

September 14, 2010

Dr. Donald Berwick, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1510-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices (RIN: 0938-AP88)

Dear Administrator Berwick:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.¹

Background

On July 23, 2010, The Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* a proposed rule titled, Medicare Program: Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices.² HHS indicates in the introductory section of this proposed rule that this proposed rule would: update the Home Health Prospective Payment System (HHPPS) rates effective January 1, 2011, update the wage index and outlier used under the HHPPS, and institute changes to the home health agency (HHA) capitalization requirements, among other changes.³

¹ Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).

² 75 Fed. Reg. 43236, July 23, 2010.

³ Id.

Advocacy was approached by home health care agencies (HHA) that are considered small businesses pursuant to the applicable SBA size standards. The stakeholders asked my office to review the above-captioned proposed rule because they believe that the regulation will significantly impact their businesses and potentially affect beneficiary access to quality care. These concerns primarily involve the rule's proposed changes to HHAs' certification and capitalization requirements. In addition, during Advocacy's review of the rule, certain aspects of CMS' compliance with the RFA arose. It is my hope that CMS will take the following comments into consideration and improve its regulatory flexibility analysis as it finalizes this rule.

HHS certified that this rule will not have a significant impact on a substantial number of small entities pursuant to the requirements of the RFA.

CMS' regulatory analysis indicates that for the purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.⁴ Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.0 million to \$34.5 million in any given year. Therefore, for the purposes of this regulation CMS treats all health care providers affected by this rule as small entities, because 90 percent or more of the health care providers meet the SBA's size standards as measured either by their annual receipts or nonprofit status.⁵ CMS states that the Secretary has concluded that the proposed rule will not have a significant impact on a substantial number of small entities.

Section 605 of the RFA requires that if the regulatory agency certifies that the rule will not have a significant impact on a substantial number of small businesses, it must include a statement providing the factual basis supporting the certification. Advocacy suggests that CMS failed to provide an adequate factual basis for its certification of no impact. In fact, there is no language in the RFA section of the rule that discloses the reasons why CMS concluded that there we be no impact on the affected small HHAs. CMS should at a minimum have provided the public with information on the number of home health care agencies and other health care entities likely to be affected by the rule. Further, CMS has guidelines (usually based on small business revenues) in place that the agency uses to determine whether a rule will have a significant impact on a substantial number of small entities. CMS failed to discuss how the impacts of this rule fall within its guidelines. This is vital for the purposes of transparency as affected small entities can use this information to provide CMS with economic impact information on the rule's projected impact on their business. Based on the public input CMS can determine the validity of their decision to certify the rule in the publication of the final regulation.

Advocacy is concerned that while CMS has certified that the rule will not have a significant impact, the affected HHAs believe that the regulation will result in a significant burden on their businesses. Advocacy believes that there is merit in bringing these small business concerns to the attention of CMS in the hope that it will add to the transparency of the regulatory flexibility analysis contained in the final rule.

⁴ Id.

⁵ Id.

Background on the “36-Month Rule” that is of primary concern to HHAs

As part of the Home Health Prospective Payment System Rate Update for Calendar Year 2010 Final Rule, CMS finalized a policy stating that “if an owner of a home health agency [“HHA”] sells (including asset sales or stock transfers), transfers or relinquishes ownership of the HHA within 36 months after the effective date of the HHA’s enrollment in Medicare, the provider agreement and Medicare billing privileges do not convey to the new owner.” This rule took effect for ownership changes on or after January 1, 2010. Prior to the effective date of the rule, however, CMS issued a Transmittal, CR 6750, on December 18, 2009 (the “Transmittal”) that greatly expanded the application of the rule in several ways and instructed contractors on the implementation of the expanded rule.

On May 6, 2010, based upon significant concerns raised by the industry related to the underlying policy reasons for the rule and the expanded interpretation of the rule, CMS rescinded the Transmittal but left the underlying regulation in effect. On July 23, 2010, CMS issued the Proposed Rule re-affirming the 36-Month Rule. The Proposed Rule, however, also added a number of exemptions from the applicability of the 36-Month Rule. Specifically, CMS proposed to prohibit the transfer of a Medicare provider number (and billing privileges) by a Medicare home health provider undergoing an ownership change if the HHA originally enrolled in Medicare or underwent a previous ownership change within the prior 36 months, except under the following circumstances:⁶

1. A publicly-traded company is acquiring another HHA, and both entities have submitted cost reports to Medicare for the previous five years;
2. An HHA parent company is undergoing an internal corporate restructuring and the HHA has submitted a cost report to Medicare for the previous five years;
3. The owners of an existing HHA decide to change the existing business structure (e.g., partnership to a limited liability corporation or sole proprietorship to subchapter S corporation), the individual owners remain the same, and there is no change in majority ownership (i.e., 50 percent or more ownership in the HHA); or
4. The death of an owner who owns 49 percent or less interest in an HHA (where several individuals and/or organizations are co-owners of an HHA and one of the owners dies).

