DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2348–F]

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: Final rule.

SUMMARY: This final rule revises the Medicaid home health service definition consistent with section 6407 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) and section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to add requirements that, for home health services, physicians document, and, for certain medical equipment, physicians or certain authorized non-physician practitioners (NPP) document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes. This rule also aligns the timeframes for the face-to-face encounter with similar regulatory requirements for Medicare home health services. In addition, this rule amends the definitions of medical supplies, equipment, and appliances. We expect minimal impact with the implementation of section 6407 of the Affordable Care Act and section 504 of MACRA. We recognize that states may have budgetary implications as a result of the amended definitions of medical supplies, equipment and appliances. Specifically, this rule may expand coverage of medical supplies, equipment and appliances under the home health benefit. There will be items that had previously only been offered under certain sections of the Act that will now be covered under the home health benefit.

DATES: *Effective date:* This rule is effective on July 1, 2016.

Compliance date: Based on public comments, we recognize that there may be operational and budgetary implications with this rule and that states and providers may need time to implement this provision. To ensure that states and providers are implementing the rule appropriately, we are delaying compliance with this rule for up to one year if legislature has met in that year, otherwise 2 years.

Exception for State Legislation.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 *et seq.*), which the Secretary determines requires state legislation in order for the respective plan to meet one or more additional requirements imposed by this rule, the respective state shall not be regarded as failing to comply with the requirements of this rule solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the state legislature that begins after the date of enactment of this rule. For purposes of the previous sentence, in the case of a state that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the state legislature. States will be expected to be in compliance by July 1, 2017 or July 1, 2018 based on legislative timeframes as described above.

FOR FURTHER INFORMATION CONTACT: Ali Smilow, (410) 786–0790.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule implements section 6407 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148), which adds the requirement that physicians document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes when ordering home health services. More specifically, section 6407(b) of the Affordable Care Act applies to Medicaid face-to-face encounter requirements set forth in the Medicare statute. Additionally, on April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), became law. Section 504 of this law amended the underlying Medicare requirements at section 1834(a)(11)(B)(ii) of the Social Security Act (the Act) to allow certain authorized non-physician practitioners (NPP) to document the face-to-face encounter. This final rule adopts in large part the provisions proposed in the proposed rule issued on July 12, 2011 (76 FR 41032), but includes conforming changes to the provisions of the proposed rule to reflect the revisions made by MACRA to the underlying Medicare face-to-face encounter requirements. In addition, this final rule clarifies that Medicaid home health services and items are not limited to home settings, and makes additional changes to the requirements for coverage of medical supplies, equipment and appliances under the home health benefit.

2. Summary of the Major Provisions

The final rule requires 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 beneficiary requires home health services occurred no more than 90 days before or 30 days after the start of services. The final rule requires that for the initial ordering of certain medical equipment, the physician or authorized NPP must document that a face-to-face encounter that is related to the primary reason the beneficiary requires medical equipment occurred no more than 6 months prior to the start of services. The face-to-face encounter for home health and medical equipment may be performed by the physician or certain authorized NPPs. The final rule maintains the role of the physician in ordering Medicaid home health services and medical equipment.

The rule also codifies current Medicaid policies for coverage of home health services, including clarifying in the definition of medical supplies, equipment, and appliances that items must be suitable for use in any setting in which normal life activities take place, other than a hospital; nursing facility, intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Additionally, the rule defines home health supplies, equipment, and appliances, to better align with the Medicare program's definition of durable medical equipment (DME) at § 414.202.

The rule codifies the policies set forth in September 4, 1998 guidance, about the use of lists or other presumptions in determining coverage of items under the home health benefit for medical equipment, including the following three points: (1) States may have a list of preapproved medical equipment, supplies and appliances for administrative ease, but not as an absolute limit on coverage; (2) States must provide and make available to individuals a reasonable and meaningful procedure for beneficiaries to request medical equipment, supplies or appliances not on the list based on a showing of medical necessity; and (3) Individuals must be informed of their

right to a fair hearing to appeal an adverse action. Additionally, the rule clarifies our interpretation that the Medicaid statute does not permit absolute exclusions of coverage as medical equipment, supplies, or appliances.

These clarifications reflect the principles embodied in the holdings of *the Skubel* v. *Fuoroli, 113 F.3d 330 (2d. Cir. 1997)* and *Detsel* v. *Sullivan, 895 F.2d 58 (2d Cir.1990*) decisions into the requirements for the provision of home health services by clarifying that Medicaid home health services may not be limited to services furnished in the home and revising the current regulatory language to specify that home health services may be provided, as appropriate, in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.

3—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs	Total benefits
Physician and certain non-physician practitioners (NPP) for DME documentation of face-to-face encounter with the Medicaid eligible beneficiary within reasonable timeframes when ordering home health services.	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 as data to determine these estimates is unavailable. For Medicare, the overall economic impact of this provision is an estimated $920 million in savings to the Medicare program from 2010–2014 and $2.29 billion in savings from 2010–2019.	The overall benefit of this rule is the expected increase in program integrity resulting in more quality home health services for Medicaid beneficiaries. Additionally, this rule will potentially serve to provide individuals with disabilities a greater ability to engage in normal activities of daily living.

B. Background

Title XIX of the Act requires that, 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 is a mandatory services for Medicaid-eligible individuals who are entitled to nursing facility services, which includes the basic categorically needy populations who receive the standard Medicaid benefit package, and can also include medically needy populations if nursing facility services are offered to the medically needy within a state. Home health services include nursing services, home health aide services, medical supplies, equipment, and appliances, and may include therapy services (physical therapy, occupational therapy, speech pathology and audiology services). For a state to receive federal Medicaid matching payments for such services, current Medicaid regulations require a beneficiary's physician to order home health services as part of a written plan of care reviewed every 60 days.

At section 6407 of the Affordable Care Act, new Medicare requirements were set forth for face-to-face encounters to support claims for home health services, and for DME, which were also made applicable to Medicaid.

Specifically, sections 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 were amended to require that the physician, or certain allowed 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), before 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 (NP) or clinical nurse specialist (CNS) (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 (PA) (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, may conduct the face-to-face encounters before the start of home health services.

Section 6407 of the Affordable Care Act also amended section 1834(a)(11)(B) of the Act to require that physician orders for DME must be supported by documentation by the physician of a similar face-to-face encounter with a physician or specified NPPs. The NPPs authorized to conduct a face-to-face encounter on behalf of a physician are the same for DME as for home health services, except that certified nurse-midwives are not included.

The timing of the face-to-face encounter for either home health or DME is specified as being within the 6-month period preceding the written order for DME, or other reasonable timeframe specified by the Secretary.

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 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 this statutory directive in the Medicaid program.

II. Summary of Provisions of the Proposed Rule

1. New Home Health Face-to-Face Requirements

In the proposed rule, we sought to implement the face-to-face requirements of section 6407 of the Affordable Care Act in a manner consistent with existing Medicaid requirements and practices. For example, in implementing the face-to-face encounter requirements of section 6407 of the Affordable Care Act with respect to home health services generally, we took into consideration the longstanding 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 used the term ''order'' in place of the Affordable Care Act's use of ''certify.''

We did not view implementation of section 6407 of the Affordable Care Act as supplanting these existing Medicaid regulatory requirements related to physician orders; the new face-to-face process is consistent with those requirements. We proposed amending the Medicaid regulations at § 440.70 to incorporate both the general home health and the medical equipment face-to-face requirements. Because DME is

not a term used in Medicaid in the same manner as in Medicare, we proposed to use the Medicaid term ''medical supplies, equipment, and appliances'' or the shortened version ''medical equipment.'' Additionally, we proposed that the face-to-face encounter can be performed through the use of telehealth, which is described in more detail in section I. of this final rule.

As previously indicated, we proposed that for home health services, the face-to-face encounter occurred no more than 90 days before or 30 days after the start of services. To align with Medicare timing requirements at § 424.22(a)(1)(v), we revised the timeframes for medical equipment and the final rule requires that for the initial ordering of medical equipment, the physician must document that a face-to-face encounter that is related to the primary reason the beneficiary requires medical equipment occurred no more than 6 months prior to the start of services. These timeframes are applicable to face-to-face encounters performed through telehealth.

2. Specification of Non-Physician Practitioners (NPPs) Authorized To Perform Face-to-Face Encounters

Under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, face-to-face encounters for home health services may be conducted by a NP or CNS (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 PA (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician. A similar definition of NPPs applies for DME under section 1834(a)(11)(B) of the Act, with one exception: Certified nurse-midwives are not included in the list of NPPs.

3. Other Medicaid Home Health Policy Changes

a. Codification That Home Health Services Cannot Be Restricted to Individuals Who Are Homebound or to Services Furnished Solely in the Home

We proposed that home health services may not be subject to a requirement that the individual be ''homebound.'' In addition, we proposed that home health services cannot otherwise be restricted to services furnished in the home itself. These policies reflect longstanding CMS interpretations of the scope of the home health policy and were discussed in a July 25, 2000 letter to State Medicaid Directors, Olmstead Update No. 3 setting forth federal interpretations of applicable law 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 Attachment 3–g to that letter, we set forth our interpretation that a requirement that home health recipients be homebound was inconsistent with the mandatory nature of the home health benefit, and the longstanding regulatory provisions at 42 CFR 440.230 and 440.240. These regulatory provisions 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.

We also proposed that Medicaid home health services may not be limited to services furnished in the home. This policy reflects the principles set forth in prior court cases on whether home health services and private duty nursing can be limited to services furnished in the home. 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. Previously, in 1990, the Second Circuit had applied similar principles to invalidate a regulation 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, 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.

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

An important component of the Medicaid home health benefit is coverage of medical supplies, equipment, and appliances, under § 440.70(b)(3). The current regulation does not further define the terms, except to indicate that the items should be suitable for use in the home. Although CMS has read this phrase to refer only to the type of items included in the benefit (excluding those types of items that are only furnished in institutional or provider settings), it has been susceptible to reading as a prohibition on use of covered items outside the home. We proposed revisions to this section to clarify 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 proposed to indicate that the 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 the items, states may not deny requests for the 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 greater alignment of the definitions of home health medical supplies, equipment and appliances with the Medicare definition of DME will help to streamline beneficiaries' access to receive needed items and provide clear and consistent guidance to states to ensure the use of the appropriate benefit category. Therefore, we proposed to define home health supplies, equipment, and appliances, to better align with the Medicare program's definition of DME at § 414.202, 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. Unlike Medicare, however, we did not propose to define the expected life of a piece of equipment and did not propose to limit equipment to items used in the home. We also proposed to define supplies as health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual, based loosely on Medicare principles, but we did not propose to require that supplies be incidental to other covered services.

The proposed standard definitions were intended to ensure that such items

will be available to all who are entitled to the mandatory home health benefit, and not restricted to individuals receiving targeted benefits through section 1915(c) 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 would be covered as such.

c. Other Issues

In the proposed rule, we noted that we were considering whether other clarifications to the home health regulations were warranted. In particular, we invited comments on 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 our interpretation of the mandatory coverage provisions to mean that a state could use such lists or presumptions as an administrative convenience but not as an absolute coverage limitation, and must provide individuals the opportunity to rebut the list or presumption using a process that employs reasonable and specific criteria to assess coverage for an item based on individual medical needs.

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 did not incorporate changes in the proposed rule 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 of the Act, we specifically solicited comments through this rule on the merits of doing so. We will address comments received below.

III. Analysis of and Responses to Public Comments

We received a total of 94 timely items of correspondence from home health provider representatives and other professional associations, State Medicaid Directors, states, beneficiaries, and other individuals. Comments ranged from general support or opposition to the proposed rule, to specific questions and detailed comments and recommendations regarding the proposed changes. A summary of the public comments and our responses are set forth below.

A. General

Comment: Some commenters expressed general support for the rule. One commenter supported CMS' goal of promoting accountability and program integrity. Other commenters supported the efforts of the Department to move toward consistency between the Medicare and Medicaid programs and ensure that home health services are delivered in accordance with sound clinical guidelines and recommendations.

Response: We appreciate the commenters' support.

Comment: Many commenters recommended that CMS specify that Medicaid home health services cannot be contingent upon a beneficiary needing skilled nursing care or therapy. Other commenters suggested revising § 441.15(c) to specify that Medicaid home health services cannot be contingent upon the beneficiary needing skilled nursing care or therapy.

Response: We have revised § 440.70(b) to clarify that coverage of Medicaid home health services cannot be contingent upon the beneficiary needing nursing or therapy services. We do not believe it is an accurate reading of section 1902(a)(10)(D) or the Act, or § 441.15 to impose such a requirement; the language of those provisions requires that the state provide the home health benefit to individuals whose benefit package includes nursing facility services, but does not require that the individual actually need such services. While it is beyond the scope of this rule to clarify and revise § 441.15(b), the clarification in § 440.70(b) will inform the reading of § 441.15(b).

Comment: Many commenters proposed that CMS amend § 440.230, which governs amount, duration, and scope to include language that reflects the policies set forth in the 1998 State Medicaid Director's letter related to the *Desario* case.

Response: We agree with commenters that the principles set forth in that letter should be incorporated into Medicaid regulations, although we disagree that these principles should be incorporated into § 440.230 as opposed to the Medicaid home health regulation at § 440.70. Accordingly, we are revising § 440.70 to include the three points made in that letter: (1) States may have a list of preapproved medical equipment, supplies, and appliances for administrative ease but not as an absolute limit; (2) States must provide and make available to individuals a reasonable and meaningful procedure for individuals to request items not on the list; and (3) Individuals are informed of their right to a fair hearing.

Comment: Several commenters requested that CMS specify that states cannot require a 60-day plan of care for medical supplies, equipment and appliances. The commenters also requested that CMS specify that states may not impose additional state restrictions that are not part of the federal requirements for supplies, equipment, and appliances such as requiring that they be limited to services for temporary recovery from specific incidents, be limited to non-routine supplies necessary for the delivery of a participant's nursing care and described in the plan of care, or any other state requirement that is not a federal requirement for receiving equipment and supplies.

Response: As stated in the existing provisions of § 440.70(a)(2), home health services are required to be provided to a beneficiary on his or her physician's orders as part of a written plan of care that the physician reviews every 60 days, except as specified in paragraph (b)(3). That exception states that a beneficiary's need for medical supplies, equipment, and appliances need only be reviewed on an annual basis, with more frequent review to be determined on a case-by-case basis based on the nature of the item prescribed. It would be inappropriate for states to require additional review of medical equipment, supplies, and appliances except where indicated on a case-by-case basis (for example, for supplies that are needed on a short term basis).

Additionally, states may place limits on the amount and duration of medical equipment, supplies and appliances, but the limits must meet sufficiency requirements set forth at § 440.230. And, as with all Medicaid services, states are not required to cover medically unnecessary services, and have the discretion to develop medical necessity criteria, but these must be based on accepted medical practices and standards.

Comment: Some commenters suggested that CMS apply the proposed prohibition on applying a ''homebound'' limitation to all Medicaid home care related program benefits, with one commenter suggesting that CMS audit state Medicaid programs for noncompliance with the homebound prohibition rule. That commenter stated that CMS should specifically review whether those state programs that

utilize a medical necessity standard as proxy for homebound.

Response: It is beyond the scope of this regulation to revise the requirements or definitions applicable to services other than home health care services. We are prohibiting the application of a homebound requirement for Medicaid home health because we have concluded that the resulting benefit would be insufficient to meet the needs of the population, and would not achieve the purposes of the mandatory benefit. We appreciate the commenters' suggestion and will take under advisement as part of our overall compliance strategy. We are revising § 440.70(c)(1) to codify the homebound prohibition for Medicaid home health services.

Comment: One commenter requested that CMS pursue the expansion of the Medicaid provision of home health services to meet the needs of our elderly citizens.

Response: Medicaid enrollees, regardless of their eligibility category, are not required to be homebound to qualify for home health benefits. Therefore, the clarification of the definition of medical equipment and supplies, and the requirement that home health services cannot be restricted to the home helps support the ability of Medicaid to best meet the needs of all eligible individuals, including the elderly.

Comment: One commenter believed that models for health care homes that compensate medical practices for complex care of chronically ill Medicaid beneficiaries should be promoted.

Response: We agree with the commenter. We have provided states with guidance and technical assistance on many initiatives that promote better care for the beneficiaries with chronic illness, including disease management strategies, health homes, and primary care case management systems. In 2014, we established the Medicaid Innovation Accelerator Program to support and focus resources on such models. More information can be found on our Web site at *http://www.medicaid.gov/state-resource-center/innovation-accelerator-program/innovation-accelerator-program.html.* Related guidance is also found on our Web site at *http://www.medicaid.gov/state-resource-center/innovation-accelerator-program/related-tools-and-guidance/related-tools-and-guidance.html.* Such models are beyond the scope of this regulation but we *intend to continue our efforts to provide technical assistance and guidance on these models.*

Comment: One commenter recommended that states be required to cover certification of home health care (at least initial certification) and ongoing care plan oversight as a medical benefit for Medicaid beneficiaries and to compensate physicians consistent with Relative Value Units for such work.

Response: Physician certification of the need for home health care could be covered by the state as a physician service or could be covered as a component part of home health care services. States have substantial flexibility to design payment methodologies for covered services. These payment methodologies can be tailored to the service delivery system in each state.

Comment: One commenter indicated that the rule should note that states must develop a strategy to educate physicians about the extension of the face-to-face requirement to Medicaid.

Response: We recognize the importance of education and expect states to educate the physician community on the new requirements implemented through the Affordable Care Act. We disagree that this administrative activity should be included as a requirement in the regulation. It is implicit with any regulation change to a benefit or to provider responsibilities that states educate impacted providers and beneficiaries about the new requirements.

Comment: One commenter endorsed adding the phrase ''medically necessary'' to § 440.70(b), to read as ''Home health services include the following medically necessary services and items.''

Response: We agree that states may limit covered services to only include medically necessary services. This flexibility is already provided in regulation at § 440.230(d). Medical necessity is not determined by us, but is determined by medical professionals. Many states employ medical professionals to establish medical necessity criteria and then review individual circumstances in light of those criteria. The phrase suggested by the commenter suggests that we would review medical necessity determinations. We do not intend to do so, and thus we are not accepting the suggestion.

Comment: One commenter indicated that there are no Current Procedural Terminology (CPT) or International Classification of Diseases (ICD) codes that specifically represent an evaluation for home health services; therefore, another model of demonstrating that a face-to-face encounter took place is needed.

Response: The face-to-face encounter can be demonstrated through the pre-existing ''evaluation and management'' codes.

Comment: One commenter expressed concern about how this provision will be implemented for those that are dually eligible for Medicare and Medicaid. Another commenter urged CMS to consider regulatory waivers, demonstrations or other initiatives to consolidate services for a dual eligible into a separate program for those beneficiaries with proportional funding from the existing federal and state programs. The commenter also indicated that CMS should undertake a significant education and outreach campaign to reach state officials, physicians, hospitals, home health providers, and organizations representing beneficiaries. The focus of the campaign would include Medicaid face-to-face requirements, and important similarities and differences with the Medicare face-to-face requirements.

Response: To the maximum extent possible, we have intentionally aligned the Medicaid rule with the Medicare requirements to reduce disparities in care and coverage for individuals who are eligible for both programs and to make it easier for providers to understand and implement the applicable rules. Currently, we are working on and publicizing a number of initiatives that speak directly to dual eligibles, increasing their continuity of care, and addressing ways in which Medicaid and Medicare rules might be better aligned. Such initiatives are out of the scope of this rule.

Comment: One commenter requested that CMS clarify or amend the definition of home health services such that this rule would not be applicable to non-medical services such as personal care attendant services.

Response: Personal care services are separately defined at § 440.167. We recognize the potential overlap between personal care services and home health aide services authorized under § 440.70. However, we disagree with the commenter's suggestion that this rule should not be applicable to services qualifying as home health aide services.

Comment: One commenter requested that CMS provide a significant amount of time before making effective, or enforcing, the final rule so that the state may prepare an accurate budget with sufficient funds for implementation and compliance.

Response: The requirements of section 6407 of the Affordable Care Act were effective upon enactment, and applied for home health services certified after January 1, 2010, as

specified in the Affordable Care Act and CMCS Informational Bulletin dated July 13, 2011; *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-7-13-11.pdf.* However, we will be delaying compliance for up to one year from the effective date of the rule if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule within the timeframes explained above. We intend to work collaboratively with states to ensure compliance with these requirements within a reasonable timeframe.

Comment: One commenter recommended that more productive emphasis be placed on training physicians in the home health assessment process so that physicians are held accountable for ordering appropriate services. The commenter also recommended that a process be put into place to audit home health services, and if a home health agency is abusing the system by providing questionable services, then a heightened authorization system be put into place for those identified high-risk agencies.

Response: As previously stated, it is implicit with any regulation change to a benefit that states inform impacted providers of new requirements and procedures. In response to the second comment, home health agencies must meet conditions of participation as determined through our survey process. The structures are designed to ensure that such agencies are qualified to furnish high-quality services that are medically necessary. To the extent that any provider, including a home health agency, is determined through the survey process to be furnishing inappropriate or unnecessary services, compliance actions can be pursued.

Comment: One commenter believed that home health services should be delivered in a consumer directed manner; the individual should be allowed to choose an agency or a consumer directed delivery option.

