

September 10, 2013

The Honorable Marilyn B. Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
Room 445-G  
200 Independence Ave, S.W.  
Washington, D.C. 20201

**Re: Medicare and Medicaid Programs: Home Health Prospective Payment System  
Rate Update for CY 2014, Home Health Quality Reporting Requirements, Cost  
Allocation of Home Health Survey Expenses (RIN: 0938-AR52)**

Dear Administrator Tavenner:

As the Chief Counsel for the Office of Advocacy (Advocacy), I am writing you regarding the above-referenced proposed rule. Advocacy is concerned that the Centers for Medicare and Medicaid Services (CMS) has certified that the rule will not have a significant economic impact on a substantial number of small entities without providing a factual basis for the certification as is required by the Regulatory Flexibility Act. Advocacy is also concerned about the methodologies and assumptions underlying CMS' economic analysis and possible alternative approaches. For these reasons set out below, Advocacy believes that CMS should improve its small entity impact analysis as it drafts the Final Regulatory Flexibility Analysis to be contained in the final rule.

**The Office of Advocacy**

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),<sup>1</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>2</sup> gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives. The Small

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<sup>1</sup> 5 U.S.C §601 et seq.

<sup>2</sup> Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et. seq.).



Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.<sup>3</sup> The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.<sup>4</sup>

### **Statutory and Regulatory Background**

Section 3131(a) of the Affordable Care Act (ACA) requires that, starting in calendar year (CY) 2014, CMS apply an adjustment to the national, standardized 60-day episode payment rate and other applicable payment amounts to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, the law provides that CMS phase-in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) in any given year, and be fully implemented by CY 2017.

On July 3, 2013, CMS published in the *Federal Register* a proposed rule titled, Medicare and Medicaid Programs: Home Health Prospective Payment System Rate Update for CY 2014, Home Health Quality Reporting Requirements, Cost Allocation of Home Health Survey Expenses.<sup>5</sup> HHS indicates in the introductory section that this proposed rule would, among other things: update the Home Health Prospective Payment System (HH PPS) rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, the low-utilization payment adjustment (LUPA) add-on, the non-routine medical supplies (NRS) conversion factor, and outlier payments under the Medicare prospective payment system for home health agencies (HHAs), effective January 1, 2014. Also, the rule proposes rebasing adjustments, with a 4-year phase-in, to the national, standardized 60-day episode payment rates; the national per-visit rates; and the NRS conversion factor as is required by the ACA.<sup>6</sup> The proposed rule suggests that the overall economic impact of the regulation would be an estimated \$290 million in decreased payments to HHAs in calendar year 2014.<sup>7</sup> While acknowledging the reduction in Medicare reimbursements to home health providers, the agency chose to certify in the RFA section of the rule that the regulation would not have a significant economic impact on a substantial number of small entities.<sup>8</sup>

Advocacy was approached by HHAs and their representatives from the National Association for Home Care and Hospice (NAHC). The stakeholders asked my office to review the above-captioned proposed rule because they believe that the proposed regulation will significantly impact their businesses and may potentially affect Medicare beneficiary access to quality care. While CMS provides some economic data in its

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<sup>3</sup> Small Business Jobs Act of 2010 (Pub. L. 111-240) § 1601.

<sup>4</sup> *Id.*

<sup>5</sup> 78 Fed. Reg. 40272, July 3, 2013.

<sup>6</sup> Section 3131(a) of the Patient Protection and Affordable Care Act of 2010. (Pub. L. 111-148).

<sup>7</sup> 78 Fed. Reg. 40274.

<sup>8</sup> 78 Fed. Reg. 40305.



Regulatory Impact Analysis as to the rule's anticipated impact on HHAs, it is my hope that in the final rule CMS will take the following comments into consideration and improve its regulatory flexibility analysis.

