Before the Federal Communications Commission Washington, D.C. 20554

In the Matter of)	
)	
Amendment of the Commission's Rules to Provide)	ET Docket No. 08-59
Spectrum for the Operation of Medical Body Area)	
Networks)	
)	

ORDER ON RECONSIDERATION AND SECOND REPORT AND ORDER

Adopted: August 20, 2014 Released: August 21, 2014

By the Commission:

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I. INTRODUCTION

1. In this Order on Reconsideration and Second Report and Order, we take further actions to foster the development and deployment of new and innovative Medical Body Area Network (MBAN) devices. MBAN technology provides a platform for the wireless networking of multiple body-worn sensors used for measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. MBAN devices promise to enhance patient safety, care and comfort by reducing the need to physically connect sensors to essential monitoring equipment by cables and wires. Because they will provide a cost-effective way to monitor patients in health care institutions, MBAN systems can provide clinicians with more extensive real-time data that will permit faster patient intervention. The resulting benefits – including reductions in emergency transfers and less exposure to hospital-acquired infections – could save countless lives and reduce nationwide health care expenses by billions of dollars. Put simply, the MBAN concept demonstrates the power of new communications technologies to improve and advance the state of health care.

- 2. In addressing petitions for reconsideration of the First Report and Order in this proceeding, we provide MBAN users with additional flexibility to enable the implementation of technical standards being developed for MBAN devices, and clarify and modify portions of our rules to facilitate the coordination, deployment, and use of MBAN systems.
- 3. In the Second Report and Order portion in this proceeding, we finalize the process for selecting a Medical Body Area Network (MBAN) Coordinator. This coordinator will facilitate use of the MBAN frequencies, which operate in shared-use bands. Collectively, our actions will allow the development of new and innovative health care applications.

II. BACKGROUND

- 4. In May 2012, the Commission modified its existing Part 95 MedRadio rules to enable the deployment of MBAN devices in the 2360-2400 MHz band. An MBAN is a low power network of sensors worn on the body controlled by a hub device that is located either on the body or in close proximity to it. MBAN devices operate on a secondary basis in the 2360-2400 MHz band that is, they must not cause harmful interference to and must accept interference from Federal and non-Federal stations operating in the band in accordance with the Table of Frequency Allocations. The 2360-2390 MHz band is allocated for the Mobile Service on a primary basis and is used for aeronautical mobile telemetry (AMT). The 2390-2400 MHz band is allocated for both the Amateur Service and the Mobile Service on a primary basis.
- 5. The MBAN rules that the Commission adopted in the *First Report and Order* are designed to prevent MBAN interference to the primary services with which they share spectrum. Under the rules, an MBAN consists of one programmer/control transmitter and multiple body-worn devices.³ The body-worn devices may communicate only with the programmer/control transmitter in their MBAN.⁴ The programmer/control transmitter may not use the 2360-2400 MHz band to relay information to a device that is not a part of its MBAN, including programmer/control transmitters that are members of another MBAN.⁵ MBAN devices in the 2360-2390 MHz band may be used only indoors within a heath care facility, while MBAN devices in the 2390-2400 MHz band may be used anywhere.⁶
- 6. To protect AMT operations, the *First Report and Order* also adopted requirements for the registration and coordination of MBAN operations in the 2360-2390 MHz band, including the functions to be performed by an MBAN frequency coordinator to be designated by the Commission. The MBAN coordinator will register all MBAN devices operating in the 2360-2390 MHz band and notify the health care facility when it may begin MBAN operations. If an MBAN in the 2360-2390 MHz band is located within line of sight of an AMT receive site, the MBAN coordinator must achieve a mutually satisfactory coordination agreement with the AMT frequency coordinator before the MBAN may operate. If interference occurs to AMT operations from an MBAN, the MBAN coordinator is responsible for identifying the source of any harmful interference and for notifying the health care facility of alternative

⁶ 47 C.F.R. § 95.1203.

¹ Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 89-59, *First Report and Order and Further Notice of Proposed Rulemaking*, 27 FCC Rcd 6422, 6423, para. 2 (2012) (*First Report and Order*).

² *Id.* at 6428-29, para. 10.

³ 47 C.F.R. Part 95, Appendix 1 to Subpart E.

⁴ 47 C.F.R. § 95.1209(g).

⁵ *Id*.

⁷ First Report and Order at 6448-57, paras. 56-73. See also 47 C.F.R. §§ 95.1223, 95.1225.

⁸ 47 C.F.R. § 95.1223(c).

frequencies for MBAN use or to cease MBAN operations. The Commission issued a Further Notice of Proposed Rulemaking (*Further Notice*) concurrently with the *First Report and Order* to seek comment on the qualifying criteria and the selection process for choosing an MBAN coordinator or coordinators, as well as the service fees for the registration and coordination process. ¹⁰

We have received two petitions seeking reconsideration of certain aspects of the First Report and Order. The American Society for Healthcare Engineering of the American Hospital Association (ASHE) on October 10, 2012 filed a petition asking that the Commission require that any MBAN device capable of operation in the 2360-2390 MHz band be registered, even if the device will be used only in the 2390-2400 MHz band. 11 GE Healthcare, Phillips Healthcare, and the Aerospace and Flight Test Radio Coordinating Council (AFTRCC)¹² (Joint Parties) jointly filed a petition on October 11, 2012 asking that the Commission make a number of modifications to the MBAN rules. 13 These modifications include narrowing the definition of health care facilities that may use MBAN devices in the 2360-2390 MHz band, relaxing restrictions on the topology of MBAN networks, requiring MBAN devices to stop transmitting in the absence of a control message, requiring registration of replacement MBAN devices only if such a device has a technically different programmer/control transmitter, and making the duties of the MBAN coordinator explicit in the rules. The Commission received no comments regarding the two petitions for reconsideration, but did receive an ex parte letter from SmartEdgeNet, LLC, objecting to the request to narrow the definition of health care facilities that may use MBAN devices.¹⁴ In addition, the Commission received comments in response to the *Further Notice* from ASHE, AFTRCC, and jointly by Philips Healthcare and GE Healthcare (Philips/GE). ¹⁵ The Commission has also received a petition for rulemaking requesting that we reallocate an unoccupied portion of the TV spectrum to support additional MBAN use. 16

III. ORDER ON RECONSIDERATION

A. Authorized Locations

8. <u>Health Care Facilities</u>. In the *First Report and Order*, the Commission restricted MBAN operation in the 2360-2390 MHz band to indoors at a "health care facility," which it defined as follows:

⁹ 47 C.F.R. § 95.1225(b)(5).

¹⁰ Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 89-59, *First Report and Order and Further Notice of Proposed Rulemaking*, 27 FCC Rcd 6422, 6457-60, paras. 75-85 (2012) (*Further Notice*).

¹¹ Petition for Reconsideration of the American Hospital Association, ET Docket No. 08-59, filed Oct. 10, 2012. The MBAN rules do not require registration of devices that operate in the 2390-2400 MHz band.

¹² AFTRCC is recognized by the Commission and the National Telecommunications and Information Administration (NTIA) as the non-government coordinator for flight test frequencies in the 2360-2395 MHz band – *i.e.* it currently holds the "AMT coordinator" role as we use that term throughout this decision.

¹³ Joint Petition for Reconsideration, GE Healthcare, Phillips Healthcare, and the Aerospace and Flight Test Radio Coordinating Council, ET Docket No. 08-59, filed Oct. 11, 2012 (*Joint Recon Petition*).

¹⁴ SmartEdgeNet, LLC December 20, 2012 ex parte filing.

¹⁵ Comments of the American Society for Healthcare Engineering of the American Hospital Association, ET Docket No. 08-59, filed Sept. 10, 2012 (ASHE Comments); Reply Comments of the American Society for Healthcare Engineering of the American Hospital Association, ET Docket No. 08-59, filed Sept. 28, 2012 (ASHE Reply); Comments of Philips Healthcare and GE Healthcare, ET Docket No. 08-59, filed Sept. 10, 2012 (Philips/GE Comments); Comments of Aerospace and Flight Test Radio Coordinating Council, ET Docket No. 08-59, filed Sept. 10, 2012 (AFTRCC Comments).

¹⁶ Petition for Rulemaking by Ben Bartlett, ET Docket No. 08-59, filed Jan. 1, 2013.

A health care facility includes hospitals and other establishments that offer services, facilities and beds for use beyond a 24 hour period in rendering medical treatment, and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including government entities and agencies such as Veterans Administration hospitals.¹⁷

- 9. The Joint Parties ask us to revise the scope of MBAN use in the 2360-2390 MHz band to apply to "...only hospitals and similar facilities that provide medical treatment for patient stays of 24 or more hours." The Joint Parties had suggested this definition in an *ex parte* pleading filed in January 2011 in which they offered an extensive set of proposed rules for establishing MBAN under a new subpart of the Part 95 rules. In the *First Report and Order*, the Commission recognized that "[a]n MBAN shares many characteristics with other established medical radio services and applications," and so it chose to authorize MBAN operations within the framework of the existing Part 95 rules. In doing so, it generally adopted versions of rules proposed by the Joint Parties that relate only to how MBAN sensors and hubs function, and that set forth registration and coordination requirements for protecting primary AMT operations. It otherwise applied the existing Part 95 rules that relate to medical devices to govern the new MBAN operations. With respect to authorized locations for MBAN devices, it adopted its proposal to mirror an existing rule that applies to the Wireless Medical Telemetry Service (WMTS).²¹
- 10. On reconsideration, we revise Section 95.1203 of our rules to limit use of the 2360-2390 MHz band to "hospitals and other establishments that offer services, facilities and beds for use beyond a 24-hour period in rendering medical treatment." Although the Joint Parties had suggested this approach as part of their comprehensive set of proposed rules, they had not discussed the rationale for this limitation until the filing of their Petition for Reconsideration. They now state with particularity the reasons why we should adopt their proposed authorized locations definition. We find that it serves the public interest to take the Joint Parties' facts and arguments into consideration. ²³
- 11. In their petition, the Joint Parties assert that further limiting the authorized locations in the 2360-2390 MHz band will "restrict use of the shared spectrum to locations where multiple MBANs will be required for effective patient care and the need for monitoring most likely could not be accommodated using the limited 2390-2400 MHz band." They claim that most facilities not permitted to use the 2360-2390 MHz band under the revised definition, which are typically smaller in size with fewer patients that need monitoring, will be able to meet their spectrum requirements exclusively within the 2390-2400 MHz band. They note that an IEEE standard for MBAN devices (802.15.6) "can support

¹⁷ See First Report and Order at 6441-42, paras. 39-40; 47 C.F.R. § 95.1203.

