



Wireless Medical Technologies: Navigating Government Regulation in The New Medical Age

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Wireless Medical Technologies:

Navigating Government Regulation in the New Medical Age

I. Introduction to Wireless Medical Devices

The digital age is changing the nature of health care delivery. While politicians are debating health care reform and how to handle rising costs, the health care industry is capitalizing on new medical technologies that will both dramatically improve care and lower cost.

We are witnessing an explosive growth in medical devices that use wireless technologies, some implanted and some worn on the body, to control bodily functions and to measure an array of physiological parameters. Implanted devices can control heart rhythms, monitor hypertension, provide functional electrical stimulation of nerves, operate as glaucoma sensors, and monitor bladder and cranial pressure. External devices monitor vital signs, assist the movement of artificial limbs, and function as miniature “base stations” for the collection and transmission of various physiological parameters. Soon, miniature transponders embedded in pills will enable doctors to track and monitor drug use.¹ As microprocessors become smaller and more powerful, it is safe to predict that someday wireless technologies will be able to monitor or control nearly every bodily function and movement.

Many wireless medical devices communicate with nearby receivers that are connected to landline networks, cellular systems or broadband facilities that access the Internet. Patients no longer need to be tethered to one spot by a tangle of cables, creating a safer workplace for medical professionals and a more comfortable environment for the patient, with a reduced risk of infection. Wireless monitoring permits patients to thrive outside medical environments, reducing health care costs and enabling physicians to obtain vital information on a real-time basis without the need for office visits or hospital admissions. For aging populations, wireless medical devices offer an important solution for preventative and managed care.

II. A Multi-Agency Regulatory Environment

Wireless medical devices pose three challenging questions for regulatory authorities: (1) are they compatible with other uses of the spectrum; (2) are they safe and effective for the patient; and (3) who should bear their ultimate cost? In the U.S., three federal agencies, the Federal Communications Commission (“FCC”), the Food and Drug Administration (“FDA”) and the Centers for Medicare and Medicaid Services (“CMS”) are charged with answering those questions and play a crucial role in regulating the market for medical devices.

Today, almost every wireless medical device requires both FCC certification and FDA authorization before it can be marketed in the U.S. For reimbursement purposes, which are often necessary for the commercial success of a medical device, CMS must determine that the device provides “reasonable and

¹ Don Clark, “Take Two Digital Pills and Call Me in the Morning,” *Wall Street Journal*, August 4, 2009.

necessary” care.

This tri-partite federal regulatory structure means that manufacturers and vendors are required to navigate myriad technical rules and policies enforced by agencies with different, and sometimes divergent, objectives. Unless these regulatory issues are taken into account at the earliest stages of the research and development process, device manufacturers could find themselves investing significant time and resources in products for which they cannot obtain government approval. Or they may find that the government will not pay for the device, curtailing or eliminating entirely the opportunity to commercialize their technology. Failure to comply with applicable regulations can bring government investigations, fines, forfeitures and other punishments, which in turn can lead to civil litigation and shareholder lawsuits. Intentional noncompliance can even result in criminal charges against corporate officers.

Currently, the FCC is in the process of allocating new spectrum and developing technical standards for several types of implants and body-worn devices. The FCC’s goal is to create new opportunities for manufacturers to integrate radio technologies into medical products to improve the treatment of patients and delivery of health care. These efforts are underway as the FDA develops new guidelines for wireless medical technologies, and indeed the two agencies are at least attempting to put together a framework for sharing information.² Together, these efforts portend major regulatory changes as the health care industry prepares for the advent of many new wireless applications.

III. FCC Oversight

Every medical device, whether implanted or worn on the body, that uses radio technology falls within the FCC’s authority to manage the electromagnetic spectrum. Under FCC rules, wireless devices must be tested for conformance to various technical standards and authorized before they may be imported, marketed or operated in the U.S.

The FCC’s main goal is to ensure that wireless medical devices, like all other radio frequency devices, operate compatibly with other spectrum users. At the same time, the FCC is responding to increasing demands of health care professionals for spectrum access where they can operate wireless devices without interference. In 2009, the FCC completed one rulemaking and initiated two new ones to allocate more spectrum for medical device applications.

² In July 2010, the FCC and FDA released a joint Memorandum of Understanding in which both agencies agreed to work together to promote initiatives related to the review and use of FDA-regulated medical devices that utilize radiofrequency emissions. The MOU is intended to promote collaboration and ultimately improve the efficiency of the regulatory processes for such devices. The goals of the MOU are to explore ways to: (1) enhance information sharing to ensure the safety and efficacy of medical devices; (2) improve the efficiency of both agencies’ regulatory schemes; (3) promote efficient utilization of “tools” and expertise for product analysis, validation and risk identification; and (4) build “infrastructure and processes” that meet the agencies’ common needs.

A. Categories of Wireless Medical Device Technologies

Generally, wireless medical devices fall into one of two informal FCC categories: short range or long range. Short range technologies transmit data from the patient to a local receiver/monitor. The local receiver may stand alone or connect to a central monitoring station. Long range technologies generally transmit patient data directly to a remote monitoring location. As new communication techniques are developed for medical applications, the FCC often must adjust its rules to accommodate these advancements.

B. Short Range Devices for Patient Monitoring, Control and Diagnostics

Available technologies and the FCC services for short range patient monitoring include:

- Inductive Implants: Historically, inductive implantable medical devices have been used to control or monitor cardio activity. Most devices operate in the bands below 200 kHz and communicate at distances of less than one foot from the patient's body.
- Medical Device Radiocommunication Service (formerly "MICS"): Allocated in 1999 for licensed communication between body implants and a nearby controller, the FCC added more frequencies to this service in 2009 for use by body-worn monitoring devices. These devices operate in the 401-406 MHz band at distances up to about 10 feet.
- Wi-Fi, Bluetooth and Zigbee: These unlicensed technologies are commonly used with cell phones, handheld devices and personal computers, but can also be used for implanted or body-worn medical devices. These devices operate in the 902-928, 2400-2483.5 and 5725-5850 MHz bands at distances up to a few hundred feet.
- Ultra-Wideband: New uses of unlicensed ultra-wideband technologies are starting to emerge for medical telemetry and imaging applications. These devices operate at very low power in almost any region of the spectrum at distances up to a few feet.
- Medical Micropower Networks: In November 2011 the FCC allocated new spectrum to accommodate the operation of implanted microstimulator devices that might lead to the creation of an artificial nervous system that could restore mobility to paralyzed limbs. These devices operate in the 413-457 MHz band at distances up to a few feet.
- Medical Body Area Networks: In May 2012 the FCC allocated new spectrum to allow a wireless personal area network ("PAN") of multiple body sensors to monitor or control patient functions. These devices operate in the 2360-2400 MHz band at distances up to a few feet.

C. Long Range Medical Telemetry

Available technologies and the FCC services for long range medical telemetry include:

- Wireless Medical Telemetry (WMTS): WMTS uses unlicensed spectrum to communicate data from body

sensors to remote monitoring locations. These devices operate in various bands between 600 and 1432 MHz band at distances up to several hundred feet.

- Worldwide Interoperability for Internet Access (WiMAX): Often referred to as a “last mile” broadband access technology, WiMAX provides wireless transmission using a variety of transmission modes, from point-to-multipoint links to portable and fully mobile Internet access. The technology provides up to 70 Mbps broadband at distances over several kilometers. The technology is based on the IEEE 802.16 standard (also called Broadband Wireless Access) and uses frequencies around 2.5 GHz in the U.S.

