

## Small Entity Compliance Guide

### **Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions; Interim Final Rule with Comment Period**

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45 CFR Parts 160 and 162

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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 interim final rule can be found on the Centers for Medicare & Medicaid Services (CMS) Web site at [http://www.cms.gov/Affordable-Care-Act/02\\_OperatingRulesforHIPAATransactions.asp#TopOfPage](http://www.cms.gov/Affordable-Care-Act/02_OperatingRulesforHIPAATransactions.asp#TopOfPage).

This interim final rule with comment period (IFC) adopts operating rules for two Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions: eligibility for a health plan and health care claim status. This rule also defines the term "operating rules" and explains the role of operating rules in relation to the adopted transaction standards. In general, transaction standards adopted under HIPAA enable electronic data interchange through a common interchange structure, thus minimizing the industry's reliance on multiple formats. Operating rules, in turn, attempt to define the rights and responsibilities of all parties, security requirements, transmission formats, response times, liabilities, exception processing, error resolution and more, in order to facilitate successful interoperability between data systems of different entities.

To determine the impact on health care providers we used Business Census data on the number of establishments for hospitals and firms for the classes of providers and revenue data reported in the Survey of Annual Services for each National Association of Insurance Commissions (NAIC) code. Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For other providers, we assumed that the costs to implement the operating rules for eligibility for a health plan and health care claim status transactions would be accounted for at the level of firms rather than at the individual establishments. Therefore, we reported the number of firms for all other providers. In the following tables, we took information from the impact analysis and break out the costs for both physicians and hospitals. As stated in the impact analysis of the IFC, we assume that vendor costs will be the same as those for providers because of our assumption that vendors will pass along their costs in the form of increased fees to their provider clients. As we

are treating all health care providers as small entities for the purpose of the regulatory flexibility analysis, we allocated 100 percent of the implementation costs reported in the impact analysis for physicians and hospitals. Accordingly, we treat all software vendors as small entities based on their relationship to providers and allocate the same costs. The following table (Table 30 of the IFC) shows the impact of the implementation costs of operating rules as a percent of the provider revenues.

### ANALYSIS OF THE BURDEN OF IMPLEMENTATION OF OPERATING RULES ON SMALL COVERED ENTITIES

NAICS Number	Entities	Total Number of Entities	Number of Small Entities	Revenues or Receipts (\$ in millions)	Small Entity Receipts of Total Receipts (percent)	Op Rules Costs Annual (\$ in millions)	Implementation Cost Revenue Receipts (Percent)
6211	Ambulatory health care services	547,561	547,561	668,453	100	136 - 272	0.0002 - 0.004
622	Hospitals	6,505	6,505	702,960	100	291 - 583	0.0004 - 0.0008
5415	Computer system design and related services	105,710	105,710	297,200	100	136 - 272	0.0005 - 0.0009

In Column I we display the NAICS code for class of entity. Column II shows the number of entities that are reported in the Business Census for 2002 and Column III shows the number of small entities that were computed based on the Business Census and Survey of Annual Service. As mentioned previously, we assume that all health care providers are small. Column IV shows revenues that were reported for 2008 in the Survey of Annual Services ([http://www.census.gov/services/sas\\_data.html](http://www.census.gov/services/sas_data.html)). Column V shows the percent of small entity revenues. Column VI shows the costs to providers for implementation of eligibility for a health plan and health care claim status operating rules. Column VII shows the costs allocated to the small entities based on the percent of small entity revenues to total revenues. Column VIII the percent of the small entity share of implementation costs as a percent of the small entity revenues. We have established a baseline threshold of 3 percent of revenues that would be considered a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold. We note that the impact in our scenarios is consistently under the estimated impact of 3 percent for all of the entities previously listed, which is below the threshold we consider as a significant economic impact. As expressed in the guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus, based on the foregoing analysis, we conclude that some small health care providers may encounter some burdens in the course of implementing the eligibility for a health plan and health care claim status operating rules. However, we are of the opinion that, for most small providers, the costs will not be significant, and for providers who are not HIPAA covered entities and do not conduct electronic health care transactions, there is no cost.

We did not include an analysis of the impact on small health plans here, because we were not able to determine the number of plans that meet the SBA size standard of \$7 million in annual receipts. In evaluating whether there were any clearinghouses that could be considered small entities, we consulted with three national associations (EHNAC, HIMSS, and the Cooperative Exchange), as well as the Maryland Commission for Health Care, and determined that the

number of clearinghouses that would be considered small entities was negligible. Revenues cited on the Cooperative Exchange Web site (<http://www.cooperativeexchange.org/faq.html>) divided clearinghouses into three revenue categories—small (\$10 million); medium (\$10 million to \$50 million) and large (\$50 million or greater). We identified the top 51 clearinghouses, and determined that they are typically part of large electronic health networks, such as Siemens, RxHub, Availity, GE Healthcare etc., none of which fit into the category of small entity. As referenced in the IFC, in a report by Faulkner and Gray in 2000, the top 51 entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of \$0.25 per transaction to \$2.50 per transaction. We determined that even based on this data, few of the entities would fall into the small entity category, and we do not count them in this analysis. Based on the results of this analysis, we are reasonably confident that the rule will not have a significant impact on a substantial number of small entities.

As stated in the HHS guidance cited earlier in this section, HHS uses a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected small entities. None of the entities exceeded or came close to this threshold. Based on the foregoing analysis, we could certify that the IFC would not have a significant economic impact on a substantial number of small entities. However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general assumptions, we invited public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of small entities affected by this IFC. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Based on this analysis, including that the overall costs to small hospitals is under the \$136 million threshold, we do not believe this rule would have a significant impact on small rural hospitals, for the reasons stated previously in reference to small entities. Therefore, the Secretary has determined that this IFC would not have a significant impact on the operations of a substantial number of small rural hospitals.