mHealth Alert: FCC Proposes Rules for MBAN

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The Federal Communications Commission (FCC) has proposed to allocate radiofrequency spectrum and establish service and technical rules for the operation of Medical Body Area Network (MBAN) systems. The FCC envisions that MBANs would provide a platform for the wireless networking of multiple body sensors used for monitoring a patient's physiological data, primarily in health care facilities. The use of MBANs would help eliminate the need for hardwired, patient-attached cables used by current monitoring technologies. The FCC's proposal is a continuation of its efforts to satisfy the spectrum requirements of wireless medical technologies, and is responsive to a request submitted by GE Healthcare (GEHC). The deadlines for submitting comments and reply comments on the FCC's proposal are 60 and 90 days, respectively, from the time the proposal is published in the Federal Register, which has not yet occurred.

The FCC envisions that an MBAN could be created through attaching multiple wireless sensors on the patient. The patient-attached devices would take readings of key information, such as temperature, pulse, blood glucose level, blood pressure, respiratory function, and a variety of other physiological metrics. Antenna components in the sensors would then transmit the data wirelessly a short distance to a hub device, which would then relay the data or processed information to another station in the facility for further centralized processing, display, and storage.

Frequency Allocation

The FCC is considering several possible frequency bands for use by MBANs.

2300-2305 MHz and 2360-2395 MHz Band

GEHC's request targeted the use of this band for MBANs. However, this band is currently used by several other services, including Aeronautical Mobile Telemetry (AMT), federal radiolocation, and amateur radio users. Nevertheless, the FCC seeks comment on the potential use of these bands by MBANs on a secondary (non-interference) basis. The FCC states that sharing between MBAN systems and AMT and radiolocation operations could be facilitated if it established exclusion zones around AMT test flight sites and MBANs were limited to indoor use. The FCC also suggests that MBAN users may be able to coordinate their operations with AMT licensees. According to GEHC, MBAN operations could avoid interference from AMT licensees by operating with a contention-based protocol that detects AMT operations.

2400-2483.5 MHz Band

This band is used by Industrial, Scientific and Medical (ISM) equipment on a non-licensed basis under the FCC's rules. In addition to ISM devices, a portion of the band is allocated to amateur radio operators, the federal radiolocation service and unlicensed equipment such as Wi-Fi routers and cordless phones. The FCC seeks comment on whether MBANs could operate in this band under current rules or whether new rules would be required to regulate MBANs using this band.

Other Frequency Bands

The FCC seeks comment on whether other frequency bands may be appropriate for MBANs, including the 5150-5250 MHz band, which is now allocated for federal and non-federal aeronautical navigation and non-federal fixed-satellite use and unlicensed national information infrastructure (U-NII) devices.

Service and Technical Rules

Service Rules

The FCC seeks comments on the following potential attributes of MBAN systems:

- **Licensing** - Whether MBANs should operate without individual licenses (and instead, be "licensed-by-rule"). Alternatively, the FCC asks whether MBANs should be licensed on a non-exclusive basis.
- **Definitions** - The FCC seeks comment on the definitions of "medical body area device," "medical body area network," "MBAN transmitter" and "MBAN control transmitter."
- **Permissible Communications and Operator Eligibility** - The FCC proposes requirements for permissible communications and operator eligibility that are generally the same as those in place for the MedRadio Service (which generally provide that devices may be used by persons for diagnostic and therapeutic purposes, but only to the extent that such devices have been provided to a human patient under the direction of a duly authorized health care professional). The FCC seeks comment on how spectrum may be used to perform backhaul from a single patient-based MBAN control transmitter to a monitoring station that receives and processes data from multiple patients. Today's MedRadio rules do not allow transmitters to be interconnected with other telecommunications systems, including the telephone network.

Technical Rules

The FCC seeks comments on the following potential technical attributes of MBAN systems:

- **Channelization** - The FCC proposes not to adopt a channelization plan.
- **Exclusion Zones** - As noted above, the FCC seeks comment on the feasibility of using exclusion zones (and the technical parameters that would apply to those zones) as a means to prevent interference to incumbent operations in the 2360-2390 MHz band.
- **Frequency Coordination** - The FCC asks whether coordination should be required by MBANs with AMT and other incumbent users and, if so, how that coordination should be conducted.

Alternatively, the FCC seeks comment on whether it should license MBANs on a non-exclusive basis, similar to its regulation of the 3650-3700 MHz band.

- **Frequency Monitoring (Spectrum-based Spectrum Access Protocols)** - The FCC invites comment on whether these techniques should be used to protect MBANs from interference from entities that share the same spectrum.
- **Transmitter Power, Emission Bandwidth, and Duty Cycle** - The FCC proposes to limit individual MBAN devices to a maximum transmit power of 1 mW equivalent isotropic radiated power (EIRP) measured in a 1 megahertz bandwidth, and a maximum emission bandwidth of 1 megahertz. It asks whether a duty cycle limit is needed to allow the functioning of contention-based spectrum access (and if so, what that duty cycle should be).
- **Channel Aggregation** - The FCC proposes that the total emission bandwidth used by all devices in any single patient MBAN communication session not exceed the maximum authorized bandwidth of 1 megahertz.
- **Unwanted Emissions** - The MedRadio rules require that emissions on frequencies 500 kHz or less above or below authorized bandwidth be attenuated by at least 20 dB below the transmitter output power, and that frequencies more than 500 kHz above or below authorized bandwidth require attenuation based on varying signal strengths. The FCC asks whether the same limits should apply for MBANs.
- **Frequency Stability** - The FCC proposes that MBANs maintain a frequency stability of +/- 100 ppm of the operating frequency over the range: 25 degrees centigrade to 45 degrees centigrade in the case of MBAN transmitters, and 0 degrees centigrade to 55 degrees centigrade in the case of control transmitters.
- **Antenna Locations** - The FCC asks whether it would be appropriate to restrict the use of MBAN transmitting antennas to indoor locations in certain frequency bands.
- **Radiofrequency Safety** - The FCC seeks comment on whether MBANs should be classified as portable devices under its radiofrequency safety rules.
- **Miscellaneous Provisions** - The FCC seeks comment on whether: 1) each MBAN transmitter should be certified, except for transmitters not marketed in the United States; 2) all non-implanted MBANs should be available for inspection upon request of an authorized FCC representative; 3) it should require manufacturers to disclose that devices must not cause harmful interference to others; 4) devices should be labeled with such information; and 5) it should specify that MBANs may be marketed and sold only for permissible uses.

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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