American Association for Homecare
Caring that Feels Right at Home

Final Rule Summary

MEMORANDUM

Date: January 4, 2016

Subject: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-6050-F)

OVERVIEW

On December 29, 2015 CMS published the final rule to Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. This final rule establishes a prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization. This rule (1) defines unnecessary utilization and creates a new requirement that claims for certain DMEPOS items must have an associated provisional affirmed prior authorization decision as a condition of payment; (2) adds the review contractor's decision regarding prior authorization of coverage of DMEPOS items to the list of actions that are not initial determinations and therefore not appealable; (3) interprets ''frequently subject to unnecessary utilization,'' by specifying a list of items that meet our criteria, and by establishing a prior authorization process.

CMS believes a prior authorization program is the solution to lowering the error rate by reviewing many of the required documentation elements outlined in applicable Medicare policies before the item is furnished and before the claim is submitted for payment. Prior authorization has the added benefit of providing a supplier some assurance of payment for items receiving a provisional affirmation decision. In addition, beneficiaries will have information regarding coverage prior to receiving the item, and will benefit by knowing in advance of receiving an item, if they will incur financial liability for non-covered items. If a supplier does not submit all of the required documentation with its first prior authorization request, it will be notified of the missing documentation and may resubmit its request. CMS proposed that requesters be permitted to submit a prior authorization request an unlimited number of times.

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

In the following sections, we've listed the proposed provisions and CMS responses to public

comment and their final decisions.

A. Proposed Prior Authorization for Certain DMEPOS Items

PROPOSED RULE:

1) "prior authorization" be defined as a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item is furnished to the beneficiary and before the claim is submitted for processing.
2) "provisional affirmation" be defined as a preliminary finding that a future claim meets Medicare coverage, coding, and payment rules.
3) ''unnecessary utilization'' be defined as the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules.
4) ''prior payment experience'' to establish which items are ''frequently'' subject to unnecessary utilization.
5) use of GAO, OIG, and CERT reports to establish Master List inclusion criteria of items that are frequently subject to unnecessary utilization.

CMS RESPONSE: We are finalizing the definitions of "prior authorization," "provisional affirmation," and ''unnecessary utilization'' at § 414.234(a) as proposed. In addition, we are finalizing the use of GAO, OIG, and CERT reports to establish prior payment history.

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

1. Inclusion Criteria and Maintenance of Master List

PROPOSED RULE:

1) Include an item on the initial Master List if the item appears on the DMEPOS Fee Schedule list, meets one of the two criteria described later in this section, and has an average purchase fee of $1,000 or greater or an average rental fee schedule of $100 or greater. CMS refers to these dollar amounts as the payment threshold. CMS stated that having the payment threshold for DMEPOS items included on the Master List would allow us to focus our limited resources on items for which prior authorization will result in the largest potential savings for the Medicare program.
2) DMEPOS Fee Schedule is updated annually and lists Medicare allowable pricing for DMEPOS, including the full payment amount for capped rental items.
3) CMS 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.
4) Any changes to the threshold would be proposed through notice and comment rulemaking.
5) In addition to the payment threshold, the item must meet one of the two following criteria:
    a. The item is identified in a GAO or HHS OIG report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.
    b. The item is listed in the 2011 or later published CERT program's Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report Durable Medical Equipment (DME) Service Specific Overpayment Rate Appendix.
6) The Master List is self-updating annually. That is, items on the DMEPOS Fee Schedule that meet the payment threshold are added to the list when the item is listed in a future OIG or GAO report of a national scope or a future CERT DME and/or DMEPOS Service Specific

Report(s).

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

CMS RESPONSE: We are finalizing the Master List inclusion criteria and Master List maintenance process as proposed in section 414.234(b). Section 1834(a)(15)(A) of the Social Security Act requires us to use "prior payment history" when identifying DMEPOS items frequently subject to unnecessary utilization. We believe using past and future GAO and OIG reports as well as CERT DME data is a way to meet this requirement. In addition, we are finalizing the proposed payment threshold, but are including an annual adjustment for inflation as stated in revised section 414.234(b)(1). The adjusted payment threshold will apply to the inclusion criteria as well as the Master List maintenance process. We are also finalizing our proposal to notify the public annually of any additions and deletions from the Master List by posting the notification in the Federal Register and on the CMS Prior Authorization website, as stated in section 414.234(f)(2).

