concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves disestablishing the special anchorage area at the north end of the main channel in Marina del Rey Harbor, California. The anchorage is rarely used and has been encroached upon by several docking facilities. This rule is categorically excluded from further review under paragraph 34(f) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 110.111 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

§ 110.111 [Removed and Reserved]

■ 2. Remove and reserve § 110.111.

Dated: April 30, 2014.

K.L. Schultz,

Rear Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 2014–12178 Filed 5–27–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 414

[CMS–6050–P]

RIN 0938–AR85

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish a prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items that are frequently subject to unnecessary utilization and would add a 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time on July 28, 2014.

ADDRESSES: In commenting, please refer to file code CMS–6050–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6050–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6050–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Maria Ciccanti, (410) 786–3107. Kristen Zycherman, (410) 786–6974.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. General Overview

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 title 42 of the Code of Federal Regulations (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.

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 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 proposed rule would implement that authority by interpreting ''frequently subject to unnecessary utilization,'' by specifying a list of items that meet our proposed criteria, and by proposing a prior authorization process.

B. Improper Payments for DMEPOS Items

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 Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111–204). For the 2012 reporting period, the CERT program determined that DMEPOS claims had an improper payment rate of 66 percent, accounting for approximately 20 percent of the overall Medicare FFS improper payment rate. This is significant since Medicare FFS DMEPOS expenditures represent approximately 3 percent of all Medicare FFS expenditures. The projected improper payment amount for DMEPOS during the 2012 reporting period was approximately $6.4 billion. It is important to note that the improper payment rate is not a ''fraud rate,'' but is a measurement of payments that did not meet Medicare requirements. The

CERT program cannot label a claim fraudulent. The CERT program develops improper payment rates for those items for which at least 30 claims are included in their sample. Since the CERT program uses random samples to select claims across providers and suppliers, reviewers are often unable to see provider billing patterns that indicate potential fraud when making payment determinations.

The CERT program uses the following categories for improper payment determinations:

- No Documentation: Claims are placed into this category when either the provider or supplier fails to respond to repeated requests for the medical records or the provider or supplier responds that they do not have the requested documentation.
- Insufficient Documentation: Claims are placed into this category when the medical documentation submitted is inadequate to support payment for the services billed. In other words, the medical reviewers could not conclude that some of the allowed services were actually provided, provided at the level billed, and/or that the services were medically necessary. Claims are also placed into this category when a specific documentation element that is required as a condition of payment is missing, such as a physician signature on an order, or a form that is required to be completed in its entirety.
- Medical Necessity: Claims are placed into this category when the medical reviewers receive adequate documentation from the medical records submitted and can make an informed decision that the services billed were not medically necessary based upon Medicare coverage policies.
- Incorrect Coding: Claims are placed into this category when the provider or supplier submits medical documentation supporting one of the following:

++ A different code than that billed.

++ That the service was performed by someone other than the billing provider or supplier.

++ That the billed service was unbundled.

++ That a beneficiary was discharged to a site other than the one coded on a claim.

- Other: Claims are placed into this category if they do not fit into any of the other categories (for example, a duplicate payment error or a non-covered or unallowable service).

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. For the 2012 reporting period, approximately 94 percent of DMEPOS improper payments were due to insufficient documentation.[1] Without sufficient documentation, Medicare is unable to determine if the item is medically necessary for the beneficiary or whether unnecessary utilization is occurring.

II. Provisions of the Proposed Regulations

A. Proposed Prior Authorization for Certain DMEPOS Items

We strive to ensure access to care for beneficiaries while also protecting the solvency of the Medicare Trust Funds. Given the unnecessary utilization of DMEPOS items and the corresponding high DMEPOS improper payment rate, we propose to establish a prior authorization process for DMEPOS items that are frequently subject to unnecessary utilization. Prior authorization is already used in other health care programs to ensure proper payment, such as in TRICARE, certain Medicaid programs, and the private sector. We believe a prior authorization process would ensure beneficiaries receive medically necessary care while minimizing the risk of improper payments and therefore protecting the Medicare Trust Fund.

We propose to define ''unnecessary utilization'' as the furnishing of items that do not comply with one or more of Medicare's coverage, coding and payment rules, as applicable. In accordance with section 1834(a)(15)(A) of the Act we propose 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. As discussed in greater detail later in this proposed rule, since the findings in these reports are the result of analysis of prior payment experience, we propose to use these reports to establish which items are frequently subject to unnecessary utilization.

