

**Q.** A provider institution would like to do research regarding genetic testing and predisposition patients may have to contracting certain kinds of cancer. To facilitate this research, the institution is hoping to receive funding through a grant. I have two questions regarding this scenario:

#1. Would health insurance companies be able to access this information and potentially discontinue coverage of these patients' health insurance? In some instances, these genetic tests are reimbursable. I realize that while the institution may have to provide the names for payment, they would not have to give the results. The testing, in and of itself, may raise some red flags to the health insurance plan. The way I read Section 164.508(b)(4), the insurance company could condition enrollment or eligibility on a patient's authorization to disclose information to them.

#2. If the entity providing the grant wants information given to them regarding the progress of the research and some of the statistical data is identifiable, could we make them a business associate to secure the information? I am not sure they would really be providing a function to us. The Data Use Agreement does not seem to apply either since in this case the provider of the treatment is also the researcher. I hope somebody can provide some guidance. Some of these issues could really complicate grant applications.

**A.** If through participation in research, an individual is opening themselves up to denial of health insurance coverage, or higher health insurance premiums, you may find it hard to find willing research participants. The Privacy rule provides four methods that can be used to share or report research findings:

*Authorization - The individual can authorize both uses and disclosures of their PHI for research-reporting purposes if this is specified in the authorization. You must abide by the specifics of the authorization and not use or disclose PHI if it is not authorized.*

*Aggregate Data - Uses and disclosures of aggregate data do not require authorization.*

*De-identified Data - De-identified data has all the information that might be used to identify an individual removed. By applying statistical principles the risk is very small that the information could be used to identify an individual. As de-identified data is not subject to the Privacy Rule, there is no need for an individual's authorization to use or disclose de-identified data.*

*Limited Data Set - The Limited Data Set (LDS) requires the removal of many of the same identifiers as de-identified data, but not all. The LDS may be disclosed only to persons or business who have entered into a "data use agreement".*

The authorization for research should specify the uses and disclosures of research findings. If the research authorization does not specifically permit disclosure of finding to health plans or health insurers, then even if the health plan discovers that an enrollee is participating in such research, researchers should not disclose individual findings to them. If an individual seeking insurance coverage is participating in a research program, PHI relating to the research cannot be provided for underwriting purposes.

If the health plan conditions reimbursement for the cost of genetic testing on obtaining the results, then this should be stated quite clearly in the authorization for research provided to the perspective research participants. In this case, you may find that you may need to use some of the grant funding to pay for the genetic testing in order to obtain a large enough test group. Don't most health plans pay for testing only for treatment and diagnosis, not for research? Using reimbursable testing as a consideration for research may be problematic and cause additional problems, not just HIPAA Privacy violations.

That is my take on this question. I would be very disappointed if this is a wrong conclusion. It would be very damaging to research initiatives, and would definitely refute respect for individual

privacy in the area of protected health information. (Barbara McGowin, CPC, Executive Recruiter, HIT Recruiting)

**A.** Barbara has provided an excellent overview of research disclosures of information, but genetic information presents some unique problems. Genetic testing done in research projects is usually not accepted for clinical use or reimbursable because it may not be done by, or in compliance with the necessary laboratory requirements. Participants who wish to have tests done for treatment planning/other clinical reasons usually have to get the tests repeated by approved labs to be used clinically and to be reimbursed by insurers. Patients can elect to pay for the tests themselves to avoid reporting to insurers, but a life insurance questionnaire can still ask an individual if they have ever taken a genetic test. A positive response, even without knowing the results, can have underwriting implications.

**B.** Although Nebraska has legislation in place to prevent genetic discrimination by employers and health insurers, there is no enforcement provision for individuals harmed by disclosures. For all of these reasons, researchers should require a specific authorization for any disclosure of genetic information. This topic raises enough issues for a book, but I'll just leave it at that. (Kathy Zeitz, Methodist Health System, Omaha)