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

PROPOSED RULE:

1) Create a Master List of Items Frequently Subject to Unnecessary Utilization
    a) There have been several reports that were national in scope and published by the HHS OIG since 2007 identifying DMEPOS items that meet the payment threshold and are frequently subject to unnecessary utilization.
        - certain lower limb prostheses
        - power wheelchairs
        - group 2 pressure reducing support surfaces
        - negative pressure wound therapy pumps

CMS RESPONSE: We will issue specific guidance regarding the prior authorization timelines in subregulatory guidance. One reason for this is to create timelines/processes that are logical for each DMEPOS item selected for prior authorization. We disagree with the suggestion to exclude all oxygen

and respiratory devices, and we have included respiratory devices that meet the inclusion criteria on the finalized Master List. Not all items on the Master List will require prior authorization. We will take comments into consideration when developing the prior authorization timeframes. We will issue the timeframes in subregulatory guidance. We believe that by doing so, we create flexibility to quickly modify the timeframes if issues are identified. Additionally, we are finalizing our authority to suspend or cease prior authorization for the entire list or individual items at any time, as discussed at the end of this section. We have updated the Master List from what was published in the May 28, 2014 proposed rule to reflect the most current application of these criteria. Consequently, we added one item to the Master List: E1390: oxygen concentrator (mistakenly left off the proposed Master List). The total number of items on the Master List is 135.

We are finalizing the Master List as proposed with two modifications. First, we are adding oxygen concentrator (E1390). The addition is bolded and italicized for easy reference on the Master List (Table 5). Second, we are removing five proposed items from the list that did not meet the criteria described in the rule. These items include the following:

1) *Custom shaped protective cover, above knee (L5705).*
2) *Custom shaped protective cover, knee disarticulation (L5706).*
3) *Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control (L5718).*
4) *Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control (L5722).*
5) *Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock (L5816).*

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

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

HCPCS	Description
E0193	Powered air flotation bed (low air loss therapy)
E0260	Hosp bed semi-electr w/ matt
E0277	Powered pres-redu air mattrs
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard
E0372	Powered air overlay for mattress, standard mattress length and
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
E0601	Continuous Airway Pressure (CPAP) Device
E1390	***Oxygen Concentrator***
E2402	Negative pressure wound therapy electrical pump, stationary or
K0004	High strength, lightweight wheelchair
K0813	Power wheelchair, group 1 standard, portable, sling/solid seat and back,

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
K0816	Power wheelchair, group 1 standard, captains chair, patient weight capacity up to and including 300 pounds
K0820	Power wheelchair, group 2 standard, portable, sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0821	Power wheelchair, group 2 standard, portable, captains chair, patient weight capacity up to and including 300 pounds
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
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
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
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
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,
L5220	Above knee, short prosthesis, no knee joint ('stubbies'), with articulated
L5230	Above knee, for proximal femoral focal deficiency, constant friction knee, shin, sach foot
L5250	Hip disarticulation, canadian type; molded socket, hip joint, single axis
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,
L5321	Above knee, molded socket, open end, sach foot, endoskeletal system, single axis knee
L5331	Hip disarticulation, canadian type, molded socket, endoskeletal system,
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
L5420	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast
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
L5510	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon,

L5520	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon,
L5530	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon,
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,
L5560	Preparatory, above knee- knee disarticulation, ischial level socket, non-
L5570	Preparatory, above knee - knee disarticulation, ischial level socket, non-
L5580	Preparatory, above knee - knee disarticulation ischial level socket, non-
L5585	Preparatory, above knee - knee disarticulation, ischial level socket, non-
L5590	Preparatory, above knee - knee disarticulation ischial level socket, non-
L5595	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, sach
L5600	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, sach
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
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
L5681	Addition to lower extremity, below knee/above knee, custom fabricated

