

# RADIO FREQUENCY MEDICAL DEVICES

## At the Intersection of FCC, FDA and Privacy Concerns

by Linda D. Bentley and Russell H. Fox

Healthcare professionals are generally eager to embrace a new technology that helps them to better serve patients. One technology increasingly employed is the so-called Radio Frequency Identification (RFID). Consumers may be familiar with RFID devices used in “SpeedPass” toll passes, and the technology is also used by companies to track inventory. An RFID system typically consists of a tag/transponder and a reader/transceiver. The tag is a microchip with an antenna and unique identifying information. Using radio frequencies, the reader sends a signal to the tag and the tag responds with the requested information.

Devices in use today employ frequencies designated for unlicensed operations, which permits their use without authorization from the Federal Communications Commission (FCC),

although the devices must meet certain FCC specifications before they can be marketed to consumers.<sup>1</sup> RFID devices can be worn externally or implanted and, when read, can provide information regarding a patient’s identity and medical information.

While RFID presents some

transmitter was programmed. RFID cannot provide healthcare professionals with real-time information about a patient’s condition.

Other wireless technologies permit the use of devices that can wirelessly transmit such real-time information. For instance, the ApexPro wireless

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exciting opportunities, the utility of the technology is limited because the information contained in the RFID transmitter is generally unchanged once it is imprinted in the device. Moreover, even RFID devices that can be re-programmed only reveal information that was available at the time the

medical telemetry systems by GE Healthcare operate in the so-called Wireless Medical Telemetry Service. In this service, patient information is transmitted from remote devices to a central monitoring location in a hospital or other medical facility.<sup>2</sup> Other examples of devices utilizing



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licensed spectrum are patient implanted devices such as cardiac pacemakers and defibrillators, which are licensed to operate in the Medical Implant Communication Service (MICS).<sup>3</sup>

GE Healthcare, and other providers, also utilize spectrum allocated for unlicensed operations to create local area wireless networks (similar to consumers' in-home wireless networks) that allow patient monitors that would otherwise be tethered to computers to be moved around a hospital or healthcare facility.<sup>4</sup>

## More Spectrum Available

Because of the explosive reliance on spectrum for functionality of medical devices, and in anticipation of even greater usage, the FCC initiated a proceeding to make more spectrum available for medical devices.<sup>5</sup> These proposed rules would promote the production of additional body-worn devices that would sense body functions and conditions and transmit that information to a device that records the information or passes it along to an external device. The FCC requested comments on: 1) the development and deployment of new wireless medical devices; 2) the suitability and availability of spectrum to accommodate these devices; and 3) the need for new FCC rules to promote the development of the devices.

High-tech companies and medical device makers commenting in the FCC's proceeding said that even the FCC's forward-looking proposals do not create sufficient capacity for additional wireless medical devices. The Alfred Mann Foundation for Scientific Research reported that it is developing a wireless wideband micro stimulator designed to work as an artificial nervous system.<sup>6</sup> According

to the Foundation, its devices require more than the 5 MHz of spectrum, used at higher power, than the FCC proposes to designate for the MedRadio service. Therefore, it identified additional spectrum bands in the 400 MHz range that it urges the FCC to reallocate for medical device use on a wideband basis. Similarly, GE Healthcare suggested that the FCC consider allocating more than 5 MHz of spectrum for wireless medical devices.<sup>7</sup> The company notes that one of the most promising concepts on the horizon is that of the body sensory network (BSN) and that BSNs require more spectrum and higher permitted power than would be available in the MedRadio service.

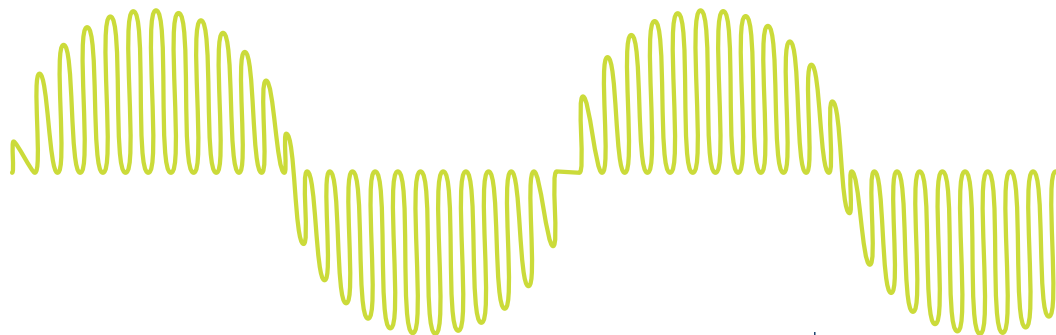
Another company, Partners Healthcare System, suggested that this proceeding puts the FCC in the "awkward position" of approving and disapproving medical devices, which lies within the Food and Drug Administration's (FDA's) jurisdiction.<sup>8</sup> According to Partners, the FCC should: 1) restrict the use of the proposed frequency allocation to devices approved by FDA; 2) license these devices by rule (as WMTS devices are licensed); and 3) require the creation, adoption and use of industry standards and communications protocols.

