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Medicaid's Revised Home Health Regulation Increasing Access to Medical Equipment Frequently Asked Questions

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Introduction

On February 2, 2016, the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), issued a final rule revising the Medicaid home health regulation at 42 C.F.R. § 440.70. 81 Fed. Reg. 5530. In announcing these long-awaited revisions, CMS explained that:

This rule will promote program integrity and provide clear guidance on the parameters of the home health benefit in Medicaid which will enable beneficiaries to receive high quality care in the community, rather than rely on care in more expensive institutional settings.¹

The revised home health regulation contains significant changes, particularly for beneficiaries with disabilities who require medical supplies, equipment, and appliances to live in the community.² Below we answer several questions about these new provisions and explain how these revisions will positively impact access to medically

¹ See <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/health-home-factsheet.pdf>.

² As explained by CMS, “[i]t is implicit with any regulation change to a benefit or to provider responsibilities that states educate impacted providers and beneficiaries about the new requirements.” 81 Fed. Reg. 5534. Advocates can also play a role in disseminating information about the new requirements to the clients they serve.

necessary medical equipment (ME), also known as durable medical equipment (DME), through the Medicaid home health benefit.³

Is Medical Equipment a Mandatory Benefit of the Medicaid Program?

Yes, the home health benefit, which includes ME, is a mandatory category of service for certain Medicaid beneficiaries. 42 U.S.C. § 1396a(a)(10)(D). This is not new. As explained by CMS, “[h]ome health is a mandatory benefit and was so before this rule or the statutory changes that led to this rule.” 81 Fed. Reg. 5539. To the extent there has been some confusion on this point, either among the states or in the courts, the mandatory nature of this benefit should no longer be in question.⁴

Specifically, “[h]ome health care is a mandatory service for Medicaid-eligible individuals who are entitled to nursing facility services.” 81 Fed. Reg. 5531. Individuals seeking home health services need not actually require the level of services provided in a nursing facility. 81 Fed. Reg. 5533. Rather, medically necessary home health services are available to individuals who are eligible for Medicaid as categorically needy, e.g. individuals receiving SSI, low income families, disabled adult children, and qualified disabled workers.⁵ In some states, individuals who are medically needy also may be eligible for home health services if nursing facility services are available to these individuals.⁶ 81 Fed. Reg. 5531; 81 Fed. Reg. 5537.

The mandatory home health benefit includes several different services, some of which must be provided to eligible beneficiaries of all ages and others, which are optional for states to provide to beneficiaries 21 years of age or older. As explained in 42 C.F.R. § 440.70(b), nursing, home health aide services, and medical supplies, equipment and appliances are mandatory for states to provide, while physical and occupational therapy, speech pathology and audiology services are optional. As with other Medicaid categories of service, home health services must be sufficient in amount, duration and scope to reasonably achieve their purpose. 42 C.F.R. § 440.230(b). Moreover, states “may not arbitrarily deny or reduce the amount, duration, or scope” of home health services “solely because of the diagnosis, type of illness, or condition” of an otherwise eligible beneficiary. 42 C.F.R. § 440.230(c).

³ Where noted, the information provided is derived from CMS’s response to public comments following the agency’s initial notice of proposed rule-making on July 12, 2011. 76 Fed. Reg. 41032.

⁴ See, e.g. *S.D. ex rel Dickson v. Hood*, 391 F. 3d 581,586 (5th Cir. 2004); *Fred C. v. Texas Health and Human Services Com’n.*, 988 F. Supp. 1032 (W.D. Tex. 1997). In each of these cases, the court mischaracterized home health services as an optional benefit.

⁵ See <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/Downloads/List-of-Eligibility-Groups.pdf> for a complete list of Medicaid categorically needy and medically needy eligibility groups.

⁶ Typically, medically needy individuals are those whose incomes exceed the maximum eligibility threshold but who are nonetheless eligible for Medicaid due to high medical expenses. Their income is subject to a spend down requirement that offsets their medical expenses. State coverage of one or more of the medically needy eligibility groups identified in the Medicaid Act is optional.