L5683	Addition to lower extremity, below knee/above knee, custom fabricated
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
L5703	Ankle, symes, molded to patient model, socket without solid ankle cushion heel (sach) foot, replacement only
L5707	Custom shaped protective cover, hip disarticulation
L5724	Addition, exoskeletal knee-shin system, single axis, fluid swing phase control
L5726	Addition, exoskeletal knee-shin system, single axis, external joints fluid
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
L5782	Addition to lower limb prosthesis, vacuum pump, residual limb volume
L5795	Addition, exoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5814	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing
L5818	Addition, endoskeletal knee-shin system, polycentric, friction swing, and stance phase control
L5822	Addition, endoskeletal knee-shin system, single axis, pneumatic swing,
L5824	Addition, endoskeletal knee-shin system, single axis, fluid swing phase
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
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,
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system,
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system,
L5930	Addition, endoskeletal system, high activity knee control frame
L5960	Addition, endoskeletal system, hip disarticulation, ultra-light material
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
L5988	Addition to lower limb prosthesis, vertical shock reducing pylon feature
L5990	Addition to lower extremity prosthesis, user adjustable heel height

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

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

PROPOSED RULE:

1) An item's presence on the Master List would not automatically require prior authorization.
2) Limited number of items from the Master List that would be subject to prior authorization. This subset of Master List items is hereafter referred to as the "Required Prior Authorization List" as described in § 414.234 (c).
3) CMS would inform the public of the Required Prior Authorization List in the Federal Register with 60-day notice before implementation.
4) Create a prior authorization program for eligible items that may be implemented nationally or locally.
5) CMS may elect to implement prior authorization nationally if claims data show that unnecessary utilization of the selected item(s) is widespread and occurring across multiple geographic areas.
6) CMS has the authority to suspend or cease the prior authorization program generally, or for a particular item or items at any time, without undertaking a separate rulemaking.
7) If CMS suspends or cease the prior authorization requirement, CMS would post notification of the suspension on the CMS Prior Authorization website, contractor websites, publications, and bulletins and include the date of suspension.
8) This rule would not affect the current Prior Authorization of PMD Demonstration.

CMS RESPONSE: We are finalizing our proposal to implement the prior authorization program locally or nationally or to suspend or cease the prior authorization requirement program generally or for a particular item or items at any time without undertaking a separate rulemaking.
We are finalizing our proposal to select an item(s) from the Master List and include it on the Required Prior Authorization List, to implement the prior authorization program locally or nationally, and to suspend or cease the prior authorization requirement program generally, or for a particular item without undertaking a separate rulemaking. We are also finalizing our authority to determine the number of item(s) selected upon initial implementation, determine the number of items selected for future implementation, and determine the frequency with which we would select the item(s). Lastly, we are finalizing the proposal that we inform the public of the Required Prior Authorization List in the Federal Register with 60-day notice before implementation.
Some commenters suggested each item selected for prior authorization be time limited (a beginning and ending date) for the prior authorization requirements; other commenters suggested that items be subject to prior authorization for the duration of the capped rental period. We will take these comments into consideration and will address it in a CMS guidance. In addition to the inclusion criteria discussed previously, future policies, regulations or response to stakeholder needs may be factored into the Master List item selection(s). While we are not finalizing any methodology or criteria for selection of items to be included on the Required Prior Authorization List, CMS may consider factors such as geographic location, item utilization or cost, system capabilities, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other

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

E. The Proposed Prior Authorization Process

PROPOSED RULE:

