Small Entity Compliance Guide

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

Federal Register Vol. 75, No. 228, Page 73710, November 29, 2010
42 CFR Parts 405, 409, 410, 411, 413, 414, 415, and 424

CMS-1503-FC, RIN 0938-AP79

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act (RFA).

The complete text of this final rule with comment period can be found on the CMS Web site on the Physician Center page at: http://www.cms.hhs.gov/center/physician.asp.

This final rule with comment period implements changes to the physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It finalizes the calendar year (CY) 2010 interim relative value units (RVUs) and issues interim RVUs for new and revised procedure codes for CY 2011.

In addition, this final rule with comment period discusses payments under the Ambulance Fee Schedule (AFS), the Ambulatory Surgical Center (ASC) payment system, and the Clinical Laboratory Fee Schedule (CLFS), payments to end-stage renal disease (ESRD) facilities, and payments for Part B drugs. This final rule with comment period also includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (CBP DMEPOS), and provider and supplier enrollment issues associated with air ambulances. Specifically this rule discusses refinements to resource-based practice expense (PE) relative value units (RVUs); rebasing of the Medicare Economic Index (MEI); geographic practice cost indices (GPCI) update; establishing malpractice RVUs for new and revised services effective before the next 5-year review; requests for additions to the list of telehealth services; specific coding issues; potentially misvalued codes; average sales price (ASP) payment issues related to outpatient drugs and biologicals; AFS issues; a CLFS issue; payment for renal dialysis services; physician self-referral issues; DMEPOS- related issues; the chiropractic services demonstration; and therapy services.

It addresses, implements or discusses certain provisions of the Affordable Care Act (ACA) provisions concerning: the physician quality reporting system; the physician feedback program; extension of the work geographic practice cost index (GPCI) floor and temporary revisions to the practice expense GPCIs and provisions for frontier states; therapy caps; physician pathology services; ambulance add-ons; mental health services; post-hospital extended care services; bone

density tests; certified nurse-midwife services; clinical diagnostic laboratory tests; misvalued codes; advanced imaging services; power-driven wheelchairs; biosimilar biological products; market basket updates; annual wellness visit providing a personalized prevention plan; preventive services; incentive payment programs for primary care services and general surgery services; disclosure requirements; Medicare claims submission requirements; DME CBP; and the collection of data to inform a Medicare prospective payment system for Federally qualified health centers (FQHCs). It also addresses certain Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provisions concerning: the physician quality reporting initiative; incentives for e-prescribing; and provider and supplier enrollment issues.

This final rule with comment period also, in accordance with the statute, announces that: the total reduction to physician fee schedule payment rates between November 2010 and January 2011, under the law as of November 2, 2010, would be -24.9 percent; the preliminary estimate for the sustainable growth rate (SGR) for CY 2011 would be -13.4 percent; and, as calculated under the law as of November 2, 2010, the conversion factor (CF) for CY 2011 would be $25.4999.

For purposes of the RFA, physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

Approximately 85 percent of suppliers of DMEPOS are considered small businesses according to the SBA size standards. Our most recent claims information includes 47,000 entities billing Medicare for DMEPOS each year. Also, approximately 80 percent of clinical diagnostic laboratories are considered small businesses according to the SBA size standards. Ambulance providers and suppliers (for purposes of the RFA) are also considered to be small entities.

In addition, most end stage renal disease (ESRD) facilities are considered small entities for purposes of the RFA, either based on nonprofit status or by having revenues of $34.5 million or less in any year. We note that a considerable number of ESRD facilities are owned and operated by large dialysis organizations (LDOs) or regional chains, which would have total revenues more than $34.5 million in any year if revenues from all locations are combined. However, the claims data we use to estimate payments for the RFA and regulatory impact analysis does not identify which dialysis facilities are parts of an LDO, regional chain, or other type of ownership. Each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, we consider each ESRD to be a small entity for purposes of the RFA.

The effects of this final rule with comment vary considerably by provider type. It does substantially reduce payments under the PFS as a result of applying the scheduled updates to the CF that, according to current law, will take place December 1, 2010 and January 1, 2011.

This rule imposes no direct Federal compliance requirements on affected entities. In order to assist physicians and others in understanding and adapting to changes in Medicare billing and payment procedures and amounts, we have developed a Web page for physician services that includes substantial downloadable explanatory materials at http://www.cms.hhs.gov/center/physician.asp. Additional material on the PFS can also be found at the Web page: http://www.cms.hhs.gov/PhysicianFeeSched/. There are also Medicare

Learning Network articles related to the physician fee schedule at: http://www.cms.hhs.gov/MLNMattersArticles/01_Overview.asp#TopOfPage.

The Internet Only Manual at http://www.cms.hhs.gov/Manuals/ is also updated to reflect changes in policy that may be included in the rule.