**I. HHS certified that this rule will not have a significant economic impact on a substantial number of small entities pursuant to the requirements of the RFA, but has not provided a factual basis for this certification.**

CMS' Regulatory Impact Analysis indicates that for the purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.<sup>9</sup> 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.<sup>10</sup> Therefore, CMS stated that the Secretary [of HHS] has concluded that the proposed rule will not have a significant impact on a substantial number of small entities.<sup>11, 12</sup>

Advocacy believes that the transparency of this proposed rule would be increased if CMS refined the RFA analysis that led the agency to certify no impact. 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. There is no language in the RFA section of the rule that discloses the reasons why CMS concluded that there will be no significant impact on the affected small HHAs. Advocacy suggests that CMS' certification would be buttressed if the agency provided an improved explanation for its conclusion that the proposed rule would not have a significant impact on a substantial number of small entities.

**II. The proposed rule analyzes economic impacts on affected entities through the measurement of volume of episodes in urban and rural locations, and not by CMS' typical measure of significant economic impact based on an analysis of affected small entity revenues.**

In order to determine if a proposed rule is likely to have a significant impact on a substantial number of small entities CMS typically uses its guidelines on proper consideration of small entities in rulemakings. The economic impact assessment is usually based on business revenue and the agency generally maintains that if the average annual impact on small entities is 3-5 percent or more, it is considered to be significant. In this regulation CMS published table 29 which reflects the measurement of impacts associated with the proposed rule.<sup>13</sup> Table 29 represents CMS' estimates on how HHA

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<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> While CMS certified no impact, the agency also suggests on page 40305 that the Regulatory Impact Analysis, discussion of alternatives, and the rest of the preamble is to be construed as an Initial Regulatory Flexibility Analysis (IRFA).

<sup>13</sup> 78 Fed. Reg 40306.



revenues are likely to be affected by the policy changes proposed in this rule by utilizing multiple criteria, including type of facility, geographic region, location in a rural or urban location, and the number of patient first care episodes.<sup>14</sup> This analysis, while informative, does not provide interested stakeholders with an assessment of the rule's impact on businesses based on size, according to an analysis of revenues. Further, it does not comport with CMS' guidelines on how to determine whether the rule will have a significant impact on HHAs.

A review of publicly available information as to what impact a reduction in Medicare payments rates would have on HHAs does nothing to inform interested parties about how any changes in the payment rate calculation might impact their revenues. Examples can be found in the March 2013 Medicare Payment Advisory Commission (MedPAC) Report to Congress (tables 9-8, 9-9 and 9-10),<sup>15</sup> MedPAC also reported differentials in HHA margins through an analysis of provider geography (urban or rural), type of business (for profit, non-profit or governmental) and volume of episodes. As such, MedPAC's analysis, taken in conjunction CMS' analysis in the proposed rule, is not necessarily an indicator of Medicare HHA margin differential as they relate to HHA's revenues.

An analysis of HHA revenue based on size 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 businesses. If specific or more granular revenue data information is not available to CMS, Advocacy recommends that CMS use Medicare margins as a proxy. Based on the public input CMS can then determine the validity of its decision to certify the rule in the publication of the final regulation.

**III. The assumptions utilized by CMS in the proposed rule and the discussion of possible alternative approaches may result in industry uncertainty as to how the regulation's provisions will impact affected entities in CY 2014 and beyond to CY 2017.**

One of the goals of the RFA is to prevent agencies from implementing one-size fits all regulations. A more granular assessment of impacts of this regulation through the use of an IRFA is important because the proposed rule seeks to implement a change in how the Medicare payment rate for HHAs is calculated through the "rebasing" formula for the national, standardized 60-day episode payment rate. While Advocacy is not asserting that the "rebasing" methodology was done incorrectly, it is suggesting that CMS' assumptions on case-mix weighting and other inputs used in the rebasing calculation were, in part, based on limited information. The uncertainty of the rebasing methodology is reflected in CMS' statement, "that as more 2012 data becomes available, we plan to update the estimated average case-mix weight for CY 2012 and adjust the case-mix weights and budget neutrality factor accordingly. Therefore, the weight reduction factor in the CY

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<sup>14</sup> *Id.*

<sup>15</sup> Medicare Payment Advisory Commission's, *Report to Congress: Medicare Payment Policy*, pages 202-203 (March 2013), available at [http://www.medpac.gov/documents/Mar13\\_entirereport.pdf](http://www.medpac.gov/documents/Mar13_entirereport.pdf).



2014 HH PPS final rule may be different from the one used to produce the proposed weights in this proposed rule.”<sup>16</sup> Because of these uncertainties, industry representatives questioned how CMS could reasonably certify that this rule will not have a significant impact on a substantial number of small entities.