D. FCC Regulation of Wireless Devices

The FCC’s detailed device authorization process is described in Appendix A. The FCC standards specify permissible frequencies, power levels, duty cycle, band sharing and frequency stability requirements, along with detailed test procedures for measuring these parameters. When advances in medical treatment are combined with radio technologies, the FCC’s rules will often lag behind these developments. In such cases, rule waivers or petitions for new rules are filed with the FCC by medical manufacturers or health care organizations.

IV. FDA Oversight

The FDA regulates the marketing of all medical devices sold or imported in the U.S. Unlike the FCC, which focuses on the interference potential of radio frequency devices, the FDA’s role is to ensure that such devices are safe and effective for patient use. The range of products that are classified and regulated as “medical devices” is quite broad and can include such products as medical information networks, cell phones programmed to remind users to take pills and conventional devices fitted with radio communication features.

A. Device Classification Scheme

Medical devices are placed into one of three classifications, based on risk. The lowest-risk devices are in Class 1, and most can be marketed without prior FDA permission; however, these Class 1 devices are still subject to other FDA regulations, such as labeling, listing and quality control requirements. Most wireless medical devices fall under Class 2 and may be marketed only after the FDA determines they are “substantially equivalent” to another device that is lawfully on the market. Class 3 devices are novel, generally high-risk devices for which the FDA requires proof of safety and effectiveness based on clinical trials.

Navigating the FDA process, which sometimes includes significant disagreements over the proper classification of the device, can be expensive and time-consuming. Because the FCC and the FDA have different objectives, the approval of one agency provides no guarantee that the device will clear the other.

B. FDA Guidance on Wireless Medical Devices

The FDA recognizes the increasing use of wireless medical devices and on August 13, 2013, issued a final guidance intended to help manufacturers navigate the approval process. The guidance covers the following

areas:

- Selection and performance of wireless technology
- Wireless quality of service
- Wireless coexistence
- Security of wireless signals and data
- EMC of the wireless technology
- Information for proper setup and operation
- Considerations for maintenance

C. FDA Regulation of Mobile Medical Apps

On September 25, 2013, FDA issued its long-awaited final guidance on mobile medical applications. As expected, FDA announced it will apply enforcement discretion and regulate only those mobile medical applications that are “medical devices” and whose functionality could pose a risk to patient safety if they do not function as intended. The guidance covers three categories of mobile medical apps:

- Mobile apps that connect to another device for purposes of **controlling or displaying, storing, analyzing or transmitting patient-specific medical device data.**
- Mobile apps that **transform the mobile platform** into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.
- Mobile apps that **perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations.**

The FDA approval process, as well as the final guidance documents, is discussed in detail in **Appendix B**.

V. CMS Oversight

Even if a device clears both the FCC and the FDA approval processes, questions as to who will pay for it and whether the device will be marketable may remain. Medicare provides coverage for medical devices and services for more than 43 million beneficiaries. Often, for a device to be commercially viable, the manufacturer must obtain a determination that the device will be covered by Medicare.

For a medical device to be eligible for Medicare reimbursement, CMS or one of its contractors must find that the device provides “reasonable and necessary” care. Coverage determinations can be made at the national or local level. A manufacturer should consider during the initial design stages how to best position its device to receive a positive coverage determination. More details regarding CMS’s procedures and coverage determinations are discussed in **Appendix C**.

APPENDIX A

Overview of FCC Regulation of Wireless Medical Devices

I. Short Range Devices for Patient Monitoring, Control and Diagnostics

(1) Inductive Implants

Historically, implantable devices used inductive coupling to communicate information between patients and doctors at frequencies below 200 kHz. Inductive devices meeting the requirements of Section 15.209 of the FCC's rules allow for the use of small antennas and generally require very little energy. Typically, information from the implanted device is accessed by means of a wand-like device placed on or close to a patient to establish the inductive communication link. Data from the implant can then be read and the implant can be programmed based on patient need.

The principal problem with implants that communicate by inductive link is that data rates are slow. As a result, the wand "reader" has to maintain contact with the patient for long periods of time, and in a therapeutic setting lengthy data transmissions can compromise patient care. Also, any movement by the patient or the reader can interrupt the session, requiring the session to be repeated. Multiple sessions with multiple implant patients can overburden a hospital's medical staff. Another problem is that there is no international harmonization of frequencies for inductive devices. This is of particular importance for patients who travel, where monitoring equipment that activates an implant in the U.S. might not be available outside the U.S. and vice versa.

Inductive implants are also used where transmission of large amounts of data is not required and continuous feedback or feedback at regular intervals is unnecessary. In addition to monitoring and controlling heart function, other common uses include monitoring of intraocular pressure, bladder pressure or cranial pressure

(2) Medical Device Radiocommunication Service (formerly the Medical Implant Communication Service)

In 1999, the FCC allocated spectrum in the 402-405 MHz band for radio communication between implanted devices and a controller either worn on the body or positioned close by. MICS is regulated under Section 95.1201 of the FCC's rules on a "licensed by rule" basis, meaning that no individual application need be filed. The 402-405 MHz band is particularly well suited for tissue penetration at relatively low power which helps extend battery life. The external controller has to be equipped with a "Listen-Before-Talk" ("LBT") frequency selection system in order to minimize interference to other licensed users in the band and to assure uninterrupted transmissions on an unoccupied channel.

MICS technology offers advantages over inductive implants. Readings may be taken from body-worn or table-top transceivers without maintaining reader contact with the patient. Further, the higher frequencies enable transmissions at high data rates.

However, for years, the MICS band languished with few users taking advantage of the new spectrum opportunity. One reason was the lack of a harmonized international standard. In 2004, the European Telecommunications Standards Institute (“ETSI”) resolved this issue by publishing an EU harmonized standard for medical implant devices in the MICS band, consistent with the FCC’s rules. Another factor in the delay of the MICS roll-out was that the LBT technology was expensive and time-consuming to perfect. There was also some concern that LBT might prevent the immediacy of communications that could be required between an implanted device and its controller.

Over time, any disinclination to use LBT appears to have been overcome since the technology has become much less expensive and simpler to install. Another reason, argued by some, is that the FCC’s LBT frequency scanning sensitivity levels are too low to detect many ambient signals so that, in practice, LBT-equipped devices can operate with little fear of not being able to gain immediate access to a channel. Finally, it may be that the original concerns of the National Telecommunications and Information Administration (“NTIA”) that incumbent spectrum users, namely radiosondes (balloon-borne instruments that measure and transmit information on atmospheric conditions), would interfere with MICS were overstated as the radiosondes have caused no difficulty to MICS users. Nevertheless, ten years after spectrum was allocated for MICS, the FCC had authorized fewer than two dozen MICS devices.

In 2009, the FCC amended its MICS rules by adding two “wing bands” at 401-402 MHz and 405-406 MHz for use by body-worn monitoring devices that do not communicate with implants. The entire service from 401-406 MHz was re-named the Medical Device Radiocommunication Service (“MDRS”). Operation in the new wing bands is permitted without the LBT requirement at very low signal levels – 250 nanowatts maximum effective isotropic radiated power (“EIRP”) as opposed to LBT-enabled 402-405 MHz implants which may operate at 30dB higher power. One small portion of the lower wing band, 401.85-402 MHz, is also permitted this higher power without the LBT requirement. Bandwidth limits in the wing bands are 100 kHz instead of the 300 kHz permitted for the LBT-enabled 402-405 MHz band. Because of the very low power limits, it was anticipated that body-worn devices in the wing bands would be used for non-critical applications such as monitoring of temperature, pulse rate and other vital signs that do not require continuous monitoring to sustain life.