Response: A service plan based on a person-centered philosophy will support the beneficiary in achieving personally defined outcomes in the most integrated community setting available. This approach will reflect what is important to the individual receiving the services in terms of personal preferences and choices to meet identified support needs. Formal participant direction requirements for a home health service plan may be required by states as they determine appropriate, and consistent with the service delivery and payment system used by the state. We did not propose to change the requirement that certain components of the home health benefit (specifically nursing, home health aide services, and therapy services) must be furnished by a home health agency. This requirement is based on the premise that these services must be properly supervised and coordinated, consistent with the beneficiary's plan of care. Changing this requirement is beyond the scope of this rulemaking.

Comment: One commenter sought CMS guidance on the responsibility of the Medicaid Agency as it relates to oversight and monitoring of home health agencies to ensure compliance with the regulations.

Response: Overall compliance with home health agency certification requirements is conducted by the state's survey agency, in partnership with us. It is expected that State Medicaid Agencies collaborate with State Survey Agencies to ensure compliance of all home health providers with appropriate requirements, including all aspects of this regulation.

Comment: Some commenters discussed transportation costs. One commenter requested clarification on Medicaid coverage of physician non-medical transportation costs for face-to-face encounters. One commenter stated that the increased need to provide transportation services for the face-to-face encounters will result in increased costs. Another commenter raised a concern related to the problem of transportation costs, stating that the mandate of existing § 431.53 ''that the Medicaid agency will ensure necessary transportation for beneficiaries to and from providers,'' when read in connection with the proposed § 440.70(c)(1), significantly increases the states' financial obligation for service delivery. Additionally, the commenter requested that CMS clarify that § 431.53 does not apply for location-independent providers such as home health agencies.

Response: States are required under § 431.53 to assure necessary transportation for beneficiaries to and from medical providers, and that applies to transportation costs necessary for face-to-face encounters. This requirement includes transportation to and from an appointment with a physician or allowed NPP to receive an evaluation for home health services. States may reimburse physicians for transportation costs when necessary to make house calls through payment rate adjustments. Physicians cannot claim separately for transportation costs, since Medicaid reimbursement is not available specifically for physician transportation costs. However, many states factor in the costs of doing business into the payment rates for physician services, and may have higher payment rates to reflect physician house calls. Additionally, in response to the commenter's concern about transportation, we would note that the face-to-face encounter can be performed through the use of telehealth, and states may have payment rates that apply specifically for telehealth services and take into account the costs of communication lines and other necessary components of a telehealth encounter (on both sides of the telehealth encounter).

Comment: Two commenters requested that CMS specify that medical supplies, equipment, and appliances are a separate stand-alone home health service. The commenter also suggested that CMS emphasize that, even if a particular item cannot be covered as medical equipment, supplies, or appliances, states should determine whether it can be covered under another Medicaid service category, such as prosthetics or rehabilitation services. Additionally, the commenter suggested that CMS should state explicitly that satisfying the criteria of either one of the two definitions (equipment and appliances, or supplies) is sufficient to require coverage when the item is medically necessary.

Response: We appreciate the commenter's suggestions. As indicated in the proposed rule, items and services that meet the criteria for coverage under the home health benefit must be covered according to home health coverage parameters. To ensure full coverage for medical equipment and appliances, we will require that, to the extent that there is overlap in coverage with another benefit, states must nevertheless provide for the coverage of these items under the mandatory home health benefit. We understand that this policy may require that some states revise their claims processing systems, and we will work with those states to assist them in meeting this requirement. We reiterate that individuals only requiring medical equipment and appliances, and not other components of the home health benefit, may receive those services from DME providers authorized by the state, without necessitating a relationship with a home health agency. The nature of medical supplies and their ability to be provided in a variety of situations calls for a more flexible approach. Supplies incident to another mandatory benefit, such as physician services or an inpatient benefit such as hospital or nursing facility, may be covered under that benefit category. Additionally, supplies incident to the clinic benefit may be covered under that benefit

category. However, regardless of coverage category, the expectation remains that individuals receive all medically necessary medical supplies meeting the definition finalized under this regulation. We are available to provide technical assistance to states to work through operational issues.

We added this clarification to the regulatory text at § 440.70(b).

Comment: Two commenters indicated that the substantial number of hours required for compliance with this rule, in combination with the relatively low reimbursement typical for care of Medicaid beneficiaries, will lead to barriers to compliance among physicians. Commenters anticipated resistance from practitioners and physicians due to the additional administrative time it will take to meet the face-to-face requirement. One commenter indicated that many doctors are stating that they do not like the additional documentation requirements and are simply not ordering home health services. One commenter stated that early indications from the Medicare requirements are that physicians have been hostile to the new requirement, particularly the documentation standards. Another commenter stated that already there are many doctors who do not accept Medicaid beneficiaries. The commenter believed that adding additional paperwork and documentation requirements like this means there will likely be even more doctors who do not participate or who do not order home health services. One commenter reported that the home health industry is having problems with some doctors not wanting to do the face-to-face, therefore they are refusing to refer any beneficiaries to home health. One commenter indicated that since the Medicare requirement went into effect their members have seen a significant drop in referrals, some as much as 25 percent. The commenter further stated that unlike Medicare, Medicaid is actually 50 different programs with varying sets of rules from state to state. The commenter expressed concern that this will cause uneven application of the rule across the country and could lead to more problems with access to care.

Response: We fully expect that physicians will comply with the requirements and that they will be reasonably compensated for the time needed to provide and document the face-to-face encounter. The face-to-face encounters can be performed by NPPs, as well as done through telehealth. Additionally, as previously indicated, for medical equipment, NPPs are now authorized to complete the documentation requirements. To the extent that physicians may be avoiding ordering home health services, or are not cooperating with the home health industry on face-to-face documentation requirements, these may be temporary responses stemming from the unfamiliarity of the requirements. States, home health agencies and DME suppliers may need to work with physicians and NPPs to help them to understand the requirements. In particular, home health agencies and DME suppliers may need to develop ongoing relationships with physicians and NPPs to ensure that face-to-face encounters occur and are properly documented.

Comment: We received many comments pertaining to access to care. Commenters expressed that the face-to-face requirement in Medicare seems to be doing little to improve oversight of the benefit and is instead reducing access to home health for otherwise eligible patients, as physicians either refuse to accept the additional paperwork burden or do so only after agencies spend additional time and resources to obtain the documentation. One commenter believed the manner in which CMS is implementing the statutory requirement will significantly affect Medicaid beneficiaries' access to care. The commenter further stated that they can cite anecdotal examples of physicians who have simply decided to no longer refer individuals for home health services because of the hassle involved. One commenter believed that Medicaid beneficiaries will be the victims of this proposal because citizens who are elderly and those with disabilities are at risk for not receiving home health services if agencies have concerns about compliance with the face-to-face requirement and cannot deliver care. One commenter supported the need to align Medicare and Medicaid rules whenever possible, but was concerned about requirements that cause barriers to access by requiring a face-to-face encounter to initiate and receive payment for home health services. Another commenter was not supportive of applying the face-to-face requirements under Medicare to Medicaid. Another commenter believed that this requirement will negatively impact access and serve as a barrier to care because of the additional administrative burden to physicians filling out the face-to-face form. One commenter indicated that physicians, hospitals, discharge planners, home health agencies, and beneficiary groups agree that the physician requirements are a barrier to access to home health care for bona fide beneficiaries who meet coverage standards. One commenter believed that the face-to-face requirement is reducing access to home health for otherwise eligible individuals. One commenter was concerned that the face-to-face requirement will impede access and provide marginal benefit as a tool to eliminate ordering of questionable services.

Response: The face-to-face requirement is mandated by statute. We have attempted to permit maximum flexibility in how the statutory requirement can be met and believe that the requirement can be accommodated without significant additional burden. We are aligning Medicaid requirements with Medicare requirements to maximize consistency in service delivery, as well as reduce administrative burden on the provider community. As discussed in this final rule, we expect states to offer appropriate provider training and for states and providers to work together to ensure this provision is implemented in a manner that supports the goal of ensuring program integrity while not serving as a barrier to access to medically necessary services.

Comment: One commenter stated that well-mom and baby visits do not meet the intent of the physician face-to-face encounter for establishing the primary reason for which home health services are required and which will ultimately result in the development of a home health plan of care.

Response: If, in the course of such a visit, the physician or other practitioner determines that home health services or medical equipment is required to address the condition of the mother or child, such a visit could be the basis for a documented face-to-face encounter to the extent that the visit involves examining the condition of the mother or child.

Comment: One commenter believed that the proposed rule fails to take into account the fact that a significant proportion of home health services furnished to Medicaid beneficiaries under managed care programs are primarily the financial responsibility of managed care organizations. Another commenter suggested that, given the increased cost associated with the face-to-face encounter requirements, CMS should query states as to how they will be adjusting rates paid to managed care plans to adjust for the increased costs in an actuarially sound manner. Other commenters requested clarification regarding the application of the regulation to home health services

provided through Medicaid managed care plans.

Response: As previously stated, neither the law nor this rule requires that the face-to-face requirement apply to Medicaid managed care. We defer to states to determine the application of the face-to-face requirement in managed care plans to best meet the needs of their beneficiaries.

Comment: One commenter was concerned that more services will be shifted to personal care attendant services resulting in potential Medicare savings at the expense of state Medicaid budgets.

Response: We believe that the concern about potential cost shifting between Medicare and Medicaid can be address by ensuring that home health plans of care include all needed home health aide services. Additionally, as indicated in a previous response, to the extent that there is overlap in coverage with an optional benefit, states must provide for the coverage of services that meet the parameters of home health services under the mandatory home health benefit.

Comment: One commenter stated that the proposed rule at § 440.70 goes well beyond the scope of statutory authority and should not be issued. This commenter requested that CMS revisit its position that home health services are a mandatory service.

Response: We disagree with the commenter. Section 1902(a)(10)(D) of the Act sets forth the requirement that a state plan for medical assistance must provide for the inclusion of home health services for any individual who, under the state plan, is entitled to nursing facility services. Because nursing facility services are mandatory for categorically needy individuals and the medically needy—if a state chooses to cover the medically needy—home health services are mandatory for the populations.

Upon consideration of public comments received, we are finalizing § 440.70 with the following revisions:

- We are revising § 440.70(b) to state that home health services cannot be contingent upon the beneficiary needing nursing or therapy services.
- We are revising § 440.70(b) to codify that items and services that meet the criteria for coverage under the home health benefit must be covered according to home health coverage parameters.
- We are incorporating into § 440.70(b)(3)(v), three basic points set forth in our 1998 guidance relating to the *DeSario* decision: (1) States may have a list of preapproved medical equipment, supplies, and appliances for administrative ease but not as an absolute limit on coverage; (2) States must provide and make available to individuals a reasonable and meaningful procedure for individuals to request items not on the list; and (3) Individuals must be informed of their right to a fair hearing. Additionally, we are including in the final rule the underlying interpretation implicit in these principles that the mandatory coverage of this benefit prohibits absolute exclusions of coverage as medical equipment, supplies, or appliances.
- We are revising § 440.70(c)(1) to codify our longstanding policy that home health services may not be subject to a requirement that the individual be homebound.

B. Introductory Text—Medical Supplies, Equipment, and Appliances (§ 440.70(b)(3))

Section 440.70(b)(3) proposed to revise the wording of the regulation to further define medical equipment, supplies, and appliances as suitable for use in any non-institutional setting in which normal life activities take place. We also proposed in § 440.70(b)(3)(i) and (ii) more detailed definitions of the terms ''medical supplies, equipment, and appliances''.

Comment: We received many comments in support of revising the introductory text of paragraph (b)(3). Several commenters supported the policy that medical equipment cannot be restricted to items that are useful in the home. One commenter further stated that potentially essential products are necessary not only for individuals to function in the home but to carry out activities of daily living while out of the home and in the community. One commenter stated that such standard is consistent with the requirements under the Americans with Disabilities Act, the Supreme Court Decision in *Olmstead* v. *LC,* and good healthcare policy. Another commenter stated that substituting suitable for use in any non-institutional setting in which normal life activities take place will improve understanding of this required characteristic of medical supplies, equipment, and appliances. Another commenter stated that this acknowledges that individuals engage in daily activities in which they may need such equipment not only in their homes, but also as they go about their daily activities in the community. Another commenter suggested including this language not only in the preamble, but also in the final regulations. Additionally, several commenters commended CMS for its statement in the preamble to the proposed rule that ''[i]tems that meet the criteria for coverage under the home health benefit must be covered as such. States will not be precluded from covering items through a section 1915(c) HCBS waiver service, such as 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.''

Response: We appreciate the perspectives the commenters had in support of the proposed revisions to the introductory language in § 440.70(b)(3). This language has been included in the final regulation.

Comment: Many commenters requested clarification of the phrase ''normal life activities.'' One commenter requested that CMS clarify or define normal life activities as absent a definition there will likely be considerable confusion between this term and activities of daily living. Another commenter reported that some states include the terminology of activities of daily living in their DME definition which enables a focus on a defined area of medical necessity. The commenter suggested that this standard is more clearly defined and thus preferable. Another commenter indicated that the term ''normal life activity,'' if not clearly defined, will result in duplication of services and increased expenditures. Another commenter indicated that ''in which normal life activities take place'' is a subjective statement where the state's administration may have to continually define and defend its interpretation in utilization management practices.

Response: To clarify, the phrase ''normal life activities'' refers to activities that could occur in or out of an individual's home. We proposed to revise the phrase ''suitable for use in the home'' to ''suitable for use in any non-institutional setting in which normal life activities take place'' to clarify that although states may continue to establish medical necessity criteria to determine the authorization of the items, states may not deny requests for the items based on the grounds that they are for use outside of the home. This clarification would not preclude states from continuing to use activities of daily living as medical necessity criteria.

Comment: One commenter indicated concern with the proposed ''expansive'' new definition of Medicaid supplies, equipment, and appliances which appears to require states to provide supplies, equipment, and appliances in any non-institutional setting. Thus, states would be required to provide, as just one example, wheelchair ramps in

settings outside the home as well as in the home.

Response: The new definition of Medicaid supplies, equipment, and appliances establishes a framework to serve as a companion to the requirement that the benefit is not limited to services and/or items suitable for use in the home, rather it is a benefit that is available to people in any setting in which normal life activities take place, other than facilities specified at § 440.70(c)(1). States may not deny requests for the items based on the grounds that they are for use outside of the home. States will continue to have flexibility to establish a reasonable definition of medical supplies, equipment and appliances that is consistent with the regulatory framework, to apply medical necessity criteria, and to have reasonable utilization control standards. We note that we do not regard this definition to expand the scope of medical equipment to include environmental or structural housing modifications. Nor does it include equipment that is designed to have a general use and will serve more people than just the Medicaid beneficiary. And a state's medical necessity and utilization control standards could reasonably preclude coverage of duplicative items or could provide coverage for rental rather than purchase of items when cost effective.

Comment: One commenter stated that what CMS characterizes in the proposed rule as clarifying language in § 440.70(b)(3) is a substantive change to the rule that goes well beyond what is statutorily allowed under Medicaid. The commenter stated that the present language of § 440.70(b)(3) correctly sets forth the scope of coverage of medical supplies and equipment as being ''suitable for use in the home'' as home health care is the purpose of this coverage category.

Response: We disagree that the proposed changes go beyond the statutory authority for CMS to interpret the meaning of the home health benefit and establish a framework for states to implement that benefit. In addition, while the changes are substantive, the changes incorporate principles that have been applied to Medicaid coverage in a number of court cases and CMS guidance, as discussed in the Background section above. As a result, the changes update the regulations to incorporate principles that are already applicable in practice.

Comment: One commenter raised concern regarding DME issues related to abuse of the equipment provided to Medicaid beneficiaries, or requests for equipment that exceeds the practical needs of the member.

Response: States may review requests to ensure that only medically necessary equipment is covered. The proposed provisions do not replace the existing Medicaid regulatory requirements at § 440.70(a)(2) and § 440.70(b)(3)(i) related to physician ordering and review of necessary medical equipment. An additional safeguard against unnecessary utilization is the face-to-face requirement and subsequent documentation requirement, which provides that physicians must describe how the health status of the beneficiary at the time of the face-to-face encounter is related to the primary reason the beneficiary requires home health services. This process should identify requests for equipment that exceed the practical needs of the individual. With regard to abuse of equipment provided to Medicaid beneficiaries, we believe it would be reasonable for states to require that the face-to-face encounter include instruction on how to properly use and care for the medical equipment at issue.

Comment: One commenter requested clarification as to whether the existing 16-bed or fewer size standard for determining whether a residential setting is an institution will be considered in determining whether supplies are suitable for use in ''non-institutional settings'' and the applicability for DME that would be used in a school setting.

Response: This provision does not change the standard for determining whether a residential setting is an institution (the16-bed standard discussed by the commenter applies only to whether a setting is an institution for mental diseases, not whether it is institutional). Home health services do not include services for individuals receiving inpatient services in a hospital, nursing facility, intermediate care facility for individuals with intellectual disabilities, or other setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Home health services would be covered for individuals residing in other types of facilities in accordance with this regulation.

Comment: Several commenters requested clarification about whether a state that offers a unique service under a section 1915(c) waiver or section 1915(i) state plan amendment must also offer those items as home health supplies, equipment, and appliances. Commenters stated that on its face, this would suggest the addition of all unique section 1915 services would also become regular home health services, available to all state plan beneficiaries. If this is the intent, it would seem a welcome expansion of services, if it is not, then clarification would be helpful. Another commenter requested clarification that HCBS waiver beneficiaries are exempt from the proposed rule under § 440.310. Another commenter asked if the assumption is correct that certain equipment and appliances may require installation and would be included in the cost of the equipment and appliances. If so, the commenter requests a distinction be made between basic installation required for equipment and appliances (medical supplies) and structural modifications required for HCBS home and vehicle modification.

Response: States may not restrict access to equipment that meets the criteria for coverage under the home health benefit by carving certain equipment out of home health and offering it only to individuals who qualify for services under a state's section 1915(i) and section 1915(c) program. States may implement standards to determine coverage under the home health benefit of medical equipment based on medical necessity and utilization control. While a state can use presumptions in applying medical necessity and utilization control criteria, which CMS does not review, the state must provide an opportunity for an individualized hearing as to whether the item is medically necessary in the particular circumstances. There will be items currently coverable under sections 1915(c) and 1915(i) that will instead be covered under the home health benefit, but there are other items that will not meet the new federal or state definitions of home health medical equipment or that may be outside of the coverage limitations in the state's approved state plan. These latter items may remain covered under a section 1915(c) or 1915(i) benefit. In response to the commenter's inquiry regarding the exemption of HCBS waiver beneficiaries, to clarify, the requirement of this rule applies to all individuals receiving state plan home health services, including those eligible for state plan services based on enrollment in a HCBS waiver program. We defer to states to establish medical necessity criteria to meet the needs of their beneficiaries.

Comment: One commenter stated concern about the implication that states cannot limit the home health benefit to those services and items that are sufficient to achieve the purpose of the benefit, as is well established in statute, regulation, and case law and

that the final regulation should clarify that only those items that the state chooses to cover within the home health benefit must be provided to Medicaid enrollees. The commenter also stated that they were concerned about the implication that some home modifications may be mandatory through the home health benefit. The commenter suggested that CMS should consider limiting that statement to the installation of certain appliances and equipment such as grab bars and other items that are available through home health agencies, and clarify that home remodels and other expensive modifications are not included in the home health benefit.

Response: This regulation clarifies the permissible scope of the home health benefit, particularly as it relates to medical supplies, equipment, and appliances. But this regulation does not remove state flexibility to adopt a reasonable definition of medical supplies, equipment, and appliances that is consistent with the regulatory framework; nor does it preclude state flexibility to include coverage limitations that do not interfere with the overall sufficiency of the benefit. Home health is a mandatory benefit and was so before this rule or the statutory changes that led to this rule. States may establish limits on mandatory benefits in their approved state plan, but must demonstrate that, despite the proposed limits, the covered benefits are sufficient in amount, duration, and scope. In addition, as we discussed in our *Desario* guidance, because of the unique nature of medical supplies, equipment and appliances, scope limitations within the applicable federal and state definitions are not consistent with sufficiency of the benefit. States should not be implementing policies that unreasonably restrict access to specific items of medical equipment. We are available to provide technical assistance to states looking to implement amount, duration, and scope limitations in home health.

In response to the commenter's concern about the implication that some home modifications may be mandatory through the home health benefit, we would like to clarify that costs of structural home modifications are not covered under the home health benefit because they would not be within the new regulatory definition of medical equipment, but instead would be costs of shelter. Similarly, vehicular modifications are not within the definition of medical equipment; they are a component of a vehicle that is not medical in nature.

In addition, we are clarifying that states may implement standards to determine coverage of equipment based on presumptions about medical necessity and utilization control, but must provide for an opportunity for individuals to have an individualized medical necessity analysis that takes into consideration the individual's person-centered plan of care. While a state can use presumptions in making applying medical necessity and utilization control criteria, which CMS does not review, the state must provide an opportunity for an individualized hearing as to whether the item is medically necessary in the particular circumstances.

Comment: One commenter stated that the source of confusion as to the proper scope of the DME benefit has not been the state's DME definition. Since CMS is proceeding on an assumption without factual basis, the commenter does not support the proposal to establish a regulatory definition of DME.

Response: This final rule does not define medical equipment, supplies and appliances; rather it sets out a framework under which a state can adopt a reasonable definition of these items. The framework provides some criteria which the state must include in its reasonable definition. We believe this framework will provide a more consistent approach to categorizing home health medical supplies, equipment, and appliances that with this guidance, states will ensure the sufficiency of the benefit so that beneficiaries will receive needed items. We have aligned the Medicaid definition of medical equipment, supplies, and appliances to the best extent possible using key components of Medicare's definition which we believe will achieve consistency for beneficiaries, providers, and program administration and ensure that beneficiaries are receiving needed items.

