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How the “IMPROVEMENT STANDARD” Improperly Denies Coverage to Medicare Patients with Chronic Conditions

By Gill Deford, Margaret Murphy, and Judith Stein

Diagnosed three years earlier with amyotrophic lateral sclerosis (ALS, otherwise known as Lou Gehrig’s disease), 68-year-old Eileen Prendergast was suddenly informed by her home health care agency that Medicare would no longer cover the home health care on which she depended. Prendergast, who needed an electric wheelchair, had recently reached the point where she could not stand on her own and required assistance to get into the wheelchair. During the eight months in which she had been receiving home health care, she had been losing the use of her arms and hands, had been diagnosed with diabetes, and, due to her immobility, had experienced skin breakdowns that required nursing care. The home health care agency provided nursing visits twice a month, physical and occupational therapies, and home health care aide services three times per week. Nevertheless, Prendergast’s Medicare Advantage Plan and home health care agency determined that, because she was “stable in her disease state” and would not improve, she did not need skilled care, and the need for such skilled care is a prerequisite to Medicare home health care coverage.

Although a determination that a victim of ALS could be in “stable condition” is a dubious one, the agency was following a Medicare tradition that has become virtually an urban myth among the providers and contractors who are largely responsible for making Medicare coverage decisions. The myth is that coverage of skilled care requires a beneficiary to be improving. The myth denies Medicare coverage to a beneficiary who has “plateaued,” is “medically stable,” or needs services for “maintenance only.” All of these shorthand terms essentially impose an improper requirement that results in termination of Medicare coverage for beneficiaries who have chronic conditions and who, sadly, are probably most in need of the care that is being denied them.

*We are grateful to Eileen Prendergast and her family for allowing us to share her story. Unlike most beneficiaries harmed by the termination of home health services in these circumstances, Prendergast’s home health coverage was reinstated because she obtained a temporary restraining order (see infra at n.2).
Prendergast’s situation is far from isolated. In various guises and using a potpourri of terminology, agencies and contractors have ingrained in their staff members the belief that the failure to satisfy the “improvement standard” dictates termination of coverage. The impact on beneficiaries with chronic conditions is staggering. As the health of beneficiaries deteriorates, their need for nursing services and physical, occupational, and speech therapies increases. The skilled care denied under the improvement standard is critical to slow the progression of the disease and to maintain functional ability. Yet these are precisely the people who are most likely to have their coverage terminated.

Neither the Medicare statute nor its implementing regulations mention or suggest an improvement standard in the context of diagnosis or treatment of illness or injury. The improvement standard derives instead from references in some Medicare manual provisions, which have been refined, simplified, and emphasized in contractors’ internal guidelines over time.

The employees who apply this phony coverage standard are simply following the guidelines laid out for them by their employers. Those improper guidelines, rather than federal statutes or regulations, are the basis for the rules that they apply. The improvement standard has become so much a part of Medicare culture that, even when presented with contrary evidence in the form of regulations and manual provisions, employees simply ignore it and state unequivocally that the improvement standard requires that coverage be terminated. Indeed, many advocates are unaware that the policy has little basis in the law and fail to challenge terminations of Medicare coverage based on it.

Because the improvement standard is not the product of notice-and-comment rule making, in theory the policy could be easily corrected. The Centers for Medicare and Medicaid Services (CMS) could simply correct the language of the offending guidelines to reflect the proper legal standard and then ensure compliance by educating and monitoring the responsible agencies and contractors. If CMS declined to act on its own, the president could issue an executive order directing CMS to take the appropriate steps to cleanse the manuals and to clarify the policy for those applying it.

Neither straightforward approach has yet occurred. At this point litigation may offer the best route to overcome the recalcitrance that seems to pervade this issue.