(3) Wi-Fi, Bluetooth and Zigbee

In 1997, just before the FCC began its efforts to establish the WMTS, the IEEE adopted the first version of the 802.11 wireless LAN standards for systems operating in the Industrial Scientific and Medical (“ISM”) band at 2.4 GHz. Initially used for short range application such as transmitting signals from a transceiver to a central nurse's station (or some other point in a hospital), subsequent versions of the 802.11 standard were later approved, offering greater ranges and different data rates (*see* Appendix A-1). The equipment associated with wireless LAN has become inexpensive and reliable, and the once-feared interference from other unlicensed Part

15 devices has not materialized. Further, Wi-Fi systems are considerably less expensive than WMTS systems and, because of worldwide standardization, easier to upgrade with various vendors' devices. There is ongoing debate as to whether devices using WMTS or 802.11-based devices will ultimately be the most successful for long range medical telemetry.

These technologies are used for products regulated under Section 15.247 of the FCC's rules which governs frequency hopping and digital modulation technologies (also known as spread spectrum) that operate in the 902-928 MHz, 2400-2483.5 MHz and 5725-5850 MHz bands. Bluetooth and Zigbee in particular are designed for low-power, short-range transmissions. Bluetooth was designed specifically as a replacement for cables between computers and peripheral devices, but it can also be used to monitor implanted or body-worn devices. Zigbee-enabled devices were designed to control and automate a network of devices and are capable of monitoring groups of implanted devices. Each technology has variable power levels and data rates. One significant difference is cost – Zigbee modules are approximately one-third the cost of Bluetooth modules and are designed to use considerably less battery power.³

(4) Ultra-wideband (“UWB”) Application

UWB medical imaging devices, operating under Section 15.513 of the FCC's rules, are just beginning to emerge. UWB devices can be used for very high data rate communications (>1 Gbps), which makes the technology potentially useful for medical applications that involve large file or database transfers. In addition, UWB devices are able to detect motion, and therefore can be used to measure heart rate, respiration, and patient body movement over a very short range (less than 1m). Because they can transmit large amounts of data, UWB imaging devices can be used to create extremely sharp images of bones and internal organs. However, because the FCC's UWB power limits are very conservative, UWB-based medical monitoring devices will continue to be limited to very short-range applications and to date the FCC has authorized only a few UWB medical imaging-monitoring devices.

(5) Medical Micropower Networks (“MMNs”)

In November, 2011, in response to a petition from the Alfred Mann Foundation, the FCC designated 24 MHz of spectrum in the 413-457 MHz range for a “medical micropower network” to accommodate operation

³ Battery life remains a significant issue with wireless implants. Batteries last only a few years and must be replaced, which means the expense and risk of another surgical procedure, no matter how minor. There are, of course, incremental increases in battery life all the time, but more dramatic advances are also occurring. European countries are developing a rechargeable battery for FES (functional electrical stimulation) implants and testing implants containing a fuel cell that can be powered by the body's own glucose. Experimentation is also being conducted with magnetic resonators to transfer power across a distance sufficient to recharge an implant's battery. It seems likely that, at some point, battery life will exceed the useful life of an implant. Until then, however, there is a premium on implant technologies that transmit over short distances and use the least power possible.

of implanted microstimulator devices using FES techniques.⁴ These devices can be “injected” into the body to form a network that would be coordinated by a portable, external master control unit. This network could serve as an artificial nervous system to restore sensation, mobility and other functions to paralyzed limbs or malfunctioning organs. The FCC requested comment on the suitability of four portions of the 413-457 MHz band for MMNs: 413-419 MHz, 426-432 MHz, 438-444 MHz and 451-457 MHz. The 410-450 MHz band is allocated primarily to the federal government, so use of the bands would require coordination with the NTIA⁵.

(6) Medical Body Area Networks (“MBANs”)

On May 24, 2012 the FCC adopted rules based on a proposal by General Electric Health Care (“GEHC”) to allocate spectrum in the 2360-2400 MHz band for another wireless telemetry network of multiple body sensors used to monitor a patient’s health.⁶ This system would not involve implanted devices. As described by GEHC, such a network could be created through attachment to the patient of multiple, inexpensive, wireless sensors or network nodes at different locations on or around a patient’s body to take readings such as temperature, pulse, blood glucose levels, blood pressure, respiratory function and other physiological metrics. This information would be transmitted to a hub that is either worn by the patient or located nearby. The hub could be equipped to initially process the information and then transmit the data to a central location. Essentially, the MBAN system is a way to collect data from multiple sensors, process the data and then send it through a WMTS system or by wire to a monitoring station. By creating the network, information that might otherwise be transmitted on separate, possibly conflicting, frequencies can be “bundled” and transmitted on a single frequency.⁷

⁴ *In the Matter of Amendment of Parts 2 and 95 of the Commission’s Rules to Provide Additional Spectrum for the Medical Device Radiocommunications Service in the 413-457 MHz Band*, Report & Order, ET Docket No. 09-36, released November 30, 2011.

⁵ Of particular concern is spectrum in the 420-450 MHz bands used on a primary basis for federal radiolocation, including ground-based, airborne and shipborne radar systems for long-range surveillance that is operated with very high power over wide bandwidths. The radar receivers are very sensitive in order to detect weak returns. Non-federal uses of the bands include land mobile base and mobile stations, and broadcasting remote pickup services. The most significant concern came from NTIA which argued that the federal government’s defense-related, high-power radar systems may cause interference to MMN systems. Moreover, NTIA suggested that hundreds of MMN transmitters might cause aggregate interference to the federal systems.

⁶ *In the matter of Amendment of the Commission’s Rules to Provide Spectrum for the Operation of Medical Body Area Networks*, First Report and Order (Order) and Further Notice of Proposed Rulemaking, ET Docket No. 08-59, released May 24, 2012.

⁷ The 2360-2400 MHz band is a particularly crowded area of the spectrum. It is allocated for sensitive federal and non-federal aeronautical telemetry for flight testing of aircraft and missiles, the radiolocation service and the Amateur Radio Service.

(7) Emerging Standards

A new wireless medical standard, IEEE 802.15.6, was recently developed for a personal area or body area network to be operated at low frequencies over very short range, with long battery life and high data rates. Proponents anticipate that the technology will be used for a very small unobtrusive body-worn device for the exchange of medical information between an implant and a wristwatch receiver.

II. Long Range Devices for Patient Monitoring and Telemetry

(1) Wireless Medical Telemetry Services (WMTS)

Before the 1990s, remote medical telemetry devices were limited to basic heart monitoring and operated under a Business Radio Service license on 18 frequencies in the 450-470 MHz band and on an unlicensed basis in the TV bands at 174-216 MHz and 470-668 MHz.⁸ Sensors were placed on the patient's chest to pick up electrical signals from the heart. These sensors were connected to a transceiver by short cables and the transceiver relayed the signals to a central nursing station, often through repeaters installed in the ceiling. The system worked reasonably well until 1998, when the first digital television trials took place in Dallas, Texas. DTV transmissions from TV channel 7 (174-180 MHz) that had not previously been used in the area for analog broadcasts began to interfere with the monitoring equipment at Baylor University Hospital.

