Supporting Statement – Part A
Durable Medical Equipment Face-to-Face Requirements
OMB 0938-New, CMS-10447

Background

To implement section 1834(a) of the Affordable Care Act, CMS published a notice of proposed rulemaking on July 30, 2012 and a final rule on November 16, 2012 (RIN 0938-AR11; CMS-1590-FC). The final rule revises §410.38(g) by requiring, as a condition of payment for certain covered items of DME, that a physician must document and communicates to the DME supplier that the physician or physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary in the 6 months prior to the written order.

During the face-to-face encounter, the physician, PA, NP, or CNS must have evaluated the beneficiary, conducted a needs assessment for the beneficiary or treated the beneficiary for the medical condition that supports the need for each covered item of DME. As a matter of practice, this information would be part of the beneficiary's medical record, which identifies the practitioner who provided the face-to-face assessment. We believe that requiring a face-to-face encounter that supports the need for the covered item of DME would reduce the risk of fraud, waste, and abuse since these visits would help ensure that a beneficiary's condition warrants the covered item of DME.

Section 1834(a)(11)(B)(ii), as added by section 6407(b) of the Affordable Care Act states that a physician must document that the physician, PA, NP, or CNS has had a face-to-face encounter (other than with respect to encounters that are incident to services involved) with the beneficiary. A face-to-face encounter must be documented by a physician and any encounter that is covered as an "incident to" service does not satisfy the requirements of this regulation.

We note that a face-to-face encounter may be accomplished via a telehealth encounter if all Medicare telehealth requirements as defined under section 1834(m) of the Act and the implementing regulations in §410.78 and §414.65 are met. Specifically, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. The rule's requirements do not supersede the requirements of telehealth and merely apply to the telehealth benefit where applicable. In general, originating sites must be located in a rural health professional shortage area (HPSA) or in a county outside of a metropolitan statistical area (MSA). The practitioner at the distant site may be a physician, PA, NP, or CNS, and the encounter must be reported with a healthcare procedure common coding system (HCPCS) code for a service on the list of approved Medicare telehealth services for the applicable year.

A single face-to-face encounter, including those facilitated through the appropriate use of telehealth, can support the need for multiple covered items of DME as long as it is clearly documented in the pertinent medical record that the beneficiary was evaluated or treated for a

condition that supports the need for each covered item of DME, during the specified period of time.

To promote the authenticity and comprehensiveness of the written order and as part of our efforts to reduce the risk of waste, fraud and abuse and, as a condition of payment, a written order must include: (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. We recognize that standards of practice may require that orders contain additional information. However, for purposes of this rule, which is focused on implementing section 1834(a)(11)(B) of the Act and reducing fraud, waste, and abuse, an order without these minimum elements would be considered incomplete and would not support a claim for payment. We believe including this information on the written order would be a safeguard against waste, fraud, and abuse by promoting authenticity and comprehensiveness of the order by the practitioner.

This requirement does not supersede any regulatory requirements that more specifically address a face-to-face encounter requirement for a particular item of DME.

Physician Documentation

The statute requires that a physician document that the physician or a PA, NP or CNS has had a face-to-face encounter with the beneficiary. When the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record, containing sufficient information to document that the face-to-face encounter meets our requirements, would be considered sufficient and valid documentation of the face-to-face encounter when submitted to the supplier and made available to CMS or its agents upon request. Some examples of pertinent parts of the beneficiary's medical record that can demonstrate that a face-to-face encounter has occurred can include: history; physical examination; diagnostic tests; summary of findings; diagnoses; treatment plans; or other information as appropriate. Further a physician must document when a face-to-face encounters is performed by a PA, NP, or CNS as part of the medical record.

Supplier Notification

Since the supplier submits the claims for the covered items of DME, the supplier must have access to the documentation of the face-to-face encounter. All documentation to support the appropriateness of the item of DME ordered including documentation of the face-to-face encounter, must be available to the supplier. As with all items and services, we require both the ordering practitioner and the supplier to maintain access to the written order and supporting documentation relating to written orders for covered items of DME and provide them to us upon our request or at the request of our contractors.

