MessageFrom: Kutkat, Lora (NIH/OD) [KutkatL@OD.NIH.GOV]
Sent: Wednesday, November 30, 2005 10:49 AM
To: [purged]
Cc: gcpquestions@oc.fda.gov
Subject: FW: HIPAA

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Hi Dr. [purged]:

My colleages at the U.S. Food and Drug Administration forwarded to me your email to answer. I work for the U.S. National Institutes of Health and help researchers with HIPAA Privacy Rule issues. I've attempted to answer your questions below.

Does the Privacy Rule apply to Pharmacovigilance Databases?

The Privacy Rule applies to covered entities (namely, most US health care providers, US health plans, and US health care clearinghouses). The Privacy Rule protects most identifiable health information that covered entities hold, including information in databases. When a US covered entity holds or maintains identifiable health information in a database, that information is typically covered by the Privacy Rule.

Can patients' names (and/or other personal identifiers) be included as part of the electronic databases in such cases?

In general, yes. However, a covered entity may need to get the patient's permission to keep the person's information in a database, depending on whether pharmacovigilance database is for research, treatment follow-up, etc. To give you a more specific answer, I'd need more information about the purpose of the database. Remember that the Privacy Rule applies only to covered entities -- not everyone or every entity that keeps identifiable health information will be covered by the Privacy Rule.

You may also wish to visit: http://privacyruleandresearch.nih.gov for additional information.

Lora Kutkat
  -----Original Message-----

From: [purged]
Sent: Friday, November 04, 2005 1:40 PM
To: 'gcpquestions@oc.fda.gov'
Subject: HIPPA

Good Afternoon,

My name is [purged], I'm an [purged] health care professional currently involved in Clinical Trials Data Management for the Pharmaceutical Industry.
I would really appreciate if you could give me an approach or any type of info related to Privacy Rule / HIPPA and its relationship to Pharmacovigilance Databases, this is, data collected from patients participating in programs of the marketed products they are receiving.
I've been navigating through several web pages, including yours, but couldn't find the exact / key contact person so I though maybe you could consider my concern or derivate it to the most accurate individual.

Does the Privacy Rule apply to Pharmacovigilance Databases? Can patients' names (and/or other personal identifiers) be included as part of the electronic databases in such cases?

Thanks in advance for your support. Your feedback would be much appreciated.
Sincerely

[purged]

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