Comment: One commenter raised a concern with home modification equipment. Specifically, the commenter stated that home modification equipment currently is not considered DME in the commenter's state and has been covered as an additional service under HCBS waiver programs. The commenter asserted that inappropriately expanding the definition to non-medical services will deplete public funding requiring states to again look at the services they provide and the rates they pay to maintain balanced budgets.

Response: As discussed above, home modifications are not a part of this new definition of medical supplies, equipment, and appliances.

Comment: One commenter stated that the current definition of medical supplies, equipment, and appliances includes the verbiage ''suitable for use in the home'' which is consistent with Medicare's requirement ''appropriate for use within the home.'' This definition does not restrict the beneficiary to the home but defines the type of equipment that is appropriate for reimbursement under the DME outpatient program.

Response: We believe that the revision to the definition of medical supplies, equipment, and appliances will clarify the breadth of the current definition to include covered items outside of the home.

After consideration of the public comments, this section is being finalized without revisions.

C. Definition—Medical Supplies, Equipment and Appliances (§ 440.70(b)(3)(i) and (ii))

In § 440.70(b)(3)(i) and (ii), we proposed to revise the current regulation text to define what constitutes medical supplies, equipment, and appliances.

Comment: Some commenters expressed support of the revised definition. Commenters supported the alignment with Medicare's definition of DME. One commenter specifically supported CMS's effort to streamline and standardize the requirements for DME across the Medicare and Medicaid program, especially as they may apply to dual eligible beneficiaries. Another commenter believed the changes will promote consistency among different payer groups. A few commenters supported the concept advanced by CMS to define medical ''equipment'' separately from medical ''supplies.''

Response: We appreciate the support of the commenters.

Comment: Many commenters requested that CMS further clarify the proposed definition of medical equipment and appliances. CMS's proposed language defining medical equipment as ''reusable or removable'' could be interpreted by states to allow exclusion of items that are custom made or customized, such as wheelchair components for the seating and positioning for individuals with the most severe orthopedic impairments. The commenters recommended that CMS eliminate this restrictive criterion from its definition of medical equipment. Many commenters further requested the substitution of the term ''reusable'' with ''non-disposable.'' One commenter requested that this rulemaking process clarify that items of DME that meet an established definition of the service must be covered by

Medicaid when medically necessary. Additionally, the commenter requested that the rules clarify that states cannot characterize items of DME as non-covered through the home health benefit because this equipment may be eligible through HCBS waiver programs.

Response: As stated in the preamble to the proposed rule, we have set out a framework for the definition of medical equipment and appliances to align with Medicare to achieve consistency for beneficiaries who may be eligible in both programs, simplify program administration and ensure that beneficiaries are receiving needed items. But, we have left considerable flexibility for reasonable state definitions of the benefit within that framework. We do not agree that the terms ''reusable or removable'' should be deleted from the framework for medical equipment because these terms have meanings that are generally understood based on use in the Medicare program. Although we appreciate commenters raising the concern that these terms could be read to prohibit the customization of equipment, we do not agree that customization would necessarily make the items unusable for other individuals.

In response to the further comment, the home health benefit is distinct from items and services that may be available through HCBS waiver programs. Medicaid coverage of medical supplies, equipment, and appliances under the home health benefit is mandatory and must be provided under the state plan to HCBS waiver enrollees. To the extent that items are not included under the approved state plan, extended coverage could be provided under section 1915(c) waiver programs. We also reiterate our statement from the proposed rule that items meeting the state plan definition of a medical supply, equipment or appliance must be provided under the home health benefit, and may not be restricted to enrollees under a section 1915(c) HCBS waiver.

Comment: We received many comments pertaining to the language ''illness or injury.'' Many commenters requested that CMS clarify this definition to ensure that individuals with congenital conditions or developmental disabilities are not denied coverage of equipment or appliances because a state determines that they do not have an illness or injury.

Response: It is not our intent to deny coverage of supplies, equipment, or appliances to individuals with congenital conditions or developmental disabilities. We expect that anyone who is determined, based on medical necessity, to need medical supplies, equipment, and appliances will receive it. Therefore, in accordance with the comments, we are revising the regulation text to include ''disability, illness, or injury.''

Comment: Many commenters raised concern with the proposed criteria defining home health supplies, equipment, and appliances to better align with the Medicare program's definition of DME. Several commenters were concerned that states may take the adoption of a regulatory definition for medical supplies, equipment, and appliances as a signal to make their policies for covering medical equipment, appliances, and supplies more restrictive than they are at present. Commenters urged CMS to state in the preamble that this is not the intention of adopting this definition. Additionally, the commenters specified their concern that the intent to align the definition with the Medicare program will lead states to erroneously deny coverage of home health services because Medicare does not cover them. Commenters further stated that one of the primary purposes of the Medicaid program is to ''furnish . . . rehabilitation and other services to help such families and individuals attain or retain capability for independence and self-care'' and there is no corresponding requirement in the Medicare Act. One commenter stated that he strongly disagrees with the alignment with the Medicare definition and that distinct definitions of ''medical equipment and appliances'' between the two programs are warranted. Another commenter stated that in the instance of defining medical equipment and appliances, alignment between the Medicare and Medicaid definition is ill-advised and unnecessary. Another commenter stated that he does not believe this clarification meets the goal of better alignment with Medicare's program definition and that, in fact, this proposed change will cause fragmentation between Medicare and Medicaid.

Response: We appreciate the commenters' concerns, but 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. Additionally, we believe that the alignment with Medicare's definition is useful to help minimize inconsistencies between the two programs. We confirm that it is not our intent to have this standard restrict the receipt of medical supplies, equipment, and appliances, and we have included language in the regulation indicating that Medicaid coverage of medical equipment is not restricted to items covered as DME in the Medicare program. Furthermore, states may choose to cover items that are not within the coverage under the home health benefit under other authorities, including section 1915(c) waivers or section 1915(i) state plan; nothing in this regulation is meant to curtail a state's innovation or expansion.

Comment: Several commenters recommended revisions to the definition. One commenter recommended revising the definition to state: ''equipment and appliances are defined as items that are used to serve a medical purpose for the beneficiary, can withstand repeated use, and can be reusable or removable''. Many other commenters recommended revising the definition of medical equipment and appliances to state that 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 or disabling condition, can withstand repeated use, and can be reusable or removable. Another commenter recommended utilizing the current industry accepted Medicare definition: (1) Can withstand repeated use; (2) Is primarily and customarily used to serve a medical purpose; (3) Generally is not useful to an individual in absences of an illness or injury; and (4) Is appropriate for use in the home.

Response: We appreciate the commenters' suggestions and we made a change in this final rule that responds to the second suggestion by incorporating a reference to disability. We did not accept the first suggested revision because it would require coverage of items that were not generally regarded as medical in nature, and we did not accept the third suggested revision because it would exclude coverage of items that would be used in normal life activities outside the home (such as, for example, walkers or wheelchairs). As indicated above, we are revising the definition of equipment and appliances to reference ''disability, illness, or injury.'' Otherwise, we will not be revising the definitions in the proposed rule.

Comment: One commenter disagreed with the proposed definition of equipment and appliances. The commenter stated that the proposed definition is improperly dependent upon how equipment and appliances are ''primarily and customarily used,'' and how they might be ''generally'' not

useful in the absence of an illness or injury. The standards should be dependent upon how equipment and appliances are needed by the particular Medicaid beneficiary. Another commenter stated that the proposed rule defines covered medical equipment by how an item is ''primarily and customarily'' or ''generally'' used, rather than adopting a person-centered approach that recognizes that people might have different medical needs.

Response: While we agree that the need for equipment and appliances should be based on an individual's needs in accordance with a person-centered plan of care, we are not accepting the suggested change because it would require coverage of items that were not generally regarded as medical in nature.

Comment: One commenter stated that the proposed definition of medical equipment and appliances would allow individuals in need of certain devices greater chance of approval.

Response: We appreciate the commenter's perspective, but it is not clear how the proposed definition would favor some devices over others. While a covered device must be within the scope of the definition of medical equipment and appliances, the approval of devices within that scope is based on a physician judgment of medical need and any state prior authorization review process. Moreover, as discussed elsewhere in this preamble, we have revised the final regulations to make clear that it sets forth a framework for coverage but that there is flexibility within that framework for states to define the precise scope of the benefit.

Comment: One commenter recommended adding language to further support the use of medically necessary and appropriate DME that has a well-established history of efficacy or, in the case of novel or unique equipment, valid peer-reviewed evidence that the equipment corrects or ameliorates a covered medical condition or functional disability. The commenter also suggested that the definition of DME should include equipment that is proven, safe, and appropriate for the treatment of a medical condition or illness.

Response: We do not believe that this additional language is necessary. This rule does not change the requirement that medical equipment must be ordered by a physician. We expect that the physician would determine medical necessity based on individual need. We further expect that physicians would order appropriate and safe medical equipment for individuals that have demonstrated effectiveness. Nothing in this rule, however, would preclude a state from establishing a prior authorization process to review claims for medical equipment (denying authorization when medical necessity is not established, subject to the individual's right to an appeal) and to initiate a dialogue with the treating physician to ensure appropriate treatment and control unnecessary utilization.

Comment: Some commenters indicated that state Medicaid programs should not be restricted to the definition of equipment that is consistent with items covered as DME under the Medicare program. The commenters recommended that CMS amend the proposed rule to set the Medicare coverage standard as the minimum scope of benefits relative to coverage of medical equipment, but allow states to provide more expansive coverage. Many other commenters cautioned the Secretary in applying Medicare's medical equipment definition to Medicaid because of the different standards that apply to the coverage of their respective home health benefits. The commenters further stated that Medicaid's definition of ''equipment and appliances'' should be flexible so that beneficiaries' needs can be met.

Response: We believe that this Medicaid framework for equipment and appliances is flexible so that individuals' needs can be met. But, in response to this and other comments, we have revised the final regulation text to make clear that coverage of medical equipment and appliances under state Medicaid programs are not restricted to the items covered as DME in the Medicare program. The alignment of the Medicaid framework with the Medicare definition is intended to achieve consistency for beneficiaries who are eligible in both programs, simplify program administration and ensure that beneficiaries are receiving needed items. The final regulation text makes clear that coverage of medical equipment and appliances are items that meet the listed criteria, but that states can elect to cover other items, including items that are not covered under the Medicare DME benefit.

Comment: Many commenters encouraged CMS to include language in the final regulation to reflect the policies set forth in the September 4, 1998 State Medicaid Director letter responding to the *DeSario* v. *Thomas* decision. One commenter stated that it is essential that CMS restate the validity of the *DeSario* SMD letter: That states may not use exclusive lists or irrefutable presumptions to limit or bar coverage of items under the DME benefit; and that states must have a reasonable process for requesting coverage of items the state has not otherwise expressly identified as covered. Another commenter stated that language should be provided in this rule if action is necessary to prevent states from employing lists and presumptions to deny coverage of appropriate medical equipment. Many commenters stated that it is necessary that the Secretary incorporate the letter's policy into regulation. Several commenters commended CMS for reemphasizing in the preamble that states may not use lists or presumptions in limiting coverage of items under the home health benefit unless states have a reasonable process for requesting exceptions to such lists or presumptions that are based upon specific criteria. One commenter further stated that codifying the interpretation by CMS contained in its State Medicaid Director Letter of September 4, 1998 would enable more people with Medicaid who rely upon DME to remain in their homes and active in their communities. Another commenter believed that it would be highly beneficial to include the principles espoused in the September 4, 1998 State Medicaid Director letter in the regulation. Another commenter supported the suggestion that federal Medicaid regulations should require that if states confine allowable medical equipment to items from a list, they allow beneficiaries to appeal for items not on that list by demonstrating that the items are medically necessary. One commenter stated that CMS appears to conflate a state's ability to limit the amount, duration, and scope of a benefit, with a determination of whether an item or service falls within the state's definition of a covered item or service. The commenter further stated that if CMS chooses to add the 1998 guidance to the regulation, it should clearly distinguish between benefit exclusions and the use of administrative lists for classes of supplies and equipment that are covered under the state's benefit.

Response: We have revised the final rule at § 440.70(b)(3)(v) to make clear that the principles we set forth in the 1998 SMD are still applicable. If a state has a predetermined list of covered, supplies, equipment and appliances, it must have a reasonable process, with an opportunity for a fair hearing to allow beneficiaries to request and receive items that are not on the state's list. Beneficiaries must be afforded the opportunity to establish that the item in question is medically necessary and within the overall state definition of covered medical equipment, and

consistent with the federal regulatory framework.

Comment: One commenter believed that the use of presumptions by their very nature moves coverage determinations away from individual-based considerations and substitutes efficiency for person-based, medical necessity determinations.

Response: Coverage determinations for medical supplies, equipment, and appliances should be based on medical necessity criteria as established by the state as applied to the individual's particular needs. The need for medical supplies, equipment, and appliances should be identified by the physician and reviewed at least annually.

Upon consideration of the public comments received, we are finalizing § 440.70(b)(3)(ii) with revisions. We are revising the definition of equipment and appliances to include the term ''disability'' and to specify that state Medicaid programs are not restricted to the items covered under DME in the Medicare program. Additionally, we have clarified that structural or home modifications are not covered under the Medicaid home health benefit and that states may not limit access to equipment eligible for coverage under home health benefits by restricting some items to only those who qualify for section 1915(i) or (c) programs. States may implement standards to determine coverage of the specific items previously funded under sections 1915(c) or (i), such as ceiling lifts or chair lifts, that could now be seen in appropriate circumstances to meet the home health definition and be medically necessary for an individual. We have also clarified that medical equipment and appliances already coverable under the home health benefit will continue to be covered. Not all medical equipment and appliances currently coverable under section 1915(c) and section 1915(i) will be coverable under the state plan under the standards set forth in this rule.

D. Setting Description (§ 440.70(c)(1) & (c)(2)

To reflect the principles expressed by the courts in both the *Skubel* and Detsel decisions discussed above, we proposed to incorporate in regulation the longstanding policy that home health services may not be subject to a requirement that the individual be ''homebound.'' In addition, we proposed to clarify that home health services cannot otherwise be restricted to services furnished in the home itself. Additionally, 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 flexibility.

Comment: Many commenters supported the proposal to specify in the regulations that Medicaid home health services must not be limited to beneficiaries who are ''homebound.'' Additionally, many commenters supported the conclusion that Medicaid home health services should not be limited to services furnished in the home. One commenter indicated that this proposed change provides flexibility for adults to receive medically necessary services at the workplace and children to participate in the community with their families while receiving necessary supports. The commenter further stated that allowing people to access home health services in the community will contribute to overall health and a reduction in costs for acute services. Commenters stated that the clear ability of people with disabilities to use their home health benefit in ''any non-institutional setting in which normal life activities take place'' will make community integration feasible for many people.

Response: We appreciate the perspectives the commenters provided about medically necessary home health services. We also believe that with home health services provided in conjunction with other optional state plan and section 1915(c) waiver services people can be supported to fully integrate into their communities.

Comment: Many commenters recommended that the regulatory language specifically indicate that a homebound requirement is not permitted. One commenter suggested revising § 441.15(c) to establish clearly that Medicaid home health coverage cannot be contingent on the beneficiary being ''homebound.'' Other commenters suggested the following language: ''Nothing in this section should be read to prohibit a beneficiary from receiving home health services in any non-institutional setting in which normal life activities take place or to permit a state to require that an individual be homebound or unable to leave his home to receive home health services.'' One commenter recommended that the final regulation amend paragraph (a)(1). The commenter believed that it is contradictory and confusing in paragraph (a)(1) to state that home health services must be provided ''[a]t [the beneficiary's] place of residence,'' and then in paragraph (c)(1) to state that services can be provided ''in any non-institutional setting in which normal life activities take place.'' The commenter also recommended that the proposed language for paragraph (c)(2) be revised to specify that services and/or service hours must be authorized to account for medical needs arising out of the home.

Response: We are revising § 440.70(c)(1) to indicate that a homebound requirement is not permitted. We believe this revision also addresses the request to revise § 441.15(c), as § 441.15(c) cross-references § 440.70. In response to the request that we amend paragraph (a)(1) as it is contradictory and confusing when read with paragraph (c)(1), we do not believe that this revision is necessary as § 440.70(a)(1) references paragraph (c) to specify ''place of residence.'' While we understand the recommendation that the language for paragraph (c)(2) be revised to specify that services and/or service hours must be authorized to account for medical needs arising out of the home, as long as the amount and duration limits applied by the state are either authorized under the approved state plan as consistent with a sufficient benefit, or based on an individualized medical necessity determination, we do not think such language is appropriate. We would, however, allow states the option to authorize additional services or hours of services to account for this flexibility to make clear that such a policy would not violate comparability requirements.

Comment: One commenter expressed concerns regarding homebound status and beneficiaries who are dually eligible for Medicare and Medicaid. The commenter stated that they support the ability of Medicaid-enrolled individuals to receive home health services without an artificial barrier based on their homebound status. However, because the prohibition on requiring a homebound status does not apply to the Medicare program, the commenter raised concern about how this will be implemented for those that are dual eligibles.

Another commenter stated that the regulation would require that certain programs revise or update existing policies to reflect that home health services cannot otherwise be restricted to services furnished in the home itself.

Response: Individuals who are dually eligible for Medicare and Medicaid will benefit from this regulation. While the prohibition on requiring a homebound status in Medicaid is not new to this regulation, codifying the prohibition and strengthening the community integration philosophy of the home health benefit will ensure the individuals receive quality Medicaid home health services. Individuals eligible for both Medicare and Medicaid

who are not determined to be homebound may not qualify for Medicare home health services. Such individuals would still qualify for Medicaid home health services, if they meet the state's medical necessity criteria for the service. We understand that some state program policies may have to be modified or updated to comport with the rule, but do not believe that this task will be overly burdensome.

Comment: One commenter recommended against using the phrase ''normal life activities.'' The commenter believed that it contains a value judgment and could be read as devaluing people who are living in institutional settings as not ''normal.'' Therefore, the commenter recommended striking the term ''normal'' and simply using ''life activities.''

Response: The phrase ''normal life activities'' is used in this rule to clarify that home health services cannot be limited based on the location in which home health services are used. We do not believe that the term ''normal'' needs to be removed from this phrase. There is no negative connotation intended.

Comment: One commenter suggested a new classification of care. Rather than ''home care,'' the commenter suggested that care for beneficiaries of covered home-care services when the beneficiary is not homebound be called ''community care.'' The commenter further stated that better distinguishing between home care and not-at-home-but-in-the-community care will help with the application of that care. While a community-based benefit can be provided within the existing infrastructure of home health care, it needs to be administered with more scrutiny and monitoring of beneficiaries. Just tracking where the care is to be delivered will require more scheduling and monitoring.

Response: Developing a new classification of care is beyond our statutory authority.

Comment: Some commenters suggested prohibiting any home care coverage standard that results in a different and/or greater scope of benefits for beneficiaries residing in facility-type residences than the scope of benefits for individuals in their own private homes. Commenters recommended that CMS clarify its suggestion/allowance that states can provide a higher level of home care benefit to individuals who reside outside an individual private home such as a rest home or assisted living facility. As written, it may be possible for a state to interpret the CMS reference on higher levels of coverage for such individuals as permitting states to have a different benefit for Medicaid beneficiaries in a facility-type residence than for those in a private home.

Response: This rule does not affect or change comparability rules, and therefore, we do not believe that individuals will receive a different and/or greater scope of benefit based on where an individual resides. We also remind commenters that the scope of a benefit that a beneficiary is authorized to receive is based on medical necessity, not the setting where the beneficiary resides. States have the flexibility to determine medical necessity criteria and therefore, the level of services a beneficiary receives is based on medical necessity, not setting.

Comment: One commenter indicated that CMS should clarify in regulation that Medicaid home health services should not be limited to services furnished in the home.

Response: We clarify that home health services cannot be limited to services furnished in the home. Additionally, we have revised § 440.70(c)(1) to indicate that home health services can be provided in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Therefore, we believe that we have sufficiently communicated and regulated the prohibition on restricting services to the home.

Comment: One commenter requested that CMS clarify whether states can specify settings in which home health care can be received. The commenter stated that states should be allowed to specify that skilled tasks associated with bathing be limited to the client's place of residence.

Response: The purpose of this provision is to ensure the delivery of home health services not only in the home, but also in the community when the beneficiary is participating in normal life activities. It is not meant to mandate service provision in any particular setting. We are also permitting states to authorize additional hours of home health services to account for medical needs that arise in the setting furnished. And, while states may set limits on the amount, duration, and scope of home health services, subject to our approval, we do not agree that states may put arbitrary limits on the places where home health services can be received.

Comment: One commenter asked, if a child is approved for services which will be provided in a school setting, is the school responsible for the nursing services, or will a nurse from the approved home health agency be required to provide services in a school setting.

Response: This does not change policy for Medicaid services provided in schools. Under the existing rule, nursing services under the home health benefit must generally be provided by a home health agency. The rule does not limit agreements and arrangements between home health agencies and schools to facilitate the provision of such services. Nor does it preclude coverage of nursing services provided in schools under another benefit category.

Comment: One commenter reported that currently their state does not contract with out-of-state home health providers and inquired as to whether a state home health nurse would be required to travel with the family, how the state would reimburse the nurses' travel.