Here we attempt to explain the demographic context in which the policy is applied and to describe the statute, regulations, manuals, and guidance that surround the improvement standard in the hope that advocates will have a clearer understanding of the problem and how it can be challenged. Litigation is often a slow and incremental method for effecting change, but in this context and at this time it may be the most appropriate vehicle for correcting this inequity.

I. People with Chronic Conditions Have a Particular Need for Health Care and Therapy

The population of the United States is aging, and more people are living longer...
with chronic conditions. The most recent study indicates that 78 percent of the forty-one million Medicare beneficiaries have at least one chronic condition, 63 percent have two or more, and a full 20 percent have at least five chronic conditions. The five most common conditions that afflict these beneficiaries are hypertension, diseases of the heart, diseases of the lipid metabolism, eye disorders, and diabetes. The negative impact caused by the improvement standard is felt most severely by Medicare beneficiaries diagnosed with chronic conditions such as multiple sclerosis, ALS, Parkinson’s disease, other neurological diseases, spinal-cord injuries including paraplegia and quadriplegia, diabetes, chronic heart failure, dementia and Alzheimer’s disease, and stroke.

Exacerbating the problem is that most Medicare beneficiaries have low incomes: 46 percent have incomes that are below 200 percent of the federal poverty level, and 16 percent are below the federal poverty level itself. The incidences of obesity, diabetes, and hypertension are higher among the poor, and those living at or near the poverty level receive fewer health screenings and are less likely to have regular access to a physician. Since more than two-thirds of African American Medicare beneficiaries have incomes below 200 percent of the federal poverty level, the impact of poverty on health and access to health care falls particularly on minority groups.

These generally impoverished and high-risk beneficiaries with chronic conditions are often in need of nursing, physical, occupational, or speech therapies. Unlike patients with acute conditions for whom health care is intended to heal or to restore functions, individuals with chronic conditions generally rely on health and therapeutic services to slow the deterioration caused by their diseases and to maintain, to the extent possible, their existing functional capabilities. By definition their underlying conditions will not improve, but this care may allow these individuals to live independently, to retain their current health status, or to slow their deterioration—in short, to maintain some quality of life. The improvement standard, however, stands directly in the way of these individuals achieving their modest goals.

II. The Improvement Standard Has No Basis in the Statute or Regulations, but Some Manual Provisions Impose that Condition

Medicare Part A covers nursing and therapy received in a hospital or skilled nursing facility (SNF). The home health care benefit provides for nursing and therapy services under either Part A or Part B. Therapy services received as an outpatient are covered under Part B. Significantly a patient can trigger Medicare coverage of either SNF or home health care by establishing a need for skilled nursing services or physical, speech, and, in certain cases, occupational therapies. Furthermore, the need for physical or speech therapies or nursing care under the home health care benefit may also allow the beneficiary to receive coverage for home health...
care aides and occupational therapy. In short, skilled therapy or nursing services are gateways to broader Medicare coverage. When these skilled services are denied, Medicare beneficiaries stand to lose other medical support services as well as the skilled services.

At this point we must state emphatically that the Medicare statute imposes no improvement standard as a prerequisite to Medicare coverage. The general statutory standard for Medicare coverage is one of medical necessity; that is, the standard is whether a given service is “reasonable and necessary.” The same subsection of the law does use the word “improve,” but only in the specific and limited context of authorizing Medicare coverage “to improve the functioning of a malformed body member.” This use of “improve” is the only reference to improvement in the statute. It is worth repeating: there is no overarching improvement standard in the Medicare statute. If the skilled services are “reasonable and necessary for the diagnosis or treatment of illness or injury,” they should be covered by Medicare.

The Medicare regulations flesh out the general medical-necessity standard. In the SNF context the regulations make it absolutely clear that improvement cannot be the quid pro quo for coverage: “The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities.”

This approach does leave open the possibility that the lack of improvement may be combined with other considerations to reach a determination that a particular individual is not eligible for coverage of skilled services, but that this regulation prohibits requiring improvement potential as a necessary precondition to Medicare coverage is beyond question.