1. The proposed prior authorization process would not create new or change existing clinical documentation requirements.
2. Proposed prior authorization process would require the same information necessary to support Medicare payment, just earlier in the process. This process allows the review contractor to confirm, to the extent possible, that all relevant coverage, coding, and clinical documentation requirements are met before the item is furnished to the beneficiary and before the claim is submitted for payment.
3. Prior to furnishing the item and prior to submitting the claim for processing, a prior authorization requester would submit evidence that the item complies with all applicable Medicare coverage, coding, and payment rules.
4. All Medicare coverage, coding, and payment rules would apply. Medicare coverage, coding, and payment rules applicable to items on the Required Prior Authorization List would also be posted on the CMS Prior Authorization website.
5. CMS will not change existing requirements regarding the entity responsible for creating required clinical documentation. Similarly, documentation requiring supplier origination (for example, product description) would still be generated by the supplier.
6. CMS or its review contractors would review the prior authorization request to determine whether the item ordered for the beneficiary complies with applicable Medicare coverage, coding, and payment rules. After receipt of all applicable required Medicare documentation, CMS or its review contractors would conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request.
7. 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. CMS proposed making this distinction clear by adding a new paragraph (t) to § 405.926 stating that a review contractor's prior determination of coverage is not an initial determination.
8. Claims associated with a non-affirmation decision, as well as claims for items subject to prior authorization but for which no prior authorization was requested, would be denied if submitted for processing. A requester who submits a claim for which there was a non-affirmation decision or for which no prior authorization request was obtained would be afforded full appeal rights on the claim.
9. CMS or its review contractors would make reasonable efforts to communicate the decision within 10 days of receipt of all applicable information. However, final timelines for communicating a provisionally affirmed or non-affirmed decision to the requester would be described in CMS guidance and posted on the CMS Prior Authorization website.
10. Requesters are allowed unlimited resubmissions of prior authorization requests.
11. If CMS or its review contractors agree that using the standard timeframes for review places the beneficiary at risk as previously described, then CMS would allow an expedited review of the prior authorization request and communicate an expedited decision. In these situations, CMS or its review contractors would make reasonable efforts to communicate

the decision within 2 business days of receipt of all applicable Medicare required documentation. This process would be further defined in CMS guidance and posted on the CMS Prior Authorization website.

12. 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.
13. Requester may resubmit a prior authorization request if the initial request was non-affirmed. Prior authorization requests would be reviewed, and a decision of a provisional affirmation or a non-affirmation would be communicated to the affected parties in the same manner as an initial request. CMS 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.
14. Medicare or its review contractors make a reasonable effort to render a provisional affirmation or a non-affirmation decision within 10 days of receiving the initial request, 2 days for an expedited request or 20 days for a resubmission.
15. Additional information about timeframes for all decisions would be described in CMS guidance to its contractors. In the May 28, 2014 proposed rule, CMS included the following illustrations of possible prior authorization scenarios:
    - Scenario 1: A requester submits to CMS (or its review contractors) a prior authorization request along with all required documentation. CMS (or its review contractors) finds that the request meets all applicable Medicare requirements. CMS (or its review contractors) would communicate a provisional affirmation decision to the affected parties. The supplier would submit the claim following receipt of a provisional affirmation decision, and the claim would be paid, as long as all other requirements were met.
    - Scenario 2: A requester submits to CMS (or its review contractors) a prior authorization request. CMS (or its review contractors) conducts a medical review of submitted documentation and determines that the request and submitted documentation does not comply with one or more applicable Medicare coverage, coding, and payment rules. CMS (or its review contractors) communicates a decision that non-affirms the request. A non-affirmation is a preliminary finding that a future claim associated with the submitted documentation and prior authorization request would be denied if submitted because the associated request and submitted documentation did not meet one or more of Medicare's coverage, coding, and payment rules. The communication to the affected parties would identify which Medicare coverage, coding or payment rule(s) was not supported in the request and submitted documentation and thus served as the basis for the non-affirmation decision. The requester could resubmit the prior authorization request. If the claim is submitted for payment without a provisional affirmation decision, it would be automatically denied. The supplier would assume liability if the item was furnished after receiving a non-affirmation decision, unless conditions for assigning liability to the beneficiary or Medicare are met. (For more information, see section 1879(h)(2) of the Act for assigned claims, section 1834(j)(4) of the Act for non-assigned claims, and our discussion in section II.F. of this final rule). A prior authorization request that is non-affirmed under section 1834(a)(15) of the Act is not an initial decision on a claim for payment for items furnished, and therefore would not be appealable. However, a claim for which a non-affirmation prior authorization decision was

received, submitted, and subsequently denied could be appealed.