¹⁸ *Joint Recon Petition* at 3-4.

¹⁹ Joint Parties January 14, 2011 *ex parte* filing. This pleading was part of a comprehensive proposal for resolving the spectrum-sharing issues that had been raised in the docket, and contained an appendix of suggested MBAN rules. The Joint Parties referenced these proposed rules – including the health care facility definition – in their subsequent discussions with the Commission.

²⁰ [R&O at para 9].

²¹ First Report and Order at 6449-50, paras. 56-58. The Commission had proposed using the existing WMTS definition, in conjunction with the use of exclusion zones, as a means to reduce the potential for interference from MBAN devices to incumbent operations. See Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 89-59, Notice of Proposed Rulemaking, 24 FCC Rcd 9589, 9597, para. 22 n. 39 (2009) (MBAN NPRM) (proposing to use the existing WMTS definition contained in Section 95.1103(b)). The Commission ultimately declined to adopt the exclusion zone approach.

²² 47 C.F.R. §1.429(c).

²³ 47 C.F.R. §1.429(b)(3).

²⁴ *Joint Recon Petition* at 3-4.

approximately 18 patients in a typical office setting using the 10 MHz of the upper band before frequency re-use methods are applied."²⁵ Reserving the 2360-2390 MHz band for a smaller subset of entities, they claim, would make the coordination process more efficient and aid in the efforts to resolve instances of harmful interference, in the unlikely event unexpected interference does occur.²⁶

- 12. We find these arguments convincing. By limiting the types (and, thus, the numbers) of medical institutions in the 2360-2390 MHz band, we will make it easier for both the MBAN and AMT coordinators to establish, implement and enforce efficient and effective coordination procedures. Further, limiting potential locations would simplify their efforts to identify and remedy any harmful interference in the extremely unlikely event it occurs. In addition, because the existing MBAN standard will support numerous patients in the 2390-2400 MHz band, and because frequency reuse techniques can augment that capacity in many situations, no health care facilities including those that do not qualify for use of the 2360-2390 MHz band will be precluded from operating MBAN systems. For this reason, we disagree with SmartEdgeNet that health care providers will be "denied the benefits of MBAN" unless we retain our existing rule. ²⁸
 - 13. <u>Antenna Locations</u>. As modified in the *First Report and Order*, Section 95.1213 states: Except for the 2390-2400 MHz band, no antenna for a MedRadio transmitter shall be configured for permanent outdoor use. In addition, any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.²⁹

The Joint Parties claim that this rule appears to exclude installation of outdoor antennas for the 2390-2400 MHz band at locations above a building's first floor, such as balconies and roof terraces, and indeed this is not the intent of the rule. We agree that this modified language of Section 95.1213 could be interpreted to restrict the placement of antennas in the 2390-2400 MHz band, insofar as the phrase "any MedRadio antenna used outdoors" from this Section's second sentence does not exclude antennas in the 2390-2400 MHz band (whether configured for permanent or temporary outdoor use). Applying the Section's height-based restrictions to these antennas, however, would run counter to the Commission's conclusions in the *First Report and Order*, that it should allow MBAN operation at any location in the 2390-2400 MHz band. In amending Section 95.1213 to effectuate these conclusions, the Commission simply exempted antennas used for transmitters in the 2390-2400 MHz band from the Section's first sentence prohibition on permanent outdoor use, but neglected to amend the language of the second sentence, which contained height restrictions that, under the earlier version of Section 95.1213, applied

²⁵ Joint Parties and ASHE February 6, 2014 ex parte filing at 2.

²⁶ *Id.* For example, the Joint Parties and ASHE assert that, in addition to reducing the actual number of registered facilities, their proposal would exclude smaller and out-patient facilities that typically lack the type of on-site IT and radio spectrum expertise that can help ensure that interference issues are identified and resolved in a timely manner.

²⁷ This action builds on the provisions the Commission previously put into place to protect incumbent flight test operations, including restricting outdoor MBAN operations in the 2360-2390 MHz band to lessen the potential for harmful interference to AMT operations and establishing a coordination process based on the premise that MBAN operations should be permitted only in areas where harmful interference to AMT operations can be avoided.

²⁸ SmartEdgeNet, LLC December 20, 2012 *ex parte* filing at 3. Should the number of MBAN applications ultimately grow to a point that health care facilities that are eligible to use only the 2390-2400 MHz band will lack the frequency capacity to fully meet their needs, we can later revisit our decision.

²⁹ First Report and Order at 6441-42, paras. 39-40; 47 C.F.R. § 95.1213.

³⁰ *Joint Recon Petition* at 15.

³¹ First Report and Order at 6441-42, paras. 39-40.

³² The earlier version of Section 95.1213 stated as follows: "No antenna for a MedRadio transmitter shall be configured for permanent outdoor use. In addition, any MedRadio antenna used outdoors shall not be affixed to any (continued....)

to MedRadio antennas designed for temporary outdoor use.³³ The intent, however, was to apply the exception for the 2390-2400 MHz band to the requirements of the second sentence as well, so that the height restrictions would apply to "any MedRadio antenna used outdoors" except for those used for 2390-2400 MHz band transmitters.

- 14. Upon reconsideration, we find expressly that it is not necessary to apply antenna height restrictions which were originally intended as a constraint on temporary outdoor use of MedRadio antennas regardless of the band in which the transmitter operated to antennas used for MedRadio transmitters operating in the 2390-2400 MHz band. Although the Joint Parties suggest that the rule be changed to permit MBAN operations in the 2390-2400 MHz band five feet above a building's roof, we conclude that, based on the permissible outdoor use in this band and the relatively low power operations of MBAN transmitters (which effectively limits any gain in coverage that is often associated with increased antenna height), there is no need to prescribe a specific antenna height limit (for either permanent or temporary outdoor antennas used for this band). Accordingly, we revise Section 95.1213 to read as follows:
 - (a) An antenna for a MedRadio transmitter shall not be configured for permanent outdoor use.
 - (b) Any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.
 - (c) Paragraphs (a) and (b) of this Section do not apply to MedRadio operations in the 2390-2400 MHz band.

B. MBAN Definition and Permissible Communications

- 15. In the *First Report and Order*, the Commission defined an MBAN as "a low power network consisting of a MedRadio programmer/control transmitter and multiple medical body-worn devices." The Commission further concluded that the existing definitions of MedRadio Programmer/Control Transmitter, MedRadio Transmitter, and Medical Body-Worn Device could be used to describe the particular components of an MBAN without modification. The Joint Parties request that the Commission modify the basic definition of an MBAN and a related rule, Section 95.1209(g) ("Permissible Communications"), to permit greater flexibility in how MBAN devices are designed and deployed.
- 16. <u>MBAN Configurations with a Single Body-Worn Device</u>. The Joint Parties ask that the MBAN definition be modified to allow the pairing of a programmer/control transmitter with a single body-worn device, claiming that the need for such an arrangement "will likely be common." We find this argument plausible. It is reasonable to assume that the type and number of body-worn devices in use on a particular patient will fluctuate, based on the changing dynamics of patient treatment and individual patients' needs. The number of body-worn devices may increase or decrease as a particular situation warrants and, at times, best treatment practices could require the use of only a single body-worn device.

³³ As the earlier version of the Section had barred permanent outdoor use of MedRadio antennas altogether, the reference in the second sentence to antennas "used outdoors" could only refer to antennas used outdoors on a temporary basis.

³⁴ MBAN users may nevertheless be subject to other Commission rules and procedures relating to antenna registration and placement. See, for example, Part 17 of the Commission's rules (setting forth rules for the construction, lighting and marking of antenna structures that could affect navigable airspace).

³⁵ First Report and Order at 6438, para. 31. See also Appendix 1 of Subpart E of Part 95 – Glossary of Terms.

³⁶ *Joint Recon Petition* at 4.

The current MBAN definition fails to accommodate such a scenario. In light of the above, we amend Appendix 1 to Subpart E of Part 95 ("Glossary of Terms") to define an MBAN as "a low power network consisting of a MedRadio programmer/control transmitter and *one or more* medical body-worn devices" (emphasis added).

- 17. <u>Use of Bedside Devices</u>. Under our rules, a medical body-worn device is defined as an "[a]pparatus that is placed on or in close proximity to the human body (*e.g.*, within a few centimeters) for the purpose of performing diagnostic or therapeutic functions." The Joint Parties claim that requiring all MBAN devices, with the exception of the single programmer/control transmitter, to be placed so close to the body could preclude the use of infusion pumps, anesthesia machines, and other bedside equipment in an MBAN.³⁸ Accordingly, the Joint Parties request that we modify or clarify this definition to remove the "few centimeters" requirement.
- 18. We clarify that bedside devices of the type described by the Joint Parties can be used in an MBAN under the existing definition. Such equipment would require a physical attachment to the patient (*e.g.* by wire or tube), and thus would meet the definition even though there are other parts of the apparatus that are located away from the body. We further clarify that the "few centimeters" language in the rule should be read as a general example and not the codification of a specific distance requirement for devices (and components thereof) that may not be directly attached to the body.
- 19. <u>Allowing Greater Flexibility in Designing MBAN Systems</u>. Section 95.1209(g) ("Permissible Communications") and the MBAN definition contained in Appendix 1 to Subpart E of the Part 95 Rules ("Glossary of Terms") establish the MedRadio programmer/control transmitter and the medical body-worn device as distinct elements that must be present in every MBAN, allow body-worn transmitters to relay information in the 2360-2400 MHz band only to a programmer/control transmitter that is part of the same MBAN, and prohibit a programmer/control transmitter from using the 2360-2400 MHz band to relay information to another programmer/control transmitter. The Joint Parties ask us to modify this "MBAN topology" to allow greater flexibility in MBAN design and use.
- 20. For the 2360-2390 MHz band, the Joint Parties request three changes to the rules related to MBAN system design that they claim will improve MBAN system operation without jeopardizing the interference protection mechanisms built into the system or undermining the Commission's reasons for restricting how MBAN systems may operate in the band.
- 21. First, the Joint Parties ask us to allow programmer/control transmitters from separate MBAN systems to communicate with each other using the 2360-2390 MHz frequencies solely for the purpose of avoiding interference, and claim that such flexibility would permit two MBAN systems to use an existing standards protocol to share the same channel and promote efficient spectrum use. The Commission adopted rules in the *First Report and Order* that limited the use of MBAN spectrum to independent systems that operate separately under well-defined requirements, and set forth specific ways the MBAN components were authorized to communicate. This approach continues to provide an appropriate framework for MBAN development and deployment. However, we also recognize that allowing MBAN systems in the 2360-2390 MHz band (as well as the 2390-2400 MHz band) to coordinate use among themselves of the available MBAN frequencies can promote efficient spectrum use. We are therefore modifying our existing rule section 95.1209(g) to provide an exception to permit communications between programmer/control transmitters of different MBAN systems for the sole purpose of avoiding interference to each other, based on the text of the existing MedRadio rules for

³⁹ *Id.* at 8. They cite a specific standard, IEEE 802.15.6, and state that the existing MedRadio rules for Medical Micropower Networks allow for such communication.

