DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS 2348–P]

RIN 0938–AQ36

Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicaid home health service definition as required by section 6407 of the Affordable Care Act to add a requirement that physicians document the existence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible individual within reasonable timeframes. This proposal would align the timeframes with similar regulatory requirements for Medicare home health services in accordance with section 6407 of the Affordable Care Act and reflects CMS' commitment to the general principles of the President's Executive Order 13563 released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.'' In addition, this rule proposes to amend home health services regulations to clarify the definitions of included medical supplies, equipment and appliances, and clarify that States may not limit home health services to services delivered in the home, or to services furnished to individuals who are homebound.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. September 12, 2011.

ADDRESSES: In commenting, please refer to file code CMS–2348–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2348–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2348–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Melissa Harris, (410) 786–3397.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. General Information

Title XIX of the Social Security Act (the Act) requires that, in order to receive Federal Medicaid matching funds, a State must offer certain basic services to the categorically needy populations specified in the Act. Home health care for Medicaid-eligible individuals who are entitled to nursing facility services is one of these mandatory services. Individuals ''entitled to'' nursing facility services include the basic categorically needy populations that receive the standard Medicaid benefit package, and can include medically needy populations if nursing facility services are offered to the medically needy within a State. Home health services include skilled nursing, home health aide services, medical supplies, equipment, and appliances, and may include therapeutic services. Current Medicaid regulations require an individual's physician to order home health services as part of a written plan of care reviewed every 60 days.

B. Summary of New Medicare Home Health Face-to-Face Statutory Requirements

Section 6407 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act), (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10605 of the Affordable Care Act, affects the home health benefit under both the Medicare and Medicaid programs.

Section 6407(a) of the Affordable Care Act (as amended by section 10605 of the Affordable Care Act) added new requirements to section 1814(a)(2)(C) of

the Act under Part A of the Medicare program, and section 1835(a)(2)(A) of the Act, under Part B of the Medicare program, that the physician, or certain allowed nonphysician practitioners (NPPs), document a face-to-face encounter with the individual (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act), prior to making a certification that home health services are required under the Medicare home health benefit. Section 1814(a)(2)(C) of the Act indicates that in addition to a physician, a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, may conduct the face-to-face encounters prior to the start of home health services.

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act to require documentation of a similar face-to-face encounter with a physician or specific NPPs by a physician ordering durable medical equipment (DME). The NPPs authorized to conduct a face-to-face encounter on behalf of a physician are the same for this provision as for the provision described above, with one exception. We interpret sections 6407(b) and 6407(d) of the Affordable Care Act to prohibit certified nurse-midwives from conducting the face-to-face encounter prior to the physician ordering DME. The timing of this face-to-face encounter is specified as being within the 6-month period preceding the written order for DME, or other reasonable timeframe specified by the Secretary. This provision also maintains the role of the physician in the actual ordering of DME.

C. Application of Home Health Face-to-Face Requirements to Medicaid

Section 6407(d) of the Affordable Care Act provides that the requirements for face-to-face encounters in the provisions described above ''shall apply in the case of physicians making certifications for home health services under title XIX of the Social Security Act in the same manner and to the same extent as such requirements apply in the case of physicians making such certifications under title XVIII of such Act.'' The purpose of this regulation is to implement that statutory directive.

In implementing the face-to-face encounter requirements of section 6407 of the Affordable Care Act, we take into consideration the existing regulatory requirements under § 440.70 that provide that a physician must order an individual's services under the Medicaid home health benefit. We read the term ''order'' to be synonymous with the Medicare term ''certify.'' For purposes of this rule, we use the term ''order'' in place of the Affordable Care Act's use of ''certify.''

We do not view implementation of section 6407 of the Affordable Care Act as supplanting the existing Medicaid regulatory requirements related to physician orders but as consistent with those requirements. The provisions of section 6407 of the Affordable Care Act make clear that the physician's order must be based on a face-to-face encounter. In addition, section 6407 of the Affordable Care Act provides that specific NPP may perform the face-to-face encounter with the individual in lieu of the physician, and inform the physician making the initial order for service under the Medicaid home health benefit.

Consistent with that view, in the proposed regulation, we would provide that the physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs performed the face-to-face encounter. The timing of this face-to-face encounter is specified as being within the 6-month period preceding the written order for home health services, or other reasonable timeframe specified by the Secretary.

