

## ***Advocacy Urges HHS Office of Civil Rights to Issue Small Business Compliance Guide***

- On November 3, 1999, the U.S Department of Health and Human Services (HHS) published in the *Federal Register* a proposed rule titled, “Standards for Privacy of Individually Identifiable Health Information (Privacy Rule)” (64 Fed. Reg. 59,917). The rule was promulgated pursuant to the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1966 (HIPAA). The regulation was intended to provide standards for preventing unauthorized disclosure of individually identifiable health information maintained or transmitted electronically by health care providers. The rule applied to health plans, health care clearinghouses, and most health care providers.
- HHS published the final rule (65 Fed. Reg. 82462) on December 28, 2000. Modifications to the final rule were adopted on August 14, 2002. The rule’s effective date was April 14, 2003. Covered entities are to comply with the regulations by April 21, 2005. Small covered entities have an additional year--until April 21, 2006--to comply.
- The Office of Advocacy was intimately involved with the review of the rule during both interagency review and the public comment period for the proposed and final rule. Because the vast majority of health care providers covered by the rule are small (based on U.S. Small Business Administration size standards), Advocacy was concerned that the rulemaking had the potential to impact the covered small entities significantly. Advocacy filed public comments on the Privacy Rule on February 25, 2000.
- One of Advocacy’s recommendations to HHS regarding the Privacy Rule was the need for the agency to complete a small business compliance guide that would instruct small businesses on how to comply with the rule’s requirements. In 1996, Congress enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA), which amended the Regulatory Flexibility Act (RFA). When an agency has determined that a rule will have a significant economic impact on a substantial number of small entities, Section 212 of SBREFA requires that the agency prepare a small business compliance guide.
- Because HHS has not published a small business compliance guide, Advocacy wrote a letter on May 15, 2003, to the Director of the Office of Civil Rights, the office within HHS charged with implementing and enforcing the Privacy Rule, encouraging the office to complete the small business compliance guide and make it available to the covered small entities.
- For the text of Advocacy’s comment letter of February 25, 2000, and the May 15, 2003, letter to the HHS Office of Civil Rights, please visit [www.sba.gov/advo](http://www.sba.gov/advo).