- Scenario 3: A claim is submitted without a prior authorization decision. The claim would be denied because there was no prior authorization request, which is a condition of payment. The supplier is liable unless the conditions for assigning liability to the beneficiary or Medicare are met. (For more information, see section 1879(h)(2) of the Act for assigned claims, section 1834(j)(4) of the Act for non-assigned claims, and our discussion in section II.F. of this final rule).

16. CMS will automatically deny payment for a claim for an item on the Required Prior Authorization List that is submitted without a provisional affirmation prior authorization decision.
17. CMS 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.
18. Add a new paragraph (t) to § 405.926 stating that a review contractor's prior determination of coverage is not an initial determination and is thus not appealable because the prior authorization decision is not an initial determination with respect to a claim for benefits under Part A or Part B. Section 405.926 contains the list of actions that are not initial determinations and thus not appealable. However, a requester who submits a claim for which there was a non-affirmation decision or for which no prior authorization request was obtained would be afforded appeal rights.

CMS RESPONSE: We agree with commenters that additional flexibility beyond the proposed timeframes may be necessary under particular circumstances to ensure adequate beneficiary access to DMEPOS on the Required Prior Authorization List. In the interest of promoting beneficiary access to care and protecting the Medicare program without placing undue burden on practitioners and suppliers, we are not finalizing the proposed prior authorization timeframes. Therefore, prior authorization timeframe requirements will be made available to stakeholders and the public in subregulatory guidance, which allows for greater flexibility in the event timeline modifications are warranted. We note the prior authorization timeframe(s) detailed in subregulatory guidance will not exceed the timeframes described in the proposed rule. We will take the comments regarding alternate processes that afford more expedient responses to the requestor (for example, the 24-hour 7-day a week model) into consideration when developing the prior authorization timeframes. We understand commenters' concerns and agree that requiring a lengthy prior authorization process for negative pressure wound therapy devices, pressure reducing support surfaces, and perhaps other Master List items, could potentially delay care and lead to negative outcomes. We will take these comments as well as other similar comments into consideration as we develop the timeframes for the prior authorization process. We will provide education specific to each item subject to prior authorization so that suppliers are informed of specific documentation requirements. Some commenters recommended using the tax ID and not the Provider Transactions Access Number (PTAN) in the prior authorization process. This way, commenters stated, the prior authorization is transferrable to new suppliers if the beneficiary relocates. We are developing the system capabilities to attach a prior authorization request to a claim. We will issue claims processing instructions in CMS guidance. At any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program. We may require action plans for standards that are not met by contractors and also consider documented past performance for future contract awards. We are finalizing prior authorization as a condition of payment. As such, if a claim subject to prior authorization is received without an associated affirmed prior authorization request, it will be denied. Once the claim is denied,

standard appeal rights apply. Several commenters recommended that CMS have a way of tracking and reporting the contractors' response times and inbound and outbound documentation submitted. Several commenters recommended that CMS make statistics of the prior authorization programs available to the public. We will take these comments into consideration as we implement the prior authorization process. We expect to create a process through subregulatory guidance that provides requesters with an efficient experience and takes into consideration public recommendations. We agree that outreach and education are extremely important. We will take these comments into consideration as we implement the prior authorization process.

We are finalizing the following proposed provisions:

1. *Create prior authorization as a condition of payment for items on the Required Prior Authorization List, as proposed in § 414.234(c)(1). Claims receiving a non-affirmation decision, as well as claims for items subject to prior authorization but for which no prior authorization was requested, will be denied if submitted for processing.*
2. *Add a new paragraph (t) to § 405.926 stating that a contractor's prior determination of coverage is not an initial determination. Section 405.926 contains the list of actions that are not initial determinations and thus not appealable.*
3. *Define a "provisional affirmation" prior authorization request decision, as proposed in § 414.234(a).*
4. *Require all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules be submitted before the item is furnished to the beneficiary and before the claims is submitted for processing, as proposed in § 414.234(d)(1).*
5. *Permit unlimited resubmissions of the prior authorization request, as proposed in § 414.234(e)(3)(ii).*
6. *Include an expedited review option and process, as proposed in § 414.234(e)(4).*

F. Other

CMS received several comments that were outside the scope of the proposed rule. Other comments were related to the proposed prior authorization rule, but did not address any of the topics discussed in this final rule. The following are some public comments along with CMS responses.

