The Centers for Medicare and Medicaid Services (CMS) received comments from stakeholders related to CMS-10447. This is a summary of the comments.

1. **Comment:**

   Several commenters requested that CMS clarify whether the hospitalist ordering the Durable Medical Equipment (DME) for the inpatient and who has the face-to-face encounter with the patient prior to discharge must meet the face-to-face encounter requirement.

   Response:

   Medicare beneficiaries discharged from a hospital do not need to receive a separate face-to-face encounter, as long as the physician or treating practitioner who performed the face-to-face encounter in the hospital issues the DME order within 6 months after the date of discharge.

2. **Comment:**

   Several commenters requested clarification that this requirement is for new DME orders and not for existing orders. Commenters were concerned that if the proposed face-to-face encounter requirements were to apply retroactively to orders already written (that is, each new shipment after the effective date of the final rule would need to comply with the requirements), suppliers may be required to obtain new physician orders for all of the Medicare beneficiaries whom they serve.

   Response:

   We clarify that this requirement is for new DME orders only. That is, items that have been ordered on or after the effective date of this final rule.

3. **Comment:**

Many commenters suggested that CMS revise the rule to require that face-to-face encounters occur only before the date of the written order, and not after the written order is issued.

Response:

After consideration of these comments we have removed the option for the face-to-face encounter to occur 30 days after the written order. We believe it is critical that the face-to-face be conducted before the item is delivered to the beneficiary's home. Allowing face-to-face encounters to occur 30 days after the order could result in medically unnecessary items being delivered to beneficiaries. Further, suppliers could deliver the item but then be unable to bill Medicare if the face-to-face encounter does not occur.

4. **Comment:**

Many commenters believed the timeframe should be revised to allow the face-to-face encounter to occur in the 6-month period preceding the order, as authorized by the statute.

Response:

In response to comments, CMS is modifying the encounter timeframe so that the face-to-face encounter must now occur 6 months prior to the written order, as opposed to the 3 months we previously had proposed. We believe this modified timeframe best balances the need to protect the Medicare Trust Funds by limiting waste, fraud and abuse while limiting burden.

5. **Comment:**

A few commenters cautioned that this proposal will cause a certain amount of confusion since certain DME items, such as power mobility devices (PMDs) as outlined in §410.38(c), have a 45 day face-to-face encounter requirement as opposed to the proposed 90 day requirement for other DME items. Commenters believe greater consistency among face-to-face requirements for DME will reduce confusion and improve compliance by healthcare professionals. Several commenters expressed a desire to have this regulation supersede the PMD face-to-face regulation.

Response:

This regulation implements section 1834(a)(11)(B) of the Act. It does not supersede the PMD regulation as specified in §410.38(c), which we issued under different authority. We believe that a longer timeframe is necessary for these DME items than the 45-day timeframe for PMDs because of the wide variety of DME items covered by this rule. This regulation does not apply to PMDs and does not supersede other regulations specific to PMDs. We look forward to engaging in extensive education to help to clarify the requirements.

6. **Comment:**

A few commenters expressed concerns that Nurse Practitioners (NP) have no control over how quickly physicians will actually document the face-to-face encounters that they conduct. The commenters were concerned that there may be instances in which it will be difficult to ensure documentation is submitted by the physician to the supplier within 30

days after an order is written, potentially delaying patient access to the equipment they need while documentation is being completed.

Response:

We have removed the ability for the face-to-face encounter to occur up to 30 days after the order. We are implementing a statutory requirement that the physician must document the face-to-face encounter even when performed by a Physician Assistant (PA), NP or Clinical Nurse Specialist (CNS) within the 6 months preceding the written order. We urge physicians, PAs, NPs and CNSs to work together to ensure that all beneficiaries receive needed DME. Additionally, we believe that 6 months prior to the written order provides sufficient time for coordination between the NP, PA, or CNS and the physician to document the face-to-face encounter. In addition, we will monitor the implementation of this rule to ensure there are no unintended consequences that negatively impact the practitioner, supplier, and beneficiary communities.