Similarly, in implementing the requirements under section 6407(b) of the Affordable Care Act, relating to DME, we take into account existing Medicaid regulatory requirements under § 440.70 requiring physician orders. Because DME is not a term used in Medicaid in the same manner as in Medicare, we use the Medicaid term ''medical supplies, equipment and appliances'' or the shortened version ''medical equipment.'' The NPPs authorized to conduct a face-to-face encounter on behalf of a physician are the same for this provision as for the provision described above, with one exception. Certified nurse-midwives are not permitted to conduct the face-to-face encounter prior to the physician ordering medical equipment. Therefore, we are proposing to amend the Medicaid regulations at § 440.70 to incorporate both the general home health and the medical equipment face-to-face requirements.

D. Other Medicaid Home Health Policy Changes

1. Clarification That Home Health Services Cannot Be Restricted to Individuals Who Are Homebound or to Services Furnished in the Home

We are proposing to incorporate in regulation that home health services may not be subject to a requirement that the individual be ''homebound.'' In addition, we are proposing to clarify that home health services cannot otherwise be restricted to services furnished in the home itself.

On July 25, 2000, we issued a letter to State Medicaid Directors, Olmstead Update No: 3, in which we discussed Federal policies relevant to State efforts to comply with the requirements of the Americans with Disabilities Act (ADA) in light of the Supreme Court decision in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999). In attachments to that letter, we set forth specific policy clarifications to allow States more flexibility to serve individuals with disabilities in various ways and in different settings.

Attachment 3-g of the letter: ''Prohibition of Homebound Requirements in Home Health'' clarified that the use of a ''homebound'' requirement under the Medicaid home health benefit violates Federal regulatory requirements at § 440.230(c) and § 440.240(b). These requirements provide that mandatory benefits must be sufficient in amount, duration and scope to reasonably achieve their purpose, may not be arbitrarily denied or reduced in scope based on diagnosis, type of illness, or condition, and that the same amount, duration and scope must be available to any individual within the group of categorically needy individuals and within any group of medically needy individuals. In the attachment, we stated that the restriction of home health services to individuals who are homebound to the exclusion of other individuals in need of these services ignores the reality that individuals with disabilities can and do live and function in the community. We further noted that developments in technology and service delivery made it possible for individuals with even the most severe disabilities to participate in a wide variety of activities in the community with appropriate supports. We also expressed the importance of ensuring that Medicaid is available to provide medically necessary home health services to individuals in need of those services who are not homebound and continue to be an important part of efforts to offer individuals with disabilities services in the most

integrated setting appropriate to their needs, in accordance with the ADA.

We are clarifying in this rule that Medicaid home health services may not be limited to services furnished in the home. This policy reflects prior court cases on the subject. In *Skubel* v. *Fuoroli, 113 F.3d 330 (2d. Cir. 1997)* the court found that the Medicaid statute did not address the site of care for the mandatory home health benefit. The court found that the State could not limit coverage of home health services to those provided at the individual's residence. In 1990, the same court ruled invalid an interpretation that limited the provision of private duty nursing services to an individual's residence. The case, *Detsel* v. *Sullivan,* 895 F.2d 58 (2d Cir.1990), involved children suffering from severe medical conditions. Following the *Detsel* case, CMS, then the Health Care Financing Administration, ultimately adopted the court's standard and issued nationwide guidance eliminating the at-home restriction on private duty nursing. To date, we have not issued similar guidance requiring nationwide adoption of the *Skubel* ruling. We are using our authority through this rulemaking opportunity to do so.

2. Clarification of the Definition of Medical Supplies, Equipment and Appliances

An important component of the Medicaid home health benefit is medical supplies, equipment and appliances, under § 447.70(b)(3). The current wording of the regulation does not further define these terms, except to indicate that these items should be ''suitable for use in the home.'' Although this phrase could be read to refer only to the type of items included in the benefit, it has been susceptible to reading as a prohibition on use of covered items outside the home. We are using this opportunity to revise that phrase to make clear that it is not a limitation on the location in which items are used, but rather refers to items that are necessary for everyday activities and not specialized for an institutional setting. Thus we would indicate that these items must be ''suitable for use in any non-institutional setting in which normal life activities take place.'' This would clarify that although States may continue to establish medical necessity criteria to determine the authorization of these items, States may not deny requests for these items based on the grounds that they are for use outside of the home.

