BNA Essential Information Expert Analysis

Mobile Health Group Asks FDA to Rethink Portions of Draft Guidance on Medical Apps

October 26, 2011

A coalition of health care and information technology organizations is asking the Food and Drug Administration to rethink portions of the draft guidance the agency issued earlier this year on regulating mobile medical applications.

The mHealth Regulatory Coalition said in an Oct. 19 comment letter to FDA on the draft guidance that it supported FDA's "step toward appropriate regulation of mobile health technologies, but there is more work to done."

The coalition noted that other groups may not support FDA regulation of mobile medical apps at this time and might call for the agency to withdraw the guidance, but that it believed "clear, predictable, and narrowly-tailored regulation is necessary to ensure patient safety and to promote innovation."

FDA published its "Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications" in the July 21 *Federal Register* (76 Fed. Reg. 43689), proposing an approach for how it will oversee software applications (apps) designed for use with smart phones and other mobile devices for health care purposes (139 HCDR, 7/20/11). Comments were due Oct. 19.

The coalition—whose members include AT&T, Continua Health Alliance, Kaiser Permanente, Nokia, Qualcomm Inc., and WellDoc—has proposed separate draft guidance to FDA for regulating mobile health products more broadly.

Intended Use Approach Too Broad

Among specific comments to FDA, the coalition said the agency's proposed approach for evaluating intended uses of mobile medical application products was "too broad and would result in unnecessary regulation of mHealth technologies."

The coalition recommended that FDA instead seek to regulate "moderate- to high-risk devices" and make efforts to exempt or exclude low-risk products from regulatory oversight. The coalition pointed to recommendations in its own proposed guidance to the agency for criteria that could be used in assessing product risks and whether, based on intended use claims, a product should be regulated.

The coalition also asked FDA to clarify which intended uses would trigger regulation by the agency.

The coalition further asked that FDA rethink how it might apply the medical device accessory rule to mobile health products because the agency's approach for regulating medical device accessories would not work well for mobile health products.

Traditionally, for oversight purposes, FDA has classified accessories in the same categories as the medical devices to which they are attached. The reasoning is that risk of an accessory to a medical device failing is the same as if the device itself failed.

“In the world of mHealth, this theory does not always hold true,” the coalition said. “A more sound approach is to rely on 1) existing and future classifications for specific products within an mHealth system, and 2) claims substantiation.”

The coalition suggested FDA develop new classifications for mHealth system products that otherwise might be treated as device accessories.

Other Recommendations

Other coalition comments called for FDA to:

- provide more guidance on the roles and responsibilities of entities involved in manufacturing of products in an mHealth system;
- modify its proposed approach for regulating app stores (such as iTunes and Android Market) as a distributor that would be subject to agency oversight; and
- encourage the use of standard software design principles for modularization of mobile health apps.

The coalition also said FDA should be clearer in communicating to the health care community what it considers to be an electronic health record and define its regulatory approach for EHRs. Likewise, the group asked FDA to better identify the scope of its jurisdiction for mobile health products.