Response: Nothing in this final rule specifically addresses this issue but, in general, nursing services are provided under the home health benefit only when provided through a home health agency in accordance with an physician's order as part of a written plan of care. To the extent that there is a medical need documented in the plan of care for out of state travel accompanied by a home health nurse, and the service can be provided consistent with the approved state plan, payment would be made to the home health agency as set forth in the approved state plan. We note that coverage of out-of-state services may be limited by a state as long as the requirements of 42 CFR 431.52 are met.

Comment: One commenter requested that the plan of care designate the home health services as In-Home or Out-of-Home services after a physician evaluation of medically necessary accommodations and staffing levels to insure the safety of beneficiaries and success of out of home services. One commenter raised concern with settings that cannot be evaluated as safe, and settings that may result in unnecessary duplication of services. The commenter also was concerned with access to care issues related to out of state care, as current state policy requires that the setting be a safe setting, and may not approve services if all health and safety issues cannot be met in the setting. The commenter believed that the rule does not address any limitations of services outside of the home and wondered whether states would be permitted to

restrict certain services. Another commenter requested that CMS consider further clarification of the site of care for home health services to acknowledge and reduce the personal risks to health care workers and to ensure the site of care selected is appropriate for the safe delivery of home health services.

Response: The plan of care should assist in identifying services and settings appropriate for the individual's need. Assessment of receipt of the services is based on medical necessity. This regulation does not set forth detailed requirements for plans of care; there are other resources for guidance on the best practices for person-centered care planning. We understand and appreciate the commenters' concerns for the personal safety of home care workers. Such concerns exist with any home care program, and are not new with this regulation. We encourage home care agencies to take measures to reduce risks to employees. With regards to duplication of services, section 1902(a)(30)(A) of the Act requires that payments are economic and efficient; payments which duplicate payment for the same service would not be economic and efficient, and therefore, would not comport with federal statute.

Comment: We received many comments pertaining to costs within this component of the regulation. One commenter stated that Medicare regulations continue to require that a beneficiary be ''confined to the home'' to qualify for Medicare-covered home health services. Therefore, for any dual eligible, state Medicaid programs will bear the entire financial burden for home health services provided in another setting outside the home. Another commenter believed that the proposed regulation goes beyond states' limits and would appear to apply to waiver and state plan benefits alike. The commenter was concerned about the potential downstream effect of expanding services available through HCBS waivers, which are case managed, to coverage of state plan benefits, which are not case managed. The commenter also stated that expanding beyond the current case-managed limitations on services or service hours would have a real and substantial fiscal effect on the state's Medicaid program. One commenter expressed concern that the new requirement would result in a large increase in cost for Medicaid home health services. Another commenter indicated that deleting the existing ''at home'' requirement for Medicaid home health services represents a substantial and unjustified expansion of states' financial liability for home health services.

Response: While most of the Medicare/Medicaid rules are aligned, this is an area in which there is a statutory difference between the programs. As a result, the rules differ. Sections 1814(a) and 1835(a) of the Act impose the Medicare homebound requirement for home health services, but there is no parallel homebound requirement under Medicaid. We understand that there may be consequences for Medicaid programs, but these consequences do not arise from this rulemaking; they are inherent in the difference between the two statutes. Additionally, we note that we would permit states the flexibility to authorize additional hours of home health services to account for medical needs that may arise outside of the home.

Comment: One commenter stated that while the proposed regulation purports to incorporate and comply with federal court decisions, the new provisions go beyond anything required or contemplated by the decisions. The commenter further stated that the proposed regulation would vastly expand the program so that the health care provided to Medicaid beneficiaries far exceeds anything available to the general population. Under the proposed regulations, a beneficiary could receive health care anywhere, including the grocery store, a museum, or even an amusement park. The proposed regulations essentially transform Medicaid from a health care program to a social services program. The commenter also believed that the proposed regulations appear to be based on an incorrect interpretation of the *Olmstead* decision. *Olmstead* cannot reasonably be read to require the dramatic expansion that would follow from the final issuance of the proposed regulations. The commenter stated they believe that the proposed regulations are not supported by the cost-neutral rationale espoused by the *Skubel* decision, and they establish a more expansive coverage policy (both substantively and geographically), when compared to the *Detsel* and *Skubel* decisions and CMS's own stated policies.

Response: This final rule does not mandate provision of services in any particular setting, but removes a barrier to the provision of home health services outside of the home itself. Removal of this barrier may permit individuals whose medical needs are such that they require home health services to participate in normal life activities not to be restricted to the home. The community integration underpinning of the home health benefit is appropriate for the Medicaid program and we refer to the principles set forth in court cases discussed herein as support for this final rule. Those principles are based on readings of the Medicaid statute, and we are adopting those readings. Furthermore, in response to the comment that we are expanding the scope of coverage more than is required by the court cases, to the extent that this is the case it is because such expanded coverage is consistent with both the overall purposes of the Medicaid statute, as section 1901 of the Act specifies to help families and individuals attain or retain capability for independence or self-care, and under section 1902(a)(19) of the Act that specifies care and services will be provided, in a manner consistent with simplicity of administration and the best interests of beneficiaries.

Comment: Some commenters disagreed with the proposed revision to the setting description. One commenter stated that the term ''home health care services'' as used in federal Medicaid law has never been further defined. In the absence of a definition, it should be assumed that the Congress intended it to mean exactly as written—health care services delivered in a beneficiary's home. Nothing in the ''face-to-face'' provision or elsewhere in the Affordable Care Act suggests the Congress intended to depart from the clear meaning and long-standing interpretation of this term. The commenter also believed that that the suggestion that covering home health services outside the home is necessary for compliance with ADA as interpreted in the *Olmstead* decision is without foundation. The proposed rule's directive that states cover home health services in non-home settings directly contravenes the flexibility that was at the heart of the *Olmstead* decision. Additionally, the commenter stated that as CMS acknowledges in the preamble, under the proposed rule, ''home health services may not be limited to services furnished in the home,'' and ''states may not limit home health services to services delivered in the home.'' Any language in the proposed rule suggesting a contrary result is misleading, and presumably intentionally so. Another commenter stated that the proposed regulations go well beyond long-established policy and the decisions in *Detsel* and *Skubel,* as well as CMS's own stated policies.

Response: As we have indicated previously, we are adopting the principles underlying the holdings of the *Skubel and Detsel* court decisions in this final rule. We believe this reading is consistent with the purposes of the Medicaid statute. We are being clear

that home health services may not be limited to services literally provided in the home. But we are not mandating that services be provided in any particular setting; that is an issue that must be addressed in a plan of care that accounts for the individual's needs, and may be subject to review by the state.

Comment: One commenter reported that the regulation would require that the Children's Services Program of the state revise or update existing policies to reflect that home health services cannot be otherwise restricted to services furnished in the home itself.

Response: While we understand that some state policies may need to be revised; such as the restriction of home health services to an individual's home. We do not believe that this will be overly burdensome.

Comment: One commenter was concerned with the lack of control in non-institutional settings. The commenter believed that issues may arise in certain settings considered non-institutional such as college dormitories. Additionally, the commenter believed restrictions based on funding, safety, distance of travel, and practical feasibility need to be addressed.

Response: Home health services are authorized based on medical necessity, not setting. However, we do recognize that there may be circumstances in which an individual and/or provider's health or welfare may be at risk, and we urge home health agencies and states to address the issues on an individual basis should they occur. We are available to provide technical assistance and guidance as needed.

Comment: One commenter stated that, under proposed § 440.70(c)(1), home health services would be significantly broadened by offering services in ''any non-institutional setting in which normal activities take place.'' The commenter was concerned that this new requirement would result in a large increase in cost for Medicaid home health services and DME, prosthetics, orthotics, and supplies.

Response: As previously stated, home health services, including DME, are authorized based on medical necessity, not setting. We acknowledge the increased cost associated with our standardizing the definition of medical supplies, equipment, and appliances, both narratively, and in our characterization of the proposed rule as being economically significant, with a likely financial impact of greater than $100 million. However, we continue to stand by the necessity of the regulatory revisions to ensure that beneficiaries receive the home health benefits to which they are entitled under the Medicaid statute.

Upon consideration of the public comments received, we are revising § 440.70(c)(1) to indicate that a homebound requirement is not permitted. Additionally, we are clarifying the settings in which individuals may receive home health services. Specifically, individuals may receive home health services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.

E. Face-to-Face Encounter (§ 440.70(f))

Section 440.70(f)(1) specifies 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 before the start of services. 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 proposed to allow an opportunity to meet the face-to-face encounter requirement through an encounter with the beneficiary within 30 days after the start of home health services.

Comment: Some commenters supported the proposed timeframes. One commenter stated that they believe that this timeframe is appropriate for authorization of most types of home health services. Another commenter stated that the requirements for face-to-face encounters with an individual's physician or NPP for approval of home health services 90 days prior or 30 days after administration will allow for the most up-to-date patient information to be incorporated into their plan of care.

Response: We appreciate the commenters' support of the proposed timeframes.

Comment: Many commenters requested that CMS delay implementation. Commenters stated that with regard to Medicare, CMS delayed implementation of the regulation to afford sufficient time for beneficiaries, physicians, hospitals and other providers to understand the parameters of the new rule. The commenters recommended that CMS employ the same caution in implementing the face-to-face requirement for Medicaid's home health benefit. One commenter further suggested delaying implementation at least one year.

Response: We recognize that there may be operational and budgetary implications with this rule and that states and providers may need time to implement this provision. In order to ensure that states and providers are implementing the rule appropriately we have revised the effective date of the rule to July 1, 2016 and will delay compliance with the rule for up to one year if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule based on the timeframes explained above.

Comment: Many commenters expressed opposition to the face-to-face requirement with one commenter requesting that CMS drop the face-to-face requirement altogether. The commenter believed that it has only been a barrier to service for beneficiaries who need care and cannot get in to see their physician. Another commenter urged CMS to remove the face-to-face requirement for home health services in the Medicaid program. One commenter stated that his state expresses opposition to CMS' proposed expansion of face-to-face requirement to Medicaid at this time. Another commenter stated that CMS's conclusion that the Congress intended the face-to-face requirement to apply to physicians' orders for home health under Medicaid is unreasonable. The commenter further stated that to require a face-to-face encounter within a prescribed period of time before a physician orders or prescribes a particular course of care or treatment calls into question the physician's exercise of professional judgment under applicable state practice acts, and undermines the physician-patient relationship. One commenter indicated that he does not support the need for a face-to-face contact by a physician or other designated health professional prior to the initiation of home health services. The commenter stated that the proposed regulation cites no substantive reason for this requirement. The commenter also recognized that this requirement may be specifically mandated by the Affordable Care Act, but reported that he does not see how such a requirement will actually serve any beneficial purpose for the beneficiary.

Response: We believe that our interpretation of the applicability of the face-to-face requirement in the same manner and to the same extent as it applies to Medicare is consistent with,

and required by, section 6407 of the Affordable Care Act.

Comment: One commenter supported aligning the timeframes with similar regulatory requirements for Medicare home health services. Another commenter specified that any face-to-face requirement for Medicaid should mirror in timing, information and signature requirements for the Medicare program and the one exception should be the requirement of homebound criteria which the commenter agrees should not be required for Medicaid beneficiaries. Another commenter recommended that the Medicaid requirement match the Medicare requirement, which would be the 6-month timeframe. One commenter recommended that CMS remove the 90-day timeframe and replace it with the 6-month timeframe found in the statute. One commenter stated that CMS halving the permissible timeframe for the face-to-face encounters from 6 months to 90 days is inconsistent with Congressional intent. The commenter also stated that requiring a face-to-face encounter within 90 days of a physician ordering home health services for a Medicaid beneficiary is not consistent with the nature and needs of the Medicaid population. Additionally, the commenter believes that the provision of the proposed rule that would allow for a face-to-face encounter ''within the 30 days after the start of the services'' is inconsistent with the purpose of the Medicaid rule requiring a physician order for coverage of home health services. One commenter urged CMS to maintain the timeframe window to be 6-months preceding the start of care to 30 days after the start of care under Medicaid.

Response: We agree with commenters who asked for alignment between Medicare and Medicaid face-to-face timing requirements. In this final rule, Medicaid requirements for the timeframes of the face-to-face requirement for home health services generally are aligned with timeframes adopted for Medicare home health. To maximize the alignment between the programs, in this final rule we have also aligned with Medicare the timeframe for the face-to-face encounter for Medicaid medical equipment, which is 6 months prior to the start of service.

Comment: A commenter stated that the proposed timeframes for face-to-face encounters may prove problematic if the visit can occur up to 30 days after the start of home health services, because under the fee-for-service system, authorizations for services would be already approved and there would be no easy way to make sure this visit, complete with documentation requirements was performed. Another commenter stated that the timeframes will be much harder to comply with for the Medicaid population.

Response: To clarify, we have extended the face-to-face encounter timeframes to permit the encounter to occur within 30 days after the start of home health services to account for individual circumstances. But we would expect that ordinarily the face-to-face encounter would occur before the start of home health services. We understand that in the individual circumstances, when the face-to-face encounter occurs after the start of services, additional coordination of the medical/home health team may be required to ensure that the visit, along with the required documentation was performed. We encourage states to work with the home health provider community to incorporate the 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.

Comment: One commenter suggested allowing longer timeframes for Medicaid face-to-face encounters and extending the 30-day post-start of care, especially for beneficiaries without a primary care physician.

Response: The timeframes proposed in this rule are aligned with Medicare's timeframes to promote consistency. Additionally, we do not agree that the 30-day post-start of care timeframe should be extended. The expectation of the rule is that that the timing of the face-to-face encounter in normal circumstances should occur within the 90 days before the receipt of services. We are providing for the 30-day post-start of care timeframe to accommodate extenuating circumstances that require immediate commencement of home health services before a physician encounter can be scheduled.

Comment: One commenter suggested that CMS state that CMS encourages the face-to-face encounter occur within 90 days prior to the start of home health services.

Response: We do not believe that a change in regulation language is necessary. We emphasized in the proposed rule and in the responses to comments that the timing of the face-to-face encounter in normal circumstances should occur within the 90 days before the start of home health services.

Comment: We received many comments regarding the face-to-face encounter for individuals who are dually eligible for Medicare and Medicaid. One commenter asked whether CMS would accept documentation of a face-to-face encounter reimbursed under Medicare when a dually-eligible individual begins home health services under Medicare and transitions to Medicaid. Specifically, since Medicaid does not require the beneficiary to be homebound, the commenter questioned whether another face-to-face encounter would need to be completed for Medicaid home health services. Several commenters recommended that CMS amend the proposal to deem the Medicare qualifying face-to-face encounter documentation as meeting Medicaid face-to-face requirements or establish a standard that the switch to Medicaid as the payer is not a ''start of care'' that would require a Medicaid qualifying face-to-face encounter. Commenters requested that CMS clarify whether there are circumstances under which an additional face-to-face encounter would be needed when beneficiaries move between Medicare and Medicaid coverage. One commenter noted that some individuals are dually eligible and may face greater challenges accessing care and services.

Response: To clarify, the face-to-face encounter is required for initial orders for home health services and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. OASIS is the ''Outcome and Assessment Information Set'' applicable for Medicare home health services and Medicaid home health services. If a face-to-face encounter was performed at the start of home health services, or to support the order for medical equipment, a new face-to-face encounter is not required if the source of payment has changed to Medicaid. Therefore, if a dually eligible individual begins home health services under Medicare and transitions to Medicaid, the Medicare face-to-face encounter documentation will meet the Medicaid face-to-face requirement. Our expectation is that Medicaid providers are aware that there is no homebound requirement to be eligible for Medicaid home health services. Dually-eligible individuals not meeting Medicare's homebound criteria would not be eligible for Medicare home health, but could still be eligible for Medicaid home health, assuming medical necessity criteria are met. In these cases, the beneficiary's physician or authorized NPP would conduct and document the face-to-face encounter, and Medicaid home health reimbursement would be appropriate.

Comment: Some commenters encouraged CMS to provide states with flexibility to extend the permissible period for the Medicaid beneficiary to secure the required encounter after the

start of care because of the unique problems often facing Medicaid beneficiaries in accessing a physician. This can be done by extending the allowable timeframe for compliance or permitting states to apply an exception process. Commenters recommended that CMS revise the proposal and specifically provide for exceptions, or provide direct authority to the states to do so. Some suggestions for exceptions included: (1) Medical contraindications to the beneficiary leaving his or her home to see a physician/NPP; (2) the beneficiary resides in a frontier area; (3) the beneficiary resides in an area designated as medically-underserved by the state; (4) the beneficiary was discharged from an inpatient setting directly into home health services; (5) the home health agency is not at fault in the failure to meet the face-to-face requirement and noncompliance is beyond the control of the agency; (6) the beneficiary enters the hospital before the encounter; or (7) the beneficiary is referred to home health from a school nurse or elder service networks.

Another commenter urged CMS to give specific guidance to states maximizing the flexibility in timing of face-to-face encounters, allowing the timeline to be extended, and allowing states to provide a good cause exceptions process in cases where beneficiaries have not been able to meet this requirement. One commenter viewed good cause exemptions as extremely important and urged that they be put in place immediately. Such good cause exemptions might include, but not be limited to, situations where the state or federal government declares a state of emergency such as a natural disaster or terrorist attack. In such a circumstance, lack of electricity, phones and equipment, and navigable roads might delay the achievement of a face-to-face encounter for more than 30 days. Another commenter indicated that there needs to be more flexibility in the timeframes after the start of care.

Response: We appreciate the comments, but do not believe revising the regulation to build in exceptions to the timeframes is necessary. We believe that the proposed timeframes will provide states, providers, and beneficiaries with the necessary flexibility to meet the face-to-face requirement. On an individual basis, circumstances beyond control (natural disaster, terrorist attack, etc.) would be taken into account if the timeframes for a face-to-face encounter for home health services were not met.

Comment: One commenter requested adding some special circumstances that allow for payment to the home care agency for efforts made to get the face-to-face documentation completed and/or get the beneficiary to seek the encounter appointment, but circumstances outside the control of the agency occur and the encounter is not completed. Another commenter stated that there needs to be flexibility in those situations where a Medicaid beneficiary is accepted for care in good faith that a face-to-face requirement will be met by the close of the qualifying period yet circumstances beyond provider control occur that result in failure to comply with this requirement on a timely basis. One commenter requested that the final rule provide good-cause exceptions in cases where beneficiaries have not been able to meet this requirement despite the best efforts of the agency seeking to serve them. Another commenter believed there needs to be clearer discussion of a hold harmless provision that would allow temporary services to be put into place pending the face-to-face encounter.

Response: We disagree that there is a need to add circumstances or situations that allow for payment to home care agencies based on unsuccessful efforts made to timely obtain the necessary face-to-face documentation, or to otherwise allow for good-cause exceptions. The timeframes provided allow enough flexibility to meet the face-to-face requirement in a timely manner. We encourage home health agencies to document efforts to facilitate face-to-face encounters before home health services are furnished, and to collaborate with physicians to ensure timely completion of encounter documentation.

Comment: One commenter stated that in certain circumstances, it should suffice that the personal physician's original diagnosis of the condition for which the individual needs home health services was based on a face-to-face encounter, irrespective of when the face-to-face encounter took place.

Response: The statute requires that a face-to-face encounter must occur within prescribed timeframes in relation to the ordering of home health services. Therefore, it is beyond our authority to allow an encounter that took place outside of those timeframes to suffice.

Comment: One commenter recommended a more flexible approach for states and health plans to follow in verifying the need for home health services.

Response: We believe that the rule provides states and health plans with flexibility while adhering to the statutory requirements.

Comment: One commenter indicated that clarification is necessary regarding the face-to-face encounter in reference to the ''start of services'' and ''initiation of services,'' because home health services can be intermittent, even though the services relate to the same episode. The commenter recommended that the face-to-face encounter for a service or item can relate back to an encounter with the primary care provider that occurred outside the 6-month timeframe, if the service or item relates to the same episode of care that occurred within the 6-month timeframe.

Response: To clarify, we are aligning Medicaid face-to-face requirements with Medicare's face-to-face requirements. A face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. However, as previously stated, this rule does not replace current regulatory requirements, and therefore, the physician should be reviewing the plan of care for home health services every 60 days.

Comment: One commenter questioned what CMS's guidance would be on the face-to-face documentation when the medical condition of the beneficiary changes before recertification. The primary reason for ordering home health will be different than what was indicated on the initial certification of the face-to-face encounter. The commenter further questioned if another face-to-face would be required to continue home health based upon the change in the individual's condition. The commenter also asked what the penalty is if the beneficiary is not able to see the physician within the 30 days after the start of care. Another commenter questioned whether long-term beneficiaries that receive certified nursing assistant (CNA) visits need a face-to-face encounter, and if so, whether it would be a one-time requirement or have to be renewed.

Response: A face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. and must be related to the primary reason the patient requires home health services. If an individual's medical condition changes and this results in the need for an additional home health service, our expectation is that the Home Health Agency would communicate the need with the ordering physician who would revised the plan of care/orders accordingly. An additional face-to-face encounter would not be required. In response to the issue regarding a penalty if the beneficiary is not able to see the physician within the 30 days after the start of care, we clarify that no payment

for home health services can be made for which a timely face-to-face encounter was not documented. However, we believe that the flexibility included in the regulations, allowing NPPs in addition to physicians to perform the face-to-face encounter, as well as allowing the use of telehealth, should prevent the scenario from happening in a majority of cases. The timeframes established in this final rule meet the program integrity and quality goals associated with the provision. In response to the question about CNA visits, all beneficiaries needing home health services are subject to the face-to-face requirement.