The home health care coverage regulations also define “reasonable and necessary” as specifically requiring an individualized evaluation. With regard to skilled nursing services, the regulations state: “The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary’s unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.”

Although another portion of the home health care regulations related to physical, speech, and occupational therapies mentions “improvement,” it does so only in the alternative, thus again prohibiting improvement as a definitive condition of coverage:

There must be an expectation that the beneficiary’s condition will improve materially … based on the physician’s assessment of the beneficiary’s restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program.

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14. 42 C.F.R. § 409.44. Speech therapy or nursing care, in addition to or instead of physical therapy, may also serve as the “skilled” service triggering Medicare coverage for home health care.

15. The standard is framed in the negative: “[N]o payment may be made … for any expenses incurred for items or services which … are not reasonable and necessary for the diagnosis or treatment of illness or injury …” (42 U.S.C. § 1395y(a) (1)(A)).

16. Id.

17. 42 C.F.R. § 409.32(c); 42 C.F.R. § 409.44(b)(1) of the home health care regulations incorporates by reference the definition of skilled nursing care under 42 C.F.R § 409.32.

18. Id. § 409.44(a).

19. Id. § 409.44(b)(3)(ii).

20. Id. § 409.44(c)(2)(ii) (emphasis added).
Thus not only does the regulation set out alternative bases for coverage, but also, even within the context of the improvement prong, the regulation restates the emphasis on the individual’s “unique” situation.

The regulations are silent, however, in the context of therapy for outpatient (Part B) services. There is no reference to improvement, maintenance, or chronic conditions one way or the other. This lack of direction has created a vacuum that has caused many of the problems in this area, for the void has been filled with numerous and sometimes inconsistent manual provisions.

For the most part, the CMS manual provisions support and reiterate the regulations in their respective areas. The manual provisions make it clear, for example, that the determination of whether a skilled service is reasonable and necessary cannot be based on “rules of thumb” but instead require assessment of the particular individual’s need for care. The Medicare Benefit Policy Manual repeats the regulatory language requiring assessment “of the beneficiary’s unique condition and individual needs” and elaborates on the point: “In addition, skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable.”

Confusion arises, however, when the manual provisions are inconsistent with the regulations. While the home health care speech–language pathology services since the provisions state that Medicare covers those services only if “it is reasonably expected that the services will materially improve the patient’s ability … in a manner that is measurably at a higher level of attainment than that prior to the initiation of the services.” This improvement standard in the manual provisions conflicts with the relevant regulations. The manual requirement results in denying Medicare coverage for, and access to, speech therapy to maintain essential functions such as speaking and swallowing.

In short, the manual provisions are all over the lot, with some reinforcing the regulations and some contradicting them. But the situation is made more confusing by the existence of Local Coverage Determinations, which are developed by individual contractors to guide the jurisdictions in which they operate. Although Local Coverage Determinations are not binding on administrative law judges, contractors’ employees tend to rely on these determinations to make decisions—even when in conflict with the regulations. Consequently elimination or correction of inappropriate language in the manual provisions would have only a limited effect unless and until the Local Coverage Determinations are also corrected and the employees are retrained to expunge the concept of an improvement standard.

III. For the Present, Litigation Is the Most Effective Vehicle for Correcting Improvement-Standard Policies

In a perfect world CMS would recognize the error of its ways and unilaterally act to eliminate the improvement standard.

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21Id. §§ 410.60(a), 410.62(a).
23Id. § 40.1.1.
24Id. § 40.2.1.
25Id. § 40.2.3.
26See 42 C.F.R. § 409.44(c)(2)(iii).
as a condition of coverage. This change could be accomplished without rule making since the regulations enunciate the correct standard and do not need to be altered. Changes in the inappropriate manual provisions would be the first step, which should be followed by a review of Local Coverage Determinations to correct those that establish more restrictive coverage conditions than the statute and regulations allow. Even if CMS would not act on its own, the president could issue an executive order that would require CMS to take those steps.

