



**Association of
American Medical Colleges**
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0400 **F** 202 828 1125
www.aamc.org

September 24, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
RIN 0991-AB56
Submitted to: <http://www.regulations.gov>

Dear Ms. Frizzera:

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 131 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians. The Association appreciates the opportunity to comment on the interim final rule, *Breach Notification for Unsecured Protected Health Information*, 74 *Federal Register* 42740.

The AAMC appreciates the efforts that the Office of Civil Rights (OCR) has taken to implement the HITECH breach notification requirement in a way that fulfills the goals of the legislation while recognizing the burden that covered entities face in complying with it. It is especially important that OCR states that "covered entities and business associates need not provide breach notification in all cases of impermissible uses and disclosures." Requiring "a risk assessment to determine if there is a significant risk of harm to the individual as a result of the impermissible use or disclosure," is a reasonable approach and one that we strongly support.

We are concerned that OCR does not recognize the limited data set (LDS) as secure information unless both date of birth and zip code also are removed. The LDS is used frequently in research, and often the research requires both date of birth and zip code, so removing these elements is not practical. The final HIPAA privacy rule was adopted after extensive opportunity for public comment. The preamble to that rule states that:

The Department agrees with these commenters that a variety of geographical designations other than five-digit zip codes are needed to permit useful and significant studies and other research to go forward unimpeded. So long as an appropriate data use agreement is in place, the Department does not believe that there is any greater privacy risk in including in the limited data set such geographic codes than in releasing the five-digit zip code. 67 *Federal Register* 53235

These comments are as cogent today as they were when written seven years ago. We are unaware of any breaches of LDS that have occurred during that time. We understand that OCR has attempted to limit the impact of its decision that the LDS will not be recognized as secure information by requiring the use of a risk assessment in the event that the LDS is breached. The preferable approach is to recognize the LDS as secure information. Researchers already are adept at using the LDS and are accustomed to taking precautions to ensure that its use is compliant with HIPAA, so we believe that the risk of breach is minimal.

The use of a risk assessment to determine if notification is required will impose a burden that will fall disproportionately on researchers and research institutions, and therefore may act as a deterrent to some researchers. Moreover, subjecting limited data sets to the breach notification requirements would force covered entities and business associates to re-identify individuals in the limited data set to contact them about the breach. Such a requirement puts the protected health information at additional risk of breach, poses a substantial administrative and financial burden to entities that regularly use limited data sets for research, and does not afford a significant improvement in privacy protection. Therefore, we request that OCR recognize that LDS is secured information, without also requiring the removal of date of birth and zip code.

If you have any questions, please contact either Ivy Baer (ibaer@aamc.org; 202-828-0499) or Tannaz Rasouli (trasouli@aamc.org; 202- 828-0057).

Sincerely,

A handwritten signature in cursive script, appearing to read "Joanne Conroy MD".

Joanne M. Conroy, M.D.
Chief Health Care Officer