

## Small Entity Compliance Guide

### **Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies**

*Federal Register* 79 FR 66119 through 66265

42 CFR Parts 405, 411, 413 and 414

CMS-1614-F, RIN 0938-AS13

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, P.L. 104-121, as amended by P.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 can be found on the CMS Web site by clicking on the link to “CMS-1614-F” at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1614-F.html?DLPage=1&DLSort=3&DLSortDir=descending>.

This final rule will update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also finalizes requirements for the ESRD quality incentive program (QIP), including for payment years (PYs) 2017 and 2018. This rule will also make a technical correction to remove outdated terms and definitions. In addition, this final rule sets forth the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); makes alternative payment rules for certain DME under the Medicare DMEPOS CBP; clarifies the statutory Medicare hearing aid coverage exclusion and specifies devices not subject to the hearing aid exclusion; will not update the definition of minimal self-adjustment; clarifies the Change of Ownership (CHOW) and provides for an exception to the current requirements; revises the appeal provisions for termination of a CBP contract, including the beneficiary notification requirement under the Medicare DMEPOS CBP, and makes a technical change to the regulation related to the conditions for awarding contracts for furnishing infusion drugs under the Medicare DMEPOS CBP.