Covered Items

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to specify covered items that require a written order prior to delivery of the item. Under section 1834(a)(11)(B)(ii) of the Act, these orders must be written pursuant to a physician documenting that a face-to-face encounter has occurred. Accordingly, to reduce the risk of fraud, waste, and abuse, we have set out a list of Specified Covered Items that would require a written order prior to delivery.

The requirement for documenting a face-to-face encounter and communicating this to the supplier is part of a Congressional statute, section 6407 of the Affordable Care Act, which requires the orders for certain items of DME be written pursuant to a face-to-face encounter. While we believe that many of the practitioners addressed in the rule are already conducting a needs assessment and evaluating or treating the beneficiary for conditions relevant to the covered item of DME. The rule may require some changes in their procedures to ensure that their documentation fulfills Medicare's regulatory requirements. Suppliers should already be receiving written orders and documentation to support the appropriateness of certain items of DME.

A. Justification

1. Need and Legal Basis

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes for specified covered items, that payment may only be made under section 1834(a) if a physician has communicated to the supplier a written order for the item, before delivery of the item.

2. Information Users

The information collection is required under section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to require, for specified covered items, that payment may only be made under section 1834(a) if a physician has communicated to the supplier a written order for the item, before delivery of the item. The

information may be requested by Medicare contractors to determine if there are improper payments or if there is a suspicion of fraud for current covered items of DME.

3. Use of Information Technology
Some of this collection of information could involve the use of automated, electronic, or other forms of information technology at the discretion of the submitter. CMS encourages compliance with all Electronic Health Record initiatives for medical documentation.

There is a signature required, at this time CMS does not accept electronic signatures. CMS offers electronic submission of medical documents (esMD) to many providers and suppliers who wish to explore this alternative for sending in medical documents. Additional information on esMD can be found at www.cms.gov/esMD.

4. Duplication of Efforts

This will represent the first face-to-face encounter requirement for the list of covered items. Along with this will be clarification of the requirements for a written order associated with these items. All other documentation requirements remain the same. A single face-to-face encounter can apply for multiple items of DME. This represents a new statutory requirement and therefore there is no other way to obtain this information.

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those small businesses order and bill Medicare for covered items of DME. The retention of the information by physicians is a routine business practice.

6. Less Frequent Collection

Since this information is only collected when potential program vulnerability exists, less frequent collections of this information would be imprudent. CMS and its agents continue to refine their tools for identifying improper billing practices.

7. Special Circumstances

More often than quarterly - This information is collected on an as-needed basis based on when the items are ordered. This process occurs on a continual basis, and delaying the collection of this information will result in additional improper Medicare payments.

Response within 30 days – Providers and suppliers are notified that they have 30 days to respond, as discussed in the Program Integrity Manual (100-08), Chapter 3, Section 2.3.2.

More than original and two copies - There is no requirement to submit more than 1 copy of the requested documentation.

Retain records more than three years - This estimate does not impose any new or additional record retention requirements beyond those requirements currently in place. Providers and suppliers are reminded that Medicare claims can be reopened for review at any time where fraud is suspected, or within 4 years of an initial determination for good cause or within 1 year for any reason.

Conjunction with a statistical survey - This information collection is not associated with a statistical survey.

Use of statistical data classification - This collection does not require a statistical data classification.

Pledge of confidentiality - This collection does not require a pledge of confidentiality.

Confidential Information - The Health Insurance Portability and Accountability Act Privacy Rule allows for the disclosure of health records for payment purposes. Medicare contractors have procedures in place to assure the protection of the health information provided.

