
PHARMACEUTICAL COMPANIES ARE NOT BUSINESS ASSOCIATES WHEN ACTING AS SPONSORS OF CLINICAL RESEARCH

SUMMARY OF POSITION

In 1996, the United States Congress enacted the Health Insurance Portability and Accountability Act (HIPAA). In 2000, the Department of Health and Human Services issued *Standards for Privacy of Individually Identifiable Health Information* under this Act (the Privacy Rule). Final modifications to the Privacy Rule were published on 14 August 2002.

The Privacy Rule establishes limitations on the use and disclosure of protected health information by "covered entities." Most health care providers are covered entities under the Privacy Rule. As such, they are subject to limitations on the use and disclosure of protected health information under the Privacy Rule. They are also required to secure the written agreement of their "business associates" to safeguard the privacy of protected health information. Third parties that perform "covered functions" on behalf of health plans, health care providers, or health care clearinghouses are considered business associates under the Privacy Rule.

Covered entities are not required to enter into business associate agreements with pharmaceutical companies in the context of clinical research for two reasons. First, clinical research is not regarded as a "covered function" under the Privacy Rule. Second, a pharmaceutical company engaged in clinical research is not a "business associate" as that term is defined by the Privacy Rule.

RESEARCH IS NOT A "COVERED FUNCTION" UNDER THE PRIVACY RULE

In the preamble to its Final Rule, HHS states that "research is not a covered function or activity." It further states that "disclosures from a covered entity to a researcher for research purposes as permitted by the Rule do not require a business associate contract."¹ It is clear from this language that in the context of clinical research, pharmaceutical companies do not perform activities that would be considered "covered functions" under the Privacy Rule.

PHARMACEUTICAL COMPANIES ARE NOT "BUSINESS ASSOCIATES" UNDER THE PRIVACY RULE

The definitions used in the Privacy Rule make clear that pharmaceutical companies are not considered "business associates" in their capacity as sponsors of clinical research. The relevant definitions are set forth below.

¹ 67 FR 53252.

Covered Entity

Under the Privacy Rule, the term “covered entity” is defined to mean a health plan, a health care clearinghouse, or a health care provider conducting certain types of financial and administrative transactions electronically.² Health care providers who transmit the following types of information are included: health care claims or equivalent encounter information; health care payment and remittance advice; coordination of benefits; health care claim status; enrollment and disenrollment in a health plan; eligibility for a health plan; health plan premium payments; referral certification and authorization; first report of injury; and health claims attachments.

A covered entity is required to enter into a written agreement with a “business associate” before disclosing any protected health information to that business associate.³ Among other things, this agreement establishes limitations on the use and disclosure of protected health information by the business associate.

Business Associate

A “business associate” is a person or entity performing certain functions or activities “on behalf of” a covered entity that involve the use or disclosure of individually identifiable health information.⁴ These functions and activities include, among others, claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; benefit management; practice management; and repricing.

A “business associate” is also a person or entity providing certain services “to or for” a covered entity that involve the disclosure of individually identifiable health information. These services are defined as legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, and financial services.

Pharmaceutical companies sponsor clinical research in order to improve or develop new drug therapies for patients. As a sponsor of clinical research, a pharmaceutical company undertakes a range of actions, including, among others, analyses of trial sites, preparation of study protocols, provision of medicines, payment of trial expenses, and monitoring and auditing of trial sites. None of these actions are undertaken “on behalf of” a covered entity. Nor do they represent “services to or for” a covered entity, as that phrase is defined in the Privacy Rule.

PROTECTING PERSONAL HEALTH INFORMATION IN CLINICAL RESEARCH

While business associate agreements between covered entities and sponsors are not appropriate, the Privacy Rule allows covered entities to transmit protected health information to sponsors pursuant to the execution of an authorization by the subject of a clinical trial, or upon receipt of a waiver of authorization from an Institutional Review Board or Privacy Board. By signing an authorization, the subject of a clinical trial agrees that protected health information resulting from that trial may be transmitted to and may be redisclosed by the pharmaceutical sponsor of the trial. Since pharmaceutical companies are not business associates when sponsoring clinical research, a business associate agreement cannot serve as a substitute for a properly executed patient authorization or waiver.

² § 160.102.

³ § 164.502(e); § 164.504(e).

⁴ § 160.103.

The members of the International Pharmaceutical Privacy Consortium appreciate the importance of safeguarding the privacy of protected health information. Pharmaceutical companies sponsoring clinical research comply with the provisions of the informed consent documents agreed to by research subjects. Among other things, these provisions describe the extent to which confidentiality of records identifying research subjects will be maintained.

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This issue paper has been prepared by the International Pharmaceutical Privacy Consortium. The member companies of the International Pharmaceutical Privacy Consortium appreciate the importance of safeguarding the privacy of patient health information, and each company is implementing its own procedures under HIPAA. This document is for educational purposes only and is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regards to the subjects mentioned in this document.