July 25, 2014

Ms. Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6050-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: MEDICARE PROGRAM: PRIOR AUTHORIZATION PROCESS FOR CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) ITEMS

Dear Ms. Tavenner;

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the proposed regulation on the Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items**.** The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including some items that may be subject to this proposed regulation. The Coalition appreciates the opportunity to offer our comments.

General Comments

While we understand and support the need to reduce improper payments in the Medicare program, the Coalition is concerned with the added burden that this proposed regulation places on clinicians and requests that CMS reconsider its proposal. By its very nature, prior authorization questions the clinician's judgment and furthermore removes the decision making from the clinicians and their patients to administrators who do not have first-hand knowledge of the patients or their conditions.

Moreover, as CMS is determining the types of products that it will include on the master list, the Coalition strongly urges CMS to exclude Negative Pressure Wound Therapy (NPWT) from any regulation requiring prior authorization due to the risk of jeopardizing the clinical condition of the patients being treated. The NPWT LCD is more complex than many traditional DME products, with detailed criteria that vary by wound type (e.g. diabetic ulcer vs. pressure ulcer vs. surgical wound) and healing progression. The

complexity requires lengthy documentation from historical medical records documenting the history of the wound (including previous treatment regimens and the current wound therapy programs, concurrent treatments depending on wound type, etc.) that are often taken from several sources. This complexity could place significant administrative burden on the agency for the processing of requests and completing medical case reviews as well as the burden to the prescriber. The interference that the prior authorization period would place on clinical protocols including timely hospital discharges for the patients requiring NPWT justifies removing it from the master list.

The Coalition has significant issues with the regulation as proposed and offer our specific comments below.

Specific Comments

Prior Authorization Timeframe

The timeframes identified by CMS in this proposed regulation for a prior authorization to be granted or denied is not reasonable. If a patient requires necessary DMEPOS it should not take up to 10 business days in order to receive a decision. Furthermore, if a prior authorization is expedited, it should not take up to 2 business days; or in the case where the authorization is requested on a Thursday or Friday, up to 4 days. This creates unnecessary delays in patient care and in our opinion is not reasonable.

The Coalition understands that private payers are able to provide same-day prior authorization approvals and we believe that, in the interest of patient care outcomes, the final rule should define circumstances that would allow clinicians (and their patients) to receive same-day approval as well as circumstances for a one day approval. It is our opinion that no prior authorization determination should take longer than 24 hours. CMS should carefully assess adopted timeframes in the context of beneficiary needs and ordering physician expectations for prompt access to DMEPOS products. As such, the Coalition recommends that should CMS move forward with this prior authorization requirement, that it looks to private payers and adopt the "same day" prior authorization approvals for most requests and identify those areas in which a 24-hour decision will be made.

In the cases where NPWT is prescribed, according to Medicare LCD policy, clinicians are initiating NPWT "…. because it is considered in the judgment of the treating physician, the best available treatment option" or the "accelerated formation of granulation tissue cannot be achieved by other available topical wound treatments." (Source: DMEMAC LCD – Negative Pressure Wound Therapy Pumps). The proposed rule would run in opposition to the best clinical judgment of the treating physicians and may force them to extend topical wound treatments that the clinician has already deemed inadequate. Unless prior authorization can be provided within the 24 hour timeframe, this policy would force clinicians to seriously disrupt wound care treatment for Medicare

beneficiaries, jeopardize patient wound healing, and potentially delay the discharge of the patient.

Reconsideration

The Coalition is equally concerned about the timeframe for reconsideration. CMS has stated in the proposed regulation that reconsiderations can take up to 20 business days. This seems excessive and would hinder access to timely and necessary patient care. As such, the Coalition recommends that a reconsideration request should be processed in no longer than 2 days.

Master List

Once an item has been identified and placed on the master list by CMS, the Agency has proposed to keep the product on the list for 10 years. The Coalition believes that this time frame is too long and not reasonable. We also believe that this timeframe is arbitrary. Technology changes rapidly and therefore we recommend that CMS once it identifies a product to be placed on the master list, to keep it there for a year.

At that time, CMS can further evaluate whether improper payments have continued. If they have not continued, the product should be removed from the list. If they have continued, the product should stay on the list for an additional year. At that point in time, CMS needs to be transparent and advise the community as to why the product was kept on the list.