8. Federal Register/Outside Consultation

The proposed rule that provided a 60-day public comment period published in the Federal Register on July 30, 2012 (77 FR 44722). There were issues related to burden that we addressed in our responses to the comments. We revised our burden estimates in the final rule based on a change in the policy from the proposed rule and to correct a math issue. Specifically, with regard to a physician's time to document occurrence of a face-to-face encounter, in the proposed rule we estimated 4,200,000 claims and 700,000 hr at a cost of $82,600,000 over a 5-year period. In the final rule we estimated 2,900,000 claims and 483,333 hr at a cost of $57,033,333 for the same 5-year period. With regard to a physician assistant, nurse practitioner or clinical nurse specialist's time's time to prepare the medical record for the review of the face-to-face encounter, in the proposed rule we estimated 4,200,000 claims and 210,000 hr at a cost of $11,550,000 of over a 5-year period. In the final rule we estimated 2,900,000 claims and 145,000 hr at a cost of $7,975,000 for the same 5-year period. The requirements in the proposed and final rules have not changed.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents to encourage their response to any request for information under this control number.

10. Confidentiality

Medicare contractors will safeguard all protected health information collected.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

To determine costs, we utilized the Bureau of Labor Statistics mean hourly rates for the professional, analyzed for the year that the original data was received. The hourly rate for a physician, including fringe benefits and overhead is estimated at $118 per hour. The hourly rate, including fringe benefits and overhead, for a NP, PA, or CNS is estimated at $55 per hour. The hourly rate for administrative assistant, including fringe benefits and overhead, is estimated at $23 per hour.

ICRs Regarding Durable Medical Equipment Scope and Conditions (§410.38(g))

As a condition of payment for certain covered items of DME, §410.38(g) specifies that a physician must have documented and communicated to the DME supplier that the physician or physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary no more than 6 months before the order is written.

In the July 30, 2012, NPRM (77 FR 44722) we proposed that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record (portions containing sufficient information to document that the face-to-face encounter meets our requirements) would be considered sufficient and valid documentation of the face-to-face encounter when submitted to the supplier and made available to CMS or its agents upon request. While we believe that many of the practitioners are already conducting a needs assessment and evaluating or treating the beneficiary for conditions relevant to the covered item of DME, the final rule may require some changes in their procedures to ensure that their documentation fulfills Medicare's regulatory requirements. Suppliers should already be receiving written orders and documentation to support the appropriateness of certain items of DME.

To promote the authenticity and comprehensiveness of the written order and as part of our efforts to reduce the risk of waste, fraud, and abuse, as a condition of payment a written order must include: (1) the beneficiaries' name; (2) the item of DME ordered; (3) signature of the prescribing practitioner; (4) the prescribing practitioner NPI; and (5) the date of the order.

Physicians are now required to document the face-to-face encounter if it was performed by a PA, NP, or CNS. To allow payment for this documentation, a G code is established for this service. Since the effective date for the final regulation is July 1, 2013, only 6 months of year 1 are included in calendar year 2013. Likewise, it was assumed that about 500,000 of these documentation services would be billed in year 1. We estimate the time for a physician to review each one of these encounters that results in an order is 10 minutes. Therefore, we

estimate that the physician documentation burden to review and document when a PA, NP or CNS performed the face-to-face encounter in year 1 would be nearly 83,333 hours and a total of 483,333 hours over 5 years. The associated cost in year 1 is nearly $9.8 million and over 5 years has associated costs of nearly $57.03 million based on the growth rate of the Medicare population. The increase is slightly more than five-fold because the number of Medicare beneficiaries would increase over time. The average annual burden over 5-years for 580,000 claims (2,900,000/5) is 96,667 hours at a cost of $11,406,667.