Comment: One commenter requested clarification of the effective date for the face-to-face requirement for certification for Medicaid home health and DME.

Response: The statutory provision became effective upon enactment on March 23, 2010, but for home health the statute indicated that the face-to-face requirements applied to physician certifications after January 1, 2010. The provisions specific to this regulation are applicable prospectively starting on the effective date. We intend to work with states and the provider community to ensure compliance. As previously indicated, we are delaying the effective date to July 1, 2016 and compliance with the rule for up to one year if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule based on the timeframes explained above.

Comment: Commenters requested that CMS clarify the circumstances where it is acceptable to perform the face-to-face encounter within 30 days after the start of home health services. One commenter requested clarification regarding the definition or description of circumstances precluding a face-to-face visit within the 90 days prior to the start of home health services. One commenter recommended that CMS clarify that the ''under normal circumstances'' standard reflects permission to allow a state flexibility to extend the encounter timetable, but not make it more restrictive. Alternatively, the commenter suggested that the phrase should be removed to avoid the imposition of stricter timetable standards. Another commenter requested that we not use the wording ''under normal circumstances,'' as unless this term is defined, it can lead to different and varied interpretations and confusion and could possibly allow states to impose a strict guideline on allowing the encounter within 30 days after the start of care.

Response: We do not agree that it is necessary to be prescriptive in defining ''under normal circumstances'' or the circumstances in which it is acceptable to perform the face-to-face encounter within 30 days after the start of home health services. Allowing flexibility in these terms is in the best interest of the beneficiaries. There could never be an exhaustive list of circumstances or parameters defining the term, and while we encourage face-to-face encounters to occur before the start of care, we do not want to unnecessarily restrict the ability of the encounter to occur within 30 days after.

Comment: A few commenters requested that CMS clarify whether the face-to-face encounter is only required for the initial visit or for recertification as well. Another commenter asked whether the rule would also identify recertification timelines such as an annual face-to-face thereafter and whether the physician would be required to see the beneficiary to reevaluate the need for care after 6 months or the proposed 90 day face-to-face encounter timeline. One commenter indicated that the requirement that the face-to-face encounters be related to the primary reason the beneficiary requires home health services will result in additional office visits. The requirement would seem to not consider beneficiaries with chronic conditions, as persons with chronic, even lifelong conditions would not need such regular monitoring for some home health services. One commenter requested clarification regarding whether or not the proposed face-to-face visits will be a billable item for providers. Another commenter requested that CMS clarify or amend the definition of home health services such that this rule would not be applicable to non-medical services such as personal care attendant services.

Response: As previously stated, the face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. There is no recertification face-to-face requirement. This final rule has not changed current Medicaid regulations which require an individual's physician to review the individual's plan of care every 60 days. In response to the commenter's question regarding billing for the face-to-face encounter, the encounter will be a billable item for providers, under the Medicaid physician benefit or the benefit authorizing payment for services provided by licensed practitioners. Amending or clarifying the definition of home health services in this rule is beyond our authority.

Comment: One commenter requested additional clarification to address differences between Medicare and Medicaid regarding ''episode of care.'' The commenter indicated that many states use systems other than Prospective Payment Systems (PPS) and stated that in these cases, additional guidance on the frequency of face-to-face encounters may be warranted.

Response: Regardless of the payment methodology system used by states, as indicated in the response above, the face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment.

Comment: One commenter indicated that their current state Medicaid rules require parents to supplement care up to 8 hours in addition to the approved direct services hours and questioned whether the proposed rule would revise the parent supplementation of care requirement.

Response: The Medicaid program, rather than the beneficiary or the beneficiary's family, is responsible for the provision of medical assistance for covered benefits. Although a state can take into account available resources in determining the amount of medical assistance required by the beneficiary, including any legal liability of third parties to provide care, it cannot impose requirements for parents to provide care as a condition of a child receiving Medicaid benefits. Nor can a state impose an in-kind deductible charge (requiring the provision of a certain amount of services as a condition for coverage of other services. The face-to-face encounter requirement does not change these requirements.

Comment: Some commenters requested clarification pertaining to managed care plans. One commenter requested that CMS clarify that the Medicaid face-to-face requirements for home health services required under the proposed regulations apply only for home health services provided through fee-for-service, and not to home health services provided under a Medicaid managed care plan. Another commenter requested clarification on how this rule would apply when members are enrolled in Medicaid managed care plans and the responsibility of plans to report physician encounters to the state.

Response: To clarify, at a minimum, benefits offered in managed care must be the same as the benefits offered in the state plan. Therefore, the approved state plan home health benefit must be offered in managed care. States must

follow statutory and regulatory requirements related to the benefits.

Comment: Commenters were concerned that the face-to-face encounter requirement will erect a barrier to timely care for individuals who are homebound and have difficulty traveling to a provider. Another commenter wanted to ensure that the face-to-face visit requirements do not impede access to necessary home health care.

Response: We recognize that some individuals may have difficulty meeting the face-to-face requirement. We believe we have accounted for these circumstances while meeting statutory requirements, by extending the timeframe of the face-to-face encounter to 30 days after the start of home health services, by allowing for NPPs to complete the face-to-face encounter, and by encouraging telehealth as an alternative for ensuring that this new requirement is implemented in a way that protects continuity of services. Additionally, as previously stated, the face-to-face encounter is required for the initial ordering of a home health service and for all episodes initiated with the completion of a Start-of-Care OASIS assessment.

Comment: One commenter recommended that CMS create a standard that establishes eligibility for Medicaid coverage of home health services 30 days prior to the face-to-face encounter.

Response: Home health services may be covered by Medicaid for up to 30 days before the face-to-face encounter is conducted; but such services are not covered if the required face-to-face encounter is not conducted within those 30 days. Furthermore such services are not covered in the absence of a physician order for the services, or a written plan of care. Medicaid payment is not available if these conditions are not met.

Comment: One commenter urged CMS to provide guidance to health professionals who order such care and providers who deliver the care to encourage them to include their mutually shared beneficiary in the process of creating the service order and care plan. The commenter also urged implementation that reasonably encourages a robust three-way dialogue among the beneficiary, the ordering health care professional and the service provider to promote person-centered and efficient care driven by the needs and preferences of the beneficiary.

Response: We agree with the commenter. It is our expectation that services are provided to individuals in a person-centered manner and that all providers work collaboratively to ensure that services are meeting the needs of the beneficiaries.

After consideration of the public comments, we are revising this section to clarify that for the initial ordering of Medicaid medical equipment, the physician must document that a face-to-face encounter that is related to the primary reason the beneficiary requires medical equipment occurred no more than 6 months prior to the start of services. Additionally, we are clarifying that a face-to-face encounter is required for initial ordering of both home health services and medical equipment. Furthermore, for home health services, a face-to-face encounter is required for the initial order and for all episodes initiated with the completion of a Start-of-Care OASIS assessment. We have also delayed compliance with the rule for up to one year if the state's legislature has met in that year, otherwise 2 years. Our expectation is that states and providers are compliant with the requirements of the final rule based on the timeframes explained above.

F. Practitioners (§ 440.70(f)(2))

The statute describes NPPs who may perform this face-to-face encounter as an NP or CNS, 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 PA (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 reasoning outlined in the Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012; Final Rule (76 FR 68525), for beneficiaries admitted to home health upon discharge from a hospital or post-acute setting, we proposed to also allow the physician who attended to the beneficiary in the hospital or post-acute setting to inform the ordering physician regarding their encounters with the beneficiary to satisfy the face-to-face encounter requirement, much like an NPP. We proposed to add a new § 440.70(f)(2) to list the practitioners that may perform the face-to-face encounters.

Comment: Some commenters supported this interpretation of the face-to-face encounter requirement.

Response: We appreciate the support of the commenters.

Comment: Several commenters requested clarification on the guidelines for patients having a face-to-face encounter from a physician in another state. One commenter requested that CMS clarify whether a state may, through a state plan amendment, choose to limit the performance of the face-to-face encounter to a subset of the allowed NPPs. Many commenters requested that the rule clarify whether the Medicaid face-to-face must be performed by a physician, and also if that physician must be registered in the CMS PECOS or any other system. If so, the physician community should be alerted, instructed and registrations confirmed well before the rule goes into effect.

Response: Many states have reciprocity agreements with neighboring states, which allow Medicaid beneficiaries in one state to receive services in another state. Section 431.52 provides the federal requirements for payment for services furnished out of state. If the beneficiary has a face-to-face encounter with a physician in a neighboring state that has a reciprocity agreement, then this would be allowed. If a physician practices in a different state that does not have a reciprocity agreement, the physician would need to be a qualified Medicaid provider in the state in which the beneficiary resides. States cannot choose to limit the NPPs approved to complete the face-to-face encounter, as the practitioners are mandated through statute. We are also clarifying that the face-to-face encounter does not need to be conducted by a physician. Per the regulations, any physician would need to be qualified to furnish physician services. It should be noted that for dually-eligible individuals, the Medicare program will likely reimburse for the encounter itself, whether conducted by a physician or NPP. Therefore, the practitioners would need to adhere to Medicare provider qualifications.

Comment: One commenter stated that for beneficiaries participating in section 1115 demonstrations or section 1915(c) HCBS waivers requiring an encounter by a physician or one by the proposed list of NPPs, it may be problematic for benefits such as non-skilled home health, DME, and supplies. Physicians may not always be able to visit beneficiaries in the settings where the benefit determinations are made (for example, assisted living, nursing homes, and other residential care settings). The commenter also stated that the assumption under this proposed rule is that a physician would be the health care professional who orders home health services. However, for non-medical in-home services such as

personal care, the healthcare professional ordering the service is often not a physician.

Response: Section 6407 of the Affordable Care Act has changed the requirements for a person to receive Medicaid home health services. As a condition of receiving covered home health services, a physician or NPP must conduct a face-to-face encounter, and the home health services must be ordered by a physician. These requirements are applicable regardless of where a person lives. Usually people who reside in assisted living facilities and residential care settings are still responsible for arranging for and attending their own doctor's visits. Although dependent upon state licensing standards, assisted living facilities and residential care settings are not likely to have physicians on staff. Physicians are available by arrangement to people who reside in nursing homes if the person does not have a physician in the community. The physicians could conduct the face-to-face encounter and order the home health service on behalf of the person who lives in the nursing home but is transitioning to a setting that comports with § 440.70(c)(1). We clarify that personal care services are outside the scope of this regulation and are not subject to the face-to-face requirements. Any component of home health services would need to be authorized in accordance with the requirements.

Comment: One commenter reported that NPs and PAs can be primary care providers in some states for Medicaid.

Response: Although NPs and PAs may be primary care providers in some states, the law requires the certifying physician to document that the physician or an allowed NPP has had a face-to-face encounter with the beneficiary.

Comment: Many commenters recommended that CMS establish standards to permit physician residents to meet the face-to-face requirements for Medicaid beneficiaries, permit Medicare enrolled physicians to perform the face-to-face for dual eligible beneficiaries, and permit physicians with limited Medicaid and/or Medicare beneficiaries, including federally-employed physicians to utilize an abbreviated enrollment process.

Response: Physician residents would be permitted to perform the face-to-face encounter as long as state law in which the resident is practicing recognizes residents as physicians. We would defer to states to make this determination. We recognize the potential issues surrounding dually-eligible individuals and the face-to-face requirement. To clarify, if a Medicare enrolled physician has completed the face-to-face requirement for a dually-eligible individual, an additional face-to-face requirement would not be needed by a Medicaid enrolled physician, should the benefit change to Medicaid services, as long as there was no new start of care. However, if a new face-to-face encounter is needed under Medicaid, the physician must be Medicaid-enrolled. This rule does not change any requirements of the laws surrounding the provider enrollment process.

Comment: Many commenters suggested allowing any physician to conduct a face-to-face encounter and certify eligibility for home health services, regardless of whether that physician or another physician is responsible for the plan of care.

Response: Any physician enrolled as a Medicaid provider (or in the case of a beneficiary dually eligible for Medicare and Medicaid, enrolled in the Medicare program) can perform the face-to-face encounter and order home health services, provided they also develop the written plan of care in accordance with § 440.70.

Comment: One commenter recommended that CMS clarify that the ordering/prescribing physician who completes the plan of care also be allowed to rely on the in-person assessment of an emergency department physician or of a physician working on behalf of an inpatient rehab or skilled nursing facility prior to the beneficiary's discharge.

Response: To clarify, the commenter's understanding is accurate.

Comment: Commenters suggested allowing any physician to work with another physician colleague sharing the face-to-face encounter and documentation responsibilities along with the certification authority.

Response: We see no reason to prohibit this arrangement.

Comment: Commenters suggested that audiologists and podiatrists be permitted to conduct the face-to-face encounter and then communicate the information to the physician who is responsible for documenting the face-to-face encounter.

Response: This is beyond our authority as statute did not include audiologists and podiatrists as NPPs.

Comment: One commenter stated that it is imperative that the Medicaid home health face-to-face encounter requirements mirror those of the Medicare program in allowing PAs to personally perform the face-to-face visits.

Response: Under the supervision of the physician, PAs are authorized to perform the face-to-face encounter for Medicaid home health.

Comment: One commenter proposed that the regulation specifically state that home care and DME providers can contract with physicians (for example, medical directors) or NPP/physician collaborating teams to complete the necessary face-to-face visits in the patient's home. The home health agency or DME provider should be permitted to compensate time associated with such visits in a manner that would allow the physician or NPP to earn hourly compensation consistent with community standards.

Response: Such an arrangement would need to include a physician who would continue to oversee the provision of home health services in accordance with the written plan of care, as specified in § 440.70.

Comment: Some commenters recommended increasing the role of advanced practice nursing in the ordering of home health services. One commenter also suggested allowing a wider range of practitioners to certify home health care (for example, nurses in advanced practice). One commenter suggested allowing states to determine whether physicians need to order home care and endorse the performance of a face-to-face encounter.

Response: Section 6407 of the Affordable Care Act requires the ordering physician to document that the physician or an allowed NPP has had a face-to-face encounter with the patient. However, the Medicare Access and CHIP Reauthorization Act of 2015 allows for certain authorized NPPs to document the face-to-face encounter for medical equipment. We are using this final rule to conform with this change to statute. With regard to the ordering of services, a change in the statute and current regulatory requirements would be required to allow an NPP to order home health services.

Upon consideration of the public comments received, we are revising this section to clarify that any physician, including the physician who attended to the beneficiary in the hospital or post-acute setting may serve as the ordering physician for home health services provided that, in accordance with § 440.70, the ordering physician also completes the written plan of care.

G. NPP Communication to Ordering Physician (§ 440.70(f)(3))

We proposed to add § 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 NPP is required to communicate the

clinical findings of the face-to-face encounter to the physician, for the physician to document the face-to-face encounter accordingly. We indicated that 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 proposed to specify that the clinical findings must be reflected in a written or electronic document included in the beneficiary's medical record (whether by the physician or by the NPP).

Comment: Many commenters requested additional information regarding communication. Several commenters suggested that the rule should clarify if there are any limits on what would constitute ''communication'' under the Medicaid rule with regards to moving information from the face-to-face physician to the ordering physician. Commenters wondered whether such communications would include fax, phone, voice, text, etc., and recommended the broadest definition of communication to help assure access for the Medicaid population. One commenter asked for CMS to clarify what type of communication would be expected to occur between the NPP conducting the face-to-face visit and the ordering physician who is documenting the face-to-face encounter. One commenter requested that CMS elaborate or further define what constitutes communication between the inpatient physician/hospitalist and community physician. The commenter inquired whether communication necessarily meant a verbal conversation or could it also include receipt or access to the beneficiary's discharge summary from the hospital. One commenter indicated that the regulation does not specify what documentation is to be sent to the ordering physician or specify what documentation the home health agency must secure.

Response: We are not prescribing at the federal level what constitutes communication, rather we simply require that the clinical findings of the face-to-face encounter must be communicated to the ordering physician. This information can be included in clinical and progress notes and discharge summaries.

Comment: One commenter advocated for reducing documentation requirements. The commenter believes it is critical that any additional changes made to the Medicare rule are also made at the Medicaid level. One commenter suggested that CMS consider very clear documentation requirements for when a hospitalist would complete a face-to-face document and report off to the ordering physician who would sign the orders. Another commenter supported that the proposed rule gives states flexibility on the content and form of documentation for the Medicaid face-to-face. The commenter stated that the proposed rule allows states to continue to use their existing form or improve their forms to reflect the face-to-face encounter and that this approach reduces confusion.

Response: Our philosophy is to align face-to-face requirements across the two programs to the extent feasible and practical. In response to the commenter who requested clear documentation requirements for a hospitalist completed face-to-face encounter, as indicated above, our rule permits states considerable flexibility to allow this information to be included in clinical and progress notes and discharge summaries. We appreciate the support of the last commenter.

Comment: One commenter believes that the statement ''this enhanced communication will result in an improved transition of care from the hospital or post-acute setting to the home health setting'' is not true. In fact it has decreased the effectiveness of discharge planning and cost home health agencies a great deal of time tracking down the forms.

Response: The intent of this provision was not to delay transitions from hospitals to community settings. We recognize the importance of smooth transitions that do not negatively impact individuals. As previously stated, we are clarifying in the final rule, that in accordance with § 440.70, home health services must be ordered by the individual's physician. We encourage all parties to collaborate in ensuring timely transitions to community care, including home health services.

Comment: One commenter stated that the proposal requiring the (inpatient) physician to communicate the clinical findings of the face-to-face to the (community) physician is not clear. The commenter asked whether CMS was now precluding the facility physician from documenting the face-to-face encounter and certifying the beneficiary. Additionally, the commenter stated that the proposal requires the findings be communicated to the physician and be in the beneficiary's medical record and asked how this documentation will be assured.

Response: As previously stated, we are finalizing this rule to indicate that any physician can order home health services, provided that the ordering physician also establishes the written plan of care in accordance with § 440.70. Additionally, the ordering physician must document that the face-to-face encounter requirements were met regardless of whether the physician performed the face-to-face encounter himself or herself. It is the physician's responsibility as a provider to ensure that the appropriate medical records are kept. Additionally, the home health agency should maintain a copy of the face-to-face documentation.

Comment: One commenter urged CMS to clarify this provision to clearly state that a NP may conduct the face-to-face evaluation and provide written or electronic documentation that will meet the requirements of both communicating the clinical findings to the physician and including them in the beneficiary's medical record.

Response: We confirm that the commenter's understanding is correct.

Comment: Some commenters requested clarification pertaining to physicians in the hospital setting and the face-to-face requirement. One commenter requested that CMS clarify that it will still be acceptable for an inpatient physician or hospitalist to initiate the plan of care for home health services, conduct the face-to-face encounter, complete and sign the face-to-face form (or support personnel completes the form based upon the physician's documentation in the medical record and then the inpatient physician or hospitalist signs it) and upon the beneficiary's discharge, the community physician develops and signs the plan of care and oversees beneficiary care. Another commenter questioned why a hospital-employed physician cannot complete a face-to-face document on a home health beneficiary.

Response: To clarify, the inpatient physician or hospitalist may also serve as the ordering physician and establish the plan of care. If this is the case, then the community physician's role in the commenter's scenario would be removed. A hospital-employed physician can also complete the face-to-face documentation for a home health beneficiary. Additionally, as previously stated, we are clarifying that the hospital-employed physician may also order home health services in accordance with the written plan of care.

Comment: One commenter stated that § 440.70(f)(3)(v), which stated ''those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record,'' lacks clarity. The commenter stated that normally, documentation of clinical findings would be carried out by the NPP or inpatient physician in his

or her own patient medical record, then applicable information extracted and transmitted to the ordering physician to incorporate into his or her own medical record, followed by extraction of the information required at § 440.70(f)(5)(i) into a document that is sent to the home health agency for its medical record.

Response: We agree with the process outlined in this scenario and believe that the regulatory requirements support this process.

Comment: One commenter reported that the inpatient physician refuses to provide the necessary information to document a face-to-face encounter to an ordering physician frequently, necessitating another face-to-face encounter once the beneficiary returns to the community.

Response: We are establishing a process that meets statutory requirements and aligns with Medicare requirements. Issues of physician cooperation are beyond the scope of this regulation, and would be better raised on an individual, institutional, or state level. While we agree that care should be provided in the most effective and efficient manner, this rule does not mandate specific roles for treating physicians.

Comment: One commenter suggested removing the documentation requirements for beneficiaries who have been in the hospital and instead require a statement from the inpatient or post-acute physician that the beneficiary had the encounter. Another commenter questioned why CMS is requiring the face-to-face encounter at all, since the hospital attending physician obviously saw the beneficiary 90 days prior to the start of care.

Response: We thank the commenters for their suggestions. However, there is a value to the statutorily required documentation of a specific face-to-face encounter that informed the physician ordering the home health or DME service. We do not think a blanket exception for hospital discharges would ensure that the ordering physician was informed by a face-to-face encounter.

Comment: One commenter recommended that the regulation clarify that it is permissible for the home care or DME provider to obtain the documentation of a recent face-to-face visit in acute or post-acute care and to make that documentation available upon request by the ordering physician, rather than require that the acute or post-acute physician routinely communicate directly to the ordering physician.

Response: We believe that it is essential that the practitioner who completed the face-to-face encounter communicate the clinical findings to the ordering physician to ensure that the physician has sufficient information to understand the need for home health services in the absence of conducting the face-to-face encounter himself or herself. As indicated above, we are not prescribing the communication at a federal level. This information can be included in clinical and progress notes and discharge summaries. To permit otherwise would not only violate the statute, it would facilitate disconnect between beneficiary health status and ordering of home health services.

