## Small Entity Compliance Guide

## HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS

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45 CFR Part 162

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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 (RFA).

The complete text of this Final Rule can be found on the Centers for Medicare & Medicaid Services (CMS) Web site at <a href="http://www.cms.hhs.gov/ICD10/01\_Overview.asp#TopOfPage">http://www.cms.hhs.gov/ICD10/01\_Overview.asp#TopOfPage</a>.

This final rule modifies the standard medical data code sets for coding diagnoses and inpatient hospital procedures by concurrently adopting the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedural Coding System (ICD-10-PCS) for inpatient hospital procedure coding. These new codes replace the current International Classification, 9th Revision, Clinical Modification, Volumes 1 and 2 and the International Classification, 9th Revision, Clinical Modification, Volume 3 for diagnosis and procedure codes respectively. The implementation date for ICD-10-CM and ICD-10-PCS is October 1, 2013 for all covered entities.

We estimate that small hospitals and most other providers and suppliers are small entities, either by being nonprofit status or by qualifying as small businesses under the Small Business Administration's (SBA's) size standards (having revenues of \$7.0 million to \$34.5 million in any 1 year). We also determined that about 200 nonprofit health care organizations that offer 213 health plans are considered small entities under the RFA because of their non-profit status, and that 97 percent of all physicians' practices and clinics also qualify as small entities under the RFA.

We estimate that the net revenue impact of this final rule on small healthcare entities will be \$1,878.8 million over 4 years. We anticipate that this final rule will not have a significant impact to individual small entities, accounting for 0.03 to 0.01 percent of ICD-10 costs of revenue receipts as depicted in Table 2 of the final rule.

This rule imposes Federal compliance requirements on small healthcare entities. In order to assist small healthcare entities in understanding and adapting to changes predicated by the required transition to ICD-10-CM and ICD-10-PCS medical code sets, we have developed a Web

page that includes substantial downloadable explanatory materials at <a href="http://www.cms.hhs.gov/ICD10/01\_Overview.asp#TopOfPage">http://www.cms.hhs.gov/ICD10/01\_Overview.asp#TopOfPage</a>

In particular, CMS is providing guidance by sharing its own ICD-10-CM and ICD-10-PCS impact analysis with the industry so that they may benefit from our "lessons learned"; a listing of national open door forums; educational resources, including fact sheets, Frequently Asked Questions, and other materials; free downloads of the medical code sets and their implementation guides; general equivalency mappings ("crosswalks") to assist entities with transitioning from the current ICD-9 to ICD-10 code sets, and more. CMS will continue to provide additional resources targeted to small entities beginning in 2010.