Fearing that interference to heart monitors might become a national medical problem, the FCC immediately started a proceeding to allocate dedicated spectrum for wireless medical telemetry. Two years later, the FCC adopted rules under Section 95.1101 for WMTS. In the process, the FCC notified manufacturers that in two years it would stop accepting equipment authorization applications for wireless medical devices in the bands subject to interference from the high-power land mobile and television broadcast stations, and labored to convince hospitals using the band for wireless telemetry to move their activities to the WMTS spectrum. Some hospitals did not move, however, and still operate the "legacy" systems⁹. Like MICS, WMTS is licensed by rule.

The FCC provided the WMTS a total of 15 MHz of spectrum in three bands, 608-614 MHz, 1395-1400 MHz, and 1427-1429.5 MHz, for the purpose of "the measurement and recording of physiological parameters and other patient-related information via radiated bi-or unidirectional electromagnetic signals."¹⁰ WMTS systems usually function by direct attachment to body sensors or through connection by wire to a short range system such as MICS. WMTS devices only need to be certified under Part 15 of the FCC's rules. This means

⁸ Unlicensed operation for biomedical telemetry devices were authorized under Section 15.242 of the FCC's rules.

⁹ The last FCC equipment authorization for a wireless telemetry device in the 174-216 and 470-668 MHz bands was granted in 2001. Section 15.242 remains in order to provide regulations for legacy equipment.

¹⁰ The FCC is deciding now whether to permit WMTS to operate on a secondary basis between 1429.5 and 1432 MHz.

that eligible licensees (essentially medical professionals) may use WMTS devices without the formality of a license application. Depending on its location, a WMTS system typically has a useful range of 30-60m.

The use of WMTS has become widespread, but it has several disadvantages. The lower band, 608-614 MHz, is subject to interference from adjacent TV channels 36 and 38. Over the years, hospitals have been forced to install special antennas and amplifiers and experiment with filtering in order to avoid the interference. Although WMTS has 15 MHz of bandwidth, the spectrum is not contiguous, which limits its flexibility and adds to the complexity and cost of developing products by requiring the filtering of some frequencies. The total spectrum is insufficient for more than a few hundred monitors per hospital and thus cannot support transmissions from an increasing number of monitoring devices. There are no uniform standards for interoperability between manufacturers, which means that once a hospital has chosen a system from one vendor it is effectively locked into using that vendor for the life of the system (which could be 10 years or longer). A lack of uniform standards also means that it is difficult for groups of hospitals to share equipment or interconnect.

(2) WiMAX

WiMAX (“World Interoperability for Microwave Access”) is generally operated at 2.5 GHz, although there are no internationally harmonized frequencies. WiMAX can transmit over considerable distances, with both fixed and mobile operations, and can theoretically transmit at data rates up to 70 Mbps (for mobile operations, 40 Mbps is a more reasonable expectation). On a small scale, WiMAX can be a direct competitor to the Wi-Fi LANS that are prevalent in most hospitals. With its large bandwidth and speed, WiMAX can transmit monitoring and diagnostic data from multiple patients without the delays inherent in low bandwidth transmissions. Only a few small WiMAX base stations are needed to cover an entire building. In larger applications, WiMAX is capable of area-wide service, connecting hospitals in a region and enabling the sharing of patient information. In its mobile form, WiMAX can be used to transmit patient data between an ambulance and a hospital.

To date, WiMAX has not proven as prevalent as its developers envisioned. On a large scale, WiMAX’s network architecture requires access points and encounters the same zoning difficulties that can inhibit coverage for cellular and PCS technology. On a small scale it must compete with the entrenched Wi-Fi systems. Further clouding WiMAX’s future is the advent of 4G technology which also promises bandwidth, speed and ubiquity and relies on an existing infrastructure.

A table of characteristics for the current medical telemetry bands is available in **Appendix A-1**.

III. Other Wireless Medical Technologies

Wireless medical devices operate not only pursuant to the FCC rules designed specifically for medical

use, but also operate in licensed and unlicensed spectrum not limited for medical purposes. For instance, the well-known “panic button” for the elderly is designed to comply with the rules intended for unlicensed control signals under Section 15.231 of the rules, the same rule that governs the operation of garage door openers or home security systems. When such a device is activated in an alarm situation it may operate continuously, a provision ideal for panic buttons.

The FCC has also set aside licensed “public safety” frequencies under the Part 90 rules which may be used for medical telemetry. These frequencies may be used by medical personnel, hospitals and ambulance services for the transmission of medical information generally. A system operating under these rules generally consists of both fixed and mobile stations, such as for the transmissions between ambulances and hospitals.

IV. FCC Regulation of Wireless Devices

(1) Equipment Marketing and Authorization

Almost every type of wireless transmitter must be certified for compliance with the FCC’s rules before it can be imported or marketed in the U.S. It is not unusual, however, that during the development of a device a manufacturer desires to show or demonstrate it to the public, prior to certification. Over the years, the FCC has adopted exceptions to the certification rule and identified circumstances where some forms of marketing are permitted.¹¹ For instance, the general marketing prohibition does not apply to marketing to retailers or wholesalers (but not end users) based on sales contracts which are contingent upon eventual compliance with the applicable equipment authorization rules. Also, a device in the pre-production or design stage may be offered for sale to business, commercial, industrial, scientific, or medical users (but not users in residential environments), provided that the prospective buyer is advised in writing at the time of the offer for sale that the equipment is subject to the FCC’s rules and will comply with the appropriate rules before delivery. In addition, the FCC allows equipment to be advertised or displayed (but not sold) at trade shows or exhibitions prior to receiving equipment authorization, provided the display is accompanied by a conspicuous notice explaining that the device has not been authorized by the FCC and may not be marketed until FCC authorization is obtained.

In addition, the FCC staff has made its own informal interpretations of the marketing rules and the circumstances under which a device may be legally marketed. Some of these interpretations can be found in the Office of Engineering and Technology’s “Knowledge Database.” Other interpretations are passed down by oral tradition, or found in copies of letters that, for one reason or other, are no longer readily available in the FCC’s files.

¹¹ The term “marketing” is defined as the selling, leasing, offering for sale or lease, advertising for sale or lease, importation, shipment, or distribution for the purpose of selling or leasing or offering for sale or lease

There is also a general rule prohibiting operation of a device before it is authorized, but as with the marketing rules, there are exceptions. Pre-compliant operation is permitted in the following instances:

- Compliance testing
- Demonstrations at trade shows (with an accompanying notice that the device may not be marketed until authorized by the FCC)
- Demonstrations at exhibitions conducted at business, commercial, industrial, scientific, or medical locations with the accompanying notice (see above)
- Operation at the manufacturer's facilities to evaluate product performance and customer acceptability during the developmental, design or pre-production stage
- Operation at a business, commercial, industrial, scientific, or medical location to evaluate performance and customer acceptability where acceptability cannot be determined at the manufacturer's facilities because of the size or unique capability of the device, again only during the developmental, design or pre-production stage.

For devices that are "licensed by rule" (such as WMTS and MDRS), a manufacturer can operate the device during a demonstration only under the authority of an FCC licensee (*e.g.*, a hospital).

(2) Importation

Even after a device has been authorized by the FCC, it may not be brought into the U.S. without documentation describing the device and providing its date of certification or, if the device is not required to be certified, a statement that the device complies with all relevant technical standards. Devices that have not been authorized may be imported in limited quantities for the purpose of testing or for the exclusive use of the federal government.