We believe using a prior authorization process would help to ensure 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 ensuring beneficiaries' access to medically necessary items. We believe this is an effective way to reduce or prevent improper payments for unnecessary DMEPOS items.

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

In Table 4, we provide our proposed Master List of initial items that, based on our criteria, are frequently subject to unnecessary utilization, hereafter referred to as the ''Master List''. We welcome comments on these criteria. We propose 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 in the paragraphs that follow, 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. The two criteria for inclusion on the list, either of which must be met, are as follows:

- The item has been 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. We are using reports dated from 2007 or later because the GAO and OIG do not always repeat analysis of specific items annually. It is 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/or 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

[1] Medicare Fee-for-Service 2012 Improper Payments Report. Retrieved February 2014 from *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/Medicare-Fee-for-Service-2012-Improper-Payments-Report.pdf.*

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. We have concluded that nationwide findings by OIG or by GAO of potentially high rates of fraud, unnecessary utilization, or aberrant or improper billings, combined with the payment thresholds established here, are good indicators that an item is ''frequently subject to unnecessary utilization'' as set out in section 1834(a)(15) of the Act.

• The item is listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program's Annual Medicare FFS Improper Payment Rate Report DME Service Specific Overpayment Rate Appendix (hereafter referred to as CERT DME Appendix). This report describes the background of the Medicare FFS and CERT programs, the incidence and rates of improper payments and the common causes of these errors. 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 proposed rule. We believe limiting this criterion to items listed in the 2011 or later CERT DME Appendix (and also meeting the payment threshold) accomplishes the intent of section 1834(a)(15) of the Act. Interested parties can access the CERT reports at *http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/CERT-Reports.html*.

As noted previously, in addition to these two criteria, we propose to use a payment threshold. This threshold would allow us to focus our limited resources on items for which prior authorization will result in the largest potential savings for the Medicare Trust Fund. 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 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. Any changes to this threshold would be proposed through notice and comment rulemaking. We welcome comment on this threshold.

We propose that the Master List be 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 and/or GAO report of a national scope or a future CERT DME Appendix. We propose that items remain on the Master List for 10 years from the date the item was added to the Master List. Based on our prior payment history, we believe 10 years is an appropriate length of time for an item to remain on the list. We selected a 10-year timeframe because we believe that 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. For example, DMEPOS items may evolve as a result of emerging technology making the item on the Master List obsolete after 10 years. In addition, we propose items be removed from the Master List and replaced by their equivalent when the Healthcare Common Procedure Coding System (HCPCs) codes representing the item has been discontinued and cross-walked to an equivalent item. We further propose that an item would be 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). DMEPOS items aging 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 Appendix report identifies the item to be frequently subject to unnecessary utilization. If an item on the Master List is identified by a GAO, OIG, or CERT DME Appendix report while on the Master List, we will follow the update process and the item will remain on the list for 10 years from the update. We propose 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 Web site.

We believe these criteria would balance our responsibilities to ensure beneficiary access to care and protect the Medicare Trust Fund while not placing an undue burden on practitioners and suppliers. All covered DMEPOS items, regardless of whether they are on the Master List, would remain subject to Medicare payment, documentation, coverage, and coding rules.

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

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

There have been several reports, national in scope, published by the HHS OIG since 2007 identifying DMEPOS items that meet the payment threshold and are frequently subject to questionable utilization. They are as follows:

• An August 2011 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. 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 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. This accounted for $95 million of the $189 million allowed DMEPOS claims in that period of time. There were two previous OIG OEI reports based on the same sample of claims that found noncompliance problems with documentation requirements and coding requirements (''*Medicare Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements*'' and ''*Miscoded Claims for Power Wheelchairs in the Medicare Program*.'') Across all three reports, it was found that 80 percent of claims did not meet Medicare requirements for the sample period in 2007.

• An August 2009 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. This amounted to an estimated $33 million in improper payments during that time.

• A June 2007 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. This amounted to an estimated $21 million in improper payments. Further 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.

There have not been any GAO reports on any specific DMEPOS item(s) since 2007.

The 2011 CERT DME Appendix is set forth in Table 1.

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 (percent)
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

The 2012 CERT DME Appendix is set forth in Table 2.

