed in the base medical review information collection requirements. We will create a new information collection requirement package that is in addition to the current base medical review information collection requirement.

We are finalizing our proposal in § 414.234(c), that as a condition of payment for certain DMEPOS items frequently subject to unnecessary utilization, a prior authorization request must be submitted prior to the submission of a claim. As a condition of payment, program policies specify that certain documentation requirements be met prior to payment. Section 1833(e) of the Act states that no payment shall be made to any provider of services or other person unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person for the period with respect to which the amounts are being paid or for any prior period. Section 1815(a) of the Act states that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider for the period with respect to which the amounts are being paid or any prior period. We are not changing the documentation requirements. Prior authorization would require information to support a Medicare provisional payment decision earlier in the process, before the item is delivered. A prior authorization request would include

evidence that the request for payment complies with applicable Medicare clinical documentation, coverage, coding, and payments rules. All documentation requirements specified in applicable policy would still apply. 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.

This final rule does not add or change any current documentation requirements. However, we believe it will initially increase the time burden associated with collecting and submitting said documentation. The increase of time burden will vary depending on the volume of claims requiring prior authorization. Based on our previously described experience with the PMD demonstration, we similarly expect the time burden to ultimately decrease due to a decrease in utilization of the item(s) subject to prior authorization. Before or on the date in which this final rule is published, we will submit a new information collection request for OMB review and approval that will illustrate the new time burden associated with collecting and submitting prior authorization documentation.

We further note that the anticipated increase in cost associated with the collection and submission of the requested data is offset somewhat by the limited protection from future audits that is afforded to suppliers under this final rule. While the prior authorization program created by this final rule may share some select features with the PMD demonstration, they are disparate enough that we cannot quantify the cost reductions. We would need sufficient item-by-item historical prior authorization program data created by this final rule to perform the necessary calculations. Until the program is operational, we can only make this assertion based on our limited experience with the PMD demonstration.

We are finalizing the definition of unnecessary utilization as the furnishing of items or services that do not comply with one or more of Medicare's clinical documentation, coverage, coding, and payment rules. Specifically, and for the purpose of this final rule, an item frequently subject to unnecessary utilization is identified as having a high incidence of fraud, improper payments or unnecessary utilization in GAO or OIG reports or the CERT DME and/or DMEPOS Service Specific Report(s), has 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 final rule implements prior authorization, a tool utilized by private sector health care payers to prevent unnecessary utilization of certain DMEPOS items. In 2014, the total utilization for all items listed in the Master List was over $1.6 billion. The Master List includes DMEPOS items frequently subject to unnecessary utilization meeting criteria described earlier in this final rule. Presence of an item(s) on the Master List would not automatically result in that item being subject to prior authorization. In order to balance provider and supplier burden with our need to protect the Medicare program, we are finalizing our proposal 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.

In 2014, there were over 2.3 million beneficiaries receiving an item from the Master List. Cost, utilization, and improper payment rates of items on the Master List vary greatly. It is important to note that not all items on the Master List have a known improper payment rate since their Master List inclusion may have been based on a 2007 or later OIG/GAO report and not the CERT DME and/or DMEPOS Service Specific Report(s). The CERT program develops improper payment rates for those items for which at least 30 claims are included in their sample.

Consequently, DMEPOS items have an associated improper payment rate if at least 30 claims for that code were included in the CERT sample.

To best estimate the impact of this final rule within a range of programmatic activity, we isolated those items on the Master List that had an associated improper payment rate. Historically, the agency has focused its finite resources towards reducing the improper payment rate. We believe that we can best estimate the impact of this final rule using that approach.

We remind readers that items on the Master List are identified as those frequently subject to unnecessary utilization, have a high incidence of fraud, improper payments or unnecessary utilization in GAO or OIG reports and/or appear on the CERT DME and/or DMEPOS Service Specific Report(s), have an average purchase fee of $1,000 or greater or an average rental fee schedule of $100 or greater, and are listed on the DMEPOS fee schedule. The total number of items on the Master List is 135.