Importantly, eligibility for ME and supplies cannot be made contingent upon a beneficiary requiring other home health services such as nursing services or therapy.⁷ 42 C.F.R. § 440.70(b). The addition of this clarification to the Medicaid home health regulation eliminates any question on this point.

Can States Limit Medical Equipment to Beneficiaries Who are Homebound?

No, on July 5, 2000, CMS issued policy guidance to the states explaining that Medicaid services must be provided in compliance with the Americans with Disabilities Act so that individuals with disabilities can live in the most integrated setting. Known as Olmstead Letter No. 3, Attachment 3-g, this guidance informed states that:

The “homebound” requirement is a Medicare requirement that does not apply to the Medicaid program. Imposing a homebound requirement on receipt of Medicaid home health benefits [] violates Medicaid regulations related to “amount, duration, and scope of services” at 42 C.F.R. § 440.230 and “comparability of services” at 42 C.F.R. § 440.240.⁸

The revised home health rule now codifies this prohibition by clearly stating that “[h]ome health services cannot be limited to services furnished to beneficiaries who are homebound.”⁹ 42 C.F.R. § 440.70(c)(1). According to CMS, “we are prohibiting the application of a homebound requirement for Medicaid home health services 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 [this] mandatory benefit.” 81 Fed. Reg. 5534. To the extent that some states have failed to comply with this policy in the past, they must now do so.

The homebound prohibition for Medicaid home health services is particularly important for individuals who are dually eligible for Medicare and Medicaid. 81 Fed. Reg. 5542-5543. While some dually-eligible beneficiaries may not qualify for Medicare home health services because they are not homebound, they “would still qualify for Medicaid home health services, if they meet the state’s medical necessity criteria for the service.” 81 Fed. Reg. 5543.

⁷ CMS has also explained that individuals who only require ME may receive this equipment from DME providers authorized by the state “without necessitating a relationship with a home health agency.” 81 Fed. Reg. 5535.

⁸ See <http://www.nasdds.org/resource-library/medicaid-hcbs-authorities/medicaid-hcbs-authorities/hcbs-waiver-state-medicaid-director-letters/olmstead-state-medicaid-director-letters/>.

⁹ Advocates should be mindful of any “medical necessity” standard for home health services that is used as a substitute for an express homebound requirement. 81 Fed. Reg. 5533-5534.

Can States Limit Coverage of Medical Equipment to Items Used in the Home?

No, the revised home health regulation clarifies that home health services cannot be limited to services provided in a Medicaid beneficiary's home. Specifically, the regulation now states that beneficiaries can receive home health services "in any setting in which normal life activities take place." 42 C.F.R. § 440.70(b)(3). The only exceptions to such settings are hospitals, nursing facilities, intermediate care facilities 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. 42 C.F.R. § 440.70(c)(1).

As with the "homebound" prohibition, this revision does not reflect new requirements for states. Instead, it codifies longstanding federal policy based upon the principles established in *Detsel v. Sullivan*, 895 F.2d 58 (2d Cir.1990), and *Skubel v. Fuoroli*, 113 F.3d 330 (2d. Cir. 1997), that private duty nursing and home health services cannot be restricted to services furnished in the home. In responding to questions about this revision, including use of the phrase "normal life activities," CMS has explained that:

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.

81 Fed. Reg. 5543.

This revision to the home health regulation is of particular importance to individuals seeking certain items of ME. For example, some state Medicaid programs deny wheelchairs to individuals who are able to ambulate short distances within their homes but who require wheelchairs for functional mobility outside of their homes. The revised regulation makes clear that such restriction is not allowed. Other states deny heavy duty wheelchair bases or other specialized components that users may require to navigate the terrain outside of their homes. Again, Medicaid programs cannot deny these specialized components on the basis that a standard wheelchair will suffice for use in the home. To the extent that any restrictions on ME are based upon an "in the home" limitation, they are unlawful and cannot be used to deny medically necessary ME.