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³⁷ Appendix 1 of Subpart E of Part 95 – Glossary of Terms.

³⁸ *Joint Recon Petition* at 5.

⁴⁰ See First Report and Order at 6440-41, para. 37.

Medical Micropower Networks.⁴¹ We emphasize that this is a limited exception to our general rule. We agree with the Joint Parties that programmer/control transmitters should continue to be barred from relaying the control message to each other,⁴² and we retain the prohibition on programmer/control transmitters relaying other information to each other, such as medical data transmitted from the bodyworn devices associated with a particular programmer/control transmitter.

- 22. Second, the Joint Parties ask that we allow two body-worn devices in the same MBAN to communicate with each other. They describe how body-worn devices are expected to operate at extremely low power levels due to their proximity to the patient's body and in order to preserve battery life.⁴³ They envision situations such as when a sleeping patient changes positions in which the signal strength of the body-worn device will no longer be sufficient to successfully deliver its data message.⁴⁴ They assert that allowing a body-worn device to relay data to a nearby body-worn device (such as one on the patient's side) would allow for continued monitoring and enhance clinical reliability.⁴⁵ The Joint Parties and ASHE also point out that such an arrangement is contemplated under recently adopted industry standards.⁴⁶ These factors change the public interest calculus. As discussed below, we find that we can permit such communications without undermining our objective of preventing harmful interference to AMT operations. The Joint Parties offer convincing reasons why allowing body-worn devices to communicate with each other could potentially enhance patient welfare. With the adoption of industry standards, it may now be both feasible and practical to produce such equipment. Accordingly, we amend Section 95.1209 of our rules to eliminate the language that precludes body-worn devices from communicating with other body-worn devices in the 2360-2400 MHz band.
- 23. Finally, the Joint Parties ask that we allow either a programmer/control transmitter or a body-worn device to perform as a "coordinator node" in an MBAN system. According to the Joint Parties, coordinator node is the "...term used in IEEE 802.15.6 for the node responsible for coordinating the MAC function (*e.g.*, assigning TDMA slots to other nodes) and being the main routing hub for communication with all other nodes in the MBAN star topology." As an example, the Joint Parties describe a scenario in which a body-worn device serves as a coordinator node to transmit information related to the technical operation of the network (*e.g.*, what communication protocols to use) to other body-worn devices within the MBAN system and aggregate the patient data that it receives from other body-worn devices. A separate device a non-body-worn device that could be at a fixed location that is not on or in close proximity to the body would maintain connectivity to a local area network in order

⁴⁷ *Joint Recon Petition* at 8-9.

⁴¹ This would allow two different MBAN systems to use the same set of frequencies by providing a mechanism for the programmer/controllers to "schedule" transmissions so as to not interfere with each other.

⁴² Joint Recon Petition at 8.

⁴³ Joint Recon Petition at 10.

⁴⁴ Id. at 10; see also Joint Parties and ASHE February 6, 2014 ex parte filing at 5.

⁴⁵ See Joint Parties and ASHE February 6, 2014 ex parte filing at 5.

⁴⁶ *Id*.

⁴⁸ See Joint Parties and ASHE February 6, 2014 ex parte filing at 3, footnote 10. The Joint Parties have variously used the terms "coordinator," "hub," and "coordinator node" to describe the same function. We have used the term "hub" throughout this proceeding to generically refer to what is now defined in the rules as a MedRadio programmer/control transmitter. We have used the term "coordinator" to refer to an MBAN coordinator – the entity responsible for indicating whether and when MBAN devices may be used in a particular place. Because neither term is the equivalent of a "hub" or "coordinator" device as described by the Joint Parties, we use the "coordinator node" term to avoid potential confusion.

⁴⁹ *Id.* at 3-4.

to receive the control message. Thus, this non-body-worn device would perform the functions required of the MBAN programmer-control transmitter under our rules.⁵⁰

- 24. Under our original decision, only the MBAN programmer/control transmitter would have been able to act as a coordinator node because "[m]edical body-worn transmitters may relay only information in the 2360-2400 MHz band to a MedRadio programmer/control transmitter that is part of the same Medical Body Area Network." However, because we are now permitting a body-worn device within an MBAN system to communicate with another body-worn device, there is no bar to assigning coordinator node functions to a body-worn device instead of the programmer/control transmitter. For this reason, we conclude that the Joint Parties will be able to design MBAN systems consistent with their request, and that no additional rule modifications are necessary.
- 25. In the *First Report and Order*, the Commission placed the above-described limitations on the types of communication allowed among MBAN system components to avoid potentially extending the range of an MBAN beyond the confines of the medical facility.⁵² This limitation was designed to prevent harmful interference to AMT operations. We find that we can modify our rules to permit bodyworn devices to communicate as described above without introducing such risks. As the Joint Parties have noted, all body-worn devices (including any that are serving in a coordinator node function) "will be configured to communicate with only one [programmer/control transmitter], either directly or indirectly," and the control message is limited to the programmer/control transmitter that manages the body-worn devices "to ensure that indoor enforcement is maintained." Furthermore, given the permitted power levels, individual MBAN systems will necessarily be limited in geographic scope. We emphasize that, under our revised rules, a body-worn device still must cease operation in the 2360-2390 MHz band if it loses communication with its associated programmer/control transmitter.⁵⁴
- 26. <u>2390-2400 MHz band</u>. In addition to the 2360-2390 MHz requests discussed above, the Joint Parties also request that the Commission eliminate all restrictions on MBAN systems that operate in the 2390-2400 MHz band, envisioning networks that consist of multiple programmer/control transmitters, networks that do not include any programmer/control transmitters, and networks where different groups of programmer/control transmitters and body-worn devices communicate between and among each other. They assert that the Commission's rationale for the MBAN system design requirements in Section 95.1209(g) relate exclusively to the 2360-2390 MHz band (where compliance with the control message requirements is necessary to avoid potential interference to AMT operations), and claim that applying the restriction to the 2390-2400 MHz band serves no purpose. ⁵⁵
- 27. While we will allow, for the 2390-2400 MHz band, the same degree of flexibility in communications among MBAN components as we are now providing for MBAN devices operating in the 2360-2390 MHz band, we are not persuaded that authorizing additional flexibility in MBAN system design for the 2390-2400 MHz band would serve the public interest. In designing the MBAN rules, the Commission recognized that entities operating in the 2360-2390 MHz band may need to default to the 2390-2400 MHz band with little advance notice in the event of harmful interference to AMT or when certain operating parameters change (such as an MBAN being taken outdoors). ⁵⁶ Our rules also require a

⁵⁰ 47 C.F.R. § 95.628(c).

⁵¹ 47 C.F.R. § 95.1209(g).

⁵² First Report and Order at 6440-41, para. 37.

⁵³ Joint Parties and ASHE February 6, 2014 ex parte filing at 6; see also Joint Recon Petition at 10.

⁵⁴ *See* para. 31, *infra*. We note that our revised rules do not preclude manufacturers from designing MBAN systems in which a body-worn device communicates with its associated programmer/control transmitter via a coordinator node.

⁵⁵ Joint Recon Petition at 4 and 6.

⁵⁶ See, e.g. First Report and Order at 6441-42, para. 40 and 6452, para. 65.

health care provider to inform the coordinator whether its equipment is capable of operating in the 2390-2400 MHz band to facilitate transitions out of the 2360-2390 MHz band.⁵⁷ We recognize that such transitions to the 2390-2400 MHz band may be challenging, given that higher power use is permitted in the band and many operations there will take place without prior coordination or registration. We find that it would be unwise to further complicate such transitions by allowing the band to be populated by medical devices operating under many different system designs. Moreover, the *First Report and Order* recognized that different MBAN devices will have to be capable of intra-service sharing, particularly given the communications reliability considerations that are vital to medical device design.⁵⁸ The Joint Parties' proposed modifications to permissible communications within the 2390-2400 MHz band could make it more difficult to achieve this objective. Thus, although the Joint Parties assert that the interference mitigation measures adopted in the *First Report and Order* are necessary only in the 2360-2390 MHz band, ⁵⁹ we find that the relationship between use of the 2360-2390 MHz band and the 2390-2400 MHz band is the more important factor here.

28. For these reasons, we will not authorize a different MBAN system design for the 2390-2400 MHz band by revising the MBAN definition for that band, as suggested by the Joint Parties. ⁶⁰ Nevertheless, we note that the Commission, in the *First Report and Order*, left open the potential to revisit the permissible use restrictions after gaining further experience with MBAN operations. ⁶¹ This approach continues to be reasonable and appropriate to the circumstances.

C. Device Operation

29. In the *First Report and Order*, the Commission adopted transmission requirements for the component parts of an MBAN – the programmer/control transmitters and body-worn devices. The Commission applied much of the existing MedRadio rule on "Permissible Communications," 47 C.F.R. Section 95.1209, to MBAN operation. Among these requirements, Section 95.1209(b), in pertinent part, addresses the operation of body-worn devices:

[N]o MedRadio implant or body-worn transmitter shall transmit except in response to a transmission from a MedRadio programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body with respect to which the MedRadio implant or body-worn transmitter is used.⁶²

Additionally, with regard to programmer/control transmitters, Section 95.628(c) states:

A MedRadio programmer/control transmitter shall not commence operating and shall automatically cease operating in the 2360-2390 MHz band if it does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation. Additionally, a MedRadio programmer/control transmitter operating in the 2360-2390 MHz band

⁵⁷ 47 C.F.R. § 95.1223. *See also First Report and Order* at 6453, para. 67 (stating that "this information will enable the coordinator to help the facility manage its MBAN operations consistent with any coordination agreements").

⁵⁸ First Report and Order at 6447-48, paras. 53-54. The Commission concluded that it was not necessary to establish a specific frequency monitoring protocol at that time, given that it appeared that the issue was being addressed within the standards setting process. *Id.*

⁵⁹ *Joint Recon Petition* at 6.

⁶⁰ *Joint Recon Petition* at 4 (requesting that "[f]or the 2390-2400 MHz band, 'MBAN' be defined as a network of one or more body-worn devices, P/Cs, or both").