In order to determine what might be on the Required Prior Authorization List to estimate the burden of this final rule, we excluded PMDs from the Master List since they are currently subject to prior authorization under a CMS demonstration and thus not eligible to be selected from the Master List to the Required Prior Authorization List until the demonstration is completed. The remaining items were cross referenced against CERT DME and/or DMEPOS Service Specific Report(s) for an associated improper payment rate. We ranked the cross-referenced 20 items by average improper payment dollars per line. Using 2014 CERT data, we developed low, primary, and high estimates of potentially affected claims for each year for the first 10 years of the program.

To calculate our low estimate of affected claims, we focused on Master List items with the highest average improper payment dollars per line. For example, during the 2014 CERT reporting period, Medicare paid for the top three DMEPOS items on the Master List associated with the highest improper payment dollars per line nearly 7,500 times. We believe limiting prior authorization to the top three items results in a low programmatic activity compared to implementing prior authorization for all items in the Master List. Consequently we use 7,500 as our low estimate of potentially affected claims for our 10-year projection (see Table 6). We did not account for Medicare growth or ramp up activities of this program for our low estimate since we selected 7,500 to represent the minimum level of program activity regardless of other factors. Based on the 2014 CERT data, if we avoided 100 percent of payment errors for the top three items, we would realize the largest gain on investment. Again, it is important to note that the ranking could change every year since it is based on the acquired CERT sample and the highest average improper payment dollars.

To calculate the highest estimate of affected claims, we looked for the top 15 DMEPOS items on the Master List with the highest average improper payments dollars per line. These items were provided nearly 400,000 times. If we avoid 100 percent of improper payments for the top 15 Master List DMEPOS items with the highest average improper payment dollars per line, we realize a significantly lower gain on investment. Subjecting 15 items to prior authorization results in high programmatic activity, thus we used 500,000 as our highest estimate of affected claims for years 8 through 10 in our projections (Calendar Years (CY)s 2023 through 2025 Table 6). We believe 500,000 accounts for Medicare growth as well as the potential

variability in ranking the highest average improper payment dollars per line of Master List DMEPOS items which may result in higher than 400,000 claim counts.

We derive our primary estimate (see Table 6) 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.

As noted earlier in this section, Table 6 lists our estimated range of potentially affected claims.

TABLE 6: 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 6 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 7 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 7: 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 8 lists the low, primary, and high estimated time burden associated with potentially affected cases.

TABLE 8: 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 [17] 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 9, lists the range estimate of PRA burden in dollars. This impact is allocated across providers and suppliers nationwide.

TABLE 9: 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

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

ESTIMATE	PRA BURDEN (in dollars)									
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 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 7) 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 6), 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.

We solicited public comment on our proposed review and cost time estimates. A summary of the comments and our responses follows.

Comment: Several commenters disagreed with the proposed review cost and time estimate believing that the estimates were too low. Some believed that the proposed review cost and time estimate may not be appropriate for certain items on the proposed Master List (that is, review of negative pressure wound therapy). Several commenters disagreed with the cost analysis for mailing the records. Some commenters stated that if the review time estimate included administrative support time, it was underestimated. Some commenters recommended including the cost of appeals.

Response: The Medicare Administrative Contractors (MACs) have experience conducting reviews and we based our time and cost estimates on their previous experience. We understand some reviews take longer than others; consequently, our estimates are averages. Suppliers have several options for submitting records. They may mail the document through postal service, they may submit them online through the MACs secure web portal or other secure electronic means, or they may fax records. We based our cost methodology on previous experience collecting medical records as well as the standard cost for a flat rate envelope for an

average size medical record. As noted earlier, this final rule does not create new documentation requirements. We expect that any entity requesting CMS payment have on hand any required medical records to support their request for Medicare payment. Appeal rights are not affected by this final rule. Therefore, the cost of the appeal process is outside the scope of this final rule.

Comment: Several commenters sought clarification on who was going to be reviewing the prior authorization requests and recommended we use an independent contractor for reviews. A commenter expressed concerns that there is no mention of resources which will be employed to make a prior authorization decision.

Response: The MACs as well as other Medicare medical review contractors currently engage in review of beneficiary's medical records to support claims. The difference is that these activities are completed after the service/item/drug is delivered and after the claim is submitted for payment. Consequently, we can estimate required resources. With prior authorization, as in traditional medical review, clinicians will review the records. Reviewing clinicians include physicians, nurses, and therapists.