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 (percent)
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
Blood glucose/reagent strips (A4253)	1,255	1,263	103,521	129,283	906,250,472	80.6
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

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

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 (percent)
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

The 2013 CERT DME Appendix is set forth in Table 3.

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 (percent)
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
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

The proposed Master List, in Table 4, includes DMEPOS items meeting both the payment threshold and utilization criteria previously discussed, and their Healthcare Common Procedure Coding System (HCPCS) codes.

TABLE 4—PROPOSED MASTER LIST OF DMEPOS ITEMS SUBJECT TO FREQUENT UNNECESSARY UTILIZATION FOR PRIOR AUTHORIZATION

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.
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.

TABLE 4—PROPOSED MASTER LIST OF DMEPOS ITEMS SUBJECT TO FREQUENT UNNECESSARY UTILIZATION FOR PRIOR AUTHORIZATION—Continued

HCPCS	Description
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.
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.
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.
L5230	Above knee, for proximal femoral focal deficiency, constant friction knee, shin, sach foot.

TABLE 4—PROPOSED MASTER LIST OF DMEPOS ITEMS SUBJECT TO FREQUENT UNNECESSARY UTILIZATION FOR PRIOR AUTHORIZATION—Continued

HCPCS	Description
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.
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.
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.
L5705	Custom shaped protective cover, above knee.
L5706	Custom shaped protective cover, knee disarticulation.
L5707	Custom shaped protective cover, hip disarticulation.
L5718	Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control.
L5722	Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control.
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.

TABLE 4—PROPOSED MASTER LIST OF DMEPOS ITEMS SUBJECT TO FREQUENT UNNECESSARY UTILIZATION FOR PRIOR AUTHORIZATION—Continued

HCPCS	Description
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.
L5816	Addition, endoskeletal knee-shin system, polycentric, 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.
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.

D. Proposed Future Process for Implementing a Prior Authorization Program for Items on the Master List

Presence on the Master List would not automatically require prior authorization. We propose implementing the prior authorization program by limiting the number of items from the Master List that are subject to prior authorization. In order to balance minimizing provider and supplier burden with our need to protect the Trust Funds, we propose to initially implement prior authorization for a subset of items on the Master List (hereafter referred to as ''Required Prior Authorization List''). We propose that we inform the public of the Required Prior Authorization List in the **Federal Register** with 60-day notice before implementation.

Additionally, we propose a prior authorization program for items on the Master List that may be implemented nationally or locally. While OIG and/or GAO and the CERT DME Appendix provide national summary data, the reports often include regional data as well. We may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis or OIG/GAO reports show that unnecessary utilization of the selected item(s) is concentrated in a particular region. Alternately, we may elect to implement prior authorization nationally if claims data analysis shows that unnecessary utilization of the selected item(s) is widespread and occurring across multiple geographic areas.

We also propose to have the authority 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. For example, we may need to suspend or cease 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 would post notification of the suspension on the CMS Prior Authorization Web site, contractor Web sites, publications, and bulletins and include the date of suspension.

We note that this proposal would apply in competitive bidding areas because CMS conditions of payment apply under the Medicare DMEPOS Competitive Bidding Program.

In summary, because the Master List would be self-updating, we propose that we would annually publish notification of any additions or deletions to the Master List in the **Federal Register** and on the CMS Prior Authorization Web site. In addition, we propose to periodically publish notification of additions and deletions to the Required Prior Authorization List (including

changes to the geographic regions in which prior authorization occurs) in the **Federal Register** and on the CMS Prior Authorization Web site. The announcement would appear in the **Federal Register** and there would be at least 60 days notice before prior authorization is required. This proposed rule does not announce the first items on the Required Prior Authorization List. We seek 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.

Since the proposed Master List contains DMEPOS items currently included in the CMS Prior Authorization of Power Mobility Device (PMD) Demonstration, we would not require prior authorization for PMDs under this proposed rule, at least until the demonstration was complete. This proposed rule would not affect the current Prior Authorization of PMD Demonstration.

The proposed prior authorization process would not create new clinical documentation requirements. Instead, it would require the same information necessary to support Medicare payment, just earlier in the process. This would ensure 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.

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. 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') Web sites. All 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 Web site. Further, this proposed rule would not change who creates the 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.

