Comments on Burdensome Certification Requirements

- **Submission of a Certificate of Medical Necessity**
  The requirements for a physician certification of medical necessity for DMEPOS is overly burdensome, with way too many specific requirements on what must be done, when, by whom, on what date, with what level of specificity, etc. In addition, the level of detail and various aspects of the requirements are explained in too many places. For instance:
    - Under Medicare IOM 100-04, Claims Processing, a signed Certificate of Medical Necessity (CMN) from the treating physician is required for CMS to pay for certain items of equipment or prosthetics/orthotics, or, if the DME POS is being billed to an HH MAC, the same items must be on the physician's order.
        - There are four sections to be completed on the CMN, some by the supplier, some by the physician (but all must be reviewed by and signed off on by the physician) and
        - Each of those four sections has up to 10 subsections.
    - There are multiple strict requirements applied to CMNs which are found in a different manual, Medicare 100-08 - Medicare Integrity Manual. For example, specific Medicare policies and instructions on the following topics are found in IOM 100-08.
        - Requirements for supplier retention of original CMNs
        - CMN formats, paper and electronic
        - List of currently approved CMNs and items requiring CMNs
        - Supplier requirements for submitting CMNs
        - Requirements for CMNs to also serve as a physician's order
        - Civil monetary penalties for violation of CMN requirements
        - Supplier requirements for completing portions of CMNs
        - Physician requirements for completing portions of CMNs"
    - Medicare Manual IOM 100-02, Medicare Benefit Policy Manual, contains pages of instructions on how DMEPOS will be evaluated by CMS (and thus what information needs to be part of the CMB) including the following three requirements:
        - The equipment meets the definition of DME (§110.1);
        - The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
        - The equipment is used in the patient's home.

      The chapter goes on to explain and define how each of these are to be judged including defining what is meant by:
        - Durability
        - Medical Equipment
            - Equipment Presumptively Medical
            - Equipment Presumptively Nonmedical
            - Special Exception Items
        - Necessary and Reasonable
            - Necessity for the Equipment
            - Reasonableness of the Equipment

- Payment Consistent with What is Necessary and Reasonable
- Establishing the Period of Medical Necessity
- Definition of a Beneficiary's Home

The above process is required for many, if not most, DME or POS items – the requirements are separate from the prior authorization requirements described below.

- **<u>Prior Authorization Requirements</u>**

While the prior authorization (precertification) process appears to currently be limited to certain items, CMS had indicated the possibility of expanding the list of items or services subject to the prior authorization process, which could lead to increase in burden.

This process is overly burdensome in that it isn't totally clear which items need prior authorization and under what circumstances. For example, there are three different but similar entries for prior authorization for DME POS – Power Mobility Devices (PMDs), Group 3 Power Wheelchairs, and Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Items. Although the pre-authorization requirements for DME POS items is somewhat understandable, the use of differing terms causes confusion. First, prior authorization does not appear to apply to all or even a majority of DME POS items or services. There is a Master List which as defined as:

> "[t]he set of 135 DMEPOS items identified as being frequently subject to unnecessary utilization. Items that meet the following criteria are included on the Master List and thus potentially subject to prior authorization:
>
> - items on the DMEPOS Fee Schedule with an average purchase fee of $1,000 or greater, or an average rental fee schedule of $100 or greater, (adjusted annually for inflation) and the subject of:
>   - HHS Office of the Inspector General (OIG) or U.S. Government Accountability Office (GAO) reports that are national in scope and published since 2007, or
>   - Comprehensive Error Rate Testing Program's Annual Medicare Fee-for-Service Improper Payment Rate Reports and/or the Supplementary Appendices for the Medicare Fee-for-Service Improper Payment Rate Reports since 2011."

Note that the Master List includes all items that are <u>potentially</u> subject to prior authorization. To find out which POS DME items are actually <u>required</u> to be pre-authorized, one needs to go to the "Required Prior Authorization List." Although I found many references to the list, I was unable to locate an actual list. The closest I came was a document that said

> The initial codes on this list requiring pre-authorization starting March 17, 2017 for 4 states includes 2 codes:
>
> - K0856: Power wheelchair, group 3 std., single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
> - K0861: Power wheelchair, group 3 std., multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds

Although I could find some information on the prior authorization requirements for DME POS, albeit fragmented and unclear, several other items came up in a search of the CMS website, including:

- Repetitive scheduled non-emergent ambulance transports
- Non-emergent HBO therapy
- Pre-authorization for certain Part D claims for hospice
- Request for Medicare Prescription Drug Coverage Determination

Other than the odd document that showed up in the search, I couldn't easily find out how to find out the current status, if any, of these demonstrations.

Another identified issue is that any information available is widely scattered. For instance, the only information I could find about pre-authorization requirements in the Medicare Manual system was in IOM 100-08, which contained a section entitled 3.10.1- Prior Authorization of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS). Besides being limited to a particular item, it wasn't terribly intuitive to look in that particular manual or especially in the pertinent chapter, which is entitled "Verifying Potential Errors and Taking Corrective Actions."

There is no requirement that the physician who prepares many of the documents to obtain prior authorization for the 2 codes needing preauthorization under DME POS should receive notice of the outcome of the prior authorization review. In a page on the Medicare website (which is, again, not easily or intuitively found, requiring one to drill down through the following levels: Home > Research, Statistics, Data and Systems > Medicare Fee-for-Service Compliance Programs > Prior Authorization for Certain Durable Medical Equipment, Prosthetic, Orthotics, Supplies Items > Physician Resources) it notes that "As the prescribing physician/practitioner, you may contact the DME MAC for a copy of the prior authorization decision letter. The DME MAC will not automatically send you a copy of the decision letter. The request for the decision letter may be included with the documentation sent to the supplier as part of the prior authorization request, or may be made separately." This is problematic – the physician should automatically receive a determination letter.

Physician Certification for Inpatient Hospitalization

As per a CMS document dated 9/5/13 and entitled "Hospital Inpatient Admission Order and Certification," the following is required: "As a condition of payment for hospital inpatient services under Medicare Part A, section 1814(a) of the Social Security Act requires physician certification of the medical necessity that such services be provided on an inpatient basis."

This requirement seems redundant and thus confusing as it basically just consolidates already mandated documentation into one body of work, which can rake any form. As specified in 42 CFR 424.11, "No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form."

The requirements for certification (not including CAHs) are listed as:

- Authentication of the practitioner order

- Reason for inpatient services
- The estimated time the beneficiary requires or required in the hospital
- The plans for posthospital care, if appropriate, and as provided in 42 CFR 424.13

However, according to this document, the above elements can be satisfied through existing documentation, absent a specific certification form. CMS and its contractors will look for the following medical record elements in order to meet the initial inpatient certification requirements:

- The authentication requirement for the practitioner order will be met by the signature or countersignature of the inpatient admission order by the certifying physician.
- The requirement to certify the reasons that hospital inpatient services are or were medically required will be met either by the diagnosis and plan documented in the inpatient admission assessment or by the inpatient admitting diagnosis and orders.
- The estimated time requirement will be met by the inpatient admission order written in accordance with the 2-midnight benchmark, supplemented by the physician notes and discharge planning instructions.
- The post hospital care plan requirement will be met either by physician notes or by discharge planning instructions.

Since CMS would be able to use already existing documentation to ensure that all criteria for certification has been met, why spell it out as a separate requirement. That makes it seem like the medical record must include a form labeled “Certification” with all of the above elements copied and pasted into it.