

Health Information Compliance Alert

Toolkit: Check Out HIPAA Privacy Rule Revisions for PHI Use in Research

HHS and others delay "Common Rule" implementation.

The feds are slashing administrative burdens again. This round clarifies language about authorization for the use of protected health information (PHI) in research.

Background: The 21st Century Cures Act instructed HHS that it must offer "'Guidance Related to Streamlining Authorization' under HIPAA for uses and disclosures of protected health information (PHI) for research," noted an HHS Office for Civil Rights (OCR) release. This mandate resulted in changes to the Common Rule, formerly known as Federal Policy for the Protection of Human Subjects.

The Final Rule published last month in the Federal Register delayed for a second time the implementation date for the revisions to go into effect, an HHS release stated. In addition, a Notice of Proposed Rulemaking from April by HHS and 16 other federal agencies allowed for "an additional 6-month delay for the general compliance date for the 2018 requirements and a flexibility that would allow regulated entities to take advantage of three burden-reducing provisions of the 2018 requirements during the delay period," according to agency guidance.

See the Final Rule in the Federal Register at www.gpo.gov/fdsys/pkg/FR-2018-06-19/pdf/2018-13187.pdf.

What's available now: During the transition period that runs from July 19, 2018 to January 20, 2019, you have three options that help you cut back on administration duties. HHS describes the provisions as follows:

"(1) The revised definition of 'research,' which deems certain activities not to be research;
"(2) The allowance for no annual continuing review of certain categories of research; and
"(3) The elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research."

Of interest: "If institutions choose to implement these three burden-reducing provisions for particular studies, such studies will be subject to the 2018 Requirements beginning on January 21, 2019," the agency guidance adds.

For more information on these updates and the changes ahead, visit www.hhs.gov/sites/default/files/hipaa-future-research-authorization-guidance-06122018-v2.pdf.