CMS or its contractors would review the prior authorization request to determine whether the item ordered for the beneficiary complies with applicable coverage, coding, and payment rules. After receipt of all applicable required Medicare documentation, CMS or its contractors would conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. 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 propose to make this distinction clear by adding a new paragraph (t) to § 405.926 stating that a contractor's prior determination of coverage is not an initial determination.

Claims receiving a non-affirmative 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-affirmative decision or for which no prior authorization request was obtained is afforded appeal rights.

CMS or its contractors would make reasonable efforts to communicate the decision within 10 days of receipt of all applicable information. However, final timelines for communicating an affirmed or non-affirmed decision to the requester would be described in CMS manual and on the CMS Prior Authorization Web site. We propose to allow unlimited resubmissions.

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 propose an exception to the initial review timeline. We are proposing that if CMS or its contractor agrees 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, CMS or its contractors would make reasonable efforts to communicate the decision within 2 business days of receipt of all applicable Medicare required documentation. This process would be further defined in CMS guidance and posted on the CMS Prior Authorization Web site. 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. We are soliciting public comment on whether the proposed process would meet our objective of ensuring beneficiary access to care and protecting the Medicare Trust Funds without placing undue burden on practitioners and suppliers.

We propose to automatically deny payment for a claim for an item on the Required Prior Authorization List that is submitted without an affirmative prior authorization decision. We believe section 1834(a)(15) of the Act authorizes the Secretary to make an affirmative prior authorization decision a condition of payment for items on the Required Prior Authorization List. As discussed earlier, section 1834 (a)(15)(A) of the Act authorizes the Secretary to develop and update a list of DMEPOS items frequently subject to unnecessary utilization. Section 1834(a)(15)(C) of the Act, titled ''Determinations Of Coverage In Advance,'' allows the Secretary to determine in advance of delivery whether payment should be made for an item on the list developed by the Secretary. We believe that Congress intended section 1834(a)(15) of the Act to establish an advanced determination process (that is, a prior authorization process) as a condition of payment for items on the list developed by the Secretary. 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 Congress' intent of reducing unnecessary utilization for the items identified by the Secretary pursuant to section 1834(a)(15)(A) of the Act. Thus, if this proposed rule is finalized, prior authorization would become a condition of payment for the items on the Required Prior Authorization List.

We propose 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 affirmative or non-affirmative would be communicated to the affected parties in the same manner as an initial request. 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. A request outside of those parameters would be treated as a new initial request. We seek public comment on the number of resubmitted prior authorization requests allowed. This supports CMS's objective to satisfy our overall goal of enabling beneficiary access to care while protecting the Medicare Trust Fund. For the purpose of this proposed rule, we suggest that Medicare or its contractor make a reasonable effort to render an affirmative or non-affirmative decision within 10 days of receiving the initial request, 2 days for an expedited request or 20 days for a resubmission. We also seek public comment on suggested timeframes for provisionally affirmative or non-affirmative decisions on resubmitted prior authorization requests. Additional information about timeframes for all decisions would be described in CMS guidance to its contractors. The following illustrates possible prior authorization scenarios:

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

In the preceding example, the granted affirmative decision is provisional because payment decisions can only be made after all requirements are evaluated. For example, a claim could have received a provisional affirmative 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, cannot be reviewed on a prior authorization request.

Scenario 2: A requester submits to CMS (or its contractor) a prior authorization request. CMS (or its contractor) conducts a medical review of submitted documentation and determines that the request and submitted documentation does not comply with one or more applicable coverage, coding, and payment rules. CMS (or its contractor) communicates a decision that provisionally non-affirms the request. A provisional 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. CMS (or its contractor) would communicate a non-affirmative decision to the affected parties. 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-affirmative decision. The requester could resubmit the prior authorization request. If the claim is submitted for payment without a provisional affirmative decision, it would be automatically denied. The supplier would assume liability if the item was furnished after receiving a non-affirmative decision, unless conditions for assigning liability to the beneficiary or Medicare, (as described in section 1879(h)(2) of the Act for assigned claims and section 1834(j)(4) of the Act for non-assigned claims and as discussed in section II.E. of this proposed rule) are met. 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-affirmative 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 described at section 1879(h)(2) of the Act for assigned claims and section 1834(j)(4) of the Act for non-assigned claims (and discussed in section II.E. of this proposed rule) are met.