(3) Enforcement

The FCC takes its equipment authorization rules very seriously. Through its Enforcement Bureau, the FCC has an active program of imposing penalties on companies who have either failed to obtain an authorization before importing or marketing a device, misled the FCC in the process of obtaining an authorization or marketed equipment not compliant with the technical standard test data reported to the FCC in the certification process. Forfeitures of tens of thousands of dollars for even minor violations are common.¹² The enforcement process is often an adjunct to policy. The FCC has been known to impose very large forfeitures for rule violations that are not particularly significant, but frustrate some over-arching

¹² Often, negotiations with the Enforcement Bureau lead to a consent decree – an agreement by which the FCC ends an investigation in return for a manufacturer or vendor agreeing to adopt a compliance program and the submission of a "voluntary contribution" to the U.S. Treasury.

regulatory objective.

(4) Equipment Authorization Process

As noted, all transmitters used for telemetry or patient monitoring must be FCC-certified prior to marketing.¹³ The certification process involves:

- **Testing:** The device must be tested to show compliance with relevant FCC technical standards by an FCC-listed laboratory, and the test report together with an application form, photographs and other information must be sent to the FCC Laboratory for approval. Alternatively, a manufacturer may choose to have its application and test report approved by a Telecommunications Certification Body (“TCB”), a private entity authorized by the FCC to grant certification applications.
- **Radiation Exposure:** A wireless medical device, either body-worn or implanted, must be tested for compliance with the non-ionizing radiation exposure limits of Section 2.2093(d) of the FCC’s rules. The limits are based on criteria published by the American National Standards Institute for localized specific absorption rates (SAR) in tissue. Compliance can be shown by computational modeling or laboratory measurement techniques. The measurement techniques require specialized equipment and expertise. At present, TCBs are excluded from evaluating SAR testing.
- **Device labeling:** If the device is an unlicensed device under the Part 15 rules (*e.g.*, Bluetooth, Zigbee wireless LANS) it must be labeled using language prescribed by the FCC in order to inform the user that it is an unlicensed device that is not protected from interference.

The technical standards are either spelled out in the FCC’s rules themselves or in procedures adopted by standards organizations and incorporated in the FCC’s rules by reference. Nevertheless, compliance with the FCC’s technical standards is not the cut-and-dried matter one might suppose. There are often disputes between manufacturers, independent test laboratories and the FCC’s own laboratory as to whether a given standard is applicable or the appropriate measurement procedures for determining compliance with a standard. Often there are disagreements between the FCC and the NTIA on proper measurement techniques. As an added complication, products incorporating different RF devices must be tested to meet the standards for both.

(5) Waivers

A wireless transmitter that complies with the FCC’s technical standards can generally obtain a certification within several months if the application is submitted to the FCC, and within several weeks if the

¹³ There are separate FCC regulations for devices containing digital circuitry. The device must also be tested to show compliance with the digital device standards but the manufacturer does not have to submit the test results to the FCC, but only verify (self-certify) that the device complies. Virtually every device that must be tested for certification must also be tested to verify compliance with the digital device standards.

application is submitted to a TCB. However, when a device does not comply with the rules, it may be possible to obtain a waiver, a lengthy process that can often take two years or more. A manufacturer seeking a waiver has to show that the device poses no greater threat of interference, or operates at a location where the possibility of interference is minimized, or perhaps should be measured using a technique better suited to reflecting compliance with the FCC's standards. Whatever the arguments made in support, a waiver petition must go on notice for public comment and then withstand a new round of comments should the FCC actually propose to grant a waiver. Usually, it can be expected that incumbent spectrum users or competitors will file an objection to a waiver petition. If the waiver requires the use of spectrum shared between government and non-government users (and most often this is the case), it is possible that the NTIA will not agree to a waiver or agree only if conditions are imposed on the petitioner. NTIA coordination alone can take months.

(6) Rulemaking

The FCC's rules are often based on snapshots of technology at a moment in time. As new technologies are developed, the FCC's rules are sometimes inadequate to accommodate them. Under these circumstances, a waiver is not a proper course of action because it would not be applicable generally. A rulemaking proceeding, on the other hand, can be used to adopt rules of generally applicability—for instance, a new spectrum allocation or formation of a new radio service. A rulemaking proceeding is governed by the Administrative Procedure Act, which requires the FCC to publish a notice of a proposed action. The public (including industry and standards groups) then has an opportunity to comment on the proposal and to file reply comments. The FCC then adopts or chooses not to adopt new regulations. As in the waiver process, it is often necessary for the FCC and the proponents of the proposed rule to negotiate with the NTIA. Coordination can be contentious and the resulting regulations are often the product of compromise. While the rulemaking process has been used to develop new technologies (*e.g.*, MICS and WMTS), it is time-consuming and mostly benefits those companies who have engaged in long term planning and can accommodate their product schedule to the FCC process. This is particularly the case for medical devices whose introduction may not only have to await adoption of a favorable rule and then FCC certification, but also FDA authorization.

(7) International Regulations

A device intended for sale internationally must also conform to the technical standards of other countries. The European countries, for instance, are in the process of internally harmonizing what had in some cases been disparate technical standards and Europe has developed its own unique approach to equipment authorization. Manufacturers wishing to sell their products abroad must navigate these regulations as well.

APPENDIX A-1 Current Medical Telemetry Bands

Standard	Frequency	Data Rate	Range
Inductive Coupling Devices	< 1 MHz	1-30 kbps	<1m
Wireless Medical Telemetry System	608-614 MHz 1395-1400 MHz 1427-1429.5 MHz	>250 kbps	30-60m
Medical Device Radiocommunication Service	401-406 MHz	250 kbps	2-10m
802.11a Wi-Fi	5 GHz	54 Mbps	120m
802.11b Wi-Fi	2.4 GHz	11 Mbps	140m
802.11g Wi-Fi	2.4GHz	54Mbps	140m
802.11n Wi-Fi	2.4/5GHz	248 Mbps	250m
802.15.1 Bluetooth Class I	2.4 GHz	3 Mbps	100m
802.15.1 Bluetooth Class II	2.4 GHz	3 Mbps	10m
802.15.4 (Zigbee)	868, 915 MHz, 2.4 GHz	40 kbps 250 kbps	75m
World Interoperability for Microwave Access (WiMAX)	2.5 GHz	70 Mbps (fixed) 40 Mbps (mobile)	Several km

APPENDIX B

Overview of FDA Regulation of Wireless Medical Devices

I. FDA Marketing Authorization Process

Medical devices that use wireless technology must also comply with the regulations of the U.S. Food and Drug Administration. A “medical device” is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is: (a) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (b) intended to affect the structure or any function of the body of man or other animals. To distinguish medical devices from drugs, a device must not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and not be dependent on being metabolized for the achievement of any of its primary intended purposes.

(1) Device Classification

Devices are classified into one of three classes, based on risk. Class 1 devices are the lowest risk, and the vast majority may be marketed without prior FDA authorization. Examples include tongue depressors, canes, and scalpel blades.

Class 2 devices are medium risk, and the vast majority may be marketed only after receiving FDA authorization via the filing of a “510(k)” premarket notification. In a 510(k) application, the submitter must show its device is “substantially equivalent” in terms of safety and effectiveness to a “predicate device” that is lawfully on the U.S. market. A device is “substantially equivalent” to a predicate device if it has the same intended use and either (1) the same technological characteristics or (2) different technological characteristics and the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device. By statute, the FDA has 90 days to act on a 510(k) submission, though the agency often requests “additional information” that will extend the total review time beyond 90 days.