⁶¹ First Report and Order at 6440-41, para. 37. We note that the Joint Parties have not explained how an MBAN would function absent a programmer/control transmitter, nor have they suggested any edits to the rules (beyond a change in the definition) that would specify how their version would operate; were we to revisit the rules as a later date, we would look to develop a more thorough record and specific proposed rule changes before proceeding.

⁶² First Report and Order at 6440-41, paras. 35-38; 47 C.F.R. § 95.1209(b).

shall comply with a control message that notifies the device to limit its transmissions to segments of the 2360-2390 MHz band or to cease operation in the band.⁶³

- 30. The Joint Parties claim that these two rules do not properly account for the communications link between the body-worn devices and programmer/control transmitters in an MBAN. Specifically, the Joint Parties assert that Section 95.1209 permits only a polled media access control (MAC) protocol that is, that the only time a body-worn device can operate is immediately after the receipt of a transmission from the programmer/control transmitter. They assert that the provision "has the effect of precluding more efficient protocols," and ask that the rule not apply to MBAN devices. Additionally, the Joint Parties ask that we amend Section 95.628(c) to specify that MBAN body-worn transmitters operating in the 2360-2390 MHz spectrum must cease transmitting in the absence of a control message, including when they lose communication with their associated programmer/control transmitter. As described below, we find that the rules provide sufficient flexibility to implement a wide variety of communication protocols, but that some minor word changes are appropriate to provide for proper body-worn transmitter operation.
- First, the Joint Parties' assertion that Section 95.1209(b) restricts MBAN body-worn devices to a single mode of operation is based upon an overly narrow reading of the rule. The rule in its current form prescribes this requirement. Nor would such a restriction be consistent with the First Report and Order, in which the Commission provided flexibility in the design of MBAN devices. For example, we opted to not include a detailed frequency monitoring specification in the MBAN rules to govern intraservice spectrum sharing among MBAN devices, and instead chose to defer to the industry standards process. 66 Additionally, when addressing the technical requirements for MBAN transmitters, the Commission specifically stated that it would allow manufacturers to design programmer/control transmitters pursuant to their own timing and operational protocols.⁶⁷ Section 95.1209(b) allows similar flexibility for the design and operation of MBAN body-worn devices. That is, the devices are required only to operate as directed by a programmer/control transmitter, without specific requirements pertaining to the timing or the order of these transmissions. Thus, while a polled access scenario would comply with the rule. 68 other access modes are permissible, provided that the body-worn devices operate in response to whatever instructions are transmitted by their associated programmer/control transmitter. This flexibility addresses the Joint Parties' concerns. Accordingly, we decline to modify the text of the rule, and reject the Joint Parties' petition for reconsideration to the extent it would eliminate the applicability of Section 95.1209(b) to MBAN operation.
- 32. Second, we address the Joint Parties' proposed amendments to Section 95.628(c) of the rules. We agree with the Joint Parties that it is "critical that all MBAN devices... cease operation in 2360-2390 MHz in the absence of a control message." Section 95.628(c) requires a programmer/control transmitter operating in the 2360-2390 MHz that fails to receive a control message to cease operation. As discussed above, Section 95.1209(b) allows body-worn transmitters to transmit only in response to a transmission from the programmer/control transmitter. Although it is implicit in our rules that body-worn

⁶⁶ First Report and Order at 6447-48, paras. 53-54.

⁶³ First Report and Order at 6445-46, paras, 48-49; 47 C.F.R. § 95.628(c).

⁶⁴ *Joint Recon Petition* at 10-11.

⁶⁵ *Id.* at 11.

⁶⁷ *Id.* at 6445-46, para. 49.

⁶⁸ We note that IEEE 802.15.6 appears to support a polled access protocol among others modes of operation.

⁶⁹ Joint Recon Petition at 11.

⁷⁰ The control message requirement was adopted, in part, to ensure that only indoor MBAN operation occurs in the 2360-2390 MHz band. *First Report and Order* at 6445-46, paras. 48-49.

devices will operate under the affirmative control of a programmer/control transmitter, we do not clearly state that body-worn transmitters must be capable of ceasing transmissions when necessary to avoid interference in the 2360-2390 MHz band. Accordingly, and as suggested by the Joint Parties, we revise Section 95.628(c) of the rules to read as follows:⁷¹

A MedRadio programmer/control transmitter and its associated medical body-worn transmitters shall not commence operating in, and shall automatically cease operating in the 2360-2390 MHz band if the programmer/control transmitter does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation. Medical body-worn transmitters shall cease operating in 2360-2390 MHz if they lose communication with their associated programmer/control transmitter. Additionally, a MedRadio programmer/control transmitter and its associated medical body-worn transmitters operating in the 2360-2390 MHz band shall comply with a control message that notifies the devices to limit transmissions to segments of the 2360-2390 MHz band or to cease operation in the band.

D. Coordination and Registration

- 33. <u>Registration Requirement for the 2390-2400 MHz Band</u>. In the *First Report and Order*, the Commission adopted a registration requirement for the 2360-2390 MHz band to facilitate coordination with AMT operations in that band, but it did not adopt a registration requirement for the 2390-2400 MHz band. In doing so, it declined to adopt ASHE's suggested rules that would have required all hospitals including those hospitals operating only in the 2390-2400 MHz band to register with an MBAN coordinator. In its petition for reconsideration, ASHE asks for a modified registration requirement that accounts for the Commission's decision not to restrict use of the 2360-2390 MHz band to hospitals. Specifically, it requests that we require registration of all devices that are capable of operating throughout the entire 2360 2400 MHz band, regardless of which portion they are actually using. Under ASHE's proposal, registration would still not be required for those devices that are capable of operating solely in the 2390-2400 MHz band segment.
- 34. In their most recent *ex parte* filing, the Joint Parties and ASHE further refine this request to take into account an MBAN user's eligibility to operate in the 2360-2390 MHz band. They state that they want us to "requir[e] registration by those hospitals or other facilities eligible to utilize the 2360-2390 MHz band of any MBAN devices that are capable of operating in the [2360-2400 MHz] band, even if, upon initial installation, the 2360-2390 MHz band will not be used." They conclude that such a requirement would help the MBAN coordinator because it "will provide the MBAN frequency coordinator, the hospital, the equipment vendor and the installer with important information as to the location of those systems that may, at some point in the future, be using the more heavily regulated 2360-2390 MHz band."

⁷¹ While a system design that embodies direct communications between the programmer/control transmitter and an associated body-worn device would certainly comply with this section, this revised rule does not diminish the flexibility that manufacturers have to design other types of system architectures to meet this requirement. This includes, for example, an MBAN system in which a body worn device that is serving as a "coordinator node" provides intermediate communications between the programmer/control transmitter and the other body-worn devices that are part of the same system of MBAN body-worn devices deployed on a patient. In this case, MBAN device operation still remains dependent upon the programmer/control transmitter receiving an acceptable control signal. *See* paras. 21-24, *supra*.

⁷² See Joint Parties and ASHE February 6, 2014 ex parte filing at 3.

⁷³ In conjunction with this requested change, the Joint Parties and ASHE state that they anticipate that the MBAN system as a whole would be registered, not each individual component of the MBAN system, and they ask that the system level of registration be clearly defined. *Id.* As we discuss below, we are modifying the registration requirements to clarify that not all components of an MBAN system need to be registered.

- 35. On reconsideration, we find that the benefits of this more limited registration requirement justify the granting of ASHE's request. Requiring health care facilities to register if they are using equipment that initially uses only the 2390-2400 MHz band, but that is also capable of operating in the 2360-2390 MHz band, will give the coordinator and health care facilities a more complete understanding of the current and potential local spectrum environment for MBANs. This requirement will allow qualifying health care facilities (and their equipment vendors and installers) to better plan their facilities with respect to appropriate efficient network architecture and systems planning and implementation. While the Commission originally declined to require registration for the 2390-2400 MHz band users because it concluded that such a requirement "would unnecessarily burden hospitals that do not need assistance from the MBAN coordinator," the revised registration requirement we adopt is narrower in scope, and requests information only from those hospitals that may eventually need to interact with the MBAN coordinator. For all of these reasons, we find that the benefits of providing the MBAN coordinator with this important additional information outweigh the fairly slight increase in registration costs for the limited number of MBAN operators discussed above.
- 36. We therefore grant ASHE's request. We will require that entities preparing to use the 2390-2400 MHz band with equipment that is capable of also operating in the 2360-2390 MHz band and who are eligible to operate MBAN systems in the 2360-2390 MHz band register the MBAN system regardless of whether they have any current intent to eventually use the 2360-2390 MHz band capacity of their equipment. We note that the registration requirement that we adopt is more limited and less burdensome than the requirement the Commission rejected in the *First Report and Order*. Specifically, we are not requiring registration of (1) MBAN systems designed to solely operate in the 2390-2400 MHz band; or (2) MBAN systems operated by an entity that is ineligible to use the 2360-2390 MHz band, even if the equipment is technically capable of being operated on those frequencies.
- 37. Registration Requirement for the 2360-2390 MHz Band. In the First Report and Order, the Commission required all MBAN devices operating in the 2360-2390 MHz band to register with a frequency coordinator. As part of the related coordination process, the MBAN coordinator will use this data to analyze the potential for harmful interference to AMT operations, and determine whether interference mitigation requirements are necessary, before each individual installation is approved for operation. The Commission adopted a new rule addressing MBAN registration and coordination, Section 95.1223, and the First Report and Order discussed the data that each MBAN user must include when registering devices with an MBAN coordinator. The Joint Parties claim that Section 95.1223(a) of the rules, as adopted, requires all MBAN devices, including disposable sensors, to be registered, and they ask that we amend the first two sentences of the rule to limit the scope of registration to programmer/control transmitters, and, in the case of replacement MBAN devices, only those programmer/control transmitters that are technically different than those the MBAN user previously registered.
- 38. Upon reconsideration, we agree with the Joint Parties that the language in Section 95.1223(a) that requires registration of "all MBAN devices [a health care facility] proposes to operate in the 2360-2390 MHz band" is broader than necessary. The Joint Parties note that the registration of programmer/control transmitters will provide the AMT coordinator with data to analyze the potential for harmful interference to AMT operations and determine whether interference mitigation is needed, and that the registration of body-worn devices which will communicate only when under the "affirmative control" of a programmer/control transmitter is not required to accomplish this objective. ⁷⁸ The Joint

⁷⁴ First Report and Order at 6450-51, para. 62.

⁷⁵ *Id.* at 6469-50, paras. 58-59.

⁷⁶ *Id.* at 6450-51, para 62; 47 C.F.R. § 95.1223.

⁷⁷ *Joint Recon Petition* at 13-14.

⁷⁸ *Id.* at 13-14.