Comment: One commenter indicated that the rule regarding communication of the clinical findings of the encounter to an ordering physician, should not apply to Medicaid unless there is a physician involved in the beneficiary's care.

Response: Current regulations at § 440.70(a)(2) require an individual's physician to order home health services as part of a written plan of care reviewed every 60 days. Therefore, the expectation is that there is always a physician involved in the beneficiary's care as a physician is required to order home health services.

Comment: Some commenters stated that NPPs should also be allowed to certify the need for home health services.

Response: The statute sets forth the requirement that only a physician is authorized to order the need for home health services. It is beyond our statutory authority to expand the role of NPPs.

Comment: One commenter stated that the proposed policy implies that NPs are somehow incapable of authorizing the ordering of appropriate home health services. The commenter indicated that states should have the flexibility to allow NPs to order home health services as well as conducting the face-to-face encounter.

Response: We disagree that this proposed policy implies that NPs are incapable of authorizing the ordering of appropriate home health services. Furthermore, the proposed rule does not replace the existing regulatory language requiring that a physician order home health services. We believe that the statute recognizes the role of NPs working in collaboration with the physician by including NPs as NPPs authorized to complete the face-to-face encounter. The statute requires that physicians order (certify) home health services.

Comment: One commenter suggested that if a physician extender performs the encounter, such as an NP or PA, the extenders should be permitted to document on the face-to-face encounter form itself, sign and date, followed by a separate physician face-to-face form review, signature and date section. The commenter also suggested that reference to attached documentation showing that an encounter within the 90 day time period occurred (such as an office note), should be permitted.

Response: As indicated above, we are not prescribing at the federal level the communication procedures, rather the requirement that the clinical findings of the face-to-face encounter are communicated to the ordering physician. This information can be included in clinical and progress notes and discharge summaries. There is no federal prohibition on a NPP documenting the face-to-face encounter and having the physician sign the documentation.

Comment: Commenters stated that CMS should clarify that inpatient physicians retain the authority to perform both the face-to-face encounter and complete the documentation and certification for the beneficiary's plan of care.

Response: We agree with the commenters and are revising the final rule to clarify that inpatient physicians may perform the face-to-face encounter, complete the documentation, and order home health services as documented in a written plan of care.

Comment: One commenter suggested that there should be one universal form for everyone.

Response: To provide states flexibility in administering and managing their Medicaid programs, we are not mandating utilization of a common form in the documentation of Medicaid services. However, there is no prohibition on states agreeing to utilize a common form to facilitate standardization.

Comment: One commenter supported a collaborative relationship between a physician and NPP.

Response: We agree with the commenter.

Comment: Some commenters expressed concern regarding the scope of providers that may order medical supplies, equipment, and appliances in the Medicaid program. One commenter believed that home health agencies should be permitted to include medical supplies in Medicaid beneficiaries' plan of care and be separately paid for those medical supplies. Another commenter stated that they believe increasing the role of advanced practice nursing would make a valuable contribution to the ordering of all service modalities under both Medicare and Medicaid.

Response: There is no prohibition on home health agencies being reimbursed for medical supplies, equipment, and appliances provided to a Medicaid beneficiary. They are part of the home health benefit, and can be included in a plan of care when ordered by a physician, as required in § 440.70. We agree with the value added to the provision of health care by advanced practice nurses; their role in the ordering of services depends on the benefit authority being utilized. In the provision of home health services, services must be ordered by a physician.

After consideration of the public comments and to align with Medicare's requirements we are finalizing this section with clarifications. Specifically, we are clarifying that we are not prescribing the communication between the NPP who performed the face-to-face encounter and the physician, rather the requirement that the clinical findings of the face-to-face encounter are communicated to the ordering physician. This information can be included in clinical and progress notes and discharge summaries. Additionally, we have clarified that attending acute or post-acute physicians may serve as the ordering physician of home health services.

H. Physician Documentation of the Face-to-Face Encounter (§ 440.70(f)(4))

In § 440.70(f)(5)(i), we proposed 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 beneficiary's medical record. The documentation must also describe how the health status of the beneficiary at the time of the face-to-face encounter is related to the primary reason the beneficiary requires home health services. In § 440.70(f)(5)(ii), we proposed 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 beneficiary and include the date of that encounter.

Comment: One commenter appreciated the modifications to the documentation rules and the clarification regarding the ''homebound'' requirement.

Response: We appreciate the commenter's support.

Comment: We received many comments pertaining to documentation requirements. One commenter suggested limiting documentation of a face-to-face encounter to a statement that services are medically necessary, the date of the encounter, the statement that the primary reason for home health services was addressed during the encounter, physician's signature and date. Another commenter suggested limiting documentation of a face-to-face encounter to a physician, NPP, or physician resident signature and date, and the date of the encounter. One commenter suggested that the face-to-face encounter be documented through a check box on the plan of care rather than a separate document. One commenter stated that documentation of any face-to-face encounter needs to be flexible enough to permit the physician or a physician designee to complete the form, prior to the physician review and signature. One commenter advocated for reducing documentation requirements. The commenter stated that it is critical that any additional changes made to the Medicare rule are also made at the Medicaid level. One commenter suggested that the documentation be limited to a few basic fields: The identity of the physician or NPP who performed the encounter; confirmation that the clinical findings support the need for home health care; the date of the encounter; and if documentation is by a different physician, the name of the physician who sent the documentation. One commenter suggested that a more broad certification requirement stating that the physician has personally reviewed the examination and certifies the need for home health care would be a more appropriate and effective use of the physician's time and efforts. One commenter believed that the requirement is simply duplicating documentation already on the plan of care where the physician is certifying the need for skilled care, the services needed, and the diagnoses supporting the need.

Response: To clarify, we are revising the proposed documentation requirements to remove the requirement that the documentation 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 beneficiary's medical record and specify what is required which is described in § 440.70(f)(5)(i) and (ii). We are not proscribing a specific method of capturing the requirements. The documentation should support the need for what was ordered. We defer to states for details; we do not see any federal barriers to making the documentation requirements administratively simple.

Comment: One commenter stated that leaving the discretion to state Medicaid programs to determine what constitutes appropriate documentation flies in the face of the desire of attempting to bring greater consistency to regulatory requirements. Another commenter stated that varying standards for documentation will create problems for all. The commenter recommended an effort to create a national standard, with an allowance for states to apply for a waiver. One commenter requested further clarification prohibiting state from requiring additional face-to-face documentation. A few commenters indicated that states should not be permitted to require additional face-to-face documentation. Some commenters urged CMS to rescind guidance that allows states to require information in excess of what is proposed by CMS to document the face-to-face encounter. One commenter stated that CMS should limit, rather than encourage, a state's opportunity to impose additional documentation requirements on home health agencies beyond those already included in the regulation. Some commenters indicated that with regard to the additional flexibility already proposed under the Medicaid face-to-face regulation, such as the opportunity for states to limit the face-to-face documentation requirements, they certainly support and would encourage CMS in the final rule to maximize the flexibility given to the states to be more accommodating in their own interpretation of the Medicaid face-to-face rule.

Response: As indicated above, we are revising the proposed documentation requirements as described in § 440.70(f)(5)(i) and (ii). From the federal perspective, our goal is to ensure that required documentation by the state is sufficient to make the linkage between the individual's health conditions, the services ordered, an appropriate face-to-face encounter, and actual service provision. We encourage documentation requirements established by states to meet this goal, while not imposing additional actual or perceived administrative burden. Electronic Health Records may be of use to support the operational requirements and provide a clear audit trail.

Comment: One commenter believed that the ordering physician should be able to rely on the discharge summary identifying a beneficiary's need.

Response: As stated in the proposed rule, we believe that it is necessary that clinical findings of the face-to-face encounter are communicated to the

ordering physician 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 not proscribing the acceptable form of communication to meet this requirement.

Comment: One commenter indicated that residents, NPs, and Pas should not only be allowed to perform the face-to-face encounter but complete the necessary documentation. Another commenter encouraged CMS to honor the laws of states that permit advanced practice registered nurses (APRNs) to manage beneficiaries independently and allow APRNs not only to conduct the face-to-face visit, but to document that they have done so. Another commenter stated that PAs and other NPPs authorized to personally perform the face-to-face encounter should be able to document the results of the exam in the patient's medical record.

Response: As previously indicated, effective April 16, 2015, for medical equipment, certain authorized NPPs are authorized to document the face-to-face encounter. For home health services, residents, NPs, and PAs, as NPPs defined in statute can complete the necessary face-to-face documentation, but the physician must sign off as the practitioner responsible for ordering home health services.

Comment: Many commenters indicated that the rule should limit the documentation required, and specify where the record of the Medicaid face-to-face encounter must be maintained or if there is a requirement in that regard. One commenter stated that CMS should revise the physician documentation requirements regarding the face-to-face encounter to reduce the paperwork burden on physicians. This approach would allow the use of the model Physician Certification and Plan of Care form with a modification of the form's certification language to include certification of the encounter date and reason related to the need for home health care. The commenter also stated that physicians, hospitals, discharge planners, home health agencies, and beneficiary groups agree that the physician requirements are a barrier to access to home health care for bona fide beneficiaries who meet coverage standards. Additionally, the commenter stated that CMS has unnecessarily expanded the scope of the required documentation. The additional documentation is not needed because the physician is already required to compose a detailed plan of treatment that sets out the patient's clinical condition and prescribed care. One commenter stated that proposed changes help to ease the burden by a small amount; however, it still creates redundant and unnecessary paperwork by requiring a certifying physician to restate the findings of the hospitalist and/or discharging physician. The commenter stated that do not understand how adding a second layer of physician review serves the purpose of CMS or the needs of beneficiaries. One commenter believed that this requirement will negatively impact access and serve as a barrier to care because of the additional administrative burden to physicians filling out the face-to-face form. Another commenter stated that many doctors are stating that they do not like the additional documentation requirements. One commenter indicated that physicians have been hostile to the new requirement, particularly the documentation standards. The face-to-face-encounters and documentation create unnecessary roadblocks to care. Another commenter reported that physician compliance with the documentation requirements has been ''horrific.'' One commenter stated that face-to-face documentation itself is viewed as an additional burden by physicians. Some commenters stated that CMS must guard against an increase in resistance and opposition from community physicians who may view the new rule as shifting documentation burdens from one physician sector to another.

Response: We agree with the goal of assuring the program requirements are not overly burdensome. In general, the documentation requirements and specifically the provision that the community physician retain documentation that describes how the beneficiary's health status warranted the ordering of home health services is consistent with current standard practice of care. However, we recognize that requiring a certifying physician to restate the findings of the hospitalist and/or discharging physician could create an additional burden. As previously stated, we are revising the final rule to allow any attending physician to order home health services, therefore, reducing the documentation requirements between inpatient physician and community physician as indicated in the proposed rule.

Comment: A few commenters requested better clarification of the requirement that the documentation of the face-to-face encounter be separated from the order. Specifically, the commenters requested that the regulation explicitly state that a copy of the face-to-face encounter documentation which contains required elements be considered valid documentation.

Response: Based on comments we are removing the requirement that the face-to-face documentation be on a separate and distinct area on the written order. In response to the commenters' second request that a copy of the face-to-face encounter documentation be considered valid documentation, it is not clear exactly what is intended. The documentation of the face-to-face encounter is not necessarily sufficient to document the physician order for home health services, which should be part of the plan of care. But if the question is whether a state would require an original or a copy, while we generally defer to states on the operational details, we expect that the documentation will generally be included in an individual's electronic health records.

Comment: One commenter stated that CMS should refrain from requiring physicians to document a face-to-face visit using specific language or by including specific criteria; record of the visit should be sufficient. The commenter also discouraged CMS from requiring detailed descriptions of the beneficiary's needs for the item the doctor orders, as it would be inconsistent with typical physician practices and could result in decreased beneficiary access. Another commenter suggested that CMS remove the requirement that the physician document how the health status relates to the primary reason the individual needs home care. The commenter believed that the clinical findings are sufficient to describe this necessity and that this section adds a documentation burden for the physician when the diagnosis and/or medical condition is already included on the plan of care the physician signs.

Response: Based on comments and Medicare requirements, we are revising the documentation requirements to align them as much as possible with Medicare documentation requirements. Specifically, for home health services, the physician responsible for ordering the services, and for medical equipment, the physician responsible for ordering services or certain authorized NPPs must document that the face-to-face encounter was related to the primary reason the patient requires home health services, occurred within the required timeframes, was performed by an authorized practitioner, and include the date of the encounter.

Comment: One commenter stated that it should suffice that the individual's physician saw the individual, and based on that visit and the physician's and

other health care providers' records of the individuals health diagnoses and needs, the physician ordered home health care. The particular ''primary reason'' for the face-to-face encounter between the individual and the physician should be of no relevance to the validity of the physician's order and plan of care. The commenter believed that with regard to § 440.70(f)(5)(i) it should suffice that documentation is made in a manner that is useful to health care providers and can be explained to state and federal authorities upon request.

Response: It is important to achieving the purposes of the requirement that the face-to-face encounter focus on the medical issues that result in the need for home health services. An encounter that focuses only on unrelated issues will not ensure accountability and utilization control. Therefore, we are retaining the proposed requirement that documentation of the encounter include an explanation of how the individual's observed health status relates to the primary reason the home health services are needed.

Comment: One commenter suggested expanding the physicians who may document this encounter to include partners of the certifying physician or urgent care center physician (for non-acute inpatient settings). If a patient goes to an outpatient clinic and sees an alternate physician, this alternate physician should be allowed to document the encounter and hand off to the primary physician to sign the plan of care. The commenter also stated that the homebound documentation requirement is not clearly addressed. The commenter suggested removing this requirement from both Medicare and Medicaid regulations and requested that CMS add to the rule that if this section is completed by the physician, it is to be disregarded.

Response: To be able to attest to the completion of the face-to-face requirement, an urgent care physician must satisfy the general requirements of § 440.70 in terms of physician development of plan of care and review of the plan of care every 60 days. Otherwise, an additional physician performing the functions must be brought in. We interpret physician to include partners as well. The homebound requirement is an area of disparity between Medicare and Medicaid as the homebound requirement is prohibited by Medicaid. However, this requirement is part of Medicare statute which we cannot waive.

Comment: One commenter expressed that specifying the guidelines for documentation at the federal level provides an opportunity for greater alignment with Medicare requirements.

Response: We agree and as indicated above, we are revising the proposed documentation requirements to align with Medicare requirements.

Comment: One commenter suggested that the face-to-face document be permitted to be completed by physician designees, who should sign and date the form, followed by the physician reviewing, signing, and dating. The commenter also stated that if a physician extender performs the encounter, the extenders should be permitted to document on the face-to-face encounter form itself, sign and date, followed by a separate physician face-to-face form review, signature, and date. One commenter requested clarification regarding whether or not an NPP can write an order and a physician can simply sign the order, rather than writing the order himself or herself.

Response: We are not prescribing who completes the documentation, but the documentation requirements must be met. As previously stated, administrative simplification is supported.

Comment: One commenter indicated that further clarification is needed from CMS on the documentation that is required from the beneficiary's primary physician, when the face-to-face encounter is conducted by NPs or PAs.

Response: The physician documentation requirements are described in § 440.70(f)(5)(i) and (ii). This documentation is required regardless of whether the physician or one of the permitted NPPs performed the face-to-face encounter.

Comment: One commenter requested guidance from the federal government regarding whether or not a physician must approve findings and referrals of NPs in cases where a NP is unable to obtain a physician's documented approval of findings to authorize an order of home health services.

Response: To clarify, we are retaining the requirement under § 440.70(a)(2) that covered Medicaid home health services must be supported by a physician order, as part of a written plan of care, regardless of whether NPs are authorized under state law to order home health services. That order should be based on the physician's own professional judgment after reviewing all available information, which can include the findings of the NP and patient medical records.

Comment: One commenter indicated that the documentation requirements are not found in statute.

Response: In accordance with section 6407 of the Affordable Care Act, the physician's order must document and be based in part on a face-to-face encounter. While it does not specify the form in which the face-to-face encounter must be documented, it clearly requires such documentation.

Comment: Some commenters stated that the person-centered-plan of care process described will add more quality and integrity to the Medicaid services than insisting that physicians add more paperwork.

Response: We agree that the person-centered-plan of care process is integral to ensuring quality Medicaid services are not inconsistent with requirements for physician orders, face-to-face encounters, and a written plan of care.

Comment: One commenter requested that CMS consider further clarification or definition of the person-centered philosophy with regard to the home health plan of care requirements for children and youth under the age of 18. The commenter indicated that their state program does not discuss clients' protected health information, including their medical treatment plans, with non-legal caregivers.

Response: We have not yet issued guidance on person-centered planning as it relates to home health. However, this process should be implemented consistent with other federal requirements that protect confidential health information such as Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Comment: One commenter stated that the need to collect additional documentation could delay urgently needed care and payment for services.

Response: We are confident that providers can determine ways that they can work together without delaying services to beneficiaries.

After consideration of the public comments and to better align with Medicare requirements, this section is being finalized with the following revisions:

- We are revising the documentation requirements to remove the requirement that the documentation 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 beneficiary's medical record.
- We are clarifying the documentation requirements and specify what is required which is described in § 440.70(f)(5)(i) and (ii).
- We are clarifying that for medical equipment, in addition to the physician, the allowed NPP, as described in

paragraph (f)(3)(ii) through (v) are authorized to document the face-to-face encounter.

I. Face-to-Face Encounter Through Telehealth (§ 440.70(f)(6))

Proposed § 440.70(f)(6) outlined that the face-to-face encounters may be performed through the use of telehealth.

Comment: Several commenters expressed support of the provision. One commenter supported CMS's proposal on the use of telehealth to conduct a home health face-to-face encounter. Another commenter was encouraged that CMS stated that states should ''implement [the telehealth] provision in a way that does not result in barriers to service delivery'' and that states should ''work with the home health provider community to incorporate the face-to-face visits in creative and flexible ways to account for individual circumstances.'' The commenter was also pleased that CMS is ready to offer technical assistance to state Medicaid agencies to use telehealth as an alternative so that the requirement may be implemented in a way that protects the continuity of services. One commenter supported CMS's decision to permit the face-to-face encounters to occur through the use of telehealth. Another commenter viewed the provision of allowing a telehealth encounter instead of a face-to-face encounter as a positive development and would like to see this option expanded whenever possible. Yet, another commenter appreciated that the proposed rule allows states that currently use telehealth or telemedicine when delivering services under Medicaid to be able to use the techniques to fulfill the face-to-face encounter. One commenter appreciated that the coverage of telehealth is discretionary.

Response: We appreciate the support of the commenters.

Comment: Commenters believed that the allowance to use telehealth or telemedicine should extend to all forms of electronic communication in compliance with the face-to-face requirement for home health services. Conversely, one commenter indicated that the proposed regulation as written could allow managed care plans and FFS providers to bill for telephone calls, emails, and faxes with another provider when the beneficiary is still at the originating site or not present in the room at all, and stated that this would have to be built into capitation rates for managed care plans. One commenter indicated that telehealth and telemedicine are two different approaches in providing health care. The use of the term ''telehealth'' implies that the provider will be able to use a telephone, email or other telecommunications to contact the beneficiary to provide the face-to-face requirements. It is unclear if it is the intention of CMS to allow telephone calls and emails to replace a face-to-face visit. One commenter commended us for the use of the term ''telehealth,'' which correctly describes the universe of health services provided by the diverse array of providers, versus ''telemedicine,'' which can be interpreted to focus on a more limited array of services offered by a particular set of providers.

Response: Telehealth and telemedicine are service delivery modalities that have very specific protocols that ensure quality patient care, and do not include all electronic communications. We recognize that there may be confusion surrounding the terms ''telehealth'' and ''telemedicine'' as the terms may have different meanings as recognized by a state in accordance with Medicaid policy, and as recognized under the Medicare statute and regulation. The Medicaid ''telemedicine'' description is modeled on Medicare's definition of telehealth services located at § 410.78, but allows states flexibility in keeping with their general authority to regulate the medical professions. It is not our intention to allow telephone calls or emails to replace the face-to-face encounter. In other words, telehealth and telemedicine are service delivery models and do not replace the requirement that a physician or NPP must have a face-to-face encounter with a beneficiary. Rather, the face-to-face encounter can be met though a telehealth delivery model that is recognized by the state as a physician or NPP encounter under its approved state plan. See *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html*.

