

May 15, 2003

Mr. Richard Campanelli
Director Office for Civil Rights
U.S. Department of Health
and Human Services
200 Independence Avenue, S.W.
Room 515F, HHH Building
Washington, DC 20201

Re: Health Insurance Portability and Accountability Act of 1996 (HIPAA) – Standards for Privacy of Individually Identifiable Health Information (hereinafter the Privacy Rule)

Dear Mr. Campanelli:

The Office of Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small businesses in Federal policy making activities.¹ The Chief Counsel for Advocacy participates in rulemakings and other agency actions when he deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors agencies' compliance with the Regulatory Flexibility Act (RFA), and works with Federal agencies to ensure that their rulemakings demonstrate an analysis of the impacts that their decisions will have on small businesses.² Because the Office of Advocacy is an independent entity within the U.S. Small Business Administration (SBA), the views expressed by the Chief Counsel do not necessarily reflect the views of the SBA, or the Administration.

Based on U.S. Small Business Administration size standards, the vast majority of health care professionals that practice under the requirements of the Privacy Rule are small entities. Recently my office heard from many health care providers, and their representatives, who voiced anxiety about how to comply with the Privacy Rule's provisions. I am writing you at this time to encourage the Office of Civil Rights (OCR) to immediately provide those small entities covered by the rule with a small business compliance guide.

As OCR is responsible for implementing and enforcing the Privacy Rule, Advocacy believes it is required to publish the compliance guide pursuant to Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA). Section 212 provides

¹ Pub. L. No. 94-305 (1976)(codified as amended at 15 U.S.C. §§ 634a-g, 637).

² Pub. L. No. 96-354, 94 Stat. 1164 (1981) (to be codified as amended at 5 U.S.C. §§ 601-612).

that compliance guides be published by the agency when it determines that the rulemaking will have a significant impact on a substantial number of small entities and prepares a final flexibility analysis pursuant to the RFA.

This is not the first time that Advocacy has requested that the U.S. Department of Health and Human Services provide small business compliance guides in connection with the Privacy Rule. Advocacy was intimately involved in the Privacy Rule during interagency review and during the public comment periods provided in the proposed and final rules. Advocacy filed public comments on the rule on February 25, 2000.³ The comment letter specifically addressed Advocacy's belief that under SBREFA, HHS had the obligation to publish compliance guides for small businesses. To Advocacy's knowledge, no such compliance guides have been issued to date.

Advocacy is also aware that on April 11, 2003, Chairman Donald Manzullo and Ranking Member Nydia Velazquez, along with various other members of the House Small Business Committee, wrote Secretary Thompson asking that HHS supplement its current guidance pursuant to SBREFA and allow for a year delay in the enforcement provisions provided for in the Privacy Rule for small providers. Advocacy supports the request made by the House Small Business Committee since guidance would be most helpful prior to having to comply with the rule.

It is my hope that you will agree to provide small health care providers with the requested compliance guide. Once completed, you have my commitment to make it broadly available to the small business community. If you have any questions about the content of this letter, please do not hesitate to contact my associate, Linwood Rayford at (202) 205-6880.

Sincerely,

Thomas M. Sullivan
Chief Counsel for Advocacy

CC: Secretary Tommy Thompson, U.S. Department of Health and Human Services
Chairman Donald Manzullo, Committee on Small Business, U.S. House of Representatives
Representative Nydia Velazquez, Ranking Member, Committee on Small Business, U.S. House of Representatives
Chairwoman Olympia Snowe, Committee on Small Business & Entrepreneurship, U.S. Senate

³ The February 25, 2000, comment letter can be found on Advocacy's web site at www.sba.gov/advo/laws/comments/hhs00_0225.html.

Senator John Kerry, Ranking Member, Committee on Small Business &
Entrepreneurship, U.S. Senate
Dr. John D. Graham, Administrator, Office of Information and Regulatory Affairs