Parties also expect that many MBAN deployments will include large numbers of disposable, body-worn sensors, and they assert that registering all MBAN devices would be "unnecessarily burdensome" and could "inhibit the envisioned evolution of MBANs." We find these arguments persuasive. We also note that, while the introductory text in Section 95.1223(a) suggests that all MBAN devices should be registered, the registration information specified in subparts (1)-(7) of the rule does not address bodyworn devices. Furthermore, subparts (3) and (5) specifically speak to "control transmitter[s]" (which we are updating to read "MedRadio programmer/control transmitter" to provide clarity and consistency). The existing rule construction may create confusion in that it could appear to be inconsistent or ambiguous. Accordingly, we amend the introductory text of Section 95.1223(a) to read as follows:

Prior to operating MBAN devices that are capable of operation in the 2360-2390 MHz band, a health care facility, as defined by § 95.1203, must register with a frequency coordinator designated under § 95.1225. Operation of MBAN devices in the 2360-2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that registration and coordination (to the extent coordination is required under paragraph (c)) is complete. The registration must include the following information:

- 39. Under our revised rules, we will not require that the MBAN user provide the coordinator with unique identifying data (*e.g.*, a serial number) for each programmer/control transmitter. We agree with the Joint Parties that it will be sufficient to provide the quantity and type (*i.e.* equipment that may have different technical characteristics) of programmer/control transmitters at each MBAN installation. We will accomplish this objective by retaining the requirement in Section 95.1223(a)(3) that programmer/control transmitter information include the manufacturer name, model number and FCC identification number. The practical effect of our revised rules is that health care facilities will be able to account for large groups of devices under a single filing.
- 40. Finally, we clarify that replacement of programmer/control transmitters having the same technical characteristics as those reported on the health care facility's registration (*i.e.*, the manufacturer name, model number and FCC identification number) will not trigger additional notification requirements under Section 95.1223(b) of the rules. The Joint Parties had expressed concerns that Section 95.1223(a), as originally written, "could be construed to require registration of identical replacement equipment as well as body-worn devices." The revisions to Section 95.1223 we are adopting will resolve any such concerns.
- 41. <u>Interaction between MBAN and AMT Coordinators</u>. Under Section 95.1225(b)(2) of our rules, the MBAN Coordinator is required to determine if an MBAN is within line of sight of an AMT receive facility in the 2360-2390 MHz band, and coordinate MBAN operations with the designated AMT coordinator. Additionally, the MBAN coordinator must approve any changes made to an authorized MBAN installation before operation could begin with the altered parameters. Accordingly, Section 95.1223(b) states, in pertinent part, that a health care facility must notify the MBAN coordinator "of any material change to the MBAN's location or operating parameters," and that it may not operate under changed operating parameters "until the frequency coordinator determines whether such changes require coordination with the AMT coordinator."

80 Id. See also Joint Parties January 30, 2013 ex parte at 4.

⁷⁹ *Id.* at 13.

⁸¹ Because different parties may manufacture under the same FCC ID or manufacture multiple models under the same FCC ID, it is appropriate to collect the manufacturer name and model number in addition to the FCC ID to allow the coordinator to take account of the specific MBAN equipment deployed at any given location.

⁸² Joint Recon Petition at 13.

^{83 47} C.F.R. § 95.1225(b)(2).

⁸⁴ 47 C.F.R. § 95.1223(b).

- 42. The Joint Parties make two requests on reconsideration. First, they ask that the MBAN coordinator duties specified in Section 95.1225 of the rules be revised to make those duties clearer and more explicit. Second, they ask for clarification that the AMT coordinator must be consulted before an MBAN location or operation is changed. Specifically, they claim that while Section 95.1223(c) of the rules requires such consultation, the text of the *First Report and Order* failed to clearly state that the Commission's rules prohibit MBAN operations under changed parameters until after the MBAN coordinator has consulted with the AMT coordinator and determined whether a new or revised coordination is required. Sec.
- 43. We find that the Joint Parties suggested edits to Section 95.1225 of the rules are not necessary. This section, which lists the duties of the coordinator, must be read in context with Section 95.1223, which outlines the coordination process in detail. The coordinator's duties are already explicitly described in Section 95.1223. Because the Joint Parties' proposed edits to Section 95.1225(b) are already addressed in Section 95.1223(c), we conclude that it would be unnecessarily repetitive to make the proposed edits.
- 44. However, it would be beneficial to further clarify the procedures for how the AMT coordinator is consulted before an MBAN location or operation is changed. The rule section that applies to changes in MBAN facilities, Section 95.1223(b), requires the MBAN coordinator to determine whether the proposed modification requires coordination with the AMT coordinator, and, if so, further requires the MBAN coordinator to complete the coordination process under Section 95.1223(c). We believe it is clear that, if the modified MBAN facility would operate line-of-sight to an AMT receive facility, it will be necessary for the MBAN coordinator to reach a coordination agreement with the AMT coordinator under Section 95.1223(c)(2) of the rules. It is less clear, however, whether coordination with or notification to the AMT coordinator would be required if the modified MBAN facility would operate beyond line-ofsight of an AMT receive facility. 87 The best course in such cases is to apply the existing procedures outlined in Section 95.1223(c)(1), which requires the MBAN coordinator to approve operation without prior coordination with the AMT coordinator, but also requires the MBAN coordinator to notify the AMT coordinator and provide the AMT coordinator with the opportunity to concur that the MBAN facility is beyond line of sight. We will revise Section 95.1223(b) of the rules to state that the MBAN coordinator must evaluate the proposed changes and comply with either (c)(1) or (c)(2), as appropriate, prior to authorizing a modified MBAN operation. Such a change satisfies the Joint Parties' request that we clarify the advance consultation requirement for the AMT coordinator, and does so in a way that complements our existing rules for coordinating MBAN operations.
- 45. <u>Notification of Interference</u>. The Joint Parties ask the Commission to amend Section 95.1223(a) of the rules to include a specific requirement that, if a health care facility or the MBAN coordinator is notified of MBAN interference to an AMT receive antenna, the MBAN user must cease transmissions on the frequencies causing interference. In conjunction with this request, the Joint Parties re-assert that an MBAN coordinator "would be the single point of communication" between the affected AMT parties and the MBAN users. Adopting this explicit requirement for shut-down in the event of

⁸⁵ *Joint Recon Petition* at 14. The Joint Parties ask us to revise the rule to read as follows (suggested new language is in italics): "(2) *Make an initial determination whether* an MBAN is within line of sight of an AMT receive facility in the 2360-2390 MHz band and coordinate MBAN operations *within line-of-sight of an AMT receive facility with* the designated AMT coordinator as specified in § 87.305."

⁸⁶ Joint Recon Petition at 15.

⁸⁷ Specifically, the use of the phrase "if so" could be read to suggest that there are cases where additional consultation with the AMT coordinator would not be required.

⁸⁸ Joint Recon Petition at 12.

⁸⁹ *Id*.

interference, they contend, would "provide important guidance to all concerned as to the serious obligations attendant to secondary MBAN operations in the shared 2360-2390 MHz band." ⁹⁰

- 46. In the First Report & Order, the Commission concluded that the rules it adopted "would accomplish the ... goal of identifying and resolving interference to AMT from MBAN users in a way that ... clearly sets forth the roles and responsibilities of the parties." To that end, Section 95.1211(c) of the rules plainly states that MBAN devices may not cause harmful interference to authorized stations operating in the 2360-2400 MHz band which places the onus of avoiding such interference squarely on the operator of these devices. Accordingly, it is the MBAN user's responsibility to respond to interference complaints, and to be prepared to cease operation as necessary to avoid causing harmful interference. We emphasize that failure to abide by this rule will subject an MBAN user to appropriate Commission enforcement action. With regard to harmful interference that occurs as a result of MBAN device operation in the 2360-2390 MHz band, we recognize that the MBAN coordinator is the most likely point of contact between affected AMT parties and MBAN users. Thus, our existing rules give the MBAN coordinator the responsibility to identify the MBAN that is the source of interference and the authority to notify the registered health care facility to cease operation as may be appropriate to the circumstances. 92 Moreover, any health care facility planning to operate MBAN devices in the 2360-2390 MHz band will have provided to the MBAN coordinator, pursuant to the rules, a point of contact in the event the MBAN user is directed to cease operation. 93
- 47. Together, the rule defining the MBAN user responsibilities and the rule describing the functions of the 2360-2390 MHz band MBAN coordinator should provide for the prompt identification and resolution of any harmful interference caused by an MBAN to AMT operations. It is not necessary to implement an additional rule to accomplish this goal, and, accordingly, we decline to adopt the Joint Parties' proposed changes. As part of the registration and coordination process, the MBAN coordinator is free to emphasize the possibility that an MBAN device operating in the 2360-2390 MHz band may be subject to a demand for immediate cessation, and to state expressly that the health care facility must be prepared to receive and respond to such a message from the MBAN coordinator, if it thinks doing so will aid in the successful operation of secondary MBAN devices in the band.
- 48. <u>Testing of Installed MBAN Equipment</u>. As part of the February 6, 2014 ex parte filing that discussed the Joint Parties' Petition for Reconsideration, the Joint Parties and ASHE stated that "[h]ospital or equipment vendors should be required to certify to the MBAN coordinator that testing of the relevant 2360-2390 MHz MBAN equipment was conducted in situ and confirmed that the equipment does not operate outdoors." They explain that AFTRCC continues to be concerned that MBAN operation could result in interference to primary AMT users, and urge the Commission "to clarify" that it expects the MBAN coordinator to require such a certification from the hospital or vendor. 96

⁹⁰ *Id*.

⁹¹ First Report and Order at 6455, para. 71.

⁹² 47 C.F.R. § 95.1225(b)(5).

⁹³ 47 C.F.R. § 95.1223(a)(7).

⁹⁴ We also disagree with the Joint Parties' suggestion that Section 95.1223 is the right place add rule language that describes an MBAN user's responsibilities. Section 95.1223 addresses the MBAN registration and coordination process. A separate rule – Section 95.1211(c) – addresses the channel use policies.

⁹⁵ Joint Parties and ASHE February 6, 2014, ex parte filing at 6.

⁹⁶ *Id*.

49. To the extent that the Joint Parties and ASHE are seeking a clarification, we find that our existing rules and processes are sufficient to address their concerns. As an initial matter, all MBAN equipment capable of operating in the 2360-2390 MHz band must be certified under the equipment authorization process to demonstrate compliance with the indoor operation restrictions. Additionally, under the existing rules, when registering with an MBAN coordinator, MBAN users must acknowledge the need to comply with these requirements. Further, we have already given MBAN coordinators broad discretion to implement coordination procedures to ensure that MBAN operations are permitted only when and where they will not interfere with AMT operations. In MBAN coordinator determines that the type of testing and certification the Joint Parties and ASHE seeks is warranted, it may ask a hospital or equipment vendor to provide such information as part of the coordination process.