Comment: Commenters urged CMS to allow states to define the form and extent of telehealth that can be used for meeting the face-to-face requirements. The commenters suggested that the rule should be amended to state: ''states can permit the use of any two-way audio/video communication medium as allowed by state law to connect the beneficiary to the physician/NPP to meet the face-to-face requirements.'' One commenter stated that telehealth services should be defined in a way that allows a beneficiary to meet the face-to-face encounter requirements through modern technologies available in their home, including two-way audio and video communications. Another commenter recommended that federal telehealth policy be revised to make the home an approved site and to encourage state Medicaid programs to pay for telehealth visits. Other commenters recommended that CMS require state Medicaid programs (and the Medicare program) to allow face-to-face encounters to take place via telehealth technology deployed in beneficiaries' homes and reimburse agencies and practitioners for the costs involved. One commenter expressed concern that the face-to-face encounter requirement will erect a barrier to timely care for beneficiaries who are homebound and have difficulty traveling to a location that is equipped with telehealth technology. One commenter requested that for special circumstances, CMS broaden the definition to include Skype encounters with beneficiary/physician or allow home monitoring devices used by home care agencies to be established in physician offices. One commenter believed that it is important that CMS maintain the telehealth flexibility which state Medicaid programs currently have of not limiting telehealth to rural health professional areas. One commenter recommended that the use of telehealth be an option in non-rural areas, in addition to rural areas. One commenter requested that CMS clarify whether a state may, through a state plan amendment, limit the use of telehealth for conducting the face-to-face encounters to rural or other geographic areas where there are issues related to transportation or access to practitioners. One commenter believed that there are many regulatory and procedural constraints which will need to be amended to enable full and successful implementation of telehealth services by all healthcare providers. One commenter stated that the telehealth requirement for Medicaid purposes should include sites of service where the patient may receive the home care or use the DME. For example, a home visiting or adult day care nurse should be permitted to establish a video visit to an office based physician, allowing the physician to assess the beneficiary's need for home care or DME. Existing tablet computer and wireless technologies make such visits practical in any setting. In rural areas, without broadband cellular service, portable videoconferencing tools that use ''plain old telephone service'' exist for this purpose. One commenter stated that the benefits of this provision are limited for Medicaid beneficiaries due to restrictions on the use of RPM (remote patient monitoring) in Medicare law.

The commenter indicated that CMS should include a provision for dual eligibles to have care coordinating access to RPM technologies under Medicare and Medicaid.

Response: In the absence of specific Medicaid statutory requirements, we are hesitant to proscribe the locations and/or technologies that states may use to meet the face-to-face requirement through telehealth. Under Medicaid policy, states have the flexibility to define coverage of telehealth including what types of telehealth to cover; where in the state it can be covered; and how it is provided. Our expectation is that care delivered using various technologies will lead to good outcomes and meet the needs of the individual while adhering to privacy requirements, including the requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We recognize the need for updated Medicaid telehealth guidance, which will be forthcoming. In the meantime, we are available to provide technical assistance.

Comment: One commenter indicated that video or recording used in telehealth or telemedicine should be confidential and done in a manner to protect beneficiary's rights.

Response: We agree with the commenter. As previously stated, the use of telehealth or telemedicine does not negate HIPAA or Medicaid privacy requirements.

Comment: One commenter stated that CMS should monitor and make known which state Medicaid agencies permit face-to-face encounters via telehealth for certification of home health services under Medicaid. The commenter also recommended that CMS develop and implement a mechanism to track which states permit the face-to-face encounter to occur through telehealth. The commenter believed that CMS should know whether and to what extent Medicaid beneficiaries have access to services via telehealth. Additionally, the commenter stated that for those state Medicaid programs that do not permit the face-to-face encounter prior to the ordering for home health services to occur via telehealth, CMS should endeavor to learn what barriers exist to prevent the use of telehealth and assist states to overcome those barriers. The commenter stated that CMS should be proactive in determining what states need to realize the goal of expanding the use of telehealth services and that CMS should encourage state Medicaid agencies to take advantage of the relative flexibility they have regarding implementing and paying for telehealth services under Medicaid. The commenter stated that when possible, CMS should adopt the innovative and cost-saving telehealth systems, as developed and implemented by states, into the Medicare regulations and policy for telehealth services. Additionally, the commenter indicated that CMS should hold state Medicaid agencies accountable for dual eligibles' access to telehealth services in general and the face-to-face pre-certification encounter in particular.

Response: We will consider the recommendations of the commenter for future action. We recognize that there are differences between Medicare and Medicaid on the issue of telemedicine and telehealth. But the general requirements for telehealth and telemedicine are not the subject of this rulemaking.

Comments: One commenter appreciated allowing telehealth as a means of meeting the face-to-face requirement, but was concerned that it will not be enough.

Response: We recognize that there may be individual circumstances and we encourage states to work with the home health provider community to incorporate the use of telehealth to meet the face-to-face requirement in creative and flexible ways to account for individual circumstances. We are available to provide technical assistance to states in achieving this goal.

Comment: Some commenters requested clarification. One commenter requested clarification on Medicaid coverage of telehealth equipment, facilities, and transmission costs. Another commenter requested that CMS clarify that telehealth encounters would qualify for FFP as a reimbursable visit.

Response: Medicaid does not reimburse for telecommunications equipment or facility costs separately. However, states could build reimbursement for the costs into the rate and states can include in the rate a separate amount for such costs. Reimbursement for services provided through telehealth is voluntary on the part of state Medicaid agencies as they are viewed as alternative methods of providing services, not as a separate type of service. Therefore, reimbursement is only available if the state has chosen to cover services provided via telehealth or telemedicine and only in the circumstances selected by the state.

After consideration of the public comments, this section is being finalized as proposed.

J. Face-to-Face-Encounter for Medical Supplies, Equipment and Appliances (§ 440.70(g))

As proposed, § 440.70(g) applies all of the requirements of § 440.70(f) to the provision of medical 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 DME, with one exception from the requirements at § 440.70(f). Per the statute, as amended by the Affordable Care Act, certified nurse midwives are not permitted to conduct face-to-face encounters required for the items, as proposed at § 440.70(g)(2). To maximize consistency between the Medicaid and Medicare programs and reduce the administrative burden on the provider community, we proposed to limit the face-to-face requirements to items that would be subject to such requirements as DME under the Medicare program. Thus, we would only require that, for items of DME 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 beneficiary requires the item has occurred no more than 90 days before the order is written or within 30 days after the order is written. Medical supplies, equipment and appliances for which a face-to-face encounter would not be required under the Medicare program as DME, would not require a face-to-face encounter before the ordering of items under the Medicaid program. The items will be of a smaller dollar value, and at a decreased risk for fraud, waste, and abuse.

Comment: Some commenters supported the proposed requirement that a face-to-face encounter must be performed prior to a physician ordering medical supplies and DME. One commenter applauded CMS' decision to limit the applicability of the face-to-face encounter requirement to the medical equipment, supplies, and appliances that are included on the Medicare program list of specific DME. Another commenter supported the consistency with Medicare timeframes for orders for DME.

Response: We appreciate the support expressed by the commenters We agree that there should be consistency with the timeframes for the face-to-face encounter for DME in Medicare and medical equipment in Medicaid. Since the proposal and comment period of this rule, Medicare has finalized their DME face-to-face rule requiring the face-to-face encounter for DME to occur no

more than 6 months prior to the start of services. Therefore, we have revised the Medicaid medical equipment face-to-face timeframes to align with the Medicare timeframe.

Comment: One commenter asked that we clarify the effective date for the face-to-face requirement for certification of Medicaid DME services. Additionally, the commenter requested clarification as to whether the face-to-face encounter for DME applies to DME furnished solely as a home health benefit or whether it also applies to DME paid for by Medicaid that is not covered as part of the home health benefit. Another commenter requested that CMS clarify whether a state may choose to extend the face-to-face requirements to include equipment, supplies, or appliances that are covered under the state's Medicaid program, but are not Medicare benefits. One commenter requested that CMS clarify that the proposals, if finalized, would not apply to medical equipment under the Medicaid program until CMS has issued a final Medicare face-to-face rule.

Response: The provisions of section 6407 of the Affordable Care Act became effective in 2010 and added the requirement that physicians document the existence of a face-to-face encounter for home health services including medical supplies, equipment and appliances. However, as previously indicated, we are delaying the effective date of this rule to July 1, 2016 and we are allowing states and providers up to one year from the effective date of the final rule to come into compliance with the rule if the state's legislature has met in that year, otherwise 2 years.

Any medical supplies, equipment, and appliances provided under the home health benefit must meet the face-to-face requirement. If the state is providing supplies, equipment or appliances under a benefit category other than home health, such as the therapy services authorized at § 440.110, or prosthetics authorized under § 440.120, the state would need to adhere to the requirements of that particular benefit. In response to the concern that we clarify that the final rule will not apply to medical equipment under the Medicaid program until we have issued a final Medicare face-to-face rule, Medicare's DME face-to-face rule was effective on July 1, 2013. Our alignment of the scope of items requiring the face-to-face encounter with Medicare does not depend on Medicare regulation. The list of DME items subject to the face-to-face encounter can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/DME_List_of_Specified_Covered_Items_updated_March_26_2015.pdf.* States may decide to apply face-to-face requirements to a broader range of medical supplies, equipment, and appliances than those for which Medicare requires an encounter, but are not required to do so.

Comment: One commenter stated that with regards to the face-to-face requirement for DME, the regulation is vague as to which party is responsible for the face-to-face documentation for billing purposes and does not sufficiently define the items that will be subject to this requirement.

Response: The physician or the NPP who completed the face-to-face encounter is responsible for documenting the encounter. However, as previously stated, this rule does not replace the existing Medicaid regulatory requirements related to physician orders. In response to the comment that the regulation does not sufficiently define the items that will be subject to the face-to-face requirement, we intend to issue guidance to states indicating how they, and providers, can access the current Medicare list of specific DME 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 DME, would not require a face-to-face encounter before the ordering of items under the Medicaid program.

Comment: One commenter stated that it is a rare physician who is able to determine what DME is appropriate for a beneficiary without the advice of rehabilitation therapists. In addition, almost all DME requires training of beneficiaries and caregivers. The commenter encouraged reconsideration of state discretion in relation to rehabilitation when DME is required.

Response: We recognize that the recommendation and determination of appropriate medical equipment is often made by providers other than the physician and we encourage a collaborative approach to determining a beneficiary's needs. The statute sets forth the practitioners who are authorized to complete the face-to-face encounter for medical supplies, equipment, and appliances and maintains the role of the physician in the actual ordering of medical supplies, equipment, and appliances. However, as stated in the preamble, only items of DME specified by CMS under the Medicare program would be subject to a face-to-face encounter requirement.

Comment: Many commenters had suggestions pertaining to CMS's proposal of exceptions to the face-to-face encounter for certain DME as specified by under the Medicare program. Commenters suggested that the face-to-face exceptions for home health medical equipment should be expanded so that only those items that are most likely to be abused require a face-to-face visit. Another commenter believed that CMS can develop a suggested list of DME that requires face-to-face encounters, but state Medicaid programs should be able to make the final decision on which items will require the face-to-face encounter. Other commenters suggested that the requirement of face-to-face encounter should apply to all medical supplies and DME.

Response: We believe that by aligning with Medicare's implementation of this provision, we will ensure that beneficiaries are receiving needed items and provide clear and consistent guidance to states. Therefore, we will not be expanding the exceptions from the face-to-face requirement beyond the list used in Medicare. Based on the previously stated rationale, state Medicaid programs could require face-to-face encounters on more items than would be required under Medicare, but not fewer items. In response to the comments suggesting that the face-to-face encounter should apply to all medical supplies and DME, we disagree as we believe that this alignment and consistency will reduce the administrative burden on the provider community.

Comment: One commenter suggested that CMS look first to its Medicare national and local coverage determinations to determine what DME items require an in-person physician visit. Additionally, the commenter stated that CMS should adhere to already established Medicare coverage policies regarding the need for a beneficiary to see his or her physician for DME rather than expand the face-to-face requirements to more routine types of DME such as canes, walkers, and commodes. The commenter also recommended that CMS not require beneficiaries who need supplies, refills, repairs, or service of their equipment to have follow-up face-to-face physician visits. Another commenter indicated that DME and medical supplies items also include basic needs such as canes, crutches, walkers, diapers, applicator sticks, just to name a few. The commenter specified that to require a physician endorsement of each of the items for a population that is already under-served and receives care exclusively from NPs in a large number of states, is not only unreasonable, but

increases costs and causes delays in care.

Response: As previously stated, only items of DME specified by CMS under the Medicare program would be subject to a face-to-face encounter requirement for the Medicaid program. Additionally, to clarify, an additional face-to-face encounter would not be required for refills, repairs, or service of equipment. The face-to-face encounter is required for the initial ordering of medical supplies, equipment, and appliances. As this rule does not preclude existing regulations, the need for medical supplies, equipment, and appliances must be reviewed by a physician annually. We believe that the requirements may be met without causing undue hardship on beneficiaries or the provider community.

Comment: One commenter strongly recommended that there be an explicit prohibition on any ownership relationship between the physician ordering the equipment/supplies/appliances and the provider of those items.

Response: We thank the commenter for the recommendation, but this is beyond the scope of this regulation.

Comment: One commenter indicated that for beneficiaries participating in a section 1115 demonstration or section 1915(c) HCBS waiver, benefits such as DME and supplies requiring a physician encounter, or one by the proposed list of NPPs, may be problematic as the benefits are often determined by non-physician case managers and the physician requirement could add additional costs to strained state Medicaid budgets.

Response: We recognize the commenter's concern. However, statute mandates the face-to-face encounter for medical supplies, equipment, and appliances under the home health services benefit. We note that this rule applies to the home health benefit as implemented in the Medicaid state plan. To the extent that state plan service is provided through a waiver or demonstration, the requirements would continue to apply.

Comment: One commenter stated that PAs should be authorized to order medical supplies and equipment for Medicaid beneficiaries, consistent with DME supplies and equipment within the Medicare program. Another commenter urged CMS to allow NPs to continue to order durable medical supplies, equipment, and appliances, as they are able to do under current regulations. One commenter was concerned about the limits being placed on NPs regarding the ordering of DME. Other commenters urged CMS to allow other practitioners who may prescribe medical supplies and DME under state law, to do so under Medicaid as well. The commenters also suggested that audiologists and podiatrists be permitted to conduct the face-to-face encounter and then communicate the information to the physician who is responsible for documenting the face-to-face encounter.

Response: We appreciate the suggestions. As previously stated, this rule does not supplant existing regulatory requirements that provide that a physician must order an individual's services under the Medicaid home health benefit. The statute maintains the role of the physician in the actual ordering of medical supplies, equipment, and appliances. Additionally, the statute sets forth the NPPs who are authorized to conduct the face-to-face encounters before the start of home health services. It is beyond our authority to change statute.

Comment: One commenter stated that certified nurse-midwives should not be prohibited from ordering DME for their beneficiaries.

Response: The statute and current regulations maintains the role of the physician in the ordering of medical supplies, equipment, and appliances.

Comment: One commenter believed home health agencies should be permitted to include medical supplies in their plan of care and be separately paid for those medical supplies.

Response: If the home health agency is a Medicaid provider of medical supplies, equipment and appliances, then it can receive payment for medical supplies, equipment, and appliances based on the physician's order and plan of care.

Comment: Many commenters recommended that the requisite timeframe be extended to 6 months for medical equipment and appliances.

Response: As indicated above, we are revising the timeframe requirements to no more than 6 months prior to the start of services. We believe that this alignment will provide consistency among the programs and less fragmented services for beneficiaries who are dually eligible.

Comment: Several commenters recommended that when home health care is complicated (for example, certain medical equipment), CMS permit a greater period of time between the face-to-face visit and receipt of services.

Response: We believe that the 6 month timeframe for the face-to-face encounter will meet the needs of beneficiaries and permit sufficient time for providers to analyze beneficiary needs.

Comment: One commenter indicated that they are confident that the overwhelming majority of orders for medical equipment are already made in an appropriate medical context. The commenter believed that it would be unnecessary for CMS to create, or require a state to create, new in-person evaluation or documentation requirements for many categories of medical equipment. Additionally, the commenter stated that when medical equipment is ordered on discharge from an inpatient stay, it would be unnecessary for CMS to impose additional face-to-face physician visit or documentation requirements because the beneficiary's need for equipment would have been evaluated during their stay.

Response: The face-to-face requirement is mandated by statute regardless of whether the majority of orders for medical equipment are already made in an appropriate medical context. We allow for the face-to-face documentation to be part of the order or an addendum to it. As previously stated, we have clarified in this final rule that the inpatient physician can order home health services, which would include medical equipment, supplies, and appliances, in accordance with § 440.70. Therefore, if the inpatient physician orders the medical equipment following all of the face-to-face requirements, including documentation of the face-to-face encounter, there would be no need for an additional face-to-face visit upon discharge. However, if the inpatient physician was not the ordering physician, it would be acceptable for the community physician (or his or her support staff) to attach a communication from a physician who cared for the beneficiary in an acute or post-acute facility, who performed the encounter (such as a discharge summary), to the order as an addendum. If, for example, a discharge summary from a physician who cared for the beneficiary in an acute or post-acute facility contains all of the needed documentation content, the ordering physician would simply need to sign and date the discharge summary and ensure it is attached as an addendum to the order. We believe that this process will help to insure continuity of care between the hospital and the community physician.

Comment: One commenter stated that there may be times where a physician might order an item such as a walker based on self-reports from the beneficiary or his or her caregiver. For example, a beneficiary may report recent falls within the home and a

doctor might order a cane or a walker before he examines the beneficiary in person. Similarly, the beneficiary may have a progressive condition and the physician determines, based on the beneficiary's self-reports and clinical history, that he or she needs different equipment. When the physician orders DME in these situations, CMS should not require a face-to-face encounter because the physician prescription is based on the beneficiary's medical history and is made in response to predictable changes in the beneficiary's condition.

Response: We appreciate the comment, however, we do not have the authority to revise the requirements of the statute which requires a face-to-face encounter for home health services as they apply to medical supplies, equipment, and appliances under the home health services benefit. Since the encounter can be conducted up to 6 months prior to the ordering of equipment, this provision should not prevent the provision of timely care.

Comment: One commenter believed that CMS should not require an additional face-to-face visit for DME identified by the home health agency nurse or other skilled clinician and communicated to the physician overseeing the plan of care. The commenter also believed that CMS should not impose a physician visit requirement for prescription renewals, supplies, and/or accessories used with a particular device, and repairs or replacement of equipment. Additionally, CMS should not extend the face-to-face requirement to ongoing supplies or other items that are ancillary to the DME prescribed but nonetheless necessary to deliver appropriate therapy.

Response: The statute identifies the authorized NPPs who may conduct the face-to-face encounter. It is beyond our authority to expand this list to include the home health agency nurse or other skilled clinician not included as an authorized NPP. We clarify that an additional face-to-face requirement would only be required if a new medical equipment, supply or appliance is needed. Renewals, repairs and the need for ancillary equipment would not trigger the need for an encounter.

Comment: One commenter stated that the extension of a requirement for a physician order to provide DME to Medicaid enrollees is an additional barrier to beneficiaries receiving the medical supplies and equipment they need.

Response: We appreciate the commenter's concern. However, as previously stated, the statute mandated the face-to-face requirement for home health services, including medical equipment, supplies, and appliances. The purpose of this regulation is to implement that statutory directive.

After consideration of the public comments, this section is being finalized with revisions to the timeframes for the face-to-face encounter for DME. Specifically, we are adding § 440.70(f)(5)(ii) which indicates that for the initiation of DME, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur no more than 6 months prior to the start of services.

Additionally, as previously indicated, we are using this rule to conform with the Medicare Access and CHIP Reauthorization Act of 2015 and clarifying that for medical equipment, in addition to the physician, the allowed NPPs, as described in paragraph (f)(3)(ii) through (v) are authorized to document the face-to-face encounter.

IV. Provisions of the Final Regulation

For the most part, this final rule incorporates the July 12, 2011 provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- We are revising § 440.70(b) introductory text to state that coverage of home health services cannot be contingent upon the beneficiary needing a nursing or therapy services.
- We are amending § 440.70(b)(3)(ii) to include the term ''disability'' to the definition of equipment and appliances and to clarify that state Medicaid programs are not restricted to the items covered under DME in the Medicare program.
- We are adding § 440.70(b)(3)(v), to state that states can have a list of preapproved medical equipment supplies and appliances for administrative ease, but not as an absolute limit on coverage; states must provide and make available to individuals a reasonable and meaningful procedure for individuals to request items not on the list; and individuals are informed of their right to a fair hearing.
- We are revising § 440.70(c)(1) to codify the homebound prohibition for Medicaid home health services; home health services may not be subject to a requirement that the individual be ''homebound.'' Additionally, we are clarifying the settings in which home health services may be provided. Specifically, we are adding the clarification that home health services may be provided in settings where normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.
- We are adding 440.70(f)(5)(i) and (ii) to specify that the ordering physician must document the face-to-face encounter which is related to the primary reason the patient requires home health services, occurred within the required timeframes prior to the start of home health services; must indicate the practitioner who conducted the encounter, and the date of the encounter.
- We are adding § 440.70(f)(2) which indicates that for the initiation of DME, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur no more than 6 months prior to the start of services.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 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.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

On July 12, 2011 (76 FR 41032), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). See below for a summary of the PRA-related comments along with our response.

Subsequent to the publication of the proposed rule, we have revised our cost estimates by using the most current U.S. Bureau of Labor Statistics' wage estimates along with our fringe benefit adjustment factor. An additional change is discussed in Collection of Information section V.B.2.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Family and General Practitioners	29–1062	89.58	89.58	179.16
Nurse Practitioners	29–1171	47.11	47.11	94.22
Physician Assistants	29–1071	46.77	46.77	93.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Carried Over From the July 12, 2011, Proposed Rule

1. ICRs Regarding Home Health Services: Physician Documentation of the Face-to-Face Encounter (§ 440.70(f) and (g))

Section 440.70(f) and (g) requires that physicians (or for medical equipment, authorized non-physician practitioners (NPPs) including nurse practitioners, clinical nurse specialists and physician assistants) document that there was a face-to-face encounter with the Medicaid beneficiary. The burden associated with this requirement is the time and effort to complete and maintain this documentation. The documentation must clearly demonstrate that the face-to-face encounter occurred within the required timeframes and indicate the practitioner who conducted the encounter along with the date of the encounter. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation. In this regard, we estimate 10 minutes for each encounter. We also estimate that there are approximately 1,143,443 initial home health episodes in a given year (this estimate is based on our 2008 claims data which is also our most recent data). Due to the lack of data for each provider type, we are dividing our 1,143,443 episode estimate into 3 equal parts of 381,147.67 for each of the three respondent types (family and general practitioners, nurse practitioners, and physician assistants). Our estimated burden for documenting, signing, and dating the beneficiary's face-to-face encounter is 190,574 hours (this estimate is based on our CY 2011 data which is also our most recent data). We acknowledge that this figure is inflated by instances in which the physician conducted the face-to-face encounter with the beneficiary, making this second 10-minute documentation burden unnecessary.

