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FCC TAKES STEPS TO MAKE MORE SPECTRUM AVAILABLE FOR WIRELESS MEDICAL DEVICES

Many medical devices, such as wireless telemetry equipment that transmits data about a patient's pulse and heart rates, require access to electromagnetic spectrum. The Federal Communications Commission ("FCC") is responsible for allocating spectrum used by these medical devices. Recognizing that growth in the sophistication of both wireless communications and medical devices presents substantial opportunities for preventive and curative care, the FCC is devoting additional resources to facilitating spectrum access for medical devices. Most recently, the FCC has (1) unveiled a plan to create more flexibility for experimental uses of spectrum for wireless health technologies and (2) allocated spectrum for new wireless Medical Body Area Networks.

Plan To Create More Flexibility for Experimental Spectrum Uses

At the FCC's mHealth Summit yesterday, FCC Chairman Genachowski announced that the FCC plans to amend its rules in the upcoming months to create more flexibility for experimental uses of spectrum for wireless health care technologies. Under the plan, the FCC would create research licenses that, in coordination with the FDA, would help get new wireless health care technologies to market more quickly. In addition, new "innovation zone" licenses would allow experimentation using certain pre-approved spectrum in specified geographic locations. Chairman Genachowski also asked Qualcomm, TheCarrot (a web and mobile platform for health management), and the Center for Integration of Medicine and Innovative Technology to lead an industry effort to develop a plan by September 2012 for addressing barriers to rapid deployment of mobile health technology.

Spectrum for New Wireless Medical Body Area Networks

Last month, the FCC allocated 40 MHz of spectrum for the operation of new wireless Medical Body Area Networks ("MBANs") in the 2360-2400 MHz band.[1] An MBAN is described as consisting of two components — a master transmitter or "hub" that is located on the body or in close proximity to it, and one or more body-worn sensors — that are used to monitor a patient's physiological functions and communicate the data back to a monitoring station. Using the newly allocated spectrum, data are transmitted from the sensors to the nearby hub, where the data can be aggregated before being sent to the remote monitoring station using existing communications networks, such as a Wi-Fi or Wireless Medical Telemetry Service network.

These new rules were prompted by a proposal submitted to the FCC in 2007 by GE Health Care. Incumbent users, consisting primarily of the aeronautics industry, initially opposed GE Health Care's proposal to allocate spectrum for MBAN operations. However, healthcare providers and the aeronautics industry reached a compromise in early 2011 to help reduce the risk of interference.

The FCC's final rules are generally consistent with the industry's compromise proposal, although there are some important technical and procedural differences. For example, while the compromise

[1] http://transition.fcc.gov/Daily_Releases/Daily_Business/2012/db0524/FCC-12-54A1.pdf.

proposal would have required health care facilities to implement a "transition plan" prior to beginning MBAN operations, the FCC concluded that this formal process is not necessary and instead adopted what it considers to be less burdensome and flexible registration and coordination requirements.

The permitted MBAN operations depend on which portion of the band will be used:

- MBANs using the 30 MHz in the 2360-2390 MHz band. MBAN operations in this band are restricted to indoor uses in health care facilities. Users of this portion of the band will be required to register with an MBAN coordinator (which, as discussed below, will be selected at a later date) and coordinate with primary licensees, if necessary.
- MBANs using the 10 MHz in the 2390-2400 MHz band. In this band, MBAN operations can be used in any location, such as in a health care facility, in a patient's home, or outdoors while the patient is in transit (e.g. ambulances). Users of this portion of the band will not be subject to registration and coordination requirements.

To help encourage the development of MBAN devices and applications, the FCC decided not to require users to apply for and receive individual licenses from the FCC. Instead, all MBANs will be "licensed by rule," which means that users will be deemed licensed as long as they abide by all technical and operational limitations.

Notably, however, MBAN operations will be permitted only on a secondary basis — users must not cause harmful interference to and must accept interference from the primary licensees in the band. In the past, the Food and Drug Administration ("FDA") has expressed concern about the potential for interference when health care providers rely on wireless medical devices. In a 2007 draft guidance document, Radio-Frequency Wireless Technology in Medical Devices, FDA commented that a quality system for devices that incorporate wireless technology should address potential concerns such as wireless quality of service, wireless coexistence, data integrity and security, and applicable EMC and telecommunications standards and regulations.[2] As a result, there is likely to be increased collaboration between the FCC and the FDA as wireless medical devices enter the market. In particular, the FCC suggested that the FDA could play an important role in specifying whether MBANs may be used to perform functions that are life-critical or time-sensitive.

In addition, the FCC has taken a number of steps in its rules to help minimize any risk of interference. Beyond requiring registration and frequency coordination by MBAN users in the 2360-2400 MHz portion of the band, the FCC believes interference risks will be low because MBAN devices may operate only over relatively short distances and at a very low power. The Commission also encouraged manufacturers of medical devices to incorporate techniques that avoid interference, such as dynamic spectrum sensing capabilities, into their MBAN devices.

In a Notice of Proposed Rulemaking issued along with its decision, the FCC proposed procedures and criteria for designating an MBAN coordinator (or coordinators) and asked whether there should be any restrictions on the service fees charged for registration and coordination. Comments on these additional issues are due 45 days after the Notice is published in the Federal Register (which has not yet occurred), and replies are due 20 days later. The FCC stated that it hopes to complete the process of selecting an MBAN coordinator by June 2013.

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[2] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM077272.pdf.

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