Comment: Several commenters believe section 1834(a)(15) of the Act requires that the prior authorization process be fully electronic and use a valid ASC x12 278 transaction.
CMS Response: We are aware of the need to be HIPAA compliant. We expect to have the ability to accept electronic 278 transmissions and will notify the public when electronic 278 transmissions can be accepted.

Comment: Several commenters recommended that the prior authorization decision should be communicated to both physician/practitioner and the supplier.
CMS Response: We will take this comment under advisement as we develop operational guidance for this rule.

Comment: Some commenters expressed concern regarding bundled items and that not all individual codes on the proposed Master List over $1,000 are standalone items and that they are used in combination with an entire multi-coded device.
CMS Response: We recognize that some items on the Master List could be ordered together. Our prior

authorization process will accommodate this circumstance. Specific instructions will be given in subregulatory guidance.

G. Liability

PROPOSED RULE:

1. A request for prior authorization must be submitted prior to furnishing the item to the beneficiary and prior to submitting the claim for processing.
2. When a claim for an item on the Required Prior Authorization List is submitted and denied, the contractor determines liability for the denied item based on sections 1834(j)(4) of the Act for non-assigned claims and 1879(h)(2)of the Act for assigned claims. Under these sections, any expenses incurred for the denied item or service are the responsibility of the supplier unless liability is transferred to the beneficiary in instances where beneficiaries are given an ABN, Form CMS–R–131, because the beneficiary knows or could be expected to know that payment would not be made.
3. The limitation on liability provision in section 1879 of the Act establishes a process for determining financial liability for certain denials of items or services. In the case of assigned DME that is subject to the prior authorization requirement established in this final rule, under section 1879(h) of the Act, a supplier is presumed to be financially liable for a claim denied if there is no prior authorization affirmation. The same holds true for non-assigned DME under section 1834(j)(4) of the Act. If the supplier collected any monies from the beneficiary for such denied items, the supplier is required to refund such monies.
4. After promulgation of the prior authorization requirement through this final rule, CMS or its review contractors would presume that the supplier knew that Medicare would automatically deny the claim for which the supplier failed to request a prior authorization, per section 1834(a)(15) of the Act. However, CMS or its review contractors would generally presume that the Medicare beneficiary does not know, and cannot reasonably be expected to know, that Medicare will deny, or has denied, payment in advance under section 1834(a)(15) of the Act.
5. Under sections 1834(j)(4) and 1879(h)(2) of the Act, when a beneficiary receives an item or service and does not know that CMS or its review contractors may deny the claim based on an unmet prior authorization requirement, the supplier is financially liable for the denied claim and is obligated to refund any payments received from the beneficiary. In cases where the beneficiary insists on getting the item without the prior authorization decision or while the decision is pending, or in cases where the prior authorization decision is non-affirmed, the supplier must issue a valid ABN to the beneficiary, in order to shift liability to the beneficiary. If the beneficiary agrees to pay for the item when signing the ABN, liability rests with the beneficiary if Medicare does, in fact, deny the claim. The ABN notifies the beneficiary that an item usually covered by Medicare may not be paid for in this instance. When completing the ABN, the supplier must provide a clear reason why Medicare may deny payment. The ABN must not be used to bypass the prior authorization process, and existing policy prohibits routine ABN issuance. In order for the ABN to be considered valid, the ABN must be issued to the beneficiary before the beneficiary receives the item or services.
6. Detailed requirements for valid ABN issuance can be found in Chapter 30 of the Medicare Claims Processing Manual (Internet Only Manual (IOM) Pub 100–04). 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.

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