August 30, 2018

Alex M. Azar II  
Secretary  
Department of Health and Human Services

Attn: CMS-1689-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Secretary Azar:

I am writing on behalf of The ALS Association to comment on CMS’ Proposed Rule 1689-P. Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig’s disease, is a debilitating, progressive, and fatal neuromuscular disease. This comment letter will focus on two components of the proposed rule – home health and home infusion - which are of critical importance to people living with ALS and their caregivers.

The ALS Association is the only national nonprofit organization fighting the disease on every front. The Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure. We lead the way in global research, helping people with ALS through our chapters and coordinating multidisciplinary health care through clinical care centers.

People with ALS rapidly lose the ability to control movement and basic functions, with the average life expectancy being two to five years after receiving a diagnosis. ALS is highly variable, and no two people are alike in terms of the disease progression. Familial ALS, a hereditary form of the disease, accounts for only 5 to 10 percent of cases. There is no cure or treatment and only three drugs can slow the symptoms.

The Centers for Disease Control and Prevention reports an enrollment of 16,000 people in the National ALS Registry. However, our chapters and clinics serve more than 20,000 people a year. More than 5,000 people every year are diagnosed with ALS.
SECTION I: COMMENTS ON HOME HEALTH

People with ALS Are Unable to Access Medicare Home Health

People living with ALS, as well as our chapters and clinic staff who serve them, report they are rarely able to find a home health agency (HHA) that will accept them as beneficiaries, despite persistent and comprehensive searches. The Medicare home health benefit has and continues to be a valuable, humane, and cost-effective alternative to institutional care. The Association is eager to work alongside the Centers for Medicare and Medicaid Services (CMS) to remove unintended barriers to this benefit for persons with ALS.

Here are the problems:

1. Despite meeting all the requirements, there are serious and persistent problems for people living with ALS accessing any Medicare home health benefits.
2. For the very few who can access the benefit, the services they receive are well below what has been ordered by their physician and to which they are entitled.
3. Finally, some beneficiaries who are receiving care are inappropriately terminated from the Medicare home health benefit.

Home Health Prospective Payment System (HHPPS) Shortchanges Vulnerable Beneficiaries

People with ALS, who are insured under either Medicare or Medicare Advantage, may be eligible for up to 35 hours per week of home health aides and nursing services combined – separate from any necessary physical therapy, speech-language therapy, or occupational therapy—so long as the Medicare home health coverage criteria are met. There is no copayment and no limit on the number of episodes as long as the Medicare beneficiary meets coverage criteria, including: 1) needs skilled services, 2) is under the care of a physician and 3) is homebound such that leaving home requires considerable and taxing effort.

The HHPPS system pays claims based on average costs for 60-day episodes of care, adjusted in very complex and statistically sophisticated ways. The HHPPS allows for outlier payments to be made to an HHA, in addition to regular 60-day episode payments for episodes with unusually large costs due to patient health care needs.
However, no more than 10 percent of any specific HHA’s total payments can be paid as outlier payments. In addition, there is an outlier cap of no more than 2.5 percent for all estimated total Medicare Home Health payments made nationwide to all HHAs.

It is important that CMS is bringing attention to the access problems of people with ALS. The problem reflects the systematic underpayment of Medicare-certified HHA services provided to persons with ALS under the Medicare HHPPS. In the proposed rule, CMS explicitly recognizes that HHAs could only hope to reduce but not eliminate serious underpayment for treating beneficiaries with ALS by use of the outlier adjustment to the HHPPS system. Sadly, even in the carefully crafted and complex illustrative case provided by CMS, the provider is underpaid by thousands of dollars per 60-day episode.

HHPPS is failing to adjust payments fully for high-cost ALS beneficiaries. We suspect this may also be true for other diseases that are similarly devastating. While CMS has indicated that continued refinements to HHPPS may reduce payment disparities at some future point, current marginal adjustments suggested by CMS will not eliminate the access problems summarized above.

**Why Is It So Difficult for a Medicare Beneficiary with ALS To Access Medicare Home Health?**

Medicare beneficiaries with ALS consistently report they are regularly rejected and misinformed about the Medicare home health benefit by HHAs. For example, beneficiaries are told that: 1) Medicare will only cover one to five hours per week of home health aide services or 2) they are not homebound if they go to church – even if it takes extraordinary effort to leave home.

How can an HHA refuse to admit an eligible beneficiary who is fully qualified and eligible to receive the Medicare home health benefit? HHAs are permitted to deny admission to any beneficiaries for whom they determine that the extent and intensity of care is beyond their agency’s treatment capacity. Thus, an agency can easily avoid acceptance of beneficiaries whose costs are predictably above Medicare payments by aggressively marketing to and serving more profitable beneficiary groups and then asserting they do not have the staffing capacity remaining to treat high-intensity ALS beneficiaries.
This leaves Medicare beneficiaries with ALS in a position where they will inevitably be denied access to home health care which they desperately need and to which they are entitled, while those with less complex and costly conditions have full access to care because they create a positive return. This unfairness is unsatisfactory for beneficiaries with ALS, their families, the agencies themselves, and, we believe, CMS itself.