In response to public comments, we have re-evaluated the provided information, collection data, and explanation. We believe that the requirements expressed in this final rule meet the utility and clarity standards. We are finalizing the provisions in the Collection of Information Requirement section, as proposed.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule codifies section 1834(a)(15)(A) and (C) of the Act to monitor payments for certain DMEPOS items by creating a requirement for advance decision as a condition of

payment. This new requirement aims to reduce the unnecessary utilization and the resulting overpayment for certain DMEPOS items.

B. Overall Impact

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2012), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Since the effect of this final rule may redistribute more than $100 million in years 8 through 10 if the high estimates are realized, it is considered economically significant.

Per Executive Order 12866, we have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this final rule. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. For details see the

Small Business Administration's (SBA) website at: www.sba.gov/content/table-small-business-size-standards (refer to the 62 sector). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities that the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, non-physician practitioners (NPPs), and suppliers, including independent diagnostic treatment facilities (IDTFs), are considered small businesses if they generate revenues of $11 million or less based on the SBA size standards. Approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the physician fee schedule (PFS). Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis for the remaining provisions and addresses comments received on these issues.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside

of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This final rule would not impose a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $144 million in any one year.

Executive Order 13132 establishes certain requirements that an agency must meet when it announces a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule, details the costs and benefits of the rule, and presents the measures we would use to minimize the burden on small entities. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

Methodology: A number of factors affect this analysis. For instance, the number of Master List items selected to be subject to the prior authorization requirement is dependent on multiple factors. Consequently, we are proposing a range of estimates to illustrate various implementation scenarios, as described in section III. of this final rule.

In addition, as the DMEPOS community acclimates to using prior authorization as part of their billing practice, there may be greater systemic or other processing efficiencies to allow more extensive implementation.

Lastly, the overall economic impact of this provision on the health care sector is dependent on the number of claims affected. For the purpose of this narrative analysis, we use the "primary" estimate to project costs. However, Table 7 lists both the low and high estimated cost projections, as well as the primary cost estimate.

The values populating Table 10 were obtained from Table 9, Range Estimate of PRA Burden in Dollars (see section III. of this final rule) and Table 11, Medicare Cost, which can be found in following pages. Together, Tables 9 and 11 combine to convey the overall economic impact to the health sector, which is illustrated in Table 10 titled, Overall Economic Impact to the Health Sector.

Based on the estimate, the overall economic cost of this final rule is approximately $1.3 million in the first year. The 5 year cost is approximately $57 million and the 10 year cost is approximately $212 million, mostly driven by the assumed increased number of items subjected to prior authorization after the first year. Paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact. However, this impact is offset by some savings as described in Table 12. We believe there are

likely to be other benefits and cost savings that result from the DMEPOS prior authorization requirement. However, many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare FFS payments (note that not all improper payments are fraudulent).

We have provided the following budgetary cash impact possibilities based on the President's 2016 Budget baseline with an assumed January 1, 2016 effective date.

TABLE 10: OVERALL COST TO HEALTH SECTOR (in Dollars)

		Year 1	5 Years	10 Years
Private Sector Cost	Low Claim Estimation	298,350	1,491,750	2,938,500
	Primary Claim Estimation	348,075	14,867,775	55,393,650
	High Estimation	397,800	28,243,800	107,803,800
Medicare Cost	Low Claim Estimation	843,750	4,218,750	8,437,500
	Primary Claim Estimation	984,375	42,046,875	156,656,250
	High Claim Estimation	1,125,000	79,875,000	304,875,000
Total Cost to Health Sector	Low Claim Estimation	1,142,100	5,710,500	11,376,000
	Primary Claim Estimation	1,332,450	56,914,650	212,049,900
	High Claim Estimation	1,522,800	108,118,800	412,678,800

The definition of small entity in the RFA includes non-profit organizations. Per the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses

according to the SBA's size standards, which define a small business as having total revenues of $11 million or less in any 1 year. While the economic costs and benefits of this final rule are substantial in the aggregate, the economic impact on individual entities would be relatively small. We estimate that 90 to 95 percent of DMEPOS suppliers and practitioners who order DMEPOS are small entities under the RFA definition. The rationale behind requiring prior authorization of covered DMEPOS items is to make sure the beneficiary's medical condition warrants the item of DMEPOS before the item is delivered.