Current Medicaid regulations do not contain any specific definition of medical supplies, equipment, and appliances under the home health benefit, other than the language discussed in the prior paragraph. States have adopted reasonable definitions of those terms, for example, based on the Medicare definition. But in the absence of a generally applicable definition of the term, there has been confusion as to the proper scope of the benefit.

We believe that a consistent approach to categorizing home health medical supplies, equipment, and appliances will ensure beneficiaries are receiving needed items and provide clear and consistent guidance to States to ensure the use of the appropriate benefit category. We are now taking this opportunity to propose criteria defining home health supplies, equipment, and appliances, to better align with the Medicare program's definition of durable medical equipment found at § 414.202. We propose that supplies are defined as ''health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual.'' We propose that medical equipment and appliances are ''items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury, can withstand repeated use, and can be reusable or removable.''

We believe these standard definitions will ensure that such items will be available to all who are entitled to the home health benefit, and not restricted to individuals eligible for targeted benefits through home and community-based services (HCBS) waivers or the section 1915(i) HCBS State Plan option. Items that meet the criteria for coverage under the home health benefit must be covered as such. States will not be precluded from covering items meeting this definition through a section 1915(c) HCBS waiver service, such as a home modification, or through a section 1915(i) State Plan option. However, the State must also offer those items as home health supplies, equipment and appliances.

3. Other Issues

We note that we are considering whether other clarifications to the home health regulations are warranted. In particular, we are considering whether it would be useful to include language to reflect the policies set forth in a September 4, 1998 letter to State Medicaid Directors, responding in part to a Second Circuit decision in *Desario* v. *Thomas,* 139 F. 3d 80 (1998), about the use of lists or other presumptions in determining coverage of items under the home health benefit for medical equipment. In that letter, we indicated that a State could use such lists or presumptions, but must provide individuals the opportunity to rebut the list or presumption with a process that employs reasonable and specific criteria to assess coverage for an item based on individual medical needs, and determine whether the list or presumption is based on an arbitrary exclusion based on diagnosis, type of illness, or condition. We have not proposed any language to reflect this policy in part because the principles at issue are not specific to home health medical equipment. We invite comment on this issue.

In addition, in the May 5, 2010 **Federal Register** (75 FR 24437), we issued the ''Medicare and Medicaid Programs: Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements'', interim final rule which was effective on July 6, 2010. Although we have not incorporated changes to the scope of providers that may order medical supplies, equipment and appliances in the Medicaid program, as section 6405(a) of the Affordable Care Act was not applicable to Title XIX, we are specifically soliciting comments through this rule on the merits of doing so.

II. Provisions of the Proposed Regulations

Please note that although the Affordable Care Act uses the term ''individual'' to refer to the Medicaid beneficiary, throughout this proposed rule we have used ''recipient'' to mirror the regulation text in the current Medicaid home health regulations. At this time, we do not intend to modify this term.

For the reasons discussed above, we propose to modify § 440.70(b)(3) to say the following: ''Medical supplies, equipment and appliances suitable for use in any non-institutional setting in which normal life activities take place.''

In § 440.70(b)(3)(i) and (ii), we propose revising the current text to define what constitutes medical supplies, equipment, and appliances. We propose to indicate that supplies are defined as ''health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual.'' We propose to indicate that medical equipment and appliances are ''items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury, can withstand repeated use, and can be reusable or removable.'' We

are specifically soliciting comment on these proposed provisions.

For the reasons discussed above, we propose to modify § 440.70(c), to add the following text to the end of the current provision: ''Nothing in this section should be read to prohibit a recipient from receiving home health services in any non-institutional setting in which normal life activities take place.'' Although the Court indicated that individuals would be limited to the same number of service hours they would have received if the home health services were provided only in their place of residence, in an effort to not limit the ability of States to offer a more robust home health benefit, we propose to allow States the option to authorize additional services or hours of services to account for this new flexibility. We also propose to add more text at the end of this provision as follows: ''Additional services or service hours may, at the State's option, be authorized to account for medical needs that arise in these settings''. This will incorporate both the *Skubel* and *Olmstead* decisions into the provision of home health services. This State flexibility would be applied to the State's Medicaid program as a whole, and would not be a person-specific flexibility. State medical necessity criteria would continue to be applied uniformly to all Medicaid individuals. We note that any such additional hours of service that are authorized by the State would be matched at the State's current Federal Medical Assistance Percentage (FMAP).