E. Liability

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 Advanced Beneficiary Notice of Noncoverage (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 rule, under section 1879(h) of the Act, a supplier is presumed to be financially liable for a claim denied if there is no affirmative prior authorization. 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 Advanced Beneficiary Notice of Noncoverage (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 a possible final rule, CMS or its contractor 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 contractor 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 contractor 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 an Advanced Beneficiary Notice of Noncoverage (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 valid and understandable reason why Medicare may deny payment so that the beneficiary realizes that Medicare coverage of the item could be supported if a prior authorization affirmation is obtained by the supplier. The ABN must not be used to bypass the prior authorization process, and our 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 the Medicare Claims Processing Manual (Internet Only Manual (IOM) 100–04): *http://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.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

In § 414.234(c), 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.

For purposes of this proposed rule, we are defining unnecessary utilization as the furnishing of items or services that do not comply with one or more of Medicare's clinical documentation, coverage, payment and coding rules, as applicable. Items frequently subject to unnecessary utilization are those identified by evaluation of past payment experience. Specifically, and for the purpose of this proposed 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 Appendix, 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. Payment made when the item does not meet Medicare policy is an improper payment. It is important to keep in mind that all fraud is considered to be improper payment, but not all improper payments are fraud.

Prior authorization would require information to support a Medicare provisional payment decision earlier in the process, before the item is delivered. This would ensure that all relevant clinical and/or medical documentation requirements are met before the item is delivered to the beneficiary and before the claim is submitted for payment. A prior authorization request would include evidence that the request for payment complies with Medicare clinical documentation, coverage, payment, and coding rules. All documentation requirements specified in policy would still apply. This proposed rule would not change who originates the documentation.

This proposed rule would implement prior authorization, a tool utilized by private sector health care payers to prevent unnecessary utilization of certain DMEPOS items. In 2012, the total utilization for all items listed in the Master List was nearly $1.3 billion. The Master List includes DMEPOS items frequently subject to unnecessary utilization meeting criteria described earlier in this proposed 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 minimizing provider and supplier burden with our need to protect the Trust Funds, we propose to initially implement prior authorization for a subset of items on the Master List. This subset of items would be called the Required Prior Authorization List. We seek public comment on the number of items selected for initial implementation of the prior authorization requirement.

In 2012, there were over 1.7 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 Report DME appendix. As discussed earlier, 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 estimate the impact of this proposed rule within a range of programmatic activity, we isolated those items on the Master List that had an associated improper payment rate. We then excluded power mobility devices from the list since they are currently subject to prior authorization under a CMS demonstration and thus not eligible to be selected from the Master List until the demonstration is completed. We ranked the remaining 25

items by average improper payment dollars per line. Using 2013 CERT data, we developed low, primary, and high estimates of potentially affected claims for each year for the first 10 years of the program, if implemented as proposed.

We base our low estimate of affected claims on the possible number of claims we can subject to the prior authorization requirements based on selecting Master List items with the highest average improper payment dollars per line. For example, during the 2013 CERT reporting period Medicare paid for the top two 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 two 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 5). We did not account for Medicare growth or ramp up activities for our low estimate since we selected 7,500 to represent the minimum level of program activity regardless of other factors. Based on the 2013 CERT data, if we avoided 100 percent of payment errors for the top 2 items, we would realize the largest gain on investment. Again, it is important to note that the average error ranking could change every year since it is based on the acquired CERT sample. Thus the top two items with the highest average improper payments could change every year.

Based on the 2013 CERT data, CMS paid for the top 22 DMEPOS items on the Master List with the highest average improper payments nearly 400,000 times. If we avoid 100 percent of improper payments for the top 22 Master List DMEPOS items with the highest average improper payments, we realize a significantly lower gain on investment. Subjecting 22 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 (CYs 2022 through 2024 Table 5). We believe 500,000 accounts for Medicare growth as well as the potential variability in ranking the highest average improper payments of Master List DMEPOS items which may result in higher than 400,000 claim counts.

Based on the 2013 CERT data, there were over 200,000 Medicare payments made for the top 16 Master List DMEPOS items with the highest average improper payments. If we avoid 100 percent of improper payments for the top 16 Master List DMEPOS items with the highest improper payments, we realize a moderate gain on investment. We derive at our primary estimate (see Table 5) by averaging the low and high estimate of potential claims affected. Subjecting 16 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 2022 through 2024 (see Table 5)). 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 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, Table 5 lists our estimated range of potentially affected claims.