The impact on DMEPOS suppliers could be significant, as the final rule changes their billing practices. We believe that the purpose of the statute and this final rule is to avoid unnecessary utilization of DMEPOS items, thus we do not view decreased revenues from items frequently subject to unnecessary utilization by DMEPOS suppliers to be a condition that we must mitigate. We believe that the effect on legitimate suppliers and practitioners would be minimal. Additionally, this final rule offers an additional protection to a supplier's cash flow as the supplier would know in advance if the Medicare requirements are met.

C. Anticipated Effects

1. Costs

a. Private Sector Costs

We do not believe that this final rule would significantly affect the number of legitimate claims submitted for items on the required prior authorization list. However, we do expect a decrease in the overall amount paid for DMEPOS items resulting from a reduction in unnecessary utilization of DMEPOS items requiring prior authorization.

In accordance with our explanation, we would select certain items from the Master List to require prior authorization by placing them on the Required List. As discussed previously, we have chosen a flexible approach that makes it difficult 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, we are proposing a range of estimates to capture various possible scenarios.

If funded for the high estimation of potentially affected claims, we could grow the program and affect as many as 500,000 claims by years 8 through 10. This estimate accounts for initial prior authorization requests only.

Resubmissions after a non-affirmation decision is rendered on an initial request are not included in the high estimation of potential claims affected. If the program grew to impact as many as 500,000 claims, the potentially impacted cases (claims and resubmissions) total would be 1,125,000. This potential growth accounts for the large fiscal increase shown in the program impact analysis.

We estimate that the private sector's costs are associated with the per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request. These costs are discussed in detail in section III. of this final rule (see Table 9). As noted in Table 9, we estimate that the private sector's average costs for years 1 through 3 would total $2.8 million.

b. Medicare Costs

Medicare would incur additional costs associated with processing the prior authorization requests. Applying the same logic previously described, we develop a range of potential costs

that are dependent on the extent of implementation. We use the range of potentially affected cases (claims and resubmissions) in Table 7 and multiply it by $50, the estimated cost to review each request. The Medicare Administrative Contractors (MACs) have experience conducting reviews and we based our time and cost estimates on their previous experience. We understand some reviews take longer than others; consequently, our estimates are averages. Table 11 lists the cost range estimates.

TABLE 11: MEDICARE COST

	COST (in dollars)									
ESTIMATE	**CY 2016**	**CY 2017**	**CY 2018**	**CY 2019**	**CY 2020**	**CY 2021**	**CY 2022**	**CY 2023**	**CY 2024**	**CY 2025**
Low	843,750	843,750	843,750	843,750	843,750	843,750	843,750	843,750	843,750	843,750
Primary	984,375	6,046,875	6,046,875	14,484,375	14,484,375	14,484,375	14,484,375	28,546,875	28,546,875	28,546,875
High	1,125,000	11,250,000	11,250,000	28,125,000	28,125,000	28,125,000	28,125,000	56,250,000	56,250,000	56,250,000

c. Beneficiary Costs

As discussed in the next section, we expect a reduction in the utilization of Medicare DMEPOS items when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. Although these rules are designed to permit utilization that is medically necessary, DMEPOS items that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify.

2. Benefits and Transfers

We can anticipate benefits because we expect a reduction in the unnecessary utilization of those Medicare DMEPOS items subject to prior authorization. We will be closely monitoring utilization and billing practices. The benefits include a changed billing practice that also enhances the coordination of care for the beneficiary. For example, requiring prior authorization

for certain items requires that the primary care provider and the supplier collaborate more frequently to order and deliver the most appropriate DMEPOS item meeting the needs of the beneficiary. Improper payments made because the practitioner did not order the DMEPOS, or because the practitioner did not evaluate the patient, would likely be reduced by the requirement that a supplier submit clinical documentation created by the practitioner as part of its prior authorization request.

