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

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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