The remainder of this section pertains to proposed changes to § 440.70 to incorporate provisions of the Affordable Care Act.

Section 6407 of the Affordable Care Act requires, as a condition for payment for home health services, documentation of a face-to-face encounter prior to an order for such services. Section 6407 of the Affordable Care Act requires that the timing of the face-to-face encounter for home health services must occur within the 6-month period preceding certification, or other reasonable timeframe determined by the Secretary. Based on the same reasoning set out in the Medicare final rule, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices as published in the November 17, 2010, **Federal Register**, we propose to determine a reasonable timeframe for the face-to-face encounter that is shorter than 6 months. The statutory goal is to achieve greater physician accountability in ordering home health services. To achieve this goal, the encounter must occur close enough to the start of home health services to ensure that the clinical conditions exhibited by the recipient during the encounter are related to the primary reason for the recipient's need for home health services. As such, we believe that encounters would need to occur closer to the start of home health services rather than the 6-month period initially indicated, but not required by the Affordable Care Act.

Consistent with the Medicare program's implementation of this provision, we propose to indicate in a new § 440.70(f)(1) that for the initial ordering of home health services, the physician must document that a face-to-face encounter that is related to the primary reason the individual requires home health services has occurred no more than 90 days prior to the start of services under the Medicaid home health benefit. We believe that in most cases, a face-to-face encounter with a recipient within the 90 days prior to the start of home health services will provide the physician and/or specified NPPs with a current clinical presentation of the recipient's condition such that the physician can accurately order home health services and establish an effective care plan, based on the encounter conducted by either the physician or allowed NPP. We also believe that a face-to-face encounter which occurs within 90 days prior to the start of services would be generally relevant to the reason for the recipient's need for home health services, and therefore such a face-to-face encounter would be sufficient to meet the goals of this statutory requirement. We recognize, however, that there may be circumstances when it may not be possible to meet this general requirement, and the individual's access to needed services must be protected. To account for these circumstances, we also propose in § 440.70(f)(1) to allow an opportunity to meet the face-to-face encounter requirement through an encounter with the recipient within 30 days after the start of home health services.

While we recognize the necessity of permitting face-to-face encounters to occur after the start of services in the instances described above, we emphasize that the timing of the face-to-face encounter in normal circumstances should occur within the 90 days prior to the start of home health services.

The statute describes NPPs who may perform this face-to-face encounter as a nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician.

The statutory provision allows the permitted NPPs to perform the face-to-face encounter and inform the physician, who documents the encounter.

Based on the same reasoning set out in the Medicare proposed rule, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012; published elsewhere in this **Federal Register**, for individuals admitted to home health upon discharge from a hospital or post-acute setting, we propose to also allow the physician who attended to the individual in the hospital or post-acute setting to inform the ordering physician regarding their encounters with the individual to satisfy the face-to-face encounter requirement, much like an NPP currently can.

We propose to add a new § 440.70(f)(2) to list the practitioners that may perform the face-to-face encounters. These practitioners include the physician already referenced in § 440.70(a)(2), and the following NPPs: A nurse practitioner or clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, and for recipients admitted to home health immediately after an acute or post-acute stay, the attending acute or post-acute physician.

We also propose to add a new § 440.70(f)(3) to indicate that if an attending acute or post-acute physician or allowed NPP conducts the face-to-face visit, the attending acute or post-acute physician or practitioner is required to communicate the clinical findings of the face-to-face encounter to the physician, in order for the physician to document the face-to-face encounter accordingly. This requirement is necessary to ensure that the physician has sufficient information to determine the need for home health services, in the absence of conducting the face-to-face encounter himself or herself. We are also proposing to specify that these clinical findings must be reflected in a written or electronic document included

in the recipient's medical record (whether by the physician or by the NPP). We are not prescribing at the Federal level the specific elements necessary to document the face-to-face encounter, as that is a matter of clinical judgment that could vary according to the individual circumstance. However, States may choose to implement a minimum list of required information to adequately document the encounter.