We believe it is more reasonable to require practitioners and suppliers to adopt new practices for fewer items at a time, rather than institute large scale change all at once. In addition, during the ramp up of the program in year 1, we will be doing education and outreach. Consequently, we estimate a smaller volume of items in year 1.

Our Office of the Actuary has provided the following budgetary cash impact possibilities based on the President's 2016 Budget baseline with an assumed January 1, 2016 effective date. The impacts are specific to the three scenarios in our potentially affected claim range: the low, primary, and high estimation of potentially affected claims (see Table 6).

TABLE 12: CY BUDGETARY IMPACT (WITH MANAGED CARE) ESTIMATE IN MILLIONS

Type of Scenario		Calendar Year											
		2016	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2016-2020 (5-Year Impact)**	**2016-2025 (10-Year Impact)**
Scenario 1: Assume Low Number of Claims	Number of Part B Claims	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	-----	-----
	Part B Impacts:												
	Direct Medicare Budgetary Savings (in millions)	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	-50	-100
	Premium Offset* (in millions)	0	0	0	0	0	0	0	0	0	0	0	0
	Total Part B (in millions)	-10	-10	-10	-10	-10	-10	-10	-10	-10	-10	-50	-100
Scenario 2: Assume Primary Number of Claims													
	Number of Part B Claims	8,750	53,750	53,750	128,750	128,750	128,750	128,750	253,750	253,750	253,750	-----	-----
	Part B Impacts::												
	Direct Medicare Budgetary Savings ($ in millions)	-10	-40	-60	-70	-80	-80	-80	-110	-120	-120	-260	-770
	Premium Offset ($ in millions)	0	10	10	20	20	20	20	30	30	30	60	190
	Total Part B ($ in millions)	-10	-30	-50	-50	-60	-60	-60	-80	-90	-90	-200	-580
Scenario 3: Assume High Number of Claims													
	Number of Part B Claims	10,000	100,000	100,000	250,000	250,000	250,000	250,000	500,000	500,000	500,000	-----	-----
	Part B Impacts:												
	Direct Medicare Budgetary Savings ($ in millions)	-10	-50	-80	-100	-120	-120	-120	-150	-160	-160	-360	-1070
	Premium Offset ($ in millions)	0	10	20	20	30	30	30	40	40	40	80	260
	Total Part B ($ in millions)	-10	-40	-60	-80	-90	-90	-90	-110	-120	-120	-280	-810

Note: Premium offset is an expected change in premium resulting from the proposed rule.

D. Alternatives Considered

1. No Regulatory Action

As previously discussed, each item on the Master List is high cost and frequently subject to unnecessary utilization. In addition, each item has been either the subject of a previous OIG or GAO report or has appeared on a CERT DME and/or DMEPOS Service Specific Report(s) (2011 or later) of DMEPOS items with high improper payment rates. Together, utilization of items on the Master List accounted for $1.6 billion. The status quo is not a desirable alternative to this final rule because current payment practices have not affected unnecessary utilization appreciably. Accordingly, the economic impact of no regulatory action would result in the lack of recoupment of some or all associated projected improper payments. Evidence of this is found in the CERT improper payment rates and the associated projected improper payment amount for all DMEPOS, which despite trending downward, have remained high for the last several years (53.1 percent in 2014). By exercising our statutory authority to establish a prior authorization process that creates a Master List of DMEPOS high cost items known to be the subject of GAO/OIG reports and/or high improper payment rates, we hope to positively affect unnecessary utilization and improper payments for DMEPOS in general.

2. Defer to Medicare Administrative Contractors (MACs)

Another alternative we considered was to allow MACs processing Medicare claims to design safeguards that positively affect improper payment rates and unnecessary utilization. However, in recent years we have required MACs to create strategies aimed at reducing improper payment and over utilization. While MACs have complied with this requirement, we have not seen sufficient effect on the improper payment rate and over utilization. The reason is that MACs are limited in their resources and authority. Often unforeseen issues or statutory