For the time being, however, those avenues do not appear to be imminent. Litigation thus may be the more effective tool. Successful lawsuits not only would provide relief to individual plaintiffs and perhaps to classes of beneficiaries but also might offer sufficient incentive for CMS to correct the problem finally. A review of the limited and relatively old litigation on this and related issues suggests that the courts have generally been amenable to challenges of this kind. The time has come to bring this issue to court again.

A. Decisions on or Related to the Improvement Standard

The most recent litigation in the area with a substantive (though limited and unpublished) result is the Prendergast case.28 As noted earlier, Prendergast was threatened with termination of her home health care on the ground that her ALS had supposedly stabilized. In granting a temporary restraining order, the district judge stated:

Her eligibility is demonstrated both because the Secretary is incorrect to view her condition as stable and because the strict [stability] standard applied by the Secretary is contrary to Medicare policy and, in judging her need for skilled nursing care for her unique situation, it is apparent, as her doctors have shown, that she needs skilled nursing care.29

The court thus rejected the improvement standard as establishing a necessary condition of coverage and recognized that the need for skilled care had to be judged on each person’s situation.30

Prendergast was preceded by several decisions that came down fifteen to twenty-five years ago. The most important of these is Fox v. Bowen, which was a Connecticut statewide class action on behalf of Part A beneficiaries in SNFs whose coverage of physical therapy was being routinely denied on the ground that the therapy was for maintenance only.31 The court made the key finding of fact that “the intermediaries often deny coverage without giving adequate consideration to the physical therapy skills required in a particular case.”32

In his legal analysis, the district judge reached two main conclusions. First, he held that the regulations “contemplate that each patient will receive an individualized assessment of his need for daily skilled physical therapy based on the facts and circumstances of his particular case.”33 Second, he concluded:

It is clearly contrary to [the] regulations for an intermediary to deny benefits on the basis of informal presumptions, or “rules of thumb,” that are ap-

28Another filed case on the issue is Anderson v. Leavitt, No. 1:09-cv-16 (D. Vt. filed Jan. 16, 2009). Since the complaint’s filing, there have been only procedural rulings.

29Prendergast v. Leavitt, No. 08-cv-1148 (D. Conn., Aug. 1, 2008) (temporary restraining order). The district court made a typographical error in using the word “liability” instead of “stability.” In the quoted language above, we put the correct word in brackets.

30Since the issuance of the temporary restraining order, the Medicare Advantage plan has informally agreed to continue to authorize the home health care at issue.


32Id. at 1240.

33Id. at 1248.
The court then took an unusual tack. Instead of concluding simply that the secretary had not followed the regulations, he applied the three-factor balancing test of Mathews v. Eldridge to hold that the secretary’s practices were in violation of the due process clause. For relief, the court enjoined the secretary from using improper standards to make physical-therapy determinations, directed that class members’ claims previously denied should be reconsidered under the proper standard, and established an ongoing process to ensure that proper Medicare coverage and therapy continue to be available.

In Smith v. Shalala the secretary had determined that an 82-year-old beneficiary with angina, memory deficits, anemia, and cataracts was no longer entitled to home health care because her condition had stabilized to the point that she no longer needed skilled nursing services. Relying on the regulations and the Home Health Agency Manual, the court rejected the notion that the services were no longer reasonable and necessary: “To hold otherwise would be illogical. The fact that skilled care has stabilized a claimant’s health does not render that level of care unnecessary: an elderly claimant need not risk a deterioration of his fragile health to validate the continuing requirement for skilled care.”

