From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, February 28, 2003 6:04 AM
To: [purged]
Subject: RE: Applicability of HIPAA Regulations to Manufacturers of Medical Products

"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: [purged]
Sent: Thursday, February 13, 2003 4:11 PM
To: gcpquestions@oc.fda.gov
Subject: Applicability of HIPAA Regulations to Manufacturers of Medical Products

Hi

I have a question regarding all the recent talk about HIPAA and its applicability to the Pharma industry and manufacturers of medical products. I am uncertain whether the FDA has a position on this.

From my cursury reading, HIPAA is primarily targeted towards health care providers that maintain electronic patient records that can identify patient names. The new regulations were instituted to provide further protection of records that can identify a patient, and that can be transferred between other service providers such as insurance companies.

45 CFR pertaining to research states

"...A covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164,514(a)-(c) of the Rule) without regard to the provisions below..."

and

"...To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. However, several special provisions apply to research authorizations:

o Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the "end of the research study;" and

o An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study."

Are drug and device sponsors of studies a "covered entity"? I have been unable to find any FDA guidance documents on this subject, and was wondering if the Agency has an opinion on this.

Our study Informed Consents contain language that informs a subject regarding patient confidentiality. Our data "de-identifies" each enrolled patient as well.

Regulation:
http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf
Articles:
http://www.bio-itworld.com/archive/030702/hippa.html

http://archive.infoworld.com/articles/hn/xml/02/05/07/020507hnhipaa.xml

http://www.bio.org/bioethics/tst041602.pdf

http://ohrp.osophs.dhhs.gov/nhrpac/documents/rschltr.pdf
Best regards,

[purged]