**Caps In Place and Outlier Payment Still Results in Loss of 20 Percent of Imputed Cost of Care**

In the proposed rule, CMS suggests that HHAs that turn away ALS beneficiaries may be unaware of the outlier payments noted earlier. We sincerely doubt that any agency that can survive the rigors of the complex HHPPS would be unaware of the outlier provisions. We believe that, while there are some agencies whose size, sophistication, and commitment to community service allow them to accept a limited number of beneficiaries on whom they consistently lose money upon Medicare payment, this is not the norm.

While we recognize that the Medicare Payment Advisory Commission does report profit margins for HHAs, the clear majority of agencies will not risk accepting an open-ended commitment to serve beneficiaries who they anticipate will systematically create losses for their agency. This is especially true for Medicare beneficiaries with ALS, given their increasing intense and costly needs.

**HHAs are aware that every beneficiary who generates a large outlier payment will also generate a loss.** HHAs understand that the fundamental operating principle underlying the calculation of the additional HHPPS “outlier” payment, by design, requires that the agency be underpaid because both the regulatory “fixed dollar loss” amount and “cost-sharing ratio” automatically reduces the payment they will receive by over 20 percent of the “imputed” cost of care. For HHAs whose actual reasonable cost of care exceeds that “imputed” average national cost, the losses will be even greater.
Serious Financial Disincentives Discourage HHAs From Accepting Medicare Beneficiaries with ALS

HHAs find themselves in a dilemma. This is true whether they operate as a profit-making enterprise with a financial obligation to their investors to avoid losses or are a mission-driven agency with a limited capacity to absorb all the losses they will incur for a high-cost beneficiary, such as someone with ALS. Accepting such beneficiaries carries with it the possibility of incurring an unacceptable level of losses. Agencies who fail to balance Medicare payment losses with positive payments become insolvent and will close, as many have.

Jimmo Settlement (Improvement Standard)

For those very few people with ALS who are able to access the Medicare benefit, the improvement standard is still a significant problem. We appreciate CMS’ efforts to implement the Jimmo Settlement, but we continue to hear reports of CMS’ contractors making denials or misinterpreting this coverage clarification to providers. Providers then incorrectly tell beneficiaries that they cannot provide maintenance therapy for persons with ALS because they will not improve. We ask CMS to: 1) redouble its efforts to rectify this situation and 2) conduct its own monitoring to enforce this provision of law.

Inadequate Recruitment of Home Health Aides to Meet Beneficiaries’ Needs

We would also like to highlight that the struggle for Medicare beneficiaries with ALS to gain access to needed services is exacerbated by agencies who indicate they are not adequately staffed with home health aides. Medicare home health aide understaffing is chronic and suggests that it is often used as deliberate means to limit access to beneficiaries with ALS and others with heavy support needs. We hear reports that those same agencies, which claim inadequate levels of home health staffing, are making referrals to nearby non-Medicare agencies who are fully staffed to provide such services, but at a private pay rate.

We urge CMS to require agencies whose licensure and certification includes the provision of home health aides to staff this service adequately.
Opportunities and Risks of Telemonitoring Nursing Visits

We understand that recognizing the costs of home health nursing services provided through telemonitoring and other telemedicine services is long overdue. Such nursing visits can provide quick intervention between in-person visits. CMS must ensure, however, that such services do not replace face-to-face, hands-on nursing visits and that all nursing services are considered qualifying services, whether provided in-person or remotely. To eliminate in-person visits limits the important role of nursing observation and treatment. To fail to consider remote visits as qualifying visits risks a beneficiary’s Medicare eligibility for continued, covered home health care under the statute.

Balancing Incentives for Therapy Visits

While we understand CMS’s good intent in its ongoing effort to reduce the over-weighting of therapy in the HHPPS payment model, we are concerned that any change ensures that the level of payment for people with ALS who might benefit from therapy remains high enough to compensate providers for the cost of therapy services. For those persons with ALS who do benefit from therapy, a change that creates a payment disincentive to provide therapy could be disastrous.

Solutions Are Urgently Needed

We urge CMS to work with The ALS Association and other partners to put in place remedies that remove barriers and streamline requirements to create access to the Medicare home health benefit for beneficiaries with ALS. Here are some specific suggestions:

1. **Stop Avoidance, Underservice, and Inappropriate Discharge of People with ALS:**
   We urge CMS to take immediate steps to stop the avoidance, underservice, and inappropriate discharge of Medicare beneficiaries with ALS by HHAs from the Medicare home health benefit. These problems are currently denying critically needed care for individuals with ALS who are entitled to the Medicare home health benefit.
2. **Undertake “Advanced Disease Management” (ADM) Payment Demonstration:**
   We urge CMS to undertake a demonstration that is a combination of the appropriate features of the Medicare home health and hospice benefits. Such a demonstration program would constitute a cost-effective alternative to the use of both benefits and ensure access to beneficiaries needing such care. This ADM benefit would blend the curative treatment approach of home health and the palliative care benefits of hospice in a manner that allows a seamless transition for persons whose disease process is highly likely to advance and result in death within a two-year period.