Furthermore, CMS needs to specify in the regulation how it "grandfathers in" the prior authorization requirement for those items that ultimately make the master list which are already being utilized by a Medicare beneficiary. The proposed regulation is silent on this matter and the Coalition believes that CMS needs to address this issue prior to the regulation being finalized.

NPWT Improper Payment Reference

CMS addresses NPWT in this proposed rule by citing it as an example in a study issued on improper payments. CMS stated in the rule, "… approximately 94% of DMEPOS improper payments were due to insufficient documentation." Insufficient documentation includes the requirement that forms be completed in their entirety. The improvement of compliance to such detailed criteria requires training, internal auditing and good hiring practices.

Based on the information set forth in the proposed rule Tables 1-3, it appears NPWT claims are included in the category of "All Codes with Less than 30 Claims" or "All Other Codes." It is noteworthy that these categories have shown improvements in Overpayment Rates from 2011 to 2013 of 20 points and 10 points, respectively.

We believe this is attributable to educational efforts by CMS and also by manufacturers to the DME suppliers using their NPWT technologies. We see these changes as moving compliance in the right direction without disruption to the critical treatment of wound care patients. As such, we urge CMS to exclude NPWT from the prior authorization regulation.

Accountability

In order to move forward with any prior authorization program, CMS and its contractors need to be held accountable. There is nothing within the proposed rule that would create any accountability for CMS or its Contractors should prior authorization requests not be processed in the timeframes proposed. If there are time frames that ultimately are determined by which CMS and its contractors have to make a prior authorization determination, there should be something contained in the regulation which identifies what would happen if those timeframes are not met.

Improper Payment Determination/Appeals

CMS has determined that there are certain items of DMEPOS in which improper payments have been made. The proposed regulation states, "payment made for the furnishing of an item that does not meet one or more of Medicare's coverage, coding, or payment – identified by the CERT, OIG, HHS, or the GAO" can be subject to the prior authorization requirement. We question whether this information takes into account those items in which an improper payment was determined by CMS yet overturned by an Administrative Law Judge (ALJ). We have seen CMS and its contractors identifying "improper payments" but when appealed are reversed by an ALJ. So we request clarification as to whether this information has been taken into consideration when making the determination by the CERT, OIG, GAO or HHS that an improper payment has been made.

Furthermore, CMS proposes, "that a contractor's prior determination of coverage is not an initial decision. 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". The Coalition requests that CMS clarifies when a decision is appealable. The regulation states that an appeal is permitted when "a claim is submitted for which there was a non-affirmative decision or if no prior authorization request was obtained". This is confusing since it seems to conflict with the previous statement that if a request is non-affirmed it is not appealable. There should be a process in place for beneficiaries to appeal unfavorable prior authorization decisions and the Coalition recommends that CMS outline all of the circumstances in which a beneficiary can appeal their initial decision as well as their decision on reconsideration in an easy to understand simplistic fashion.

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Clarification

The Coalition seeks clarification in the following situations:

- CMS has stated that it will automatically deny payment for a claim for an item that is on the Required Authorization list that is submitted without an affirmative prior authorization decision. The Coalition requests clarification on this matter. Specifically – if a clinician provides care to a patient and prior authorization was not obtained OR prior authorization was submitted but in the clinical judgment of the clinician the patient condition warranted providing the item immediately and the patient could not and should not wait for a prior authorization determination – is there anything that the clinician can do after the fact? Is this situation curable? If so under what circumstances? Similarly, the proposed rule should provide clarification on when it is permissible to bypass the prior authorization process versus the ABN process.
- Furthermore, we seek clarification on why a supplier would be liable for a claim denied if there is no affirmative prior authorization obtained by the clinician? If a physician is supposed to submit the prior authorization but does not – why would a supplier be deemed financially liable? Furthermore, if CMS is stating that it is the responsibility of the supplier to obtain prior authorization – the Coalition believes that this will not only create an administrative nightmare, but the process will be significantly slower thus impacting beneficiary access and care.
- From a process point of view, the Coalition would like to ensure that the following processes are transparent: the method that CMS initially chooses products for the Master List, and then decides which products to keep on and take off the list.

The Coalition appreciates the opportunity to provide our comments. If you need more information or have any questions, please do not hesitate to contact me.