Physician Time to Document Occurrence of a Face-To-Face Encounter

	Year 1	5 Years
Number of claims affected	500,000	2,900,000
Time for physician review of each claim	10 min	10 min
Total Time	83,333 hours	483,333 hours
Estimated Total Cost (Hours times $118)	$ 9,833,333	$57,033,333

We assume it will take 3 minutes for a PA, NP, or CNS to prepare the medical record for the review of the face-to-face encounter which would be considered part of the third party disclosure. For the 500,000 orders used in the previous estimate, this creates a total of 25,000 hours at a cost of about $1.4 million in year 1 and nearly 145,000 hours over 5 years at a cost of nearly $8 million based on the growth rate of the Medicare population. Though consistent with previous estimates, we believe that using a PA, NP, or CNS hourly rate creates a high burden impact estimate since most of these tasks would more than likely be completed by administrative personnel. We invited but received no public comments on our estimates related to the appropriateness of these estimates. The average annual burden over 5-years for 580,000 claims (2,900,000/5) is 29,000 hours at a cost of $1,595,000.

Physician Assistant, Nurse Practitioner or Clinical Nurse Specialist Time

	Year 1	5 Years
Number of claims affected	500,000	2,900,000
Time for PAs, NPs, or CNSs to gather and provide each claim	3 min	3 min
Total Time	25,000 hours	145,000 hours
Estimated Total Cost (Hours times $55)	$ 1,375,000	$ 7,975,000

The final rule creates only a minimal change in the normal course of business activities in regards to recordkeeping as medical records are required to be maintained for items/services. Although we believe the documentation of a needs assessment, evaluation, and/or treatment of a beneficiary for a condition relevant to an item of DME is a common practice, it is possible that some practitioners may not be documenting the results of all encounters so there may be additional impact for some practitioners.

The final rule requires that the supplier have access to the documentation of the face-to-face encounter (required when CMS conducts an audit), CMS already accounts for the audit burden associated with the exchange of documentation for claims subject to prepayment review (approved under OCN 0938-0969). As a business practice we recognize that some

suppliers may receive the documentation of the face-to-face for all applicable claims, voluntarily.

We believe that the requirements that are set out in the final rule meet the utility and clarity standards. We invited but received no public comments on this assumption and on ways to minimize the burden on affected parties. The recordkeeping requirement in §410.38(g)(5) and the requirement to maintain and make the supplier's order/additional documentation available to CMS upon request is subject to the PRA, but we believe that these requirements are usual and customary business practices as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

Summary of Annual Burden Estimates

Regulation section(s)	OCN	Respondents	Responses	Burden per response (hr)	Total burden (hr)
410.38(g) re: Physician	0938-New	580,000	580,000	10 min	96,667
410.38(g) re: PA, NP, or CNS				3 min	29,000
Total	**n/a**	**580,000**	**580,000**	**13 min**	**125,667**

13. Capital Costs

There are no capital costs associated with this collection. Providers and suppliers maintain these medical records and routinely submit them to various healthcare entities.

14. Cost to Federal Government

CMS estimates that cost associated with the face-to-face requirement is $233 million per year.

15. Changes to Burden

This is a new information collection.

We revised our burden estimates in the final rule based on a change in the policy from the proposed rule and to correct a math issue. Specifically, with regard to a physician's time to document occurrence of a face-to-face encounter, in the proposed rule we estimated 4,200,000 claims and 700,000 hr at a cost of $82,600,000 over a 5-year period. In the final rule we estimated 2,900,000 claims and 483,333 hr at a cost of $57,033,333 for the same 5-year period. With regard to a physician assistant, nurse practitioner or clinical nurse specialist's time's time to prepare the medical record for the review of the face-to-face encounter, in the proposed rule we estimated 4,200,000 claims and 210,000 hr at a cost of

$11,550,000 of over a 5-year period. In the final rule we estimated 2,900,000 claims and 145,000 hr at a cost of $7,975,000 for the same 5-year period. The requirements in the proposed and final rules have not changed.

16. Publication/Tabulation Dates

    There are no plans to publish or tabulate the information collected.

17. Expiration Date

    This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

    There are no exceptions to the certification statements.

B. Collection of Information Employing Statistical Methods

This collection of information does not employ statistical methods.