7. **Comment:**

Many commenters expressed a belief that instructions and requirements related to the order need to be clear and less burdensome. Commenters expressed the need for clarity and/or requested removal of the need for physicians to describe "necessary and proper usage instructions", diagnosis codes, and the National Provider Identifier (NPI) in the written order.

Response:

We appreciate the commenters' recommendation. We agree that instructions that limit burden are important. We have removed the proposed requirement for orders to include:

"necessary and proper usage instructions" and the diagnosis. Due to the large number of covered DME items and the fact that there could be many diagnoses and usage instructions for each, we agree that these proposed requirements may be overly burdensome. While this information will not be required on the DME order under this regulation, we will still expect to see related diagnoses included in the beneficiary's medical record. We would also expect "necessary and proper usage instructions" to be provided to the beneficiary or care giver for proper usage of the item. The remaining five elements listed: (1) the beneficiary name; (2) the item of DME ordered; (3) prescribing practitioner NPI; (4) the signature of the prescribing practitioner; and (5) the date of the order are the minimum needed for CMS to consider the order valid. This does not supersede other requirements.

8. **Comment:**

Several commenters stated that for some DME items, the proposed face-to-face encounter requirements represent a significant change for Medicare beneficiaries, providers and DME suppliers. Commenters noted that even though some of the proposals are relatively minor, such as requiring the prescribing practitioner's NPI to be included on the written orders, they require providers and suppliers to change their standard practices. Such "minor" changes are significant since non-compliance may adversely affect the payment for DME.

Response:

We appreciate these comments. Our goal is to limit provider and supplier burden while still preventing waste, fraud and abuse. To that end, in response to comments, we have

removed the requirement that instructions for necessary and proper usage, and the diagnosis be included on the order. However, we are retaining the other requirements as a way to limit waste, fraud and abuse.

9. **Comment:**

Several commenters believed a standardized form that documents the elements CMS and its contractors require for coverage of a DME item should be recognized by CMS as part of the beneficiary's medical record and should establish the beneficiary's medical need for the item.

Response:

The amount of necessary clinical information needed to demonstrate that all coverage and coding requirements are met will vary depending on the item/service. For example, we have National and Local Coverage Determinations which address many of these items/services. The commenters appear to be describing a template. However, we do not prohibit the use of templates to facilitate record-keeping. We also do not endorse or approve any particular templates. A physician or practitioner may choose any template to assist in documenting medical information.

We do caution, however, that some templates provide limited options and/or space for the collection of information such as by using "check boxes," predefined answers, and limited space to enter information. We discourage the use of such templates. Our experience with claim review shows that 'limited space' templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met. Furthermore, physicians or practitioners should be aware that

templates designed to gather selected information primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. These 'limited space' documents often do not provide sufficient comprehensive information to adequately show that the medical necessity criteria for the item/service have been met.

10. Comment:

A few commenters expressed a belief that the documentation requirements should be the same for physicians as they are for nurse practitioners and other non-physician providers.

Response:

We agree that the documentation requirements for the face-to-face encounter should be the same. However, it is duplicative to have the physician document that the face-to-face occurred when they themselves conducted the face-to-face encounter. Therefore, we are not requiring additional documentation requirements for the physician in addition to what they are required to document during the actual face-to-face encounter.

11. Comment:

Some commenters believe that if an ordering physician certifies the date of a face-to-face encounter on the signed written order that should be sufficient documentation for the supplier to establish medical necessity for the DME items. This method of documentation is most efficient for physicians, and it is easily verified by DME suppliers when establishing that medical necessity requirements are met.

Response:

While we appreciate this comment, a verification of a date added to a written order does not prove that an adequate face-to-face occurred. Detailed face-to-face documentation is required to ensure the item of DME is medically necessary and appropriate for the individual beneficiary.

12. Comment:

Commenters believe there is no justification for requiring less information on the beneficiary's medical need for DME if a physician personally conducts the evaluation than if a nurse practitioner assesses the patient. Typically, the physician communicates the order directly to the supplier who, in turn, initiates intake and assessment based on a written confirmation of the physician's verbal order, which is later ratified by the physician's signature and date.