TABLE 5—RANGE OF ESTIMATES OF POTENTIALLY AFFECTED CLAIMS

Estimate	Number of potentially affected claims									
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
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

If implemented, this proposed rule would allow unlimited resubmissions of prior authorization requests. To account for unlimited resubmissions, we multiplied the low, primary, and high estimates of potentially affected claims in Table 5 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 Power Mobility Device (PMD) Demonstration. Once multiplied 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).

Table 6 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 6—RANGE OF POTENTIALLY AFFECTED CASES

[Potential claims and resubmissions of associated prior authorization requests]

Estimate	Number of potentially affected claims									
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
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. 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 × 0.5 hours) and the total high estimated burden per year for years 2 and 3 is 112,500 hours (225,000 × 0.5 hours). Table 7 lists the low, primary, and high estimated time burden associated with potentially affected cases.

TABLE 7—TIME BURDEN ASSOCIATED WITH POTENTIALLY AFFECTED CASES

Estimate	Number of hours									
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
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

We then multiply the time burden estimate to an average loaded hourly rate of $35.36 (actual hourly rate of $17.86 + fringe benefits) [2] 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 8 lists the range estimate of PRA burden in dollars. This impact is allocated across providers and suppliers nationwide.

TABLE 8—RANGE ESTIMATE OF PRA BURDEN IN DOLLARS

Estimate	PRA burden (in dollars)									
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Low	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350
Primary	348,075	2,138,175	2,138,175	5,121,675	5,121,675	5,121,675	5,121,675	10,094,175	10,094,175	10,094,175
High	397,800	3,978,000	3,978,000	3,978,000	9,945,000	9,945,000	9,945,000	19,890,000	19,890,000	19,890,000

We also estimate the cost of mailing medical records to be $5 per request for prior authorization. However, many of the records are received via fax machines which have lower associated costs than traditional mail. Additionally, we offer electronic submission of medical documentation (esMD) to providers and suppliers who wish to use a less expensive alternative for sending in medical documents. Additional information on esMD can be found at *www.cms.gov/esMD.*

In instances when the supplier must first obtain the medical records from a health care provider, we estimate that the mailing costs are doubled ($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 6) for which the mailing costs could be doubled in the first year. However, 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 × $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.

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

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–6050–P, Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed 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 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

[2] Based on Bureau of Labor Statistics information (29–2070 Medical Record and Health Information Technician 2012).

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 rule may possibly redistribute more than $100 million in years 8 through 10, it may have an economically significant impact if the high estimates are realized. 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 proposed 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 $7.0 million to $35.5 million in any 1 year. For details see the Small Business Administration's (SBA) Web site 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 $10 million or less based on 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 proposed 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 603 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 proposed 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 2014, that threshold is approximately $141 million. This proposed 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 $141 million in any one year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed 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 proposed 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 proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

As discussed under the section III. of this proposed rule (Collection of Information Requirements section), the number of Master List items selected to be subject to the prior authorization requirement created if this proposed rule is finalized 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 proposed rule.

We believe there are a number of factors that may contribute to the potential growth assumed in the scenarios presented. For example, 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.

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 9 lists both the low and high estimated cost projections, as well as the primary cost estimate.

The values populating Table 9 were obtained from Table 10, Private Sector Cost and Table 11, Medicare Cost, which can be found in following pages. Together, Tables 10 and 11 combine to convey the overall economic impact to the health sector, which is illustrated in Table 9 appropriately titled, Overall Economic Impact to the Health Sector.

Based on the estimate, the overall economic impact of this proposed rule is approximately $1.3 million in the first year. The 5-year impact is approximately $57 million and the 10-year impact 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 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 fee-for-service payments (note that not all improper payments are fraudulent). We are soliciting comment on the potential increased costs and benefits associated with this provision.