In a new § 440.70(f)(4)(i), we propose to require that the physician's documentation of the face-to-face encounter must be either a separate and distinct area on the written order, an addendum to the order that is easily identifiable and clearly titled, or a separate document easily identifiable and clearly titled in the recipient's medical record. The documentation must also describe how the health status of the recipient at the time of the face-to-face encounter is related to the primary reason the recipient requires home health services. In a new § 440.70(f)(4)(ii), we propose to require that the physician's documentation of the face-to-face encounter be clearly titled, and state that either the physician himself or herself, or the applicable NPP, has conducted a face-to-face encounter with the recipient and include the date of that encounter.

Finally, we propose to add a new § 440.70(f)(5) to indicate that the face-to-face encounters may be performed through the use of telehealth. We are aware that many States currently make use of telehealth or telemedicine in the delivery of Medicaid services. Medicaid has issued informal guidance on the parameters of telehealth and telemedicine that is modeled after Medicare requirements. We are proposing to allow States to continue utilizing their current telehealth technologies as they apply to the implementation of this provision, however we are cognizant that State Medicaid telehealth policies may not align with Medicare's. We wish to minimize duplication and fragmentation of services for beneficiaries who are dually-eligible for Medicare and Medicaid, and therefore we are specifically soliciting comment on approaches to telehealth policy that would further this goal.

In a new § 440.70(g), we propose to apply all of the requirements of § 440.70(f) to the provision of supplies, equipment and appliances as described in § 440.70(b)(3) to the extent that a face-to-face encounter would be required under the Medicare program for durable medical equipment, with one exception from the requirements at § 440.70(f). The Affordable Care Act does not permit certified nurse midwives to conduct face-to-face encounters required for these items. This is reflected in our proposed § 440.70(g)(2).

The proposal to limit the face-to-face requirements to items that would be subject to such requirements as durable medical equipment under the Medicare program is based on the aim of maximizing consistency with the Medicare program's implementation of section 6407 of the Affordable Care Act and reducing administrative burden on the provider community. Thus we would only require that, for items of durable medical equipment specified by CMS under the Medicare program as subject to a face-to-face encounter requirement, the physician must document that a face-to-face encounter that is related to the primary reason the individual requires the item has occurred no more than 90 days before the order is written or within 30 days after the order is written. We intend to issue guidance to States indicating how they, and providers, can access the current Medicare list of specific durable medical equipment items subject to the face-to-face requirement.

Medical supplies, equipment and appliances for which a face-to-face encounter would not be required under the Medicare program as durable medical equipment, would not require a face-to-face encounter prior to the ordering of items under the Medicaid program. These items will be of a smaller dollar value, and at a decreased risk for fraud, waste and abuse. We welcome public comment on this approach.

We recognize the difficulty that some recipients with complex medical needs may face in participating in a face-to-face encounter (such as issues with accessing transportation, obtaining caregiver support, etc.,) particularly in rural areas. Once this rule is finalized, we expect States to implement this provision in a way that does not result in barriers to service delivery, as this is not the intent of the legislation. The statute specifically references telehealth as an alternative for ensuring that this new requirement is implemented in a way that protects continuity of services. We encourage States to work with the home health provider community to incorporate these face-to-face visits in creative and flexible ways to account for individual circumstances. We are available to provide technical assistance to States in achieving this goal.

In keeping with a movement across all Medicaid services, we expect the plans of care developed to address a recipient's home health needs be done in a way that embraces a person-centered philosophy. For clarification and consistency among programs, our expectation regarding the person-centered philosophy is that the plan of care reflects what is important to the recipient and for the recipient. The person-centered approach is a process, directed by the recipient with long-term support needs, or by another person important in the life of the recipient who the recipient has freely chosen to direct this process, intended to identify the strengths, capacities, preferences, needs, and desired outcomes of the recipient. The person-centered process includes the opportunity for the recipient to choose others to serve as important contributors to the planning process.