Response:

We are not requiring less information on the need for DME if a physician conducts the evaluation than would be deemed appropriate if a nurse practitioner assesses the patient. We are not requiring additional documentation requirements for the physician above what they are required to perform in documenting the actual face-to-face encounter.

13. Comment:

Many commenters expressed a desire to limit their burden. Commenters expressed that overly unnecessary copying, drafting, and distribution of records from the Physician to the physician supplier is burdensome at the very least, interferes with the physician-patient relationship, and is generally not in the best interests of the Medicare beneficiary.

Response:

We have worked to develop a rule that weighs our responsibility to implement the statutory provision, while minimizing provider and supplier burden. As a result of comments, we are allowing flexibility on how the supplier is notified of the face-to-face encounter. We have tried to limit the burden by requiring that the physician sign/cosign the pertinent portion of the medical record to document when a face-to-face encounter was performed by a NP, PA or CNS. This step is not needed when the physician personally conducts the face-to-face encounter.

14. Comment:

Several commenters expressed concerns that physicians have reported deceptive practices by DME suppliers who have sent letters to physicians on letterhead appearing to be co-branded with CMS but without CMS authorization. The letters have indicated that because the DME supplier is undergoing a CMS audit, the physician must produce extensive and costly medical record documentation and submit it to the DME supplier.

Response:

Suppliers are required to have the documentation available upon request by CMS. CMS has worked to limit the burden associated with this regulation. However, the CMS seal and logo are for the official use of CMS and its authorized contractors only and must not be used by suppliers or others within the private sector. Under section 1140 of the Act, individuals or organizations may be subject to a civil money penalty for the misuse of words, symbols, or emblems or names in reference to Social Security or Medicare. If physicians have information about suppliers or others who are misusing CMS words,

symbols, or emblems, they should contact the Health and Human Services Office of Inspector General. Organizations or individuals concerned about suppliers who may be misrepresenting themselves or CMS should contact the contractor that processes their claims. CMS requires that suppliers have access to the documentation to support their claims. Suppliers may request supporting documentation, including documentation of a face-to-face encounter, from the physician, but suppliers must not misuse CMS words, symbols, or emblems when making those requests. Suppliers may, of course, share unaltered CMS educational material.

15. Comment:

Commenters suggested that CMS clarify in its regulation that after a physician or beneficiary has submitted a medical record and documentation of the face-to-face visit to the DME supplier, the DME supplier must retain a copy of that already-submitted record, and the physician is not required to supply subsequent medical records or documentation to the DME supplier.

Response:

The face-to-face encounter is a condition of payment for the supplier. Suppliers must make this information available to CMS upon request.

16. Comment:

Commenters urged CMS to give physicians and other practitioners maximum flexibility by allowing them to choose among the options CMS has proposed. To avoid creating new burdens for physicians, commenters recommend that the new process for

communicating documentation to suppliers resemble, as closely as possible, current processes used by physicians. Commenters believe that this may be similar to the second option discussed in the proposed rule, and, if this is the case, they recommended using that option.

Response:

In response to comments, we are not requiring a particular method of transmission for supplier notification that the face-to-face encounter has occurred in order to limit burden and not create a hindrance to access to care. Practitioners and suppliers can communicate the information and requirements through existing business processes for transmitting this information. CMS will monitor the effects of this provision on beneficiaries' access to medically necessary DME. We also note that this documentation must be made available to suppliers to allow them to ensure all requirements are met. Suppliers must make this documentation available to CMS upon request.

17. Comment:

Many commenters believe that the adopted rules should give adequate protection to downstream DME suppliers who act in good faith in response to information communicated by physician practices. Commenters believe that whatever documentation and communication policies CMS adopts for face-to-face encounters should give suppliers absolute peace of mind that their subsequent dispersing of DME items will not later be second-guessed by CMS or its contractors.

Response:

We believe that by removing the ability for the face-to-face encounter to occur 30 days

after the written order suppliers will be afforded more protection as all documentation will be available at the time of order. Completion of the face-to-face requirement is a condition of payment and could be subject to audit. Therefore, this documentation must be available to CMS on request. CMS will monitor the effects of this provision on beneficiaries' access to medically necessary DME.

