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Health Headlines

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**HHS Seeks Input On Proposals To Revamp The "Common Rule" Governing Research On Human Subjects –** On July 22, 2011, the Department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rulemaking (ANPRM) seeking input on significant changes under consideration to the regulations, known as the Common Rule, governing research on human subjects. The current version of the Common Rule was "first being formulated" in the early 1980's and HHS believes that significant changes since that time "have altered the methods and aims of research with human subjects." For example, "there have been major increases in the volume of research, in multi-site studies, and in health services and social sciences research" and "new technologies for research" including genomics, imaging, [and] informatics."

Among the significant changes contemplated by HHS are the following:

- Requiring specific data security and patient privacy protections, "calibrated to the level of identifiability of the information being collected," instead of leaving each internal review board ("IRB") to determine that there are "adequate provisions to protect the privacy of subjects."
- Expanding the coverage of the Common Rule to any study conducted by a U.S. institution that receives Common Rule funds, instead of only covering research that is itself funded with Common Rule funds.
- Creating a single web-site where all adverse events can be reported instead of having such events "reported to multiple agencies and on multiple time-lines, with no central database as a repository for such data."
- Replacing the "relatively vague language about how consent forms should be written" with "greater specificity about . . . what information they should contain, so they can be shorter, more user-friendly, less confusing, [and] contain all of the key information"
- Requiring written consent from individuals to conduct research on their biospecimens even if the specimens have been stripped of identifiers (the "consent could be obtained using a standard, short form by which a person could provide open-ended consent for most research uses of a variety of biospecimens").
- Encouraging a single IRB to review all of the U.S. sites in a multi-state study.
- Ensuring consistency in interpretations of the Common Rule across all Common Rule agencies and the FDA unless a difference is "justified by differences [in] the missions of those agencies."
- No longer requiring continuous IRB review "after all subjects in the study have completed any study interventions and the only remaining procedures are standard-of-care procedures."
- No longer requiring continuing annual reviews of "studies that are eligible for expedited review unless the reviewer, at the time of initial review, determines that continuing review is required, and documents why."

HHS has prepared a chart showing a comparison of existing rules with some of the changes being considered that is available at the "read a table" link on HHS's website, **here**. This website also contains links to the news release and actual ANPRM regarding the Common Rule changes.

The ANPRM comment period closes 5:00 p.m. Monday, September 26, 2011. HHS will use the comments and its deliberations from this Advanced Notice of Proposed Rulemaking to issue specific proposals in a Notice of Proposed Rulemaking. There will then be another opportunity to comment on HHS's specific proposals prior to finalization.

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**FDA Issues Draft Guidance On Mobile Medical Applications –** The U.S. Food and Drug Administration (FDA) recently released its "Draft Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications." Citing the quickly expanding field of mobile applications, the FDA released the Guidance to provide information as to how the FDA intends to apply its authority to certain software applications that may be used on mobile platforms.

According to the FDA, at the present time it will extend its regulatory authority to a specific type of mobile application: the "mobile medical app." For purposes of the Guidance, the FDA defines "mobile medical app" as a mobile app that falls under the definition of "device" in the Federal Food, Drug, and Cosmetic Act and either: (1) is used as an accessory to a regulated medical device or (2) transforms a mobile platform into a regulated medical device. The Guidance explains that the intended use of a mobile application, such as the use shown through marketing or advertising by manufacturers, determines whether such application meets the definition of a "device."

As set forth in the Guidance, for mobile medical applications that are subject to FDA regulation, manufacturers should satisfy the criteria associated with the applicable device classification. The Guidance provides detailed information on examples of mobile medical applications and regulatory requirements and also seeks comments by October 19, 2011.

A more detailed summary on the Guidance may be found **here**, and the Guidance may be read **here**.

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**CMS Announces $575 Million Recovered Through RAC Program** – On July 27, Senator Thomas R. Carper (D-Del.), Chairman of the Senate Subcommittee on Federal Financial Management, highlighted a recent report from the Centers for Medicare and Medicaid Services (CMS) announcing that the Medicare Recovery Audit Contractor (RAC) Program has recovered $575 million in overpayments through June 2011. The Report tallied amounts collected from October 2009, when CMS implemented the program nationally, through last month.

The amount of overpayments recovered by CMS is growing. From October 2009 through September 2010, the RAC program collected $75.4 million. The first quarter of 2011 brought in $81.2 million, followed by $185.2 million in the second quarter, and $233.4 million at the close of the third. CMS also reported that $109.6 million in underpayments have been identified and paid to providers since the inception of the program. The RAC program currently focuses on Medicare Parts A and B but will expand to include Medicare Parts C and D and Medicaid by the end of 2011.

In his July 27 statement, Senator Carper said "[t]his report shows that the amount the Centers for Medicare and Medicaid Services recovered in this quarter alone comes close to the amount it recovered in the first two quarters combined." However, the Senator cautioned that while this is "remarkable progress in just a few months," CMS has much more work ahead, as "[r]ecent estimates put the total number of Medicare fee-for-service improper payments at a staggering $34.3 billion annually." A copy of the CMS report is available by clicking **here**. Senator Carper's press release is available **here**.

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