requirements cause the MACs to reprioritize their work and respond to CMS direction to focus on an issue not previously on their strategy. In addition, their current practices of pre-payment or post-payment manual medical reviews are costly, and thus are used on a very small percentage of claims. Both create burdens for the claim submitter. For example, in a pre-payment medical review, the claim submitter has already furnished the item or service. Payment is held until the claim submitter supplies the MAC with requested documentation supporting their request for payment. Submitters may be confused about the type of documents being requested and, as a result, submit incomplete documentation. The submitter has only one opportunity to submit the appropriate documentation, which if insufficient, will result in the submitter not receiving his or her payment. In post-payment reviews, the submitter has furnished the item or service and has received payment. Similar to pre-payment reviews, the submitter may be confused about the documents needed to support the payment. If the payment is denied, the MAC is obligated to recover the payment. Claim submitters have told us that returning payment, or requesting an appeal to defend the payment, is burdensome and costly.

By requiring documentation before the claim is submitted and before the item or service is furnished, the submitter and contractor are afforded unlimited opportunities to clarify requirements to receive a provisional affirmation decision. By addressing this process in advance of furnishing the item or service or submitting the claim, we believe there will be less items and/or services paid improperly and unnecessarily utilized, as well as less burden on providers.

3. Alternate Prior Authorization Program Strategies

Another alternative we considered in response to public comments was to subject 100 percent of the 135 items on the Master List to prior authorization at the same time rather than

establishing a prior authorization program for a certain Master List item for a particular state or MAC jurisdiction.

Using 2013 data, as cited in footnote 4, this approach would impact 11 million beneficiaries and potentially 91,000 DME suppliers. If we looked at 2014 data per footnote 5, the impact of implementing prior authorization for 135 items on the Master List would affect 10 million beneficiaries and potentially 90,000 suppliers. We recognize that an impact of this magnitude would allow the DMEPOS community little time to alter current business practices and adjust to the collection and submission requirements of the prior authorization process. Furthermore, we believe that subjecting all of the 135 items on the Master List to prior authorization would maximize both administrative and provider burden alike due to the sheer volume of items and suppliers affected.

In addition to maximizing supplier and administrative burden, we believe this approach could potentially create beneficiary access to care issues. By utilizing prior authorization for all 135 items on the Master List at the same time, we believe that our ability to suspend, cease or make adjustments to the prior authorization process would be hampered by the volume of items and affected suppliers. This could lead to a delay in processing prior authorization requests and result in beneficiaries waiting for reasonable and medically necessary DMEPOS items they would otherwise receive. In addition, we believe that establishing prior authorization for select items on the Master List rather than all 135 items on the Master List allows us to monitor and balance programmatic activity with return on investment while safeguarding program integrity and beneficiary access to care.

We recognize that DMEPOS suppliers may have some difficulty tracking what items are on the Required Prior authorization List versus what items are on the Master List, given that

changes could happen frequently. However, we believe two separate lists will maximize flexibility and allow us to be as responsive as possible to suppliers' and beneficiaries' concerns.

E. Accounting Statement and Table

As required by OMB Circular A4 (available at http://www.whitehouse.gov/omb/circulars_default/), in Table 13 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this final rule.

TABLE 13: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, BENEFITS, AND COSTS

Category	Primary Estimate	Low Estimate	High Estimate	Units		
				Year Dollars	Discount Rate	Period Covered
Transfers						
Annualized Monetized ($million/year)	53.5	10.0	74.7	2015	7%	2016 - 2025
	56.0	10.0	78.3	2015	3%	2015 - 2025
	Savings to the Medicare program due to the reduced unnecessary utilization, fraud, waste, and abuse.					
Costs						
Annualized Monetized* ($million/year)	4.9	0.3	8.9	2015	7%	2016 - 2025
	5.3	0.3	9.6	2015	3%	2016 - 2025
Annualized Monetized** ($million/year)	13.9	0.8	27.0	2015	7%	2016 - 2025
	14.9	0.8	29.0	2015	3%	2016 - 2025

Notes

* These costs are associated with the private sector paperwork.

** These costs are associated with the processing the prior authorization requests for Medicare.

F. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides our Regulatory Flexibility Analysis. In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405 — FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 405.926 is amended by adding paragraph (t) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(t) A contractor's prior authorization determination related to coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C.1302,

1395hh, and 1395rr(b)(1)).