HHAs’ comments on the 36-Month Rule

HHAs are primarily concerned with interpretation and implementation of the “36-Month” Rule. HHAs told Advocacy that in the past CMS has indicated that the intent of the 36-Month Rule was to create a balance between the need to permit legitimate business transactions and the need to protect the Medicare program from fraud and abuse. The HHAs agree with the underlying purpose of the regulation; however, they feel that some aspects of the 36-Month Rule create unintended consequences that will negatively impact their businesses and patient access to care. Some of their concerns are as follows:

1. The HHAs acknowledge CMS’ willingness to entertain and propose the four exemptions to the 36-Month Rule (as is encouraged by the RFA §603(c)). However, the HHAs are concerned that the purchaser of an HHA that does not qualify for one of the narrow exemptions would be required to enroll in the Medicare program as a new HHA and

⁶ As defined at 42 CFR 489.18.

incur the time and expense of having to obtain a state survey or accreditation from an approved accreditation organization if such a transaction takes place within 36 months from the original date of enrolment or the last ownership change involving that HHA. The HHAs assert that this process could take months, impose additional administrative burdens and cost, create a competitive advantage to a small number of businesses and negatively impact Medicare beneficiary access to care.

2. HHAs believe that the 36-Month Rule will reduce their access to capital. This is because many banks have stopped lending money to HHAs as a result of the proposed 36-Month Rule. HHAs suggest that because of the nature of the home health industry and its relatively small amount of tangible fixed assets, lenders will loan to an HHA only if they can effectively secure that debt through foreclosure. Under the proposed 36-Month Rule, however, if a lender were forced to foreclose on an HHA within 36 months of its most recent ownership change, or even if the foreclosure occurred beyond 36 months but the lender desired to resell the HHA within 36 months of foreclosure, the existing provider number would be deactivated and new Medicare enrollment would be required. Thus, the proposed 36-Month Rule effectively eliminates the option of foreclosure as security for lenders. With no viable replacement for that security, finalization of the 36-Month rule as currently proposed will eliminate meaningful infusions of debt capital into the home health industry.
3. The proposed 36-Month Rule will significantly impair the ability of HHAs to obtain vital equity capital infusions, whether or not the HHA has been in existence for more than 36 months. A new enrollment and related survey can take up to a year to successfully obtain and it is difficult for any business to incur expenses absent revenue for that amount of time. Requiring new Medicare enrollment would result in this untenable reality. Moreover, the requirement in the proposed rule that the 36-Month Rule clock “restart” after each transaction is a significant deterrent to capital investment. While an individual or an organization may have every intention of maintaining their ownership for more than 36 months at the time of its initial investment, many personal and professional things can occur to impact that timing. Prohibiting these entities from exiting their investment for 36 months will simply cause many of them to be unwilling to invest in the home health industry.
4. HHAs believe that the 36-Month Rule will result in the disruption of access to care for Medicare and Medicaid beneficiaries in the event that a HHA undergoes a prohibited transaction. For example, many states require a HHA to maintain a valid Medicare certification as a prerequisite for participation in the state’s Medicaid program, even though the HHA does not provide services to Medicare beneficiaries. The HHAs point out that there already exists a shortage of Medicaid-certified home health providers in many areas, a problem that would be exacerbated by the 36-Month Rule.
5. HHAs suggest that the 36-Month Rule’s requirement that a survey be undertaken is duplicative with CMS’ authority to conduct a survey of any HHA within two months of a change in ownership, administration, or management.⁷ The HHAs suggest that CMS should consider changes to this provision of the 36-Month Rule.

⁷ See 42 U.S.C. § 1395bbb(c)(2)(B)(i).

6. The HHAs point out that the majority of HHAs are small privately-held businesses that lack the resources of some publically-held HHAs. They suggest that CMS provided too much relief under the exemption for “public companies” in the 36-Month Rule that will serve to provide those businesses with a competitive advantage.

Conclusion

The HHAs offer an alternative to CMS that will solve some of the concerns outlined above. They suggest that CMS clarify in the regulation that the 36-Month Rule does not apply to HHAs that have submitted cost reports to Medicare for more than 36 months. They believe that this will allow CMS to balance the protection of the Medicare program without restricting legitimate transactions by HHAs. Advocacy has been told that the HHAs will provide CMS with language that will effectuate this recommendation in their comments to the proposed rule.

Advocacy requests that CMS take Advocacy’s RFA comments and the concerns identified by the affected industry into consideration as the agency finalizes this rule. Thank you for your attention to the above matter. If you have any questions or concerns, please do not hesitate to contact me or Linwood Rayford at (202) 205-6533, or linwood.rayford@sba.gov.

Sincerely yours,

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

Linwood Lee Rayford, III
Assistant Chief Counsel Advocacy

Cc: Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs