From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, February 28, 2003 5:58 AM
To: [purged]
Subject: RE: HIPAA Question

"Dear Mr. [purged],

Thank you for your inquiry regarding HIPAA and its implementation. There are a number of guidance documents about HIPAA that are available from the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) web site (http://www.dhhs.gov/ocr/hipaa/). We suggest you visit this web site and review these guidances. Should you continue to have questions about the implementation of HIPAA after you have reviewed information posted to the OCR web site, there are instructions on that web site for submitting your questions to OCR.

You may want to note that most covered entities have until April 14, 2003, to comply with the patient privacy rule; under the law, certain small health plans have until April 14, 2004 to comply.

Additional guidances, including one that is expected to address frequently asked questions related to the implementation of HIPAA for FDA regulated products, are being developed. Once these documents are finalized, they too will be electronically available from the OCR web site.

I hope this information helps.

Sincerely,

Pat Beers Block

-----Original Message-----
From: Zeltwanger, Andrew [mailto:AZeltwanger@medrad.com]
Sent: Wednesday, February 12, 2003 12:04 PM
To: gcpquestions@oc.fda.gov
Subject: HIPAA Question

Dear Good Clinical Practice Representative,

My name is [purged]. I am a Regulatory Affairs Analyst with [purged] Recently, I have been part of an effort here to review, and revise if necessary, [purged] Clinical Testing Procedures and Protocols. As we are educating ourselves on HIPAA privacy issues, the following question was raised:

What is the definition of a medical record?

For example: If we were testing a MR coil we designed to increase resolution of the shoulder, and as part of that test imaged several subjects, would that information constitute a medical record, since no diagnosis or treatment would result form the imaging? Would it make a difference if we did not attach any identifiers (name, age, sex, SSN, etc) to the file? If number of identifiers is the basis of the definition of a medical file, how many can be present for the information to still be considered "un-identified"? (for example, if we were imaging the pelvis or breast, it would be impossible to disguise/remove the fact that our subject was male or female).

Your advice on this issue would be greatly appreciated.
Thank you for your time and efforts.

Sincerely,

[purged]