E. Equipment Authorization

- 50. In the *First Report and Order*, the Commission expanded the existing MedRadio equipment authorization requirements, with appropriate modifications to reflect the MBAN spectrum band and use restrictions, to apply to MBAN devices. ¹⁰¹ The Joint Parties have asked us to reconsider certain aspects of these rules.
- 51. <u>Attached Antennas and Operation in the 2360-2390 MHz Band</u>. The Joint Parties request that Section 95.1213 of the rules, which describes MBAN antenna placement, be modified "to clarify that an antenna must be permanently affixed to its MBAN transmitter" for devices operating in the 2360-2390 MHz portion of the band. They state that this requirement is necessary to prevent the use of unapproved antennas that could result in increased effective radiated power, which, in turn, could "undermine the technical validity of the coordination." ¹⁰²
- Allowing manufacturers to produce devices with flexible antenna components will permit MBAN devices to be tailored to different kinds of applications and to potentially address future needs for MBAN deployment to fit different health care environments. We see little risk that MBAN users will make post-market device modifications. It may be physically difficult for end users to make such modifications, and health care facilities would be unlikely to try given that the modification of an MBAN device could affect a user's other regulatory responsibilities, such as those pertaining to the use of medical devices under applicable Food and Drug Administration (FDA) rules. We are not aware of any issues with unauthorized modification of the existing base of MedRadio devices that operate under our existing rules, nor have the Joint Parties provided any supporting evidence that this is a common occurrence that would support additional rules tailored to MBAN operation in the 2360-2390 MHz band. In sum, we conclude that the benefits of enabling equipment manufacturers to respond flexibly to the needs and interests of the health care facilities that use their devices outweigh the small risk of an MBAN

⁹⁷ To the extent that the Joint Parties and ASHE are instead seeking reconsideration of the rules adopted in the *First Report & Order*, they have not previously raised this matter and we reject such a request as untimely.

⁹⁸ See 47 C.F.R. §§ 95.603, 95.628 and 95.1203.

⁹⁹ See 47 C.F.R. § 95.1223(a)(7).

¹⁰⁰ See First Report and Order at 6456, para. 72 (stating that the MBAN coordinator must "[d]evelop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements").

¹⁰¹ First Report and Order at 6442-43, paras. 41-42.

¹⁰² *Joint Recon Petition* at 15-16.

¹⁰³ We emphasize that, under our rules, such antennas would still have to be supplied with the transmitter and shall be considered part of the transmitter for equipment authorization purposes. Thus, each individual multiple antenna and MBAN transmitter combination will require separate approval.

 $^{^{104}}$ For example, the anticipated small scale of many of the MBAN body-worn devices may make it impossible for an end-user to modify the antennas.

end user modifying its equipment in a way that undermines the validity of the coordination. Moreover, our existing rules already protect against the potential harm described by the Joint Parties. Specifically, Section 95.639(f)(5) of the rules states that "[t]he antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization." Given the requirement that an MBAN device be certificated, any changes to the device that result in increased power would require a new application for equipment certification. 107

53. *Equipment Labeling Requirement*. The labeling requirement for MBAN devices is as follows:

MedRadio programmer/control transmitters operating in the 2360-2400 MHz band shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

"This device may not interfere with stations authorized to operate on a primary basis in the 2360-2400 MHz band, and must accept any interference received, including interference that may cause undesired operation."

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device. 108

- The Joint Parties' request that, in the event that the warning is not included on the device label, the Commission should require that the warning be placed on the front page of the instruction manual in capital letters. They assert this would ensure that "all personnel are fully aware of the operating status of MBAN devices." We are not persuaded that including such specific labeling requirements in our rules is necessary or appropriate. The Commission considered adopting labeling requirements in the First Report and Order, and concluded that it was appropriate to apply the existing requirements from the existing family of MedRadio devices to MBAN devices, along with special provisions for placing information in the instruction manual in lieu of direct placement on the transmitter. 110 This decision was based on an analysis of "the potential for interference to and from MBAN devices," and after the determination "that our rules will support MBAN operation on a secondary basis."¹¹¹ The Joint Parties have not offered any reason for us to question this analysis, or to convince us why we need to take additional steps to ensure that "all personnel are fully aware" of the status of MBAN devices. Finally, we note that in the event that harmful interference occurs within the 2360-2390 MHz band, where protection of primary AMT operations is of particular concern, the efficacy of the labeling requirement as a prophylactic against interference is supplemented by the role of the MBAN coordinator, who has the authority to contact the MBAN user and direct that user to take appropriate actions. 112 For these reasons, we deny the request and affirm Section 95.1217(a)(3) as adopted.
- 55. <u>Publication of Equipment Authorization Requirements</u>. Additionally, the Joint Parties have asked that we take steps to ensure that the requirements for equipment authorization of MBAN

 $^{^{105}}$ Section 95.639(f)(3) was redesignated Section 95.639(f)(5) in the *First Report and Order* without any editorial changes.

¹⁰⁶ 47 C.F.R. § 95.603(f).

¹⁰⁷ See 47 C.F.R. § 2.1043(a).

¹⁰⁸ 47 C.F.R. 95.1217(a)(3).

¹⁰⁹ *Joint Recon Petition* at 16. We note that the Joint Parties referred to Section 95.1225(b)(2) of the Commission's Rules. The context of their request indicates that the actual rule they were addressing is the one we discuss above.

¹¹⁰ First Report and Order at 6442-43, para. 42.

¹¹¹ *Id*.

¹¹² See para. 45, supra.

devices be "clear for all to follow."¹¹³ They assert that the "unique and innovative nature of the spectrum sharing embodied in the MBAN rules" and the transmission restrictions in the 2360-2390 MHz band make it vital for "all parties [to] have confidence that equipment manufactured and marketed will be in strict compliance with the Commission's rules"¹¹⁴ To that end, the Joint Parties have submitted a list of "expected attestation and certification requirements for MBAN equipment,"¹¹⁵ and suggest "continuing this discussion with the Commission's Laboratory Staff."¹¹⁶ We agree that a clear understanding of the equipment authorization rules and how they apply to MBAN devices is important for the successful development and deployment of MBAN systems. The Joint Parties do not propose specific rule modifications to accomplish this goal, and we likewise see no need to make any changes to the rules. Instead, we will draw on existing resources to ensure that information regarding authorization procedures for MBAN equipment is published in a readily accessible manner, and that MBAN equipment is authorized in compliance with Commission rules. For example, we expect OET's Laboratory Division to use its Knowledge Database (KDB) to disseminate guidance relating to MBAN device certification, ¹¹⁷ and that Commission staff will continue to answer any questions regarding equipment authorization procedures and practice. ¹¹⁸

IV. SECOND REPORT AND ORDER

- 56. The Commission's rules require that MBAN operations in the 2360-2390 MHz be registered and coordinated to ensure that AMT operations in this band are protected from harmful interference. The registration and coordination functions are to be performed by a frequency coordinator to be designated by the Commission. An MBAN coordinator will be required to maintain a database of MBAN registrations that includes the locations of MBAN systems that operate in the 2360-2390 MHz band, determine when MBAN transmitters are within line-of-sight of AMT receive facilities, coordinate MBAN operations with the coordinator for AMT services, notify registered MBAN users when they must change frequencies or cease operations consistent with a coordination agreement between the MBAN and AMT coordinator, and develop procedures to ensure that MBAN users operate consistent with the coordination requirements.¹¹⁹
- 57. In the *Further Notice*, the Commission requested comment on a number of issues related to designating the MBAN coordinator(s) for the 2360-2390 MHz band. Specifically, the Commission made proposals and sought comment on the number of MBAN coordinators, the term of service, qualifying criteria for selecting a coordinator, fees for service, and the selection process. In addition, the

¹¹³ *Joint Recon Petition* at 17.

¹¹⁴ *Id*.

¹¹⁵ See Joint Parties September 7, 2012 ex parte filing.

¹¹⁶ Joint Recon Petition at 17.

¹¹⁷ See Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405 and 405-406 MHz, ET Docket No. 06-135, RM-11271, Memorandum Opinion & Order, 25 FCC Rcd 10414, 10417-18, para. 9 (2010) (noting that OET's Laboratory Division has published information on average power measurements for MedRadio devices in the Knowledge Database). The Knowledge Database is an OET on-line database containing policies, procedures and answers to common equipment authorization questions. It is available at www.fcc.gov/labhelp.

¹¹⁸ OET's Laboratory Division, for example, has already provided MBAN-related information to Telecommunications Certification Bodies. *See* http://transition.fcc.gov/oet/ea/presentations/presentations.tcb.2013.html?apr13#secapr12 (providing a link to an April 10, 2013 presentation by Steven Jones, Technical Research Branch, titled "Medical Body Area Networks (MBANs)").

¹¹⁹ First Report and Order at 6456, para. 73. See also 47 C.F.R. §§ 95.1223 and 95.1225.

Commission noted that its proposals for the MBAN coordinator selection procedures were based on the procedures it adopted for selecting the coordinator for the Wireless Medical Telemetry Service (WMTS). The comments we received generally support the proposals made in the *Further Notice*.

- 58. As discussed in more detail below, we adopt specific procedures regarding selection of the MBAN coordinator. Initially, we will select only one MBAN coordinator for a ten-year term. After the ten-year term, the coordinator will serve until either it elects not to continue as coordinator or is removed by the Commission. The MBAN coordinator may rely on a third-party consultant for technical services necessary to fulfill its responsibilities, but will be required to disclose information about the technical qualifications of the third-party consultant and the contractual arrangement it has with the consultant. The MBAN coordinator will be required to provide service on a non-discriminatory basis to all eligible health care institutions and will be permitted to charge reasonable fees that reflect only its actual costs (including the costs associated with coordination, such as the AMT coordinator's cost and the expense of any third-party technical consultant). The Wireless Telecommunications Bureau (Bureau), acting under delegated authority as provided in the Commission's rules, will select the MBAN coordinator. The Bureau will execute a Memorandum of Understanding (MOU) with the selected coordinator, which will describe the duties and responsibilities of the coordinator and provide for removal of the coordinator if circumstances warrant.
- 59. <u>Single Coordinator</u>. As proposed in the *Further Notice*, we will select only one MBAN coordinator at this time. We find that selecting a single MBAN coordinator is appropriate given the characteristics of the MBAN service. This approach is warranted, given that the health care community represents a small part of the radiofrequency user ecosystem and the number of MBAN registrants is likely to be proportionally small. Having only one coordinator will simplify MBAN registration for health care institutions because there will be a single point of contact and the registration process will be analogous to the WMTS registration process that is familiar to many entities in this specialized group. With a single MBAN coordinator, the AMT coordinator will need to develop procedures for addressing potential frequency conflicts with a single entity and there will be no need to develop procedures to share registration data. It will also avoid having multiple parties create and maintain duplicative registration and coordination systems. All commenters supported selecting only one MBAN coordinator. ¹²³
- 60. We recognize that there are potential drawbacks in the selection of only one MBAN coordinator. Competitive forces, which could drive the coordinator to find ways to charge the lowest fees possible and which could incentivize the coordinator to provide the most efficient service to the MBAN user community, will be absent under a single coordinator approach. We note that the authority already delegated to the Bureau to certify frequency coordinators for the services it administers ¹²⁴ allows it to introduce competitive coordination into a service with an exclusive coordinator. ¹²⁵ In light of the potential drawbacks in the selection of only one MBAN coordinator and the benefits of competition, the

¹²⁰ Further Notice, 27 FCC Rcd at 6460, para. 85.