Demonstrating “substantial equivalence” can be tricky business. There is no “application form” to fill out. For most types of devices, there is not even a blueprint to follow and manufacturers must do their best to determine the information that will be required by the FDA. In some cases, the FDA has published guidance documents that provide recommendations for the information to be submitted to the agency. In other cases, the FDA has formally recognized certain international consensus standards as providing information relevant to the “substantial equivalence” analysis. In any event, use of experienced counsel to prepare a 510(k) to demonstrate “substantial equivalence” and to deal with any issues raised by the FDA can help to avoid needless expenditure generating information the FDA does not need, thereby expediting FDA authorization.

Class 3 devices are high risk devices, or are devices found not substantially equivalent to a Class 1 and 2

predicate device through the 510(k) process. These devices must be “approved” by the FDA via a pre-market approval application. The PMA process is much more involved than a 510(k) and typically includes the submission of data from experimental use of the device on humans to support claims made for the device. By statute, the FDA has 180 days to act on a PMA submission, though in practice the review is usually significantly longer. As new medical devices are developed using wireless technology, manufacturers may find themselves unexpectedly in Class 3, though there is a process by which manufacturers may seek to have their devices reclassified to Class 1 or Class 2 after a 510(k) application is refused.

A PMA filing is a very serious – and expensive – undertaking. The FDA filing fee alone is over \$200,000, compared to just a few thousand dollars for a 510(k) filing. Because a PMA typically requires the submission of human clinical trial data, it is advisable to meet with the FDA staff and come to an understanding as to the scope of the clinical data to be gathered and the protocols used. Several different types of meetings with the FDA are available, including informal advisory meetings and more formal meetings during which agreement may be reached as to the information to be submitted in the PMA. Prior to conducting a clinical trial, the manufacturer must also obtain an “investigational device exemption” from the FDA to permit use of the device on humans for testing purposes.

Determining how the FDA will regulate a device, and particularly a somewhat novel device, is often complex in itself. Research regarding existing devices and informal contacts with the FDA staff may be useful. If needed, a “513(g)” application may be filed requesting a formal opinion on how the device will be regulated.

(2) Wireless Devices Regulation

Medical devices incorporating wireless technology may be exempt from the 510(k) program, require 510(k) authorization, or require more stringent PMA approval, depending on the nature of the device. For example, “panic buttons” that are worn on the body and allow a person to place a telephone call remotely to an emergency response center are regulated by the FDA as “powered communication systems,” but as of 1998 are exempt from the 510(k) program. An “ingestible telemetric gastrointestinal capsule imaging system” used to detect abnormalities of the small bowel consisting of an ingestible capsule containing a light source, camera, transmitter, and battery also requires 510(k) authorization. An implantable pacemaker that utilizes telemetry for the relay of information and instructions is an example of a Class 3 device that requires a PMA.

Regardless of the regulatory path to obtaining marketing authorization, all medical devices must be “listed” with the FDA, and all establishments that engage in FDA-regulated activity must “register” with the FDA. Once registered, such establishments are subject to inspection for compliance with the FDA’s Quality System Regulation.

Finally, for devices incorporating software, as often occurs with devices utilizing wireless technology, the FDA requires that the software be separately validated. The documentation required will vary depending upon the risk posed by the automated operation. The FDA has a guidance document that explains the type of

documentation that may be required.¹⁴

II. FDA Recommendations for Devices Incorporating Wireless Technology

Having a product certified by the FCC is not sufficient to guarantee it will be authorized for marketing by the FDA as a medical device. Unlike the FCC, the FDA does not have specific technical requirements for wireless medical devices, but rather the device must either be found “substantially equivalent” under the 510(k) program or safe and effective under the PMA program (assuming it is not a Class 1 device exempt from the FDA marketing authorization requirements).

To assist manufacturers through the FDA authorization process, on August 13, 2013, the FDA released a detailed guidance on “Radio-Frequency Wireless Technology in Medical Devices.”¹⁵ Standards referenced in the FDA’s document are listed in **Appendix B-1**. The FDA’s guidance document discusses seven considerations for medical devices that incorporate RF technologies:

A. Selection and performance of wireless technology

A medical device’s wireless technology and capabilities should be appropriately matched to the device’s functions and intended uses. In addition, issues relating to the integrity of data transmitted wirelessly (including latency and throughput, detection, correction, and corruption control and/or prevention) and safety-related requirements of the device should be considered. Potential risks that can affect consistent and timely wireless medical device functions include data corruption and loss and interference from simultaneous transmitters in a given location. Parameters such as bit error rate, packet loss, and signal-to-noise ratio are useful in assessing and assuring data integrity and timeliness of data transmission.

Many medical devices are authorized to operate as unlicensed devices under Part 15 of the FCC rules in the industrial, scientific, and medical (ISM) frequency bands (e.g., 2400-2493.5 MHz) and are therefore not entitled to interference protection. In many cases, RF wireless medical devices and transmission streams can incorporate technology (e.g., frequency hopping protocols, correction protocols) to minimize effects of interference that may lead to data errors or corruption. Also, to help protect against EMI to other medical devices in the vicinity, FDA recommends that wireless medical device manufacturers limit the RF output of their devices to the lowest power necessary to reliably accomplish the intended functions.

¹⁴ Available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm>

¹⁵ Available at <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077210.htm>

When choosing a wireless frequency band or a commercial wireless radio component, the FDA recommends that manufacturers consider:

- International availability and band allocation (e.g., applicable International Telecommunication Union Radiocommunication Sector recommendations) for medical devices because medical devices serve patients located in multiple geographic locations and patients may change their geographic locations;
- Whether the device needs to have primary or secondary radio service classification;
- How incumbent users of the selected and adjacent bands can impact a medical device's operation;
- Interference mitigation techniques for shared RF wireless frequency bands; and
- For implantable and body-worn medical devices, tissue propagation characteristics and specific absorption rates.

Under the FDA's Quality System Regulation, procedures and controls must be established for wireless medical devices and their components to ensure that the device and its components conform to specified design requirements related to the RF wireless considerations.

B. Wireless Quality of Service

Wireless Quality of Service (QoS) refers to the level of service and performance needed for the wireless functions of the medical device. Connections lost without warning, failure to establish connections, or degradation of service can have serious consequences for medical devices, compromising the transmission of high-priority alarms, time-sensitive data, and real-time control of devices. When evaluating the necessary QoS, manufacturers should consider acceptable latency, acceptable level of probability for loss of information within the network, accessibility, and signal priorities of the network.

C. Wireless coexistence

The selection of frequency and modulation should take into account other RF wireless technologies and users that might be expected to be in the vicinity of the wireless medical device system. These other wireless systems can pose risks that could result in medical device signal loss or delay that should be considered in the risk management process. The FDA recommends that manufacturers address a device's environmental specifications and needs, including:

- Associated sources of EMD expected in specific known use environments; and
- Co-channel and adjacent channel interference from medical devices and other users of the RF band.

If a wireless medical device is expected to be used in proximity to other users of the same frequency, the FDA recommends addressing the risk of interference through testing for coexistence of the device's wireless system

in the presence of the number and type of in-band sources expected to be in proximity to the device, even including situations such as when patients are sitting adjacent to one another in a waiting room.

D. Security of wireless signals and data

The FDA recommends that wireless medical devices utilize wireless protection (e.g., wireless encryption, data access controls, secrecy of the “keys” used to secure messages) at a level appropriate for the risks presented by the medical device, its environment of use, the type and probability of the risks to which it is exposed, and the probable risks to patients from a security breach. The FDA recommends that the following factors be considered during device design and development:

- Protection against unauthorized wireless access to device data and control, including use of protocols that maintain the security of the communications while avoiding known shortcomings of existing older protocols; and
- Software protections for control of the wireless data transmission and protection against unauthorized access.

