Small Entity Compliance Guide

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2016

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CMS-1631-FC, RIN 0938- AS40

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.

The complete text of this final rule with comment period can be found on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-FC.html?DLPage=1&DLSort=3&DLSortDir=descending.

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) 2015 interim relative value units (RVUs) and establishes interim RVUs for new, revised and misvalued procedure codes for CY 2016.

It also addresses, implements or discusses changes to several of the quality reporting initiatives that are associated with PFS payments – the Physician Quality Reporting System (PQRS), as well as changes to the Physician Compare tool on the Medicare.gov website. Furthermore, the rule continues the phased-in implementation of the physician value-based payment modifier (Value Modifier), created by the Affordable Care Act, that will affect payments to certain physician groups based on the quality and cost of care they furnish to beneficiaries enrolled in the traditional Medicare fee-for-service program. Finally, the rule addresses changes to other Medicare programs which are listed in the Table of Contents within the rule.

This final rule with comment period also, in accordance with the statute, announced that for January 1, 2016 through March 31, 2016, the PFS update will be 0.23 percent. This is consistent with section 101 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93) (PAMA) that established a 0.0 percent update through March 31, 2015. After applying the required budget neutrality adjustment, the conversion factor for January 1, 2016 through March 31, 2016 will be \$35.8013. According to statute, after March 31, 2016 the standard calculation of the PFS CF under the SGR formula would apply. Therefore, from April 1, 2016 through

December 31, 2016, in the absence of congressional action, the conversion factor will be \$28.2239.

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, according to the Small Business Administration size schedule. 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.

This rule imposes no direct federal compliance requirements with significant economic impacts on small entities. In order to assist physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) in understanding and adapting to changes in Medicare billing and payment procedures, we have developed webpages that include additional material on the PFS at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-FC.html.