

Advocacy Suggests that the Centers For Medicare and Medicaid Services' Initial Regulatory Flexibility Analysis Could be Improved by a Further Analysis of Industry Costs, and that Alternatives Exist that Could Minimize the Impact of the Rule on Small End-Stage Renal Disease Dialysis Providers

On August 30, 2013, the Office of Advocacy (Advocacy) filed comments with the Centers for Medicare and Medicaid Services (CMS) providing the agency with its Regulatory Flexibility Act suggestions and industry concerns about the potential economic impacts associated with the 2014 End-Stage Renal Disease Prospective Payment System proposed rule. A copy of Advocacy's comment letter may be accessed at <http://www.sba.gov/advocacy/816/752735>.

On July 8, 2013, CMS published a rule in the *Federal Register* (78 Fed. Reg. 40836) that proposed to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year 2014 (hereinafter known as the 2014 ESRD PPS rule). The Affordable Care Act provided that beginning in 2012, and each subsequent year, CMS is to reduce the market basket increase factor by a productivity adjustment described in the Social Security Act. The American Taxpayer Relief Act of 2012 required CMS to compare 2007 patient utilization data of certain ESRD drugs with data from 2012, and to reduce the single payment amount to reflect CMS' estimate of the change in utilization of ESRD related drugs.

CMS complied with the statutory provisions outlined above in the 2014 ESRD PPS proposed rule by analyzing the impacts associated with the adjustment of the market basket calculation and the change in ESRD drug utilization. CMS also complied with the Regulatory Flexibility Act by concluding that the proposed rule would have a significant impact on a substantial number of small ESRD dialysis providers, and the agency published an Initial Regulatory Flexibility Analysis (IRFA).

- CMS estimated that in 2014 the proposed rule would result in a 9.4% reduction in payments to the small providers, a total decrease of \$970 million in payments to ESRD facilities. The IRFA suggested that approximately 18% of ESRD dialysis facilities are small based on Small Business Administration size standards.
- Representatives from the National Renal Administrators Association (NRAA) approached Advocacy and voiced concerns that the proposed rule underestimated the economic impacts on their industry and that alternatives existed that would serve to lessen those impacts if CMS adopted them in the final rule.
- Advocacy asked CMS to reassess its cost estimates based upon the cost data provided by the affected industry, the Government Accounting Office (GAO), and the Medical Advisory Commission (MedPAC) – an independent congressional agency established to advise the Congress on issues affecting the Medicare Program. Advocacy also provided CMS with alternatives to the rule's provisions, including a phased-in approach that would reduce the cost of compliance with the rules for ESRD dialysis providers.

For more information, visit Advocacy's web page at <http://www.sba.gov/advocacy/816/752735>, or contact Linwood Rayford at (202) 205-6533.