This process and the resulting service plan will assist the recipient in achieving personally defined outcomes in the most integrated community setting in a manner that reflects what is important to the recipient to ensure delivery of services in a manner that reflects personal preferences and choices, and what is important for the recipient to meet identified support needs.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Proposed § 440.70(f)(3) and (g)(1) require NPPs and attending acute or post-acute physicians to communicate the clinical findings of the face-to-face encounter to the ordering physician. The burden associated with these

requirements would be the time and effort required for the NPP and attending acute or post-acute physicians to complete this communication. This is estimated at 10 minutes for each encounter. We estimate that there would be 1,143,443 initial home health episodes in a year based on our 2008 claims data. As such, the estimated burden for the NPP and attending acute or post-acute physicians documenting, signing, and dating the recipient's face-to-face encounter would be 190,574 hours for CY 2011.

Proposed § 440.70(f)(4) and (g)(1) would require that physicians document the existence of a face-to-face encounter with the Medicaid eligible recipient. The burden associated with these requirements would be the time and effort required for the physician to complete and maintain this documentation. The ordering physician's burden for composing the face-to-face documentation, which would include determining how the clinical findings of the encounter support eligibility; writing, typing, or dictating the face-to-face documentation; signing, and dating the recipient's face-to-face encounter is estimated at 10 minutes for each encounter. We estimate that there would be 1,143,443 initial home health episodes in a year based on our 2008 claims data. As such, the estimated burden for the physician documenting, signing, and dating the recipient's face-to-face encounter would be 190,574 hours for CY 2011. We acknowledge that this figure is inflated by the instances in which the physician himself or herself conducted the face-to-face encounter with the individual, making this second 10-minute documentation burden unnecessary.

This notice of proposed rulemaking also serves as the required 60-day **Federal Register** notification for aforementioned information collection requirements. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, [CMS–2348–P] *Fax:* (202) 395–6974; or *E-mail: OIRA_submission@omb.eop.gov.*

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Statement of Need

This regulation is necessary to implement Section 6407 of the Patient Protection and Affordable Care Act of 2009 (the Affordable Care Act), (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10605 of the Affordable Care Act which affects the home health benefit under both the Medicare and Medicaid programs.

Section 6407(a) of the Affordable Care Act (as amended by section 10605) added new requirements to section 1814(a)(2)(C) of the Act under Part A of the Medicare program, and section 1835(a)(2)(A) of the Act, under Part B of the Medicare program, that the physician, or certain allowed nonphysician practitioners (NPPs), document a face-to-face encounter with the individual (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act), prior to making a certification that home health services are required under the Medicare home health benefit. Section 1814(a)(2)(C) of the Act indicates that in addition to a physician, a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, may conduct the face-to-face encounters prior to the start of home health services.

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act to require documentation of a similar face-to-face encounter with a physician or specific NPPs by a physician ordering durable medical equipment (DME). The NPPs authorized to conduct a face-to-face encounter on behalf of a physician are the same for this provision as for the provision described above, with one exception. Certified nurse-midwives are not permitted to conduct the face-to-face encounter prior to the physician ordering DME. The timing of this face-to-face encounter is specified as being within the 6-month period preceding the written order for DME, or other reasonable timeframe specified by the Secretary. This provision also maintains the role of the physician in the actual ordering of DME.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We tentatively estimate that this rulemaking may be ''economically significant'' as measured by the $100 million threshold, and, therefore, may be a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis which to the best of our ability presents the costs and benefits of the rulemaking.

The CMS Office of the Actuary estimated Section 6407 as having no potential impact on Federal Medicaid costs and savings. According to the CMS Actuarial estimates, Section 6407 would bring an estimated $350 million in

savings to the Medicare program from 2010–2014 and $870 million in savings from 2010–2019. Although this provision applies to Medicaid in the same manner and to the same extent as the Medicare program, no estimates (costs or savings) were noted for the Medicaid program.

Although there is no quantitative data to arrive at a specific dollar figure to attribute to the additional medical supplies, equipment, and appliances that may now be authorized in accordance with § 440.70(b)(3), we acknowledge the potential for this provision to surpass the threshold for economic significance. We wish to note however, that this provision may result in offsetting benefits to both beneficiaries and State budgets, including the ability for individuals to return to or enter the workforce, thereby increasing the pool of taxpayers, and decreasing reliance on other Medicaid benefits, including institutional care. Although there is no specific estimate regarding these benefits, they nonetheless should be taken into account. We are specifically soliciting comment on the potential increased costs and benefits associated with this provision, as well as the various sections throughout the RIA.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. For details, see the Small Business Administration's final rule that set forth size standards for health care industries, (65 FR 69432, November 17, 2000). Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately $136 million. This proposed rule will not result in an impact of $136 million or more on State, local or tribal governments, in the aggregate, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