¹²¹ See 47 C.F.R. § 0.131(m).

¹²² Further Notice at 6458, para. 78.

¹²³ AFTRCC Comments at 2: ASHE Comments at 4-6: Philips/GE Comments at 2-3.

¹²⁴ The Bureau has delegated authority to perform various functions assigned to it under the rules, *see* 47 C.F.R. § 0.331, including "[c]ertifies frequency coordinators; considers petitions seeking review of coordinator actions; and engages in oversight of coordinator actions and practices," *see* 47 C.F.R. § 0.131(m).

¹²⁵ See, e.g., Industrial Telecommunications Association, Order, 19 FCC Rcd 7614, 7618-19 para. 10 (WTB PSCID/MD 2004).

Bureau will consider, in the future, whether to certify one or more additional coordinators if it determines that such an action would serve the public interest. 126

- 61. <u>Term of Service</u>. As proposed in the *Further Notice*, we will require that the MBAN coordinator agree to serve a ten-year term. As we explained in the *Further Notice*, a ten-year term is appropriate for several reasons. A shorter term may not provide enough time for the health care community and coordinators to develop a working relationship because of the length of time that it will likely take to fully develop and broadly deploy MBAN equipment. A ten-year term will provide a substantial period of time for the Commission to evaluate the MBAN coordinator's performance. All commenters supported a ten-year term for the MBAN coordinator. After the initial ten-year term, the MBAN coordinator will continue to serve until the coordinator acts to vacate the role or the Commission acts to remove the coordinator under the procedures discussed below.
- We also adopt the proposal in the Further Notice to require that the MBAN coordinator transfer the MBAN registration data to another entity designated by the Commission if the coordinator cannot or chooses not to continue as coordinator. 129 We direct the Bureau to incorporate this requirement into the MOU that it will execute with the MBAN coordinator. As part of the MOU, the Bureau should also address what notice the MBAN coordinator must give the Commission to provide adequate time to select a replacement coordinator, in the event that the coordinator intends to vacate the coordinator role. This notice will have to provide sufficient time for the Bureau to select a replacement coordinator, for the replacement coordinator to establish a registration and coordination system, and for the incumbent MBAN coordinator to transfer the registration data to the replacement coordinator. We note that for WMTS, five months elapsed from the Commission soliciting applications for a coordinator until it selected a coordinator. Consequently, we conclude that a six-month notice, at a minimum, would be an appropriate time frame for ensuring continuity in the coordinator role. ¹³⁰ In the *Further Notice*, we recognized that it is possible that the coordinator would not continue in its role at some point. In such a case, these notice and transfer requirements will be necessary to ensure an effective transition of coordinators. The provisions will help us avoid having a period of time during which there would be no functioning MBAN registration and coordination regime or creating a re-registration burden on MBAN licensees.
- 63. Because the role of the MBAN coordinator is essential to prevent harmful interference to a primary service, we believe it is important to allow the MBAN coordinator to be replaced by the Commission if necessary. Consistent with the existing procedures for the WMTS coordinator, we delegate to the Bureau the authority to remove the MBAN coordinator after giving adequate notice if it determines that such an action would serve the public interest. The Bureau can include specific provisions in the MOU, including the notice it will give the coordinator. We conclude that a six-month

¹²⁸ ASHE Comments at note 15; AFTRCC Comments at 2-3; *Cf.* Philips/GE Comments at 4 (stating that the coordinator should have at least a ten-year term with expectation of renewal).

¹²⁶ If the Bureau selects more than one MBAN coordinator, we direct the Bureau to require the MBAN coordinators to work out procedures to share information on a regular and timely basis so that each coordinator has a complete registration database, provides consistent coordination results, and can provide coordination services without delay. The Bureau shall resolve any issues on which the coordinators cannot reach agreement pursuant to its delegated authority.

¹²⁷ Further Notice at 6458, para. 79.

¹²⁹ Further Notice, 27 FCC Rcd at 6458, para. 79. To ensure that the transfer of registration data is of practical use, we further specify that the MBAN coordinator must transfer the registration data in a useable format.

¹³⁰ The specific time period will be set by the Bureau as part of the MOU.

¹³¹ Memorandum of Understanding between The United States Government, The Federal Communications Commission, and the American Society of Health Care Engineering of the American Hospital Association Regarding Frequency Coordination for the Wireless Medical Telemetry Service, para. 10.

notice for the Commission to terminate the tenure of the MBAN coordinator is appropriate because, as discussed above, it will provide sufficient time to ensure continuity in the coordinator role. 132

- 64. <u>Qualifying Criteria</u>. In the *Further Notice*, the Commission sought comment on the minimum qualifying criteria that should be established for selecting an MBAN coordinator and proposed that parties interested in being designated an MBAN coordinator must, at a minimum, demonstrate that they meet the following criteria:¹³³
 - Ability to register and maintain a database of MBAN transmitter locations and operational parameters;
 - Knowledge of or experience with medical wireless systems in health care facilities (e.g., WMTS);
 - Knowledge of or experience with AMT operations;
 - Ability to calculate and measure interference potential between MBAN and AMT operations and to enter into mutually satisfactory coordination agreements with the AMT coordinator based on the requirements in Section 95.1223(c);
 - Ability to develop procedures to ensure that registered health care facilities operate an MBAN consistent with the requirements in Section 95.1223.
- 65. These criteria are designed to ensure that the designated coordinator can successfully accomplish the functions required by our rules. The Commission also sought comment on whether we should require that the MBAN coordinator provide service on a non-discriminatory basis.
- 66. We will require an applicant applying to become the MBAN coordinator to demonstrate that they meet the five criteria that we proposed in the *Further Notice*, which all commenters supported. We find that these criteria "ensure that the designated coordinator can successfully accomplish the functions required by our rules." Accomplishing these functions will require knowledge of both medical wireless systems and AMT operations and the ability to calculate and measure the interference potential between these two systems. The MBAN coordinator will have to enter into coordination agreements with the AMT coordinator to prevent and resolve harmful interference. The MBAN coordinator will be required to maintain a database of MBAN networks for use in identifying and resolving harmful interference to AMT operations and develop procedures to ensure that MBAN networks operate in accordance with the Commission's rules. All of these tasks are captured by the qualifying criteria we are adopting.
- 67. ASHE and Philips/GE propose additional criteria for selecting the MBAN coordinator. According to ASHE, the MBAN coordinator should have "a working knowledge of the health care environment and the ability to work with health care facilities" to assure that interference mitigation "will

¹³² We note that the WMTS MOU provides identical notice periods for the Commission to terminate the coordinator and for the coordinator to vacate the coordinator role. The Commission's rules specify that the Bureau engage in oversight of frequency coordinators and the WMTS MOU was signed by the Bureau on behalf of the Commission. *Id.*; 47 C.F.R. § 0.131(m). Thus, termination of the tenure of the WMTS coordinator may be undertaken by the Bureau on behalf of the Commission.

¹³³ Further Notice at 6458-59, paras. 80-81.

¹³⁴ Philips/GE Comments at 4; ASHE Comments at 6; AFTRCC Comments at 2.

¹³⁵ *Further Notice* at 6458-59, para. 80.

¹³⁶ 47 C.F.R. §§ 95.1223(c)(2) and 95.1225(b)(2); Further Notice at 6454-55, paras. 69-71.

¹³⁷ 47 C.F R. § 95.1225(b)(2).

¹³⁸ 47 C.F.R. § 95.1225(b)(4).

not compromise patient health and safety."¹³⁹ ASHE claims technical proficiency with frequency coordination alone will not ensure that patient health and safety is considered during the coordination process because the MBAN coordinator may have to direct the licensee to move the MBAN system to another frequency or suspend operation if harmful interference to AMT operations is detected. ASHE also supports adding the requirements that the MBAN coordinator have experience working with hospitals and medical device vendors, have institutional knowledge of the health care industry, and have the MBAN user community as a core constituency. ¹⁴⁰ Philips/GE states that the MBAN coordinator must be able "to demonstrate up-to-date knowledge and experience with state-of-the-art software propagation tools" and the ability to make measurements if necessary. ¹⁴¹ Philips/GE also claims that the coordinator must be familiar with the hospital environment and propagation mitigation tools to work with the AMT coordinator to design technical solutions to interference when required. ¹⁴²

- We decline to add the additional criteria suggested by ASHE and Philips/GE to the core criteria that we are adopting. As an initial matter, we note that some of these elements are already addressed by the five criteria we are adopting. For example, we are requiring that the MBAN coordinator demonstrate the ability to calculate and measure interference. We view Philips/GE's suggestion that the coordinator demonstrate experience with state-of-the-art propagation tools as a necessary part of that requirement. Similarly, ASHE's proposed requirement that the MBAN coordinator have a working knowledge of the health care environment is captured by the requirement we are adopting that the coordinator demonstrate knowledge or experience with medical wireless systems in health care facilities. Other elements of the proposed criteria describe qualities that would likely be useful for an MBAN coordinator to possess but do not appear essential for performing the coordination obligations required by the rules we have adopted, are insufficiently concrete to warrant certification, or would be expected to attend compliance with the criteria we have specified. Such additional criteria include experience working with hospitals, institutional knowledge of the health care industry, and ability to work with medical device vendors. 143 While we will not establish such proposed criteria as prerequisites to serving as an MBAN coordinator, or otherwise to require coordinator candidates to demonstrate such criteria, we recognize that the knowledge and skills reflected in those proposed criteria may be useful in differentiating between multiple MBAN coordinator candidates. We therefore invite MBAN coordinator candidates to describe such capabilities and how those capabilities would augment the candidate's ability to satisfy the core criteria.
- 69. The *Further Notice* also sought comment on whether an MBAN coordinator candidate could rely on a third-party contractual arrangement to demonstrate compliance with the core criteria and, if so, what amount of disclosure of a contractual arrangement should we require as part of the selection process. ASHE notes that the Commission has not typically specified what functions coordinators can outsource to third parties and that there is no reason to impose such a restriction here. According to ASHE, the MBAN coordinator should be allowed to rely on a consultant to build the MBAN registration

¹³⁹ ASHE Comments at 7.