Is Medical Equipment Defined in the Revised Home Health Regulation?

Yes, for the first time since the inception of the Medicaid program, there is now a federal definition of medical supplies, equipment and appliances. For beneficiaries with disabilities, the addition of this standardized definition is likely the most significant change to the Medicaid home health regulation. As explained by CMS, "in the absence of a generally applicable definition of [medical equipment], there has been confusion as to the proper scope of the benefit." 83 Fed. Reg. 5532. Under the revised regulation, medical supplies, equipment and appliances are defined as:

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.

42 C.F.R. § 440.70(b)(3)(i)

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.

42 C.F.R. § 440.70(b)(3)(ii)

While CMS has defined these services to "better align" with the Medicare definition of durable medical equipment,¹⁰ the revised regulation is clear that "Medicaid coverage of equipment and appliances is not restricted to the items covered as durable medical equipment in the Medicare program." 42 C.F.R. § 440.70(b)(3)(ii). States that have previously limited their Medicaid DME benefit in this manner can no longer do so.

The new federal definition of medical supplies, equipment and appliances will expand the scope of covered items in many states. One way in which this expanded coverage may occur relates to ME items that states restrict to individuals receiving section 1915(c) home and community based (HCBS) waiver services or services through the section 1915(i) HCBS state plan option. According to CMS, "[t]here will be items currently coverable under sections 1915(c) and 1915(i) that will instead be covered under the home health benefit . . ."¹¹ 81 Fed. Reg. 5538. These items include such

¹⁰ Medicare defines DME at 42 C.F.R. § 414.202 as:

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

¹¹ Equipment that does not meet the new federal definition under home health may remain covered under a section 1915(c) waiver or 1915(i) benefit. 81 Fed. Reg. 5538.

equipment as ceiling lifts or chair (stair) lifts, when such items meet the new ME definition.¹² 81 Fed. Reg. 5542. In particular, these items are covered through the Medicaid home health benefit when they are reusable or removable and do not require structural/home modifications to install.¹³ 81 Fed. Reg. 5542.

Another area for expanded coverage may result from the provision clarifying that home health services include “medical supplies, equipment, and appliances *for use in any setting in which normal life activities take place*” (*emphasis added*). 42 C.F.R. § 440.70(3). As explained above, some states have erroneously interpreted the statement that ME must be “suitable for use in the home” to be a prohibition on use of ME items outside of the home. The revised regulation clarifies that this type of limitation on the location where ME can be used is wrong.

Finally, the scope of covered ME will expand in some states that presently deny access to certain items of equipment to beneficiaries who are 21 years of age or older. States cannot apply an age requirement for the item of ME when age is irrelevant to medical need for the device. For example, states cannot deny wheelchairs with integrated standing features to adults while approving this same equipment for children. Moreover, states cannot characterize an item of ME under an optional category of service that it does not make available to adults in order to limit the availability of that item to children.

To ensure full coverage for medical equipment and appliances, we will require that, to the extent there is overlap in coverage with another benefit, states must nevertheless provide for coverage of these items under the mandatory home health benefit.

81 Fed. Reg. 5535.

The bottom line is this - - if the item meets the ME definition established in 42 C.F.R. § 440.70(b)(3)(ii), it must be covered through the home health benefit. 81 Fed. Reg. 5541. The same is true for medical supplies. According to CMS, “the expectation remains that individuals receive all medically necessary supplies meeting the definition finalized under this regulation.”¹⁴ 81 Fed. Reg. 5536.

¹² This is consistent with the 2013 guidance provided by CMS to Texas Medicaid explaining that “medically necessary ceiling lifts will be reimbursed by CMS as part of the Texas home health benefit if these lifts meet the state’s definition of DME.” See CMS Letter to Texas Health and Human Services Commission, May 21, 2013. <http://www.nls.org/files/Disability%20Law%20Hotlines/National%20AT%20Advocacy/TXDMEfinal05212013.pdf>.