Kuebler v. Secretary of U.S. Department of Health and Human Services is not technically an improvement case, but the analysis is applicable to this area. The challenge was to the secretary’s determination that the care at a nursing home was custodial only and therefore not covered by Medicare. Citing several other decisions, the court based its analysis on the view that “the legal standard for determining the need for skilled nursing care is not analysis of services provided but consideration of the patient’s condition as a whole.” Thus the district judge rejected the secretary’s technical definition of custodial care: “[T]he courts have consistently interpreted the term in light of the statute’s benevolent congressional purpose using a nontechnical approach, common sense meaning, and consideration of the needs and underlying condition of the claimant insured as a whole.”

The court held in favor of the beneficiary because of the secretary’s dual failure of not using a correct standard in evaluating the need for skilled care and of ignoring the treating physician’s opinion.

B. Potential Problems with Litigation in This Area

Besides the problems inherent in any challenge to the federal government’s policies, cases disputing application of
Medicare’s improvement standard face hurdles that advocates need to consider in planning litigation.

An early consideration would be whether to bring the case as a class action. While a series of individual cases may ultimately push CMS to change its policy, successful class actions would be the most effective means to achieve that result. To allege and have a class certified is certainly possible, as illustrated by the Fox and Hooper cases, but the nature of the challenge poses problems that may discourage a court from certifying a class. For instance, might a class include everyone affected by the improvement standard in a given locale, or would it have to be limited to those denied coverage either because of the application of a particular manual or Local Coverage Determination provision or because they were seeking a particular kind of care? Certainly the broader the class definition, the louder the government will complain that commonality and typicality are not satisfied.

Furthermore, because Medicare is part of the Social Security Act, litigation in this area has additional potential problems. The first is the jurisdictional requirement that the plaintiff must have “presented” a claim in order for the court to have jurisdiction under 42 U.S.C. § 405(g). Since courts have been applying this requirement more strictly of late, at the very least a beneficiary (or an organizational plaintiff) must bring the claim to the attention of the secretary before filing a lawsuit. Beneficiaries in Parts A and B may file a claim only after the service has been provided. Consequently, if the provider does not believe that the service will be covered, the beneficiary must request that the provider file a claim—a so-called demand bill—and the beneficiary will probably have to pay for the service up front. This requirement may preclude beneficiaries of modest means from obtaining the care and having a claim filed. Nevertheless, regardless of why the claim is not filed, that failure renders a court without jurisdiction to consider the claim.

A related issue is the question of administrative exhaustion. While a court may waive exhaustion, the factors at issue in the waiver analysis often create problems. These factors—whether the claim is collateral to a claim for benefits, whether requiring exhaustion would cause irreparable harm, and whether the purposes of exhaustion would be served (sometimes expressed as whether exhaustion would be futile)—have been discussed and analyzed in depth for over thirty years. Different lower courts have reached different conclusions on crucial points.

This article is not the place for an in-depth analysis of the area, but that failure to exhaust is problematical must be acknowledged. Of course, for beneficiaries who can proceed through the administrative process while paying for their services, the exhaustion problem does not exist. But frequently beneficiaries do not have that luxury, and, having presented their claim, they may need to proceed directly to court.

The improvement standard, by various names, has been with us for many years, causing probably tens or hundreds of thousands of Medicare beneficiaries to be deprived of coverage for needed care.
By now the standard is so imbedded that many decision makers do not accept, even when confronted with the evidence, that the Medicare statute does not authorize the standard and the relevant regulations explicitly indicate the opposite. As long as some manual provisions and Local Coverage Determinations suggest that coverage should be terminated when an individual has plateaued or is not improving or is stable, beneficiaries will continue to lose Medicare coverage and access to necessary health care. This result is especially distressing for those who have chronic diseases and who are simultaneously the most in need of the care and the most likely to have the improvement standard applied to them to deny coverage.

Litigation has not been common in this area, but, as the size of the Medicare population and the need for skilled care increase, more and stronger efforts must be undertaken. Advocates for older people and those with disabilities should recognize the existence of this problem and should give careful consideration to litigating the issue when feasible.

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