

August 29, 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 Program; End-Stage Renal Disease Prospective Payment System,
Quality Incentive Program, and Durable Medical Equipment, Prosthetics,
Orthotics, and Supplies (RIN 0938-AR55)**

Dear Administrator Tavenner:

The Office of Advocacy (Advocacy) respectfully submits the following comments on the above-referenced proposed rule. For 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. Advocacy also believes CMS should take into consideration industry's suggested alternatives, in order to minimize the rule's impact on small dialysis providers.

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),¹ as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),² 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 Business Jobs Act of 2010 requires agencies to give every appropriate consideration to

¹ 5 U.S.C. § 601 et seq.

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

comments provided by Advocacy.³ 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.⁴

Background

Section 3401(h) of the Affordable Care Act (ACA) established that beginning in calendar year (CY) 2012, and in each subsequent year, the Secretary [of HHS] shall reduce the market basket increase factor by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Social Security Act (Act).⁵ In addition, section 1881(b)(14)(I) of the Act, as added by section 632(a) of the American Taxpayer Relief Act of 2012 (ATRA),⁶ requires the Secretary, by comparing per patient utilization from 2007 with such data from 2012, to reduce the single payment amount to reflect the Secretary's estimate of the change in the utilization of end-stage renal disease (ESRD) related drugs and biologicals.⁷

On July 8, 2013, the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* a proposed rule titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies."⁸ CMS indicates in the introductory section of this proposed rule that this proposed rule would, among other things update and make revisions to the ESRD prospective payment system (PPS) for CY 2014.

In the RFA section of the rule, CMS estimates that approximately 18 percent of ESRD dialysis facilities are deemed to be small entities per the SBA's size standards (defined as having total revenues of less than \$35 million).⁹ The rule assumes that there are 614 independent facilities and 400 hospital-based "small" facilities.¹⁰ The overall impact of the CY 2014 changes is projected to be a 9.4 percent decrease in payments.¹¹ CMS estimates that the proposed revisions to the ESRD PPS will result in a decrease of approximately \$970 million in payments to ESRD facilities in CY 2014.^{12,13} Based on

³ Small Business Jobs Act of 2010 (PL 111-240) § 1601.

⁴ *Id.*

⁵ Pub. L. 111-148.

⁶ Pub. L. 110-275.

⁷ Effective January 1, 2011, ESRD-related laboratory services and drugs and biologicals previously separately billable under Medicare Part B were included in the ESRD PPS. Utilization of ESRD drugs in 2011 was lower, on average, than it was in 2007, driven largely by a decline in the utilization of erythropoiesis stimulating agents (ESAs). As a result, Medicare may have paid more than necessary for dialysis care in 2011 because the bundled payment rate in that year was based on 2007 utilization levels.

⁸ 78 Fed. Reg. 40836, July 8, 2013.

⁹ 78 Fed. Reg. 40888.

¹⁰ *Id.*

¹¹ 78 Fed. Reg. 40839.

¹² 78 Fed. Reg. 40881.

the number of small entities and the anticipated decrease in revenue, CMS determined that this rule will have a significant impact on a substantial number of small entities and the agency appropriately performed an Initial Regulatory Flexibility Analysis (IRFA).¹⁴

Advocacy was approached by representatives of the National Renal Administrators Association (NRAA), which is primarily comprised of community based small dialysis organizations, both for-profit and non-profit providers serving patients in urban, rural and suburban areas in both free-standing and hospital-based facilities. NRAA indicated, and the data reflects, that two large dialysis companies provide the bulk of Medicare beneficiary ESRD dialysis services. Advocacy reviewed this rule specifically as it relates to impacts on small dialysis providers. NRAA believes that CMS should use its broad-based legal authority and statutorily granted discretion to make more equitable adjustments to the proposed payment system, especially for small providers. The proposed ESRD PPS rate is essentially comprised of calculations for the ESRD bundled market basket reduced by the productivity adjustment called for in the ACA, the wage index budget neutrality adjustment factor, and the drug utilization adjustment provided for in the Act.¹⁵ NRAA submits that CMS failed to take into account industry costs associated with the U.S. budget sequestration, and cost for their operating, overhead and reporting expenses when it decided to implement the full reduction provided for in section 1881(b)(14)(I) of the Act in this rule. Also, NRAA believes the proposed rule's assumptions lack transparency on issues such as the cost of drugs in 2007, and the inflation calculation for those drugs in 2014 dollars. The Medicare Payment Advisory Commission (MedPAC) notes that certain drugs represent a significant portion of ESRD costs.¹⁶