¹³ Conversely, CMS maintains that structural home modifications and vehicular modifications are not covered under the home health benefit as they do not meet the new regulatory definition of medical equipment. 81 Fed. Reg. 5539.

¹⁴ CMS has acknowledged that the “nature” of medical supplies calls for a flexible approach in that these items may be provided “incident to another mandatory service” such as physician services or inpatient hospital services. 81 Fed. Reg. 5535.

Can States Exclude Items of ME from Coverage through the Home Health Benefit?

No, in 1998, the Health Care Financing Administration (HCFA, now CMS) issued policy guidance to the states clarifying that absolute exclusions of medical equipment, as erroneously upheld by the Second Circuit in *DeSario v. Thomas*, are unlawful.¹⁵ This guidance became known as the *DeSario* Letter and was relied upon by the Supreme Court to vacate the Second Circuit's erroneous decision. *DeSario v. Thomas*, 139 F.3d 80 (2nd Cir. 1998), *rev'g* 963 F. Supp. at 120 (D.Conn. 1997), *cert. granted, vacated and remanded sub nom Slekis v. Thomas*, 525 U.S. 1098 (1999).

The revised home health regulation now codifies the principles contained in the *DeSario* Letter and expressly affirms that “[s]tates are prohibited from having absolute exclusions of coverage on medical equipment, supplies, or appliances.” 42 C.F.R. § 440.70(b)(3)(v). Noting that states may maintain a list of preapproved medical supplies, equipment, and appliances for “administrative ease” the regulation is clear that:

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.

As explained by CMS, “because of the unique nature of medical supplies, equipment, and appliances, scope limitations within the applicable federal and state definitions are not consistent with the sufficiency of the benefit.” 82 Fed. Reg. 5539. States that currently exclude certain items of ME by rule, policy, or practice must bring their home health benefit into compliance with the revised home health regulation by eliminating such exclusions. If an item of equipment meets the federal definition of ME, it must be covered by Medicaid. For such items, the only remaining question is whether the individual requesting the item has established his or her medical need for the device.

Is a Face-to-Face Encounter Required to Obtain Medical Equipment?

Yes, the addition of the face-to-face-encounter for home health services is perhaps the most controversial change to the Medicaid home health regulation. The revised regulation incorporates the face-to-face encounter requirement for home health services set out in Section 6407 of the Patient Protection and Affordable Care Act of 2010 and Section 504 of the Medicare Access and CHIP Reauthorization Act of 2015.¹⁶ While the face-to-face encounter has been required for Medicare home health services since 2011, this is a new requirement for such Medicaid services.¹⁷ Notably, the Medicaid

¹⁵ See <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD090498.pdf>.

¹⁶ Numerous home health organizations and professional medical associations have opposed this new requirement, based in part, on their experience with the Medicare face-to-face encounter requirement.

¹⁷ This face-to-face encounter requirement applies to all home health services; however, the timing of these encounters for other services differs from what is described herein for ME.

face-to-face encounter applies only to items of ME specified by CMS to be subject to this requirement under the Medicare program. 81 Fed. Reg. 5558.

Upon implementation of this new requirement by the states, Medicaid beneficiaries seeking ME must have a face-to-face encounter with the ordering physician or a non-physician practitioner such as a nurse practitioner, a clinical nurse specialist, or a physician assistant.¹⁸ 42 C.F.R. § 440.70(f)(3). This face-to-face encounter can be conducted through the telehealth procedures that are utilized by the state. 42 C.F.R. § 440.70(f)(6). However, the face-to-face encounter must occur no more than 6 months prior to the start of service and “must be related to the primary reason the beneficiary requires medical equipment.” 42 C.F.R. § 440.70(f)(2). The physician ordering the ME or supplies must document the “clinical correlation” between the face-to-face encounter and the requested item of ME. 42 C.F.R. § 440.70(f)(5). Failure to follow these procedures for any item of DME specified by CMS under the Medicare program will result in the denial of Medicaid payment for the requested ME. 42 C.F.R. § 440.70(g)(1).