3. **Undertake Demonstration on Alternative Payment:**
   We urge CMS to undertake a demonstration to test whether an alternative payment mechanism under the home health benefit, similar to Disproportionate Share Payments or Special Needs Plans, would provide full access to home health care for ALS and similar beneficiaries.

4. **Fix the Outlier Cap:**
   We urge CMS to exempt additional payments for high-cost beneficiaries from the 10 percent agency specific outlier cap as well as the 2.5 percent national aggregate outlier cap, either by deeming them a supplemental PPS payment or seeking legislative relief in such cases.

5. **Pay Full Reasonable Costs:**
   We urge CMS to identify specific diseases, including ALS, that are systematically underpaid, even under outlier policy, and exempt outlier payments for such beneficiaries from the fixed dollar loss amount and cost sharing percentage up to the full reasonable cost of care at those agencies accepting them for care.

6. **Adequately Supply Home Health Aides:**
   We urge CMS to require agencies whose licensure and certification includes the provision of home health aides to staff this service adequately. Alternatively, CMS could mandate that all agencies be staffed with adequate resources to serve all beneficiaries on a first-come, first-served basis and suspend all admissions until their staffing allows admissions to resume in the order of qualified Medicare beneficiaries seeking services.
7. **Fully Enforce Jimmo Settlement Agreement (Improvement Standard):**
   We urge CMS to redouble its efforts to guarantee, as outlined in the Jimmo Settlement Agreement (January 2013), that coverage cannot be denied based on the absence of potential for improvement for the Medicare home health benefit.

8. **Telemonitoring Should Be A Qualifying Service But Not Replace In-Person:**
   We urge CMS to ensure that telemonitoring nursing services do not replace face-to-face, hands-on nursing visits and that all nursing services be considered as qualifying services, whether provided in-person or remotely.

9. **Carefully Consider Therapy Payment Changes:**
   We urge CMS to carefully design any changes in payment for therapy under the HHPPS so that it is neither over-weighted nor underweighted to prevent creating yet a new barrier to access for ALS and other beneficiaries.

**SECTION 2: COMMENTS ON HOME INFUSION**

Intravenous therapy has taken on new significance to those with ALS because Radicava, the first new drug in 22 years that slows the progression of ALS symptoms, was approved by the Food and Drug Administration (FDA) in 2017. It requires long-term intravenous administration. Although Radicava will not be directly impacted by the proposed rule, we believe that the growing use of home intravenous therapy demands our interest in the proper implementation of this benefit.

We are pleased that CMS has begun implementation of Section 5012 of the 21st Century Cures Act of 2016, which includes a new service under Medicare, Home Infusion Therapy Services. This service is much-needed to allow individuals who require intravenous therapy to receive care at home without meeting the overly restrictive requirements imposed under the home health benefit, such as the homebound requirement.

As you recognize elsewhere in this proposed rule, several aspects of the current HHPPS are having the unintended effect of creating barriers to access to the Medicare home health benefit for individuals with ALS because of their complex treatment needs.
We urge CMS to be particularly sensitive to the unintended access problems that have been created in the home health benefit, so they are not repeated in the implementation of this new and valuable home infusion benefit.

Specifically, we are very concerned that analysis by the National Home Infusion Association indicates that CMS’ interpretation of the statute as reflected in the proposed rule is inaccurate and may fail to pay adequately to encourage participation by qualified providers in this benefit and ensure high quality care for beneficiaries. We believe that congressional intent was clear that the payment be sufficient to cover all the professional services needed to safely and effectively administer Part B infusion drugs and train beneficiaries and families to administer the drug. These services are more than a skilled nursing service and require the involvement of pharmacists and, potentially, other professionals.

Finally, we also urge that coverage guidelines for home infusion therapy clearly make continued coverage available even if the beneficiaries and/or family are unwilling or unable to be trained to assume responsibility for the infusion themselves.

CONCLUSION

In conclusion, we urge CMS to work with The ALS Association and other stakeholders to quickly explore and put in place solutions to problems experienced by Medicare beneficiaries with ALS – for both the Medicare home health and the Medicare home infusion benefits. If you need further information, please feel free to contact Kathleen Sheehan, vice president of public policy at The ALS Association, at ksheehan@alsa-national.org or (202) 464-8645.

Thank you for the ability to comment. I look forward to working with you to improve services for people living with ALS.

Sincerely,

Neil Thakur, Ph.D.
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The ALS Association
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