As a result of the above concerns, NRAA believes that the 2014 ESRD PPS base rate will result in many small providers operating at a negative Medicare profit margin,¹⁷ and will impact Medicare beneficiaries' access to care, especially in isolated rural areas.¹⁸

¹³ The \$970 million decrease in payments is comprised of a \$210 million increase from the market basket update and a \$1.02 billion decrease from the reduction in drug utilization as well as other reductions from the productivity adjustment, updates to outlier thresholds, and updates to the wage index.

¹⁴ 78 Fed. Reg. 40888.

¹⁵ 78 Fed. Reg. 40838.

¹⁶ Medicare Payment Advisory Commission's (MedPAC), *Report to the Congress: Medicare Payment Policy*, 148-149 (March 2012) (hereinafter MedPAC 2012), available at http://www.medpac.gov/documents/Mar12_EntireReport.pdf (noting that 3 drug classes constitute 98 percent of dialysis drug spending and approximately 33 percent of total dialysis spending; see also Figure 6-2).

¹⁷ In support of its negative margin argument, NRAA contracted with Avalere Health which conducted an analysis of 2012 small and independent dialysis provider revenues and costs. The study evaluated the impact on dialysis providers of the U.S. budget sequestration and the cuts proposed in this rule. Avalere concluded that the sequestration cuts would have a -5% impact on providers' Medicare margins, and a combination of sequestration cuts and reductions in this rule would result in 76% of small and medium independent providers showing a negative Medicare margin.

¹⁸ MedPAC 2012 at pages 162 and 163.

CMS should improve its IRFA by taking a closer look at industry size, costs, and entertain reasonable alternatives.

Advocacy applauds CMS for concluding that this proposed rule will have a significant economic impact on a substantial number of small entities, and for preparing an IRFA. However, Advocacy believes that the rule's transparency would be improved if CMS complied with section 603 of the RFA and: 1) improved its description of small entities likely to be impacted by the rule; 2) provided further details on the rule's impacts on affected small ESRD facilities; and 3) entertained reasonable alternatives to the provisions of the proposed rule pursuant to RFA section 603(c). Such alternatives might include adoption of the transition or phase-in period on which CMS solicited comments in the proposed rule.¹⁹

1. CMS Should Improve its Description of Affected Small Entities.

In the RFA section of the rule, CMS estimates that approximately 18 percent of ESRD dialysis facilities are considered small entities according to SBA size standards.²⁰ CMS also includes a broad breakout of impacted ESRD facilities based on the number of treatments in Table 12.²¹ Still, it is difficult to determine how Table 12 translates into the number of small entities affected by the rule since Table 12 only identifies large dialysis organizations (LDOs) and non-LDO subcategories for which the crosswalk to the rule's SBA size standard (less than \$35.5 million in total revenue in any one year) remains unclear. As such, it would be helpful if CMS provided a version of Table 12 tailored to the size standards utilized in the IRFA.

By improving its description of small entities impacted by this regulation in the final rule, CMS would improve the transparency of its IRFA and enable small entities to better anticipate and comment on the impacts of this rule.

2. CMS Should Improve its Description and Analysis of Costs.

Advocacy suggests that it would be helpful if the IRFA included a breakout of Medicare margins by size categories. For example, MedPAC's 2012 Report to Congress includes a table summarizing 2010 Medicare margins by type of freestanding provider.²² Based on the 2010 cost report and outpatient claims submitted to CMS, this table (replicated below) provides overall estimated Medicare margins, a breakout of margins according to the two largest dialysis organizations (3.4 percent margin; 69 percent of spending) and all other organizations (.1 percent margin; 31 percent of spending), urban (3.4 percent) versus rural (-3.7 percent) margins, and by volume of more (7.7 percent) or less (-2.3 percent) than 10,000 treatments.²³

¹⁹ 78 Fed. Reg. 40843.