Security management should also consider that certain wireless technologies attempt to make automatic connections to quickly assemble and use a network (e.g., a discovery mode such as that available in Bluetooth communications). For certain types of wireless medical devices, this kind of discovery mode could pose safety and effectiveness concerns, for example, where automatic connections might allow unintended remote control of the medical device.

For more information on this topic, see the FDA’s June, 2013 draft guidance [“Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.”](#)¹⁶

E. EMC of the wireless technology

FDA recommends that EMC be an integral part of the development, design, testing, and performance for RF wireless medical devices, including consideration of applicable telecommunications standards and regulations and the potential for device RF emissions that might cause EMI with other equipment. Risk management activities should include using risk analysis to identify any potential issues associated with EMC and determining risk acceptability criteria based on information about the device and its intended use, including foreseeable misuse, sources of environmental EMD (e.g., radio transmitters, computer RF wireless equipment), and the potential for RF emissions to affect other devices.

EMC testing should include tests focused on the medical device wireless functions and technology. Some voluntary consensus standards such as the FDA-recognized consensus standard IEC 60601-1-2 “Medical Electrical Equipment – Part 1-2: General requirements for safety and essential performance – Collateral

¹⁶ Available at <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356186.htm>.

standard: Electromagnetic compatibility – Requirements and tests” contain an exemption from the electromagnetic immunity provisions in the “exclusion band” (passband) where the medical device’s RF wireless receiver or transmitter operates. According to the FDA, such standards do not adequately address whether the wireless communications will operate properly in the presence of in-band EMD (e.g., other RF emissions overlapping the frequency band utilized by the medical device wireless signals). Therefore, the medical device’s wireless communication(s) should be actively transmitting while testing for susceptibility during all EMC immunity testing.

F. Information for proper set-up and operation

Proper user instructions are critical to help assure proper set-up, configuration, and performance of the wireless medical device. The FDA suggests considering the following:

- The specific RF wireless technology type (e.g., IEEE 802.11b), characteristics of the modulation, and effective radiated RF power;
- Specification of each RF frequency or frequency band of transmission and the preferred frequency or frequency band (if applicable), and specification of the bandwidth of the receiving section of the equipment or system in those bands;
- A warning that other equipment could interfere with the medical device or device system, even if the other equipment complies with CISPR emission requirements;
- Information about the needed quality of service and security for the wireless technology;
- Functions and performance of the wireless data transmissions including data throughput, latency, and data integrity;
- Information about any limitations on the number, output power, or proximity of other in-band transmitters used in the vicinity that might adversely impact a device’s system operation;
- Information for the user to understand the RF wireless technology’s capabilities and be able to recognize and address issues that might arise. For devices with intended use locations that are in complex RF wireless environments and consist of multiple wireless products, this should include assessment and management of the RF wireless transmitters and their use in the vicinity including transmitters both inside and outside the facility;
- Information for the user to understand the implications and limitations of using RF wireless technology outside the United States, where allocations and technical parameters may be different, possibly affecting the functioning of the device.

G. Considerations for maintenance

The FDA recommends that manufacturers continue to manage the risks associated with the use of wireless technology for the entire life cycle of the device. The procedures for implementing corrective and preventive action must include, among other things, analyses for possible trends in nonconformance information and complaints, such as reports of failures, which could include erratic or unexpected behavior of the medical device.

Because electromagnetic emissions and exposure can vary significantly with various structures, materials, and RF wireless emitter sources in the vicinity, FDA recommends that in analyzing failure trends manufacturers consider factors such as location, user application, and repeat component failures. Potential problems include:

- Additional events that may have contributed to the EMI or disruption of wireless technology resulting in inappropriate or unnecessary diagnostic procedures or interventions;
- Additional equipment used in conjunction with the device;
- Environmental conditions that might have contributed to the event; and
- Repeated device failures at the same facility or in other geographic areas.

When servicing electrically powered medical devices, care should be taken to ensure EMI protection is maintained and in good condition. Such EMI protection can include components that may be removed during service such as shields, metal covers, ferrite beads, bonds, screws, ground wires and straps. In addition, metal surfaces that are intentionally left bare for RF shielding continuity should not be painted. To reduce EMI susceptibility as electronic equipment ages, connector contacts that might have oxidized should be cleaned because oxidized contacts can act as semiconductors.

III. FDA Mobile Medical Applications Guidance

FDA identified three categories of mobile medical apps as the focus of its oversight:

- Mobile apps that connect to another device for purposes of controlling or displaying, storing, analyzing, or transmitting patient-specific medical device data. Examples include remote display of data from bedside monitors, display of previously stored EEG waveforms, or apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform.
- Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Such mobile apps are regulated just like the transformed platform. Examples include mobile apps that allow use of the attachment of electrocardiograph (ECG) electrodes to a mobile platform to

measure, store, and display ECG signals.

- Mobile apps that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations. Examples include apps that use patient-specific parameters to calculate dosage or create a dosage plan for radiation therapy or image processing software.

Mobile apps for which FDA intends to use “enforcement discretion” and not regulate include apps that:

- Help users self-manage their diseases or conditions without providing specific treatment or treatment suggestions;
- Provide users with simple tools to organize and track their health information;
- Provide easy access to information related to users’ health conditions or treatments;
- Help users document, show, or communicate potential medical conditions to health care providers;
- Automate simple tasks for health care providers; or
- Enable users or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

FDA also clarified that the following persons would not be regulated as medical device manufacturers:

- Manufacturers or distributors of mobile platforms such as smartphones or tablets who do not specifically intend or market their products for medical device functions.
- Distributors of apps who are engaged only in providing an online market place where mobile medical apps may be available, such as online marketplaces like “Google Play” and the “iTunes Store.”
- Licensed practitioners, including physicians, dentists, and optometrists, who manufacture a mobile medical app or alter a mobile medical app solely for use in their own professional practice

APPENDIX B-1

Standards Applicable to Wireless Medical Devices

Association for the Advancement of Medical Instrumentation (AAMI)

AAMI TIR No. 18-2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities

ANSI/AAMI PC69:2007, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

ANSI/AAMI/IEC 60601-1-2:2007/ (R) 2012, Medical Electrical Equipment—Part 1–2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. This is the U.S. version of the IEC 60601-1-2 standard (see IEC below)

American National Standards Institute (ANSI) Accredited Standards Committee C63 (ASC C63)

ANSI C63.4:2009, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

ANSI C63.10:2009, American National Standard for Methods for Testing Unlicensed Wireless Devices

ANSI C63.18:1997, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

ANSI C63.19:2007, American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids

Electrostatic Discharge Association (ESD Association)

ANSI/ESD S20.20-2007, ESD Association Standard for the Development of an Electrostatic Discharge Control Program for Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices)

Federal Communications Commission

Code of Federal Regulations, Title 47 – Telecommunications, Chapter I - Federal Communications Commission, Subchapter A – General

- Part 2 – Frequency Allocations and Radio Treaty Matters; General Rules and Regulations
- Part 15 – Radiofrequency Devices
- Part 18 – Industrial, Scientific, and Medical Equipment

Subchapter D - Safety and Special Radio Services

- Part 95 – Personal Radio Services

International Electrotechnical Commission (IEC)

The IEC 60601 family specifies safety standards for medical electrical equipment. EMC is addressed in IEC 60601-1-2, and IEC 60601-2-X provides standards for particular types of medical electrical equipment.

IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests. This is a collateral standard to the third edition of IEC 60601-1. The third edition of IEC 60601-1-2 was published in 2007 and contains essentially the same information that was in the second edition IEC 60601-1-2:2001 and Amendment 1:2004, reformatted according to the third edition of the IEC 60601-1 standard. Emissions and immunity requirements in the third edition IEC 60601-1 are specified under Clause 17.

IEC 60601-2-X standards are for particular types of medical electrical equipment. Requirements of IEC 60601-2-X standards supersede those of IEC 60601-1 and IEC 60601-1-2. Some IEC 60601-2-X standards specify higher immunity test levels or special test setups for EMC. Some might not have been amended yet to reference the third (2007) edition of IEC 60601-1-2 and might still reference an earlier edition. Modifications to IEC 60601-1 for EMC are specified in Clause 17 in the IEC 60601-1-2:2007 edition and Clause 36 in earlier editions. (NOTE: Subclause numbers for similar provisions in IEC 60601-1-2:2007 are different from those in earlier editions.)

IEC 61326-1:2005, Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 1: General requirements. Edition 2.0 was published in 2012.

IEC 61326-2-1:2005, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-1: Particular requirements - Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications. Edition 2.0 was published in 2012.

IEC 61326-2-6:2005, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment. Edition 2.0 was published in 2012.

IEC 60050-161:1990, International Electrotechnical Vocabulary – Chapter 161: Electromagnetic compatibility. Amendment 2 was published in 1998. IEV online: <http://www.electropedia.org/>

IEC TR 80001-2-3: 2012, Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-3: Guidance for wireless networks

Institute of Electrical and Electronic Engineers (IEEE)

P11073-00101-2008 - Guide for Health Informatics–Point-of-Care Medical Device Communication–Guidelines for the Use of RF Wireless Technology. There are several standards under the IEEE 11073 family that address health informatics point-of-care medical device communications and provide useful information.

IEEE Std 802.15.2-2003 IEEE Recommended Practice for Information Technology— Telecommunications and Information Exchange between Systems— Local and Metropolitan Area Networks— Specific Requirements Part 15.2: Coexistence of Wireless Personal Area Networks with Other Wireless Devices Operating in Unlicensed Frequency Bands.

International Organization for Standardization (ISO)

Most ISO standards for medical electrical equipment reference clauses in IEC 60601-1, including Clause 17 (previously Clause 36) and IEC 60601-1-2.

ISO/TR 16056-1, Health informatics – Interoperability of telehealth systems and networks — Part 1: Introduction and definitions

ISO/TR 16056-2, Health informatics – Interoperability of telehealth systems and networks — Part 2: Real-time systems

ISO/TR 18307, Health informatics – Interoperability and compatibility in messaging and communication standards – Key characteristics

ISO 14708-1, Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking, and for information to be provided by the manufacturer

ISO 14708-2, Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers

ISO 14708-3, Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators.

ISO 14708-4, Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pumps

ISO 14971 Second edition 2007-03-01 Medical devices — Application of risk management to medical devices

ISO 14117, Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.

ISO technical report TR 21730, Health Informatics – Use of mobile wireless communications and computing technology in healthcare facilities – Recommendations for the management of unintentional electromagnetic interference with medical devices (ISO/TR 21730: 2007(E)).

RTCA, Inc.

RTCA/DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment

APPENDIX C

Overview of CMS Regulation of Wireless Medical Devices

Most CMS coverage determinations are made on a local or regional level by clinicians at the contractors that pay Medicare claims, such as BlueCross BlueShield. Manufacturers seeking a “local coverage determination” must work with a local contractor to determine the information that will be required in a request for a determination.

In certain cases, CMS may deem it appropriate to develop a national coverage determination (“NCD”) for an item or service to be applied on a national basis for all Medicare beneficiaries meeting the criteria for coverage. CMS initiates an NCD process by “opening” the NCD via a posting on the CMS coverage website. Development of a complete, formal request for an NCD can be initiated either by an outside party or internally by CMS staff. Outside parties are encouraged by CMS to engage in preliminary discussions with the agency regarding issues that may affect review of their requests. A requestor may be a Medicare beneficiary, manufacturer, provider, supplier, medical professional association, health plan, or any other party.

CMS itself may initiate an NCD in the following circumstances:¹⁷

- Providers, patients, or other members of the public have raised significant questions, that are supported by CMS’s initial review of available data, about the health benefits of currently covered items or services, specifically regarding the Medicare population interpretation of new evidence or re-interpretation of previously available evidence indicates that changes may be warranted in current policies
- Local coverage policies are inconsistent or conflict with each other to the detriment of Medicare beneficiaries. For instance, the noted variation is not related to local differences in the capabilities of health care providers to use the technology effectively which can be resolved over time, but rather is causing significant disparities in the care available to Medicare beneficiaries that are unlikely to be addressed effectively through provider training and education or through the local coverage process
- Program integrity concerns have arisen under existing local or national policies and there is significant evidence of wide variation in billing practices not related to variation in clinical need, or of potential for fraud under existing policies
- The health technology represents a substantial clinical advance and is likely to result in a significant health benefit if it diffuses more rapidly to all patients for whom it is indicated

¹⁷ Even Congress may seek to legislate certain coverage. See, e.g., S. 631 of the 110th Congress, a bill to amend Title XVIII of the Social Security Act to provide for coverage of remote patient management services for chronic health care conditions under the Medicare Program.

- More rapid diffusion of the technology is likely to have a significant programmatic impact on Medicare and on other Medicare-related public policies (e.g., reduction in health inequalities)
- Significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology. The presence of significant uncertainty about benefits and risks is of particular concern when rapid diffusion of the item or service is likely when:
 - Use of the new item or service likely conflicts with existing NCDs
 - Available evidence suggests that local variation is not warranted

As part of the NCD process, CMS may request an external “technology assessment,” the primary purpose of which is to evaluate the clinical and scientific evidence pertaining to the clinical benefits and risks of the technology. Certain issues may also be referred to the Medicare Evidence Development and Coverage Advisory Commission (“MEDCAC”). As of early 2010, cost effectiveness is not a factor CMS considers in making NCDs, though economic considerations may be discussed as part of the technology assessment. Considering the “comparative effectiveness” of different treatments is a hot-button topic in the health care reform debate and could possibly benefit wireless devices that can be shown to reduce hospital stays and doctor visits.

If neither a technology assessment nor referral to the MEDCAC is necessary, CMS has six months to render a proposed decision on a request for coverage. If a technology assessment or referral to the MEDCAC is made (and no clinical trial is requested), CMS has nine months to issue a proposed decision. The proposed decision is posted on the CMS website (or made public by other “appropriate” means) for a 30 day public comment period. A final decision will be issued not later than 60 days after the conclusion of the comment period.

Manufacturers who intend for the U.S. government to pay for their devices via the Medicare program should take certain issues into account beginning with the device design. For example, a manufacturer may wish for its device to be deemed “substantially equivalent” under the FDA’s 510(k) program, yet be novel enough to warrant being treated as a new device by Medicare entitled to a higher payment. Device design should therefore take into account the kind of information that payers may be looking for to justify a higher payment.

If a new Current Procedural Terminology (“CPT”) code is needed to identify new physician activity, significant work is required to have a new code issued by the American Medical Association. It may also be necessary to obtain a new Health Care Financing Administration Common Procedure Coding System Code (“HCPCS Code”) from CMS.