18. Comment:

Several commenters expressed a concern that the ordering practitioner has little interest or incentive to ensure the necessary paperwork is provided to the supplier since the practitioner/physician still gets reimbursed for their services regardless of whether they have inadequate documentation and fail to provide such documentation to the suppliers. A few commenters stated that the DME supplier should not be responsible for scheduling the face-to-face visits to ensure the requirement is met. Commenters also believed physicians who are continually noncompliant with the rule should be subject to corrective action.

Response:

We encourage suppliers and practitioners to work together to ensure that beneficiaries receive necessary and appropriate care. Completion of the face-to-face requirement is a condition of payment. Therefore, this documentation must be available to CMS upon request. We believe that by removing the 30 days after the order is written timeframe for the face-to-face encounter, the supplier will be able to know before delivery if all requirements have been meet. CMS does provide education on documentation requirements to physicians and other practitioners including through MLN articles.

19. Comment:

Commenters stated that requiring that a physician sign-off on commonly prescribed items, such as blood glucose monitors and standard wheelchairs that are currently ordered by NP, PA, and Advance Practice Nurses including CNSs may create a barrier for consumers, many of whom routinely receive this needed equipment from nonphysician practitioners , and runs contrary to current Medicare reimbursement practice. Several commenters raised concerns that the agency's broad list of proposed covered items includes several items that NPs and CNSs order routinely for frequent conditions and diagnoses, such as glucose monitors. Commenters stated that requiring physician documentation before these items may be supplied is likely to delay patient care and potentially lead to serious complications and more severe conditions.

Response:

We are implementing the statutory requirements of this provision to require a physician has to document the occurrence of a face-to-face encounter for certain covered items of DME. Face-to-face encounters conducted by NPs, PAs, and CNS are allowed, but as the statute states these encounters must be documented by a physician. CMS does not believe that this regulation will create a barrier to beneficiaries including those who are prescribed orders from PAs, NPs and Advance Practice Registered Nurses including CNSs .

We use a criterion driven approach to select these items and are implementing this provision in accordance with the statute. We do not believe that this requirement will delay a beneficiary from getting necessary care particularly with the longer timeframe. In

addition, we will monitor the implementation of this rule to ensure there are no unintended consequences that negatively impact the practitioner, supplier, and beneficiary communities.

20. Comment:

Commenters were very concerned that the proposed rule does not make clear that the burden to obtain documentation of face-to-face encounters will not be placed on pharmacies.

Response:

We worked to implement this statute in a way that limits burden to providers and suppliers while ensuring beneficiary access to care. All entities billing Medicare for a covered item of DME are subject to this provision. CMS does not believe that it is appropriate to carve out an exception for pharmacies. If a pharmacy bills Medicare for one of these covered items then this documentation must be available upon request.

21. Comment:

Commenters encouraged the Agency to (1) assess regularly how additional documentation requirements could limit patient access to DME items and increase the documentation burden on providers, (2) describe what types of educational programs it will develop to help providers understand the DME documentation requirements necessary for Medicare coverage, and (3) evaluate what incentives could be offered to encourage providers to focus on reducing documentation error rates.

Response:

We do not believe that this requirement will limit patient access to necessary DME particularly in light of the longer timeframe. We balanced the need to protect the Medicare Trust Funds while limiting burden. We are not being prescriptive on how the face-to-face encounter must be communicated to the supplier and believe this will help limit provider burden. CMS will issue an MLN article regarding this requirement. Incentives for document error rate are outside the scope of this regulation.

22. Comment:

Commenters appreciated CMS's efforts to reduce waste, fraud and abuse. Commenters stated that CMS should apply the new encounter and documentation requirements initially to a smaller number of HCPCS codes and first evaluate the impact of the requirements on beneficiary access to DME and costs to providers before expanding the list in the future.

Response:

CMS believes that this is an important requirement aimed at reducing waste, fraud and abuse. CMS utilized a criterion driven approach to select these items and did not receive sufficiently detailed alternative criteria to those proposed to be implementable. CMS will monitor the effects of this requirement on reducing waste, fraud and abuse and monitor beneficiary access to care.