## FCC Granting Waivers

While the FCC works to draft final rules to govern wireless medical devices, it has considered and granted specific requests from companies to

operate and manufacture particular devices. DexCom, Inc. designed a glucose-monitoring sensor that is implanted in the body. The sensor monitors the patient's blood glucose level and sends an alarm to an external device when the glucose level fall outside the acceptable range. DexCom proposed to transmit the information from the implanted device to the monitor using radio frequencies not designated for such use. Before DexCom could launch such a device, it was required to obtain a waiver of the FCC rules.<sup>9</sup> DexCom was permitted to proceed with the manufacturing and marketing of the devices for a three-year period, or until the FCC implements rules governing the frequencies utilized by DexCom. In granting the request, the FCC recognized the "significant medical value of these devices as presently constituted for current diabetic patients."<sup>10</sup>

In a more recent decision, the FCC granted similar requests from Respironics, Inc. and Boston Scientific Corporation.<sup>11</sup> Respironics markets devices that monitor sleep patterns and caloric expenditures. One of its products is not in compliance with the FCC's rules and, therefore, the FCC granted it a limited waiver to continue operating until it redesigns the existing product. In finding that grant of a waiver was in the public interest, the FCC found that there are "no alternative devices available now or in the future."<sup>12</sup> The



FCC recognized that a design was possible that complied with its rules, however, it did not wish to disrupt the availability of such devices by requiring Respirationics to remove them from the market. Instead, it granted a period of one year for Respirationics to design a compliant device.

Boston Scientific is developing a next generation of devices, such as pacemakers, for cardiac patients.<sup>13</sup> Like Respirationics, Boston Scientific sought a waiver to continue to market non-compliant devices until it developed the next generation of compliant devices. Although Boston Scientific sought eight to 10 years to do so, the FCC granted it three years. The FCC reasoned that the public interest necessitated a more expeditious development and, if Boston Scientific could not provide it, the market would most likely do so.<sup>14</sup>

achieve its primary intended purposes through chemical action within or on the body of man ... and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”<sup>15</sup> This means that if the device is to be marketed with claims of medical utility, such as to provide access to medical information that will assist medical personnel in diagnosing, monitoring, or treating an illness or condition, it will be treated as a medical device and will be subject to premarket notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) or FDA approval of a premarket approval application (PMA). A 510(k) premarket notification must demonstrate that a device is substantially equivalent to another legally marketed device that does not require PMA. The PMA process is more complex, and must provide

wrong-procedure, and wrong-patient surgeries.<sup>17</sup> Another device that was cleared by FDA is an implantable RFID microchip containing a unique electronic identification number that is used to access patient identity and health information stored in a database.<sup>18</sup> This application, although not widespread, has interesting potential applications for individuals with chronic health conditions and allergies. It could also be useful for patients who are unconscious or otherwise unable to communicate with providers upon arrival at the hospital. However, it has also raised concerns about the privacy and security of personal health information (PHI). It is interesting to consider whether or not such an application presents privacy risks beyond those associated with conventional medical records systems.

Access, use and disclosure of medical information is presently governed at the federal level by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and by state privacy laws that may be stricter than HIPAA. HIPAA dictates standards for maintaining both the privacy and the security of PHI, and applies to “covered entities” or healthcare providers who possess or transmit PHI.