C. Conclusion

We tentatively estimate that this rule may be ''economically significant'' as measured by the $100 million threshold as set forth by Executive Order 12866, as well as the Congressional Review Act. The analysis above provides our initial Regulatory Impact Analysis. We have not prepared an analysis for the RFA, section 1102(b) of the Act, section 202 of the UMRA, and Executive Order 13132 because the provisions are not impacted by this rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 440

Grant programs—health, Medicaid.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—Definitions

2. Section 440.70 is amended by—

A. Redesignating paragraphs (b)(3)(i) and (ii) as (b)(3)(iii) and (iv), respectively.

B. Revising the introductory text of paragraph (b)(3).

C. Adding new paragraphs (b)(3)(i) and (ii).

D. Adding paragraphs (c)(1) and (2).

E. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§ 440.70 Home health services.

* * * * *

(b) * * *

(3) Medical supplies, equipment, and appliances suitable for use in any non-institutional setting in which normal life activities take place.

(i) Supplies are defined as health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual.

(ii) Equipment and appliances are defined as items that are primarily and customarily used to serve a medical purpose, generally not useful to an individual in the absence of an illness or injury, can withstand repeated use, and can be reusable or removable.

* * * * *

(c) * * *

(1) Nothing in this section should be read to prohibit a recipient from receiving home health services in any non-institutional setting in which normal life activities take place.

(2) Additional services or service hours may, at the State's option, be authorized to account for medical needs that arise in these settings.

* * * * *

(f) No payment may be made for services referenced in paragraphs (b)(1), (2), and (4) of this section, unless the physician referenced in paragraph (a)(2) of this section documents that there was a face-to-face encounter with the recipient that meets the following requirements:

(1) For the initiation of services, the face-to-face encounter must be related to the primary reason the recipient requires home health services and must occur within the 90 days prior to or within the 30 days after the start of the services.

(2) The face-to-face encounter may be conducted by one of the following practitioners:

(i) The physician referenced in paragraph (a)(2) of this section;

(ii) A nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, working in collaboration with the physician described in paragraph (a) of

this section, in accordance with State law;

(iii) A certified nurse midwife, as defined in section 1861(gg) of the Act, as authorized by State law;

(iv) A physician assistant, as defined in section 1861(aa)(5) of the Act, under the supervision of the physician described in subparagraph (a) of this section; or

(v) For recipients admitted to home health immediately after an acute or post-acute stay, the attending acute or post-acute physician.

(3) The allowed nonphysician practitioner, as described in paragraph (f)(3)(ii) through (iv) of this section, or the attending acute or post-acute physician, as described in paragraph (f)(3)(v) of this section, performing the face-to-face encounter must communicate the clinical findings of that face-to-face encounter to the ordering physician. Those clinical findings must be incorporated into a written or electronic document included in the recipient's medical record.

(4) To assure clinical correlation between the face-to-face encounter and the associated home health services, the physician responsible for ordering the services must:

(i) Document the face-to-face encounter as a separate and distinct area on the order itself, as an easily identifiable and clearly titled addendum to the order, or a separate document easily identifiable and clearly titled in the recipient's medical record, to describe how the health status of the recipient at the time of the face-to-face encounter is related to the primary reason the recipient requires home health services.

(ii) Must indicate the practitioner who conducted the encounter, and be clearly titled and dated on the documentation of the face-to-face encounter.

(5) The face-to-face encounter may occur through telehealth, as implemented by the State.

(g)(1) No payment may be made for medical equipment, supplies, or appliances referenced in paragraph (b)(3) of this section to the extent that a face-to-face encounter requirement would apply as durable medical equipment under the Medicare program, unless the physician referenced in paragraph (a)(2) of this section documents a face-to-face encounter with the recipient consistent with the requirements of paragraph (f) of this section except as indicated below.

(2) The face-to-face encounter may be performed by any of the practitioners described in paragraph (f)(2)of this section, with the exception of certified nurse-midwives, as described in paragraph (f)(2)(iii)of this section.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

Dated: March 2, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 3, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–16937 Filed 7–5–11; 4:15 pm]

BILLING CODE 4120–01–P