Health IT Alert: FCC Seeks Comments on Converged Communications and Health Care Devices; Schedules Public Meeting

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By Russell H. Fox

The Federal Communications Commission (FCC) is asking the public for comments by June 25, 2010 on questions regarding regulatory challenges and safety for patients and other users of medical devices that include radio elements and of systems that can be tied into broadband networks. As part of its efforts, the FCC will conduct a joint meeting with the Food and Drug Administration (FDA) entitled "Enabling the Convergence of Communications and Medical Systems: Ways to Update Regulatory and Information Processes" on June 26-27 at the FCC's office from 8:00 AM to 5:30 PM each day. The purpose of the meeting is to gather information about the challenges and risks posed by the proliferation of medical implants and other devices that utilize radio communications to effectuate their functions, and the challenges and risks created by the integration of broadband communications with health care devices and applications.

Background

There have been two principal areas of growth in the use of wireless technologies that support health care. The first involves devices that use radio technology to monitor body functions and conditions, including critical elements, and deliver treatment and therapy. Examples of such implant and body-worn devices include blood glucose monitors and automated insulin pumps, heart monitors, pacemakers, defibrillators, and neutral pathway replacements that stimulate muscle movement.

The second growth area has been the proliferation of devices and applications using commercial networks, including those with Internet access, to communicate with health care providers. Examples of devices that use commercial communication networks include a smartphone application that displays real-time fetal heartbeat and maternal contraction data allowing obstetricians to track a mother's labor and wearable patch-like sensors that transmit health data over commercial wireless networks to practitioners, caregivers, and patients.

FCC Questions for Comment

In advance of its joint meeting with the FDA, the FCC asks interested parties to submit comments by June 25, 2010 on the topics listed below. Comments will be considered as part of the meeting on June 26-27, and presumably going forward as the FCC and FDA regulate in these areas.

- Data integrity and reliability issues arising from the use of licensed spectrum, the use of unlicensed devices and commercial networks and applications
- The needs, uses and risks for "medical grade" wireless technology and communications
- Medical device and security issues—inadvertent and intentional intrusion and nonfunction and malfunction
- Trends in medical devices using allocated spectrum and using unlicensed spectrum and devices and applications using commercial networks. Consideration of various wireless networking scenarios and use cases
- The need to define levels of "criticality" of device function that can be used for determining reliability requirements
- Environmental factors and delivery settings that affect risk management
- The relationship between FDA approval/clearance and FCC certification of applications, post-market and compliance requirements

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For assistance in this area please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

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