An RFID chip containing an identifier that leads to a file in a database appears to fit within the existing regulatory scheme. In this instance, it is the database that contains the PHI, not the chip, and the access, use, and disclosure of the database information as well as its security would be governed by HIPAA. The risk of inappropriate access to the database does not appear to differ from the risk of inappropriate access to a conventional paper or electronic

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## *Depending on the intended use of an RFID or other wireless device, a medical device may also be subject to regulation by FDA.*

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### **FDA's Role in RFID Devices**

Depending on the intended use of an RFID or other wireless device, a medical device may also be subject to regulation by FDA. A medical device is defined in pertinent part as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man ... which does not

more scientific evidence than a 510(k), including clinical data, that a device is safe and effective for its intended purpose.

One of the first FDA-approved uses of radiofrequency signal transmitters and receivers was for the transmission of a patient's physiological signals, such as electrocardiographs and other vital signs over the telephone lines to a healthcare provider. These devices came to market via the 510(k) procedure.<sup>16</sup> Subsequently, FDA cleared an RFID tag that is placed on a patient's skin prior to surgery to minimize the likelihood of wrong-site,

medical record system. If the database associated with an RFID identifier or any other wireless transmission device was compliant with HIPAA, there would be appropriate access controls to ensure that more than a unique identification (ID) was necessary to enter the database.

It is unclear how an RFID chip or a medical device that broadcasts real time PHI might fit within the existing legal framework. This type of system would present unique issues such as traveling patients being subject to different state privacy laws as they moved from state to state. It is not clear whether PHI in the possession of someone who is not a covered entity would be subject to HIPAA protections at all. Perhaps an implanted microchip that is linked to a patient's medical record is like a patient carrying a paper copy of her medical record, which is not subject to HIPAA protections. Of greater concern is whether access to such a system could be monitored to prevent inappropriate use of a patient's information. Could anyone with a reader/transceiver access the information?

Like many medical decisions, the choice of utilizing technology may require a risk-benefit analysis and a calculation of whether the privacy risks are outweighed by the benefits in a patient's particular situation..  $\Delta$

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<sup>1</sup> 47 C.F.R. §§ 15.241, 15.242 and 15.37.

<sup>2</sup> *Investigations of the Spectrum Requirements for Advanced Medical Technologies*, Notice of Proposed Rulemaking, Notice of Inquiry and Order, 21 FCC Rcd 8164, ¶ 6. (2006).

<sup>3</sup> *Id.*, ¶ 7.

<sup>4</sup> Comments of GE Healthcare, (Oct. 31, 2006).

<sup>5</sup> *Investigations of the Spectrum Requirements for Advanced Medical Technologies*, Notice of Proposed Rulemaking, Notice of Inquiry and Order, 21 FCC Rcd 8164 (2006).

<sup>6</sup> Comments of The Alfred Mann Foundation, (Oct. 31, 2006).

<sup>7</sup> Comments of GE Healthcare, (Oct. 31, 2006).

<sup>8</sup> Comments of Partners Healthcare System, Inc., (Oct. 31, 2006).

<sup>9</sup> *DexCom, Inc.*, Order, 21 FCC Rcd 875 (2006).

<sup>10</sup> *Id.* ¶ 15.

<sup>11</sup> *Respironics, Inc. and Boston Scientific Corp.*, Order, 39 CR 1195, DA 06-2316 (Nov. 16, 2006).

<sup>12</sup> *Id.* ¶ 10.

<sup>13</sup> *Id.* ¶ 5.

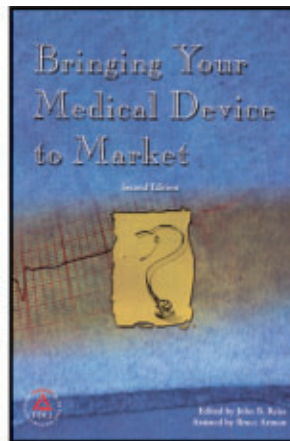
<sup>14</sup> *Id.* ¶¶ 12-13.

<sup>15</sup> 21 U.S.C. § 321(h).

<sup>16</sup> See 21C.F.R. § 870.2910, Radiofrequency physiological signal transmitter and receiver, which are classified as Class II devices for which a 510(k) is required.

<sup>17</sup> See 21 C.F.R. § 878.4660 Skin marker, which is classified as a Class I device for which no 510(k) is required.

<sup>18</sup> See 21 C.F. R. § 6300 Implantable radiofrequency transponder system for patient identification and health information. This type of device is a Class II device that is exempt from the 510(k) requirement under certain circumstances.



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