2. Section 414.234 is added to subpart D to read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

(a) Definitions. For the purpose of this section, the following definitions apply:

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing.

Provisional affirmation is a preliminary finding that a future claim meets Medicare's coverage, coding, and payment rules.

Unnecessary utilization means the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules.

(b) Master list of items frequently subject to unnecessary utilization. (1) The Master List of Items Frequently Subject to Unnecessary Utilization includes items listed on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies fee schedule with an average purchase fee of $1,000 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U)) or greater or an average rental fee schedule of $100 (adjusted annually for inflation using CPI-U) or greater that also meet one of the following two criteria:

(i) The item has been identified as having a high rate of fraud or unnecessary utilization in a report that is national in scope from 2007 or later published by any of the following:

(A) The Office of Inspector General (OIG).

(B) The General Accountability Office (GAO).

(ii) The item is listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program's Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report DME and/or

DMEPOS Service Specific Report(s).

(2) The Master List of DMEPOS Items Frequently Subject to Unnecessary Utilization is self-updating annually and is published in the **Federal Register**.

(3) DMEPOS items identified as having a high rate of fraud or unnecessary utilization in any of the following reports that are national in scope and meeting the payment threshold criteria set forth in paragraph (b)(1) of this section are added to the Master List:

(i) OIG reports published after 2015.

(ii) GAO reports published after 2015.

(iii) CERT program's Annual Medicare FFS Improper Payment Rate Report DME and/or DMEPOS Service Specific Report(s) published after 2015, also referred to as the Comprehensive Error Rate Testing (CERT) program's Annual Medicare FFS Improper Payment Rate Report DME Service Specific Report(s).

(4) Items remain on the Master List for 10 years from the date the item was added to the Master List.

(5) Items that are discontinued or are no longer covered by Medicare are removed from the Master List.

(6) An item is removed from the list if the purchase amount drops below the payment threshold (an average purchase fee of $1,000 or greater or an average monthly rental fee schedule of $100 or greater).

(7) An item is removed from the Master List and replaced by its equivalent when the Healthcare Common Procedure Coding System (HCPCS) code representing the item has been discontinued and cross-walked to an equivalent item.

(c) Condition of payment—(1) Items requiring prior authorization. CMS publishes in the **Federal Register** and posts on the CMS Prior Authorization website a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment.

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List of Items Frequently Subject to Unnecessary Utilization (as described in paragraph (b) of this section). CMS may consider factors such as geographic location, item utilization or cost, system capabilities, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region.

(iii) The Required Prior Authorization List is effective no less than 60 days after publication and posting.

(2) Denial of claims. (i) CMS or its contractors denies a claim for an item that requires prior authorization if the claim has not received a provisional affirmation.

(ii) Claims receiving a provisional affirmation may be denied based on either of the following:

(A) Technical requirements that can only be evaluated after the claim has been submitted for formal processing.

(B) Information not available at the time of a prior authorization request.

(d) Submission of prior authorization requests. A prior authorization request must do the following:

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including all of the following:

(i) Order.

(ii) Relevant information from the beneficiary's medical record.

(iii) Relevant supplier produced documentation.

(2) Be submitted before the item is furnished to the beneficiary and before the claim is submitted for processing.

(e) Review of prior authorization requests. (1) After receipt of a prior authorization request, CMS or its contractor reviews the prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules.

(2) If applicable Medicare coverage, coding, and payment rules are met, CMS or its contractor issues a provisional affirmation to the requester.

(3)(i) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(ii) If the requester receives a non-affirmation decision, the requester may resubmit a prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(4) Expedited reviews. (i) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function.

(ii) If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the

beneficiary's ability to regain maximum function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

(f) Suspension of prior authorization requests. (1) CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking.

(2) CMS provides notification of the suspension of the prior authorization requirements via—

(i) **Federal Register** notice; and

(ii) Posting on the CMS prior authorization website.

Dated: November 2, 2015

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Andrew M. Slavitt,

Acting Administrator,
Centers for Medicare & Medicaid Services.

Dated: November 20, 2015

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Sylvia M. Burwell,

Secretary,
Department of Health and Human Services.

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