While not explicitly stated in the revised regulation, CMS has explained that states have the discretion to determine whether the face-to-face encounter requirement will apply to Medicaid managed care. 81 Fed. Reg. 5564. If a state requires Medicaid managed care organizations to comply with this requirement, the managed care plans must report to the state “in a manner similar to fee-for-service [Medicaid].” 81 Fed. Reg. 5564.

Who Decides Medical Necessity for Medical Equipment?

Nothing in the revised regulation changes the existing requirement that home health services must be ordered by the beneficiary's physician. 81 Fed. Reg. 5541. See 42 C.F.R. § 440.70(a)(2). This requirement is consistent with the longstanding principle of the Medicaid program that treating health care providers play a central role in determining the medical necessity of requested services.¹⁹ The new face-to-face encounter requirement for ME confirms that the beneficiary's physician and related health care providers continue to be responsible for establishing an individual's medical need for medical equipment and supplies.

Although the revised home health regulation does not define or otherwise address medical necessity for these services, several statements by CMS in the commentary merit attention. Noting that a covered item of ME must be within the scope of the definition of medical equipment and appliances, CMS is clear that “the approval of devices within that scope is based on a physician judgment of medical need.” 81 Fed. Reg. 5541. Rejecting one commenter's suggestion that the rule include language requiring ME to be supported by peer-reviewed evidence, CMS explains that the revised home health rule “does not change the requirement that medical equipment must be ordered by a physician.” 81 Fed. Reg. 5541. While states have discretion to establish

¹⁸ Some states require that certain ME requests be supported by evaluations conducted by physical, occupational, or speech therapists. Nothing about the new face-to-face encounter changes these requirements.

¹⁹ See S. Rep. No. 404, 89th Cong., 1st Sess., reprinted in 1965 U.S.C.C.A.N. 1943.

medical necessity criteria, such criteria must be based on accepted medical practices and standards. 81 Fed. Reg. 5533. According to CMS, "[w]e expect that the physician would determine medical necessity based upon individual need." 81 Fed. Reg. 5541.

When Does the Revised Home Health Regulation Take Effect?

That depends. Medicaid's revised home health regulation is effective July 1, 2016. In response to public comment, however, CMS has advised that states will be expected to be in compliance by July 1, 2017 or July 1, 2018, depending upon when the state legislature meets. 81 Fed. Reg. 5530, 5535. Regardless of the final implementation date for each state, it is important to note that the revisions to the home health regulation that do not create new requirements, but rather, codify existing policy and case law, remain in effect at this time. As explained by CMS,

While the changes [to the regulation] are substantive, the changes incorporate principles that have been applied to Medicaid coverage in a number of court cases and CMS guidance . . .

81 Fed. Reg. 5538.

Thus, the homebound prohibition is currently in effect, as it has been since 2000. The same is true for the principles established in *Detzel* and *Skubel* that home health services cannot be restricted to the home. Finally, all states are currently subject to the principles contained in the *DeSario* Letter. Thus, absolute exclusions of ME are currently prohibited, just as they have been since at least 1998.

Conclusion

According to CMS, the revisions to the Medicaid home health regulation were necessary to ensure that "beneficiaries receive the home health benefits to which they are entitled under the Medicaid statute." 81 Fed. Reg. 5545. Proper implementation of these requirements will eliminate the unlawful barriers to medical equipment and supplies that have existed in some states for decades and will provide greater support for individuals with disabilities to remain in their homes or return to their communities.²⁰

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²⁰ To obtain more information about Medicaid advocacy for medical equipment, see *Funding Assistive Technology through State Medicaid Programs* <http://nls.org/files/Disability%20Law%20Hotlines/National%20AT%20Advocacy/Medicaid%20DME%20Manual%20FINAL%20Nov%202015.pdf>.