The estimated cost to document the face-to-face encounter, which varies by practitioner, consists of $29.74 (0.167 hr × $179.16/hr) for a family and general practitioner, $15.64 (0.167 hr × $94.22/hr) for a nurse practitioner, and $15.52 (0.167 hr × $93.54/hr) for a physician assistant. We estimate an aggregated cost of $23,355,067 (see the burden table in section V.C. of this final rule). The requirements and burden will be submitted to OMB under control number: 0938–1188 (CMS–10434).

Upon consideration of the public comments received, we are finalizing this section as proposed.

Comment: Several commenters reported that the estimated burden does not accurately account for home health agency burden. One commenter further stated that 35 minutes per beneficiary should be added to home care agency time if the form is completed correctly the first time. If the form is not correct, 25 to 45 minutes should be added to 25 percent of the beneficiaries. Another commenter stated that in reality, the face-to-face is already taking up another 30 to 45 minutes on the home health agency side plus at least 15 minutes on the physician side. Another commenter stated that the estimate does not include the time that is required for home health agencies and medical equipment companies to ensure that the encounter occurred and that the documentation is received and in compliance with federal and state requirements. To ensure that the encounter has occurred and the required documentation is in place, the commenter reported that state home health agencies would need an additional 0.5 FTE in an agency with an average census of 100 to 120 beneficiaries. Another commenter stated that the estimates do not include the time and effort for the home health agency to contact and recontact the physicians to obtain the correct documentation. The commenter estimated that the burden on home health agencies is at least as much as it is on the physicians and requested that this burden be included in our estimate.

Response: We do not agree that the new requirements will add administrative requirements to home health agencies. Home health agencies are currently required to obtain the physician's order prior to implementing home health services. We do not believe that the additional documentation requirements as defined at § 440.70(f)(5) will add to the existing requirements.

Comment: One commenter stated that home health agencies do not typically cover costs through Medicaid reimbursement when serving Medicaid beneficiaries. Consequently, the additional administrative burden that would be placed on home health agencies because of the face-to-face requirement would further exacerbate this problem.

Response: We recognize the commenter's concern. This is a statutory requirement that is applicable across Medicare and Medicaid. We encourage home care agencies to communicate with their state Medicaid agencies to discuss the impact of the requirements on current Medicaid reimbursement rates. We also encourage home care agencies to share best practices for complying with the requirements in cost effective ways.

Comment: Many commenters provided feedback on additional items to include in our burden estimates. One commenter specified the following items: The education of each physician on how to complete the form (10 minutes); time for the home care agency to audit each form (10 minutes per form) and to notify the physician of the

missing or incomplete information (5 minutes per notification—and consider that 25 percent of the forms are inaccurate and must be returned to the physician for revision); time for home care intake to coordinate and access the form (10 minutes) and time for home care office personnel to track and log the form (10 minutes); time for home care agency staff to educate beneficiaries on the requirement (5 minutes); time for home care agency staff to track the appointment compliance if the encounter was not completed by the time the beneficiary was admitted to home care (10 minutes); if the physician did not complete the form correctly the first time, add physician office personnel time to communicate the issue to the physician and pull the medical records and physician time to review the medical record and redocument (10 minutes minimum); and add burden for the home care agency to obtain the encounter documentation from the community physician if it was performed in a hospital. These commenters indicated that this new interpretation could add up to 30 minutes to coordinate. Another commenter indicated that additional support personnel time is required in physicians' offices as staff field the telephone calls from home health beneficiaries and agencies to request documentation, schedule encounters, and secure the documentation in an acceptable and compliant condition.

Response: We would like to remind commenters that we do not have any standard form that we require to be completed. Rather, we defer to state Medicaid agencies to work with the provider community to develop a documentation form that will best meet the documentation requirement. Since this provision became effective in 2010, we believe that documentation forms should be already in place.

Comment: Many commenters indicated that CMS did not include components in its burden estimates. One commenter stated that no impact was estimated for the implementation of the requirement for medical equipment, supplies, and devices. The commenter also indicated that our estimate does not include the cost to both state and federal governments of the additional physician visits that will occur and have to be paid for in order to meet the requirements. Another commenter stated that the burden estimate does not account for the time it may take to collect and review pertinent test results, specialist reports or assessments performed by clinicians such as physical therapists and occupational therapists. Another commenter indicated that there is no time identified for getting the documentation from the NP to the physician for endorsement and back, nor the time and personnel to support such coordination.

Response: We believe that our estimates accurately reflect new burdens. In response to the comment pertaining to the services performed by physical therapists and occupational therapists, we did not account for additional time for physical therapy and occupational therapy services as the services are presumed covered in existing regulatory language. We do not believe that the burden for the situations described would be significant. We view administrative functions such as the transmission of information between NPs and physicians as an existing part of the duties of administrative personnel and do not need to be quantified as additional burden.

Comment: One commenter requested that CMS clarify its plans to collect the additional documentation from physicians about the face-to-face encounters and what role states and health plans may have in the process.

Response: The intention of the comment is not clear. We defer operational procedures for implementing this provision to the states and therefore, the state will communicate to fee-for-service providers and managed care plans the details of how it will be implemented. We will not be collecting documentation from physicians.

Comment: One commenter reported that physicians complain that they receive different forms from agencies and suggested that there be one universal form for everyone. Additionally, the commenter reported that the forms are returned incomplete and not timely and the education of how to complete the documentation is lengthy.

Response: We defer to state Medicaid agencies for operational details. We encourage states to use universal forms where appropriate. As previously indicated, the statutory provision became effective in 2010 and therefore, states should have appropriate forms in place.

2. ICRs Regarding Home Health Services: Communication of Clinical Findings (§ 440.70(f)(4))

Section 440.70(f)(4) requires that NPPs and attending acute or post-acute physicians communicate the clinical findings of the face-to-face encounter to the ordering physician. The clinical findings must be incorporated into a written or electronic document that is included in the beneficiary's medical record. While we set out burden in the proposed rule, we believe the requirement and burden are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). Specifically, we believe that the time, effort, and financial resources to communicate the findings of the encounter would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

Comment: Several commenters indicated that the proposed burden is underestimated. One commenter further stated that the proposal significantly underestimates the burden to both FFS providers and to managed care plans. Another commenter stated that not all face-to-face encounters will be limited to 10 minutes, depending on the health state of the beneficiary being examined. Another commenter indicated that 10 minutes for NPPs and attending acute or post-acute physicians to communicate the findings of the face-to-face encounter to the ordering physician does not account for the time required for each face-to-face encounter nor for the time for staff to send endorsements back and forth between the involved parties.

Response: We are not attempting to be overly burdensome. We are requiring a general description of beneficiary's health condition. We believe that 10 minutes on average is an appropriate amount of time as this should be a routine provision of care. We note that the time required to conduct the actual encounter with the beneficiary could vary widely. The 10 minute estimate had referred to the time it would take for the health status to be communicated to the ordering physician. Although we set out burden in the proposed rule, we believe that that the requirement is a usual and customary business practice and the burden is therefore exempt from formal OMB approval under the authority of the PRA.

Comment: One commenter recommended that we work to streamline the requirements for documenting the in-person visit.

Response: We believe that providing states with the flexibility to determine their own documentation requirements will best meet the unique needs of the beneficiaries served, states, and providers. We would like to reiterate that we are not prescribing the specific types of information that has to be documented, but rather we are requiring an overall description of the linkage of the health status and the services ordered.

C. Summary of Annual Burden Estimates

TABLE 2—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s) in Title 42 of the CFR	OMB Control No. (CMS ID No.)	Respondents	Total responses	Time per response	Total annual burden (hr)	Labor rate ($/hr)	Total capital/ maintenance costs ($)	Total cost ($)
440.70(f) and (g) ..	0938–1188 (CMS–10434).	381,147.67	381,147.67	10 min (0.167 hr)	63,651.66	179.16	0	11,403,831.41
		381,147.67	381,147.67	10 min (0.167 hr)	63,651.66	94.22	0	5,997,259.41
		381,147.67	381,147.67	10 min (0.167 hr)	63,651.66	93.54	0	5,953,976.28
Total	.....	1,143,443.01	1,143,443.01	10 min (0.167 hr)	190,954.98	n/a	0	23,355,067.10

D. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please identify the rule (CMS–2348–F) the ICR's CFR citation, CMS ID number and OMB control number, and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer;

Fax Number: (202) 395–5806 or

Email: OIRA_submission@omb.eop.gov.

ICR-related comments are due March 3, 2016.

VI. Regulatory Impact Statement (or Analysis)

A. Statement of Need

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 NPPs, document a face-to-face encounter with the beneficiary (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act), before 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 NP or CNS (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 PA (as defined in section 1861(aa)(5) of the Act), under the supervision of the physician, may conduct the face-to-face encounters before 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 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 before 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.

The Affordable Care Act applied both of the provisions to the Medicaid program.

B. Public Comments on the Regulatory Impact Analysis

Comment: We received many comments pertaining to the fiscal impact of this regulation. One commenter stated that the regulation needs to look further into the overall cost of changing the common practice for in-home care providers and make sure the quoted $100 million is on target. One commenter stated that the need for frequent documented encounters outlined in the rule will result in a duplication of effort and result in unnecessary costs. Increased costs will result from both the increase in encounters and from additional administrative oversight to monitor compliance with encounter and documentation requirements. Another commenter stated that the expansion of services that will result from the proposed regulations will come at considerable and untenable cost to the states. Another commenter reported that the fiscal impact of the face-to-face requirement for the commenter's state would be an increase of over $3 million per year in additional expenditures. The commenter stated that the regulation specifies that home health care services are a mandatory service to all categorically needy Medicaid beneficiaries, as well as mandatory to all medically needy if the state makes this population eligible for nursing home care. The fiscal impact of this change is estimated to be an additional $5 million per year for the state. Another commenter reported that states will incur costs and administrative burdens regarding the following: (1) Providing notice to providers through Medicaid bulletins, billing guides and provider handbooks about the face-to-face encounter requirement; (2) examining medical records by program integrity staff to ensure the face-to-face requirement has been met; and (3) providing notice to providers of the updated list of DME items that require a face-to-face encounter, as periodically updated by CMS. Another commenter stated that the proposed regulation would vastly expand the program. If the changes are made, a state and its taxpayers would be obligated to pay for a seemingly limitless benefit. One commenter recommended that CMS estimate the additional costs associated with the proposed expansion of home health services.

Response: While we recognize that states may have initial increases in costs, we do not believe that the potential increases outweigh the possible offsetting benefits to both beneficiaries and state budgets. The face-to-face encounter provision promotes program integrity and an effectively implemented home health benefit will enable beneficiaries to receive high quality care in the community, rather than rely on care in more expensive institutional settings. However, to allow states time for

budgetary planning and operational changes, we are allowing states up to one year to come into compliance with this rule if the state's legislature has met in that year, otherwise 2 years.

Comment: A few commenters reported on the regulatory impact with regard to health care providers. One commenter stated that an increased cost will be imposed on every order to accommodate the endorsement of a physician for the order. Another commenter reported that they expect that practitioners and physicians will ask for an increase in their fees. Another commenter stated that managed care plans and fee-for-service providers would also suffer from reduced physician productivity, which would increase the cost of treatment authorization. Another commenter stated that state Medicaid payment rates for physicians are significantly below Medicare rates and additional requirements are not likely to encourage practitioners and providers to serve the Medicaid population at the current depressed reimbursement rates.

Response: In response to the concerns that an increased cost will be imposed on every order to accommodate the endorsement of a physician for the order, we do not view implementation of section 6407 of the Affordable Care Act as supplanting the existing Medicaid regulatory requirements related to current practice for physician orders but is consistent with those practices. We do not agree that this rule will reduce physician productivity or have an impact on current cost structure. We encourage the provider community to collaborate with their State Medicaid Agencies to ensure continued dialogue on rate structures and reimbursement methodologies.

Comment: One commenter stated that the additional documentation would also impose a burden on the managed care plans and vendors under contract to perform billing services. The vendors would have to create protocols to ensure review of the appropriate documentation, which may include software development and system changes. The commenter indicated that the placement of face-to-face documentation into a beneficiary's medical record under the proposed rule would require new software development. This would occur at significant cost to managed care plans, fee-for-service providers, and/or software companies. The commenter also stated that the increased cost of treatment authorization for managed care plans would have to be incorporated into the capitation rates and if face-to-face visits are not billable, plans and fee-for-service providers would bear increased costs for treatment authorization due to higher transportation expenses and/or costs of telehealth equipment, facilities, and transmission. The commenter also believed that his state would incur significant costs in staff time and system changes to enact the proposed rule, including: (1) Drafting an analysis and possible state plan amendment; (2) preparing a regulation package; (3) providing training and education materials to providers; (4) developing changes to billing systems; (5) revising health plan contracts and recalculating capitation rates; and (6) performing periodic audits and investigations to ensure compliance. Additionally, the commenter stated that the increased cost of treatment authorization for managed care plans would have to be incorporated into the capitation rates. Another commenter reported that the current level of payment for home health agencies does not begin to cover the costs of providing services. The commenter stated that adding an additional documentation requirement to every admission further diminishes the impact of this substandard payment.

Response: As previously stated, this rule does not require states to apply the face-to-face requirement to Medicaid managed care. We defer to states to determine the application of the face-to-face requirement in managed care plans to best meet the needs of their beneficiaries. We are requiring that if states direct their managed care plans to comply with face-to-face encounter requirements, the plans report on this in a manner similar to fee-for-service. We do agree that when states choose to require their managed care plans to meet these requirements they should take this into consideration while setting actuarially sound rates. While the rates may increase, this is not a certainty as managed care prior authorization requirements and/or existing reporting structures may already be in place within capitation rates to adequately cover the costs. We reiterate that the face-to-face encounter is an appropriate activity for which to be reimbursed under the Medicaid physician benefit, or, if a NPP is the practitioner performing the encounter, under the appropriate benefit established to reimburse those providers under the state plan. This reimbursement is provided for the face-to-face encounter. If a NPP performs the face-to-face encounter, there is no additional reimbursement available for the physician to document that the face-to-face encounter occurred. Managed care plans, providers, and State Medicaid Agencies are encouraged to collaborate to determine appropriate reimbursement structures and once those are determined, the state's actuary should be informed in order to consider those assumptions during the capitation rate development.

Comment: One commenter stated that the face-to-face encounter increases the burden on home care agencies by placing the onus on the providers to ensure that the encounter takes place in the manner prescribed by the final rule. Additionally, the commenter stated that the proposed rule did not address or consider the financial and operational burdens imposed on agencies and that it is home care agencies and not physicians that risk non-payment for services rendered if discrepancies regarding the face-to-face encounter arise. The commenter further stated that much of the Medicare face-to-face education was done by home care providers, resulting in even greater burden on agencies. Another commenter stated that the entirety of the face-to-face requirement is extraordinarily burdensome on small home health agencies and unnecessary for quality care outcomes and cost savings. Additionally, the commenter indicated that the face-to-face requirement penalizes home health agencies that are unable, due to size or geographic location, to secure the services of an independent physician.

Response: We do not view the implementation of the face-to-face requirement as replacing existing regulatory requirements, but rather enhancing existing regulatory language. We believe that aligning with Medicare's implementation of this requirement will allow for consistency and reduce the burden on providers. Additionally, the rule expands the providers who may complete the face-to-face encounter to include NPPs and allows for the use of telehealth, which we believe will reduce the burden on home health agencies securing the services of an independent physician.

Comment: One commenter stated that they believe that the existing Medicare face-to-face requirement has proven in many ways to be an ineffective and burdensome requirement on physicians, home health agencies, and patients, with little positive impact on program integrity, which should not be replicated for Medicaid cases.

Response: The face-to-face requirement for both the Medicare and the Medicaid programs is required by statute, and we anticipate that Medicaid agencies will work with providers to

effectively and efficiently implement the provision.

Comment: Some commenters reported that many providers have needed to devote full-time staff to the task of tracking down paperwork and following up with the physicians' offices on face-to-face documentation that is already duplicative of long-established service authorization records and standards.

Response: We appreciate the commenters' concerns. We believe that providers have established administrative procedures in place, and therefore, do not believe that the additional face-to-face requirements will be overly burdensome or result in significant costs.

After consideration of the public comments, this section is being finalized without revisions. However, as previously indicated, to allow time for budgetary planning and operational changes, we are allowing states up to one year to come into compliance with this rule if the state's legislature has met in that year, otherwise 2 years.

C. 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 estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and, therefore, is a major rule under the Congressional Review Act. Accordingly, we have prepared a final Regulatory Impact Analysis which to the best of our ability presents the costs and benefits of the rulemaking.

According to the CMS Actuarial estimates, section 6407 of the Affordable Care Act would bring an estimated $920 million in savings to the Medicare program from 2010–2014 and $2.29 billion in savings from 2010–2019. Although this provision applies to Medicaid in the same manner and to the same extent as the Medicare program, there were no estimates (costs or savings) generated for the Medicaid program as data to determine these estimates is unavailable.

The certification of the need for home health care by a physician would be a covered physician service or, at state option, could be covered as a component part of home health care services. States have substantial flexibility to design payment methodologies for covered services. These payment methodologies can be tailored by benefit and/or provider type. Therefore, there may be an increase in costs, but the scope of these increases are not measurable due to state flexibilities.

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 beneficiaries 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 the benefits, they nonetheless should be taken into account. In the proposed rule, we specifically solicited comment regarding the potential increased costs and benefits associated with this provision, as well as the various sections throughout the RIA. After consideration of public comments, we are finalizing the burden costs estimates associated with the provisions in this regulation with no revision.

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 $7.5 million to $38.5 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 final rule will not have a significant economic impact on a substantial number of small entities. Entities affected by this rule should already be administering these changes for Medicare purposes as the statutory change was effective in 2010. Entities should already have systems in place to accommodate this change for the Medicaid population.

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 604 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 2015, that threshold level is $144 million. This final rule will not result in an impact of $144 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.

D. Conclusion

We estimate that this final rule will 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 final 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.

The Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

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).

■ 2. Section 440.70 is amended by—
■ a. Revising paragraph (b) introductory text.
■ b. Revising paragraph (b)(3) introductory text.
■ c. Redesignating paragraphs (b)(3)(i) and (ii) as paragraphs (b)(3)(iii) and (iv), respectively.
■ d. Adding new paragraphs (b)(3)(i) and (ii) and paragraph (b)(3)(v).
■ e. Adding paragraphs (c)(1) and (2).
■ f. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§ 440.70 Home health services.

* * * * *

(b) Home health services include the following services and items. Paragraphs (b)(1), (2) and (3) of this section are required services and items that must be covered according to the home health coverage parameters. Services in paragraph (b)(4) of this section are optional. Coverage of home health services cannot be contingent upon the beneficiary needing nursing or therapy services.

* * * * *

(3) Medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place, as defined at § 440.70(c)(1).

(i) Supplies are health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness or injury.

(ii) Equipment and appliances are items that are primarily and customarily used to serve a medical purpose, generally are not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reusable or removable. State Medicaid coverage of equipment and appliances is not restricted to the items covered as durable medical equipment in the Medicare program.

* * * * *

(v) States can have a list of preapproved medical equipment supplies and appliances for administrative ease but States are prohibited from having absolute exclusions of coverage on medical equipment, supplies, or appliances. States must have processes and criteria for requesting medical equipment that is made available to individuals to request items not on the State's list. The procedure must use reasonable and specific criteria to assess items for coverage. When denying a request, a State must inform the beneficiary of the right to a fair hearing.

(c) * * *

(1) Nothing in this section should be read to prohibit a beneficiary from receiving home health services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board. Home health services cannot be limited to services furnished to beneficiaries who are homebound.

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

* * * * *

(f) No payment may be made for services referenced in paragraphs (b)(1) through (4) of this section, unless the physician referenced in paragraph (a)(2) of this section or for medical equipment, the allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v), with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) documents that there was a face-to-face encounter with the beneficiary that meets the following requirements:

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

(2) For the initiation of medical equipment, the face-to-face encounter must be related to the primary reason the beneficiary requires medical equipment and must occur no more than 6 months prior to the start of services.

(3) 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 referenced 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 referenced in paragraph (a) of this section; or

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

(4) The allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (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 beneficiary's medical record.

(5) 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 which is related to the primary reason the patient requires home health services, occurred within the required timeframes prior to the start of home health services.

(ii) Must indicate the practitioner who conducted the encounter, and the date of the encounter.

(6) 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 (DME) under the Medicare program, unless the physician referenced in paragraph (a)(2) of this section or allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v) of this section documents a face-to-face encounter with

the beneficiary consistent with the requirements of paragraph (f) of this section except as indicated in paragraph (g)(2) of this section.

(2) The face-to-face encounter may be performed by any of the practitioners described in paragraph (f)(3) of this section, with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) of this section.

Dated: July 28, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 21, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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