TABLE 9—OVERALL ECONOMIC IMPACT 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 Economic Impact 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 total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this 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 ensure the beneficiary's medical condition warrants the item of DMEPOS before the item is delivered. The impact on these suppliers could be significant; if finalized, the proposed rule would change the billing practices of DMEPOS suppliers. We believe that the purpose of the statute and this proposed rule is to avoid unnecessary utilization of DMEPOS items, thus we do not view decreased revenues from items subject to unnecessary utilization by DMEPOS providers and suppliers to be a condition that we must mitigate. We believe that the effect on legitimate suppliers and practitioners would be minimal. This proposed rule would offer 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 proposed rule would significantly affect the number of legitimate claims submitted for these items. 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.

As described in section III. of this proposed rule, we propose to rely on a criterion-driven approach to select items that would require prior authorization.

In accordance with our proposals, we would select certain items from the Master List to require prior authorization by placing them on the Required List. As discussed previously, it is impossible 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-affirmative 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 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. We apply this time-burden estimate to initial submissions, resubmissions, and expedited requests (cases). (See Tables 7 and 8 of this proposed rule.)

TABLE 10—PRIVATE SECTOR COST

Estimate	Cost (in dollars)									
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Low	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350	298,350
Primary	348,075	2,138,175	2,138,175	5,121,675	5,121,675	5,121,675	5,121,675	10,094,175	10,094,175	10,094,175
High	397,800	3,978,000	3,978,000	3,978,000	9,945,000	9,945,000	9,945,000	19,890,000	19,890,000	19,890,000

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 6 and multiply it by $50, the estimated cost to review each request. Table 11 lists the cost range estimates.

TABLE 11—MEDICARE COST

Estimate	Cost (in dollars)									
	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
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 will be 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

There would be quantifiable benefits because we expect a reduction in the unnecessary utilization of those Medicare DMEPOS items subject to prior authorization. It is difficult to project the decrease in unnecessary utilization. However, 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 ensures 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 2015 Budget baseline with an assumed October 1, 2014 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 5).

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

Type of scenario		Calendar year											
		2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2015–2019 (5-year impact)	2015–2024 (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 Costs & Benefits:												
	Benefits (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 Costs & Benefits:												
	Benefits ($ in millions)	−10	−40	−60	−70	−80	−80	−80	−100	−120	−120	−260	−760
	Premium Offset ($ in millions)	0	10	10	20	20	20	20	20	30	30	60	180
	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 Costs & Benefits:												
	Benefits ($ in millions)	−10	−50	−70	−90	−110	−110	−110	−140	−150	−150	−330	−990
	Premium Offset ($ in millions)	0	10	20	20	30	30	30	30	40	40	80	250
	Total Part B ($ in millions)	−10	−40	−50	−70	−80	−80	−80	−110	−110	−110	−250	−740

*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 Appendix (2011 or later) of DMEPOS items with high improper payment rates. Together, utilization of items on the Master List accounted for $1.3 billion. The status quo is not a desirable alternative to this proposed rule because current payment practices have not affected unnecessary utilization appreciably. Evidence of this is found in the CERT improper payment rates for all DMEPOS, which have remained high for the last several years (67 percent in 2011, 66 percent in 2012). By creating 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 practice 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 submit incomplete documentation. The submitter has only one opportunity to submit the appropriate documentation and if insufficient will not receive their 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 provisionally affirmative 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.

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 proposed rule. This estimate includes the estimated FY 2013 expenditures.

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
Costs						
Annualized Monetized *	4.9	0.3	8.9	2014	7%	2015–2024
($million/year)	5.3	0.3	9.6	2014	3%	2015–2024
Annualized Monetized **	13.9	0.8	27.0	2014	7%	2015–2024
($million/year)	14.9	0.8	29.0	2014	3%	2015–2024
Transfers * **						
Annualized Monetized	−53.5	−10.0	−68.1	2014	7%	2015–2024
($million/year)	−56.0	−10.0	−71.4	2014	3%	2015–2024
From Whom to Whom	Federal government to Medicare providers.					

* These costs are associated with the private sector paperwork.
** These costs are associated with the processing the prior authorization requests for Medicare.
*** Savings to the Medicare program due to the reduced unnecessary utilization, fraud, waste, and abuse.

F. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. In accordance with the provisions of Executive Order 12866, this regulation 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 proposes to amend 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 as follows:

■ a. In the introductory text, removing the phrase ''but are not limited to—'' and adding in its place the phrase ''but are not limited to the following:''

■ b. In paragraphs (a)(2) and (b) through (q), removing ''; '' and adding in its place ''.''.

■ c. In paragraph (r), removing ''; and'' adding in its place ''.''.