²⁰ 78 Fed. Reg. 40888.

²¹ 78 Fed. Reg. 40882.

²² See Table 6-8, MedPAC 2012 at 162.

²³ *Id.*

**Medicare margin in 2010 varies by type of freestanding provider
(Table 6-8 of MedPAC 2012 Report to Congress)²⁴**

Provider Type	Percent of Spending	Medicare Margin
ALL	100	2.3
Affiliated with one of two largest dialysis organizations	69	3.4
All Others	31	.1
Urban	85	3.4
Rural	15	-3.7
More than 10,000 treatments	54	7.7
Less than or equal to 10,000 treatments	46	-2.3

In addition, the IRFA should acknowledge disproportionate cost impacts to small dialysis organizations that may result from economies of scale in providing bundled dialysis services (such as ability of LDOs to vertically integrate product supply provisions and in-house pharmacies, and industry consolidation trends).²⁵ The MedPAC 2012 Report to Congress notes that “[d]ifferences exist in cost growth trends and adjusted cost per treatment (adjusted for differences in labor costs and patient case mix) between the two largest dialysis organizations and all other freestanding facilities.”²⁶ The two largest dialysis chains now constitute 60 percent of all facilities and the two largest dialysis organizations appear to receive only 54 to 63 percent of their revenues from Medicare.²⁷ As noted above, small dialysis providers operate on much smaller Medicare margins likely based on economies of scale and other factors.

MedPAC also reports that small dialysis organizations already appear to struggle with recent additional reporting burdens. For example, they may not be fully realizing the benefits of current comorbidity payment adjusters as a result of complex reporting requirements that may compel small organizations to weigh the relative costs of hiring additional labor.²⁸ MedPAC also expressed concern that the gap in the Medicare margin between urban and rural facilities continues to widen, a concern that overlaps with those of impacted small organizations given their geographic distribution.²⁹ Finally, MedPAC also noted that the U.S. budget sequestration would alter impacts of the spending recommendations included in the 2012 report.

²⁴ *Id.* at 164.

²⁵ *Id.* at 149-150.

²⁶ *Id.* at 162.

²⁷ *Id.* at 149.

²⁸ MedPAC 2012 at 148.

²⁹ *Id.* at 163.

3. CMS Should Entertain Reasonable Alternatives.

RFA section 603(c) provides that any IRFA shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. In section (e) of its Regulatory Impact Analysis, CMS indicates that it considered proposing to implement the reduction using a transition. "For example, we considered transitioning the reduction over a 2 or 3-year period."³⁰ However, CMS does not discuss why it declined to proceed with the alternative. Clearly CMS believes that it has the authority to entertain such flexibilities.

The NRAA indicated to Advocacy that it will recommend to CMS that any reduction be phased in for all providers, and that small providers be given additional time to absorb any further reductions. This request seems to be consistent with the spirit and intent of the RFA, especially since CMS was amenable to entertaining such an alternative. In the final rule CMS should also consider additional time for small dialysis organizations to comply with reporting requirements for the rule.

Conclusion

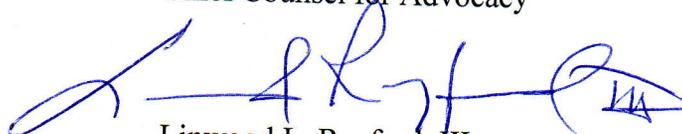
Advocacy requests that CMS take Advocacy's RFA comments and the concerns identified by the affected industry into consideration as the agency finalizes this rule. Advocacy believes that CMS should improve its small entity impact analysis as it drafts the Final Regulatory Flexibility Analysis (FRFA) to be contained in the final rule. Also, CMS should take into consideration industry's suggested alternatives, including a phased in implementation of the Medicare reimbursement reductions, designed to minimize the rule's impact on small dialysis providers.

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.

Sincerely yours,



Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy



Linwood L. Rayford, III
Assistant Chief Counsel Advocacy

³⁰ 78 Fed. Reg. 40883.