Section 3131(d) of the ACA required CMS to analyze any concerns associated with the HH PPS, demonstration authority to test any PPS changes on the industry, and Medicare beneficiary home health access to care. The ACA also required CMS to phase-in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) in any given year, and be fully implemented by CY 2017. CMS’ Regulatory Impact Analysis did not provide the affected entities with a projected analysis of the payment outlook from 2015 through 2017 as the proposed rule only covers CY 2014.<sup>17</sup> Further, an improved IRFA will help CMS acquire the data necessary to comply with the agency’s HH PPS analytical mandate under the ACA. More specifically, as a straightforward way to improve the Regulatory Impact Analysis and the IRFA, CMS could build off the analysis in the Abt report<sup>18</sup> to provide more detail on its assumptions and findings. For example, through review of the Regulatory Impact Analysis and Abt report, industry was able to determine the overarching methodology CMS applied in its rebasing approach (the percent difference in the average payment relative to average cost per episode). However, industry was unable to determine the methodology utilized in calculating the four year phase-in rate and remains unclear on the exact data limitations that lead to the use of payment proxies. CMS could clarify these uncertainties by incorporating elements of the Abt report into the Regulatory Impact Analysis and offering further explanation for those issues which affected entities remain unclear.

Small businesses routinely tell Advocacy that regulatory certainty is of the utmost importance to their ability to plan for the future. In the RFA section’s discussion of alternatives, CMS outlines approximately four regulatory directions that it considered while drafting the proposed rule. The alternatives discussed include: 1) a downward adjustment to the costs per-visit as a result of the findings from the audits of 98 Medicare home health cost reports; 2) updating costs by the home health payment update percentage rather than the full home health market basket; 3) setting the target national, standardized 60-day episode payment rate for rebasing at 5 percent below the estimated cost per episode derived from the 2011 cost reports; and 4) implementing a prospective reduction for nominal case-mix growth for 2014. While Advocacy commends CMS for including this discussion of alternatives in the RFA section of the proposed rule,

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<sup>16</sup> 78 Fed. Reg. 40281.

<sup>17</sup> CMS explains its reasons for limiting the impacts of this rule to CY 2014 in the preamble and in the Regulatory Impact Statement, however, on page 40308 CMS refers to “annualized monetized transfers” in its Accounting Statement (tables 30 and 31). This terminology typically indicates an annualized valuation over a stream of time and assumes a particular discount rate rather than a first year or single year impact. CMS should clarify and explain this point in the final rule.

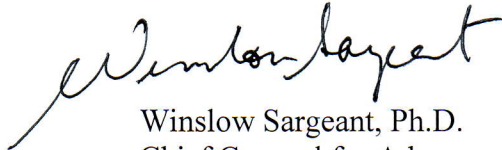
<sup>18</sup> Abt Assoc., Inc. *Analysis in Support of Rebasing & Updating Medicare Home Health Payment Rates* (June 21, 2013) (prepared for Centers for Medicare and Medicaid Services, Chronic Care Policy Group, Division of Home Health & Hospice).

Advocacy is concerned by CMS' statement with respect to alternatives one through three that, "We plan to continue to evaluate these alternative factors for rebasing and may consider incorporating these factors into the CY 2014 HH PPS final rule." If CMS intends to implement any of these alternatives in the final rule then the agency should have analyzed how the alternatives could have achieved the statutory objective of the rule while minimizing the burden on small entities.

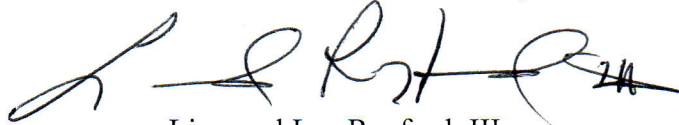
### **Conclusion**

Advocacy requests that CMS take Advocacy's RFA comments and the small business concerns identified by the affected industry into consideration as the agency finalizes this rule. Thank you for your attention to the above matters. 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](mailto:linwood.rayford@sba.gov).

Sincerely yours,



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Cc: Howard Shelanski, Acting Administrator, Office of Information and Regulatory Affairs