■ d. Adding a new paragraph (t).

The addition reads 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

■ 3. 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)).

■ 4. Subpart D is amended by adding a new § 414.234 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 or greater or an average rental fee schedule of $100 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 Service Specific Overpayment Rate Appendix.

(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 in any of the following reports and meeting the payment threshold criteria set forth in paragraph (b)(1) of this section are added to the Master List:

(i) Future published OIG reports that are national in scope.

(ii) Future published GAO reports.

(iii) Future Comprehensive Error Rate Testing (CERT) program's Annual Medicare FFS Improper Payment Rate Report DME Service Specific Overpayment Rate Appendix.

(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) Items for which the average purchase fee and average rental fee is reduced to below the inclusion threshold of average purchase fee of $1,000 or greater or an average rental fee schedule of $100 or greater, are removed from the list.

(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 Web site 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 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.

(ii) 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 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 Medicare coverage, coding, and payment rules.

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

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

(ii) If the requester receives a non-affirmative 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 makes reasonable efforts to communicate the decision within 2 business days of 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 Web site.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 12, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 20, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Editorial note: This document was received by the Office of the Federal Register on May 22, 2014.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 68b

RIN 0925–AA10

[Docket No. NIH–2007–0930]

National Institutes of Health Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to issue regulations to implement provisions of the Public Health Service Act authorizing the NIH Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes (UGSP). The purpose of the program is to recruit appropriately qualified undergraduate students from disadvantaged backgrounds to conduct research in the intramural research program as employees of the NIH by providing scholarship support.

DATES: Comments must be received on or before July 28, 2014 to ensure that the NIH will be able to consider the comments in preparing the final rule.

ADDRESSES: Individuals and organizations interested in submitting comments, identified by RIN 0925–AA10 and Docket Number NIH–2007–0930, may do so by any of the following methods:

Electronic Submissions. You may submit electronic comments through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. The NIH is no longer accepting comments submitted to the agency by email.

Written Submissions. You may send written submissions in the following ways:

- Fax: 301–402–0169.
- Mail: Attention: Jerry Moore, NIH Regulations Officer, National Institutes of Health, Office of Management Assessment, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20892.
- Hand Delivery/Courier (for paper, disk, or CD–ROM submissions): Attention: Jerry Moore, 6011 Executive Boulevard, Suite 601, Rockville, MD 20892.

Instructions for all Comments. All comments received must include the agency name, Regulatory Information Number (RIN), and the docket number for this rulemaking. All comments received may be posted without change, including any personal information provided.

Docket. For access to the docket to read background documents or comments received, go to the eRulemaking.gov Portal and insert into the ''Search'' box the docket number ''NIH–2007–0930'' and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, telephone 301–496–4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On June 10, 1993, the NIH Revitalization Act of 1993 (Pub. L. 103–43) was enacted. Section 1631 of this law amended the Public Health Service (PHS) Act by adding section 487D (42 U.S.C. 288–4). Section 487D authorizes the Secretary, acting through the Director of the NIH, to carry out a program of entering into contracts with individuals under which the Director agrees to provide scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the NIH. In return, the individuals agree to serve as employees of the NIH in positions that are needed by the NIH and for which the individuals are qualified. The individuals must be enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education and must be from disadvantaged backgrounds. Section 487D of the PHS Act further states that, concerning penalties for breach of scholarship contract, the provisions of section 338E of the PHS Act shall apply to the program to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

The 1993 amendment of the PHS act led to the establishment of the NIH Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes (UGSP). The purpose of the program, since it began selecting participants in 1997, is to recruit appropriately qualified undergraduate students from disadvantaged backgrounds to conduct research in the intramural research program as employees of the NIH by providing scholarship support. The UGSP provides a diverse and highly qualified cadre of individuals seeking careers compatible with NIH employment opportunities.

The NIH is proposing to amend title 42 of the Code of Federal Regulations by adding Part 68b to govern the administration of the UGSP. The proposed rule establishes program regulations necessary to implement and enforce important aspects of the UGSP. In general, the proposed rule specifies the scope and purpose of the program, the eligibility criteria, the application process, the selection criteria, and the terms and conditions of the program.

The rationale used by the NIH in developing the eligibility and selection criteria of this proposed rule is explained as follows. For eligibility, the definition for ''Individual from