¹⁴⁰ *Id.* at note 11.

¹⁴¹ Philips/GE Comments at 4.

¹⁴² *Id.* at 4-5.

¹⁴³ The Commission's rules require that the MBAN coordinator determine the source of interference and notify healthcare facilities of alternative frequencies available for MBAN use or to cease operation. 47 C.F.R. § 95.1225(b)(5). It is not the MBAN coordinator's role to redesign individual MBAN networks to avoid harmful interference. Therefore, in-depth institutional knowledge of the healthcare industry and ability to work with medical device vendors are not requirements for the MBAN coordinator under the Commission's rules.

¹⁴⁴ Further Notice at 6459, para. 82.

¹⁴⁵ ASHE Comments at 9.

database, analyze the technical data, and conduct coordination between line-of-sight MBAN and AMT receivers. ASHE explains that the Commission took note of ASHE's intention to contract for technical and administrative support in designating ASHE as the WMTS coordinator. ¹⁴⁶ Philips/GE adds that having a coordinator who contracts for expert assistance is in the public interest and that the Commission's experience in relying on outside coordinators demonstrates the advantages of such relationships. ¹⁴⁷

- 70. We find that the MBAN coordinator should be able to rely on a contract with a third party for technical expertise, and we will consider such arrangements as part of a candidate's demonstration that it satisfies the core qualifying criteria. We recognize that it may be difficult to identify a single entity that satisfies all the minimum qualifying criteria that we are adopting — e.g., no one entity may have expertise in both wireless medical systems in health care facilities and AMT operations, as well as database management and frequency coordination. Because the potential registered MBAN user base is limited to certain sectors of the health care community, the number of potential candidate MBAN coordinators may be limited. 148 A candidate that lacks expertise in the core criteria may choose to rely on a third party for technical support to demonstrate that it would be able to provide all of the MBAN registration and coordination functions with minimal delay. Given that no registered MBAN devices can be deployed until an MBAN coordinator is established, it would not serve the public interest to risk inordinate delays in the rollout of this service by unnecessarily limiting the potential field of candidates for MBAN coordinator with a rule that forecloses reliance on a third party to provide technical support. If the MBAN coordinator does rely on a third party for technical support, the performance of this third-party consultant is important to the efficient functioning of the MBAN coordination regime. We note that the Bureau may exercise its authority to terminate the tenure of the MBAN coordinator if the third-party technical consultant stops providing service to the MBAN coordinator and the Bureau is not persuaded that either the MBAN coordinator can perform these necessary duties without assistance of a third-party consultant or use of a replacement consultant will allow the coordinator to meet its obligations under our rules. 149
- 71. We find that MBAN coordinator candidates that rely on third party contracts to demonstrate compliance with the core qualifying criteria will need to disclose certain information about such contracts, as described below. As we noted in the *Further Notice*, the Commission staff determined that third party contracts were not a significant factor in selecting a WMTS coordinator because the WMTS coordinator would not have to resolve frequency conflicts. Unlike the WMTS coordinator, who registers WMTS users and notifies other WMTS users of potential frequency conflicts, the MBAN coordinator will have to perform technical calculations, make measurements in certain cases, and coordinate MBAN operations with the AMT coordinator. Because AMT is a primary service entitled to interference protection from MBAN operations, it is important for us to be confident that the designated MBAN coordinator can perform the required functions under the rules and will be directly responsible to the Commission if the Commission has to intervene in resolving any coordination disputes that may arise. Consequently, to demonstrate compliance with the core qualifying criteria, the MBAN coordinator will

¹⁴⁷ Philips/GE Comments at 5.

¹⁴⁶ *Id*. at 10.

¹⁴⁸ To date, the only entity to express an interest in this docket in becoming the MBAN coordinator is ASHE. ASHE has indicated that it will need to negotiate a contract with an expert consultant. ASHE Reply at note 13.

¹⁴⁹ This is consistent with our decision above to delegate authority to the Bureau to remove the MBAN coordinator if it determines that such an action would serve the public interest. This ability of the Bureau to terminate the MBAN coordinator will be part of the MOU between the MBAN coordinator and the Commission.

¹⁵⁰ Further Notice at 6459, para. 82.

¹⁵¹ Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, ET Docket No. 99-255, PR Docket No. 92-235, *Report and Order*, 15 FCC Rcd 11206, 11217-18, paras. 32-33 (2000).

need to disclose certain information in third party agreements. Although we agree with ASHE's contention that the identity of and the technical experience of the expert consultant needs to be provided, ¹⁵² we find that demonstration of the core qualifying criteria will require the disclosure of more detailed information because the relationship between the MBAN coordinator and a third-party technical expert will affect both the coordinator's ability to carry out its responsibilities and the program's ability to continue if either the coordinator or the third-party expert must relinquish its role.

- 72. We direct the Bureau to require that applicants for the MBAN coordinator role relying on a third party consultant make a number of attestations regarding the consultant and the contract between the consultant and the applicant, and to take this information into account when judging the suitability of applicants for the MBAN coordinator position. This information must include the identity and qualifications of any third-party technical consultant the MBAN coordinator will rely on, the length of time that the contract between the MBAN coordinator and the third-party consultant would be in effect, and under what circumstances that contract could terminate. Because of the important role that a third-party technical consultant can play in preventing harmful interference to AMT operations, the technical qualifications of the consultant and the circumstances under which the consultant may stop providing services are important to the Commission's confidence in the MBAN coordinator.
- The MOU should also recognize the possibility that the technical consultant would stop providing service to the MBAN coordinator. Upon such an occurrence, the MBAN coordinator would need time to employ a replacement consultant who meets the Commission's high standards and, if such a coordinator is not found, the Commission needs time to replace the MBAN coordinator. The Bureau has the discretion to include such requirements in the MOU it executes with the MBAN coordinator. For example, the MOU could require that the MBAN coordinator include in its contract with the third-party consultant that the consultant must give a six-month notice before ending the contractual arrangement with the MBAN coordinator and that the MBAN coordinator be required to inform the Bureau within ten days of learning that the third-party consultant will cease to perform some of the necessary duties of the MBAN coordinator. 153 A six-month notice should provide sufficient time for either the MBAN coordinator to engage a competent replacement consultant, develop its own ability to undertake the consultant's function, or for the Bureau to begin a search for a new MBAN coordinator, if necessary. Additionally, the MOU could require that the contract between the coordinator and third-party consultant requires a consultant that maintains the database to transfer the MBAN registration data in a useable form to another party if either the MBAN coordinator or the consultant terminates the contract or the contract expires, the MBAN coordinator vacates the coordinator's role, or the Commission replaces the MBAN coordinator. As we discussed above, the transfer of the registration data is important to help us avoid having a period of time during which there would be no functioning MBAN registration and coordination regime or creating a re-registration burden on MBAN licensees. Such provisions would be useful as they would ensure that the MBAN coordination functions are not interrupted if the relationship between the MBAN coordinator and third-party technical consultant ends.
- 74. <u>Fees for Service</u>. As the Commission proposed in the *Further Notice*, we will permit the MBAN coordinator to set fees for MBAN registration and coordination. The alternative having the Commission or the Bureau prescribe fees is not practical for a number of reasons. The Commission or the Bureau will not have the information about the cost associated with registration and coordination to set fees. This is particularly the case for non-line-of-sight coordination, which may involve significant engineering analysis and field measurements. Over time, the registration and coordination fees will likely have to be modified to reflect changing costs, which the Commission or Bureau may find difficult to

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¹⁵² ASHE Comments at 8.

¹⁵³ For example, if the consultant gives the MBAN coordinator the required six month notice for ending the contract, the MBAN coordinator will need to notify the Bureau within ten days of receiving that notice.

accomplish in a timely matter. All commenters supported the Commission's proposal to let the MBAN coordinator establish the fees for registration. ¹⁵⁴

- 75. In the *Further Notice*, the Commission also sought comment on whether the Commission should "adopt any fee requirements for MBAN registration and coordination, including for example whether service fees should only recoup costs and how such a requirement should be evaluated and whether service fees should be reasonable and non-discriminatory." All commenters supported requiring that fees be reasonable and non-discriminatory. We will require that the fees charged for MBAN registration and coordination be reasonable and reflect only the MBAN coordinator's actual costs of providing the coordination and registration functions. The MBAN coordinator will be required to provide the coordination and registration functions on a not-for-profit basis. Requiring that the MBAN coordinator provide services on a not-for-profit basis is necessary because, with likely only one MBAN coordinator, we cannot rely on competitive market forces to serve as a check on the fees associated with MBAN registration and coordination. If competitive forces are introduced and more than one coordinator is selected, however, we recognize that the need for such regulations may no longer exist and may need to be reconsidered. We also will require that the MBAN coordinator must provide services on a non-discriminatory basis to all eligible health care institutions.
- 76. The Commission also sought comment in the *Further Notice* on whether MBAN users should be responsible for the reasonable costs incurred by the AMT coordinator in effecting the coordination and, if so, what procedure should be put in place for the MBAN user to pay such costs. ¹⁵⁷ The *Further Notice* also asked whether the MBAN coordination fees should exclude the cost the AMT coordinator incurs for coordinating Federal AMT operations. Phillips/GE and AFTRCC agree that the MBAN users should be responsible for all the AMT coordinator's cost of the MBAN coordination including the cost of coordinating Federal AMT operations. ¹⁵⁸ AFTRCC and ASHE both suggest that the MBAN coordinator collect all coordination fees and remit a portion of the fees to AFTRCC (the current AMT coordinator), but that this matter should be left to agreement by the AMT and MBAN coordinators rather than prescribed by the Commission. ¹⁵⁹
- 77. As an initial matter, we conclude that the MBAN coordinator should establish MBAN user fees that include all costs associated with MBAN registration and coordination, including the cost of any third-party technical consultant employed by the MBAN coordinator and the fees of the AMT coordinator. This approach establishes a single pay point for MBAN users and will simplify the registration and coordination process for them, and is supported by the record. As with the other costs for which the MBAN user is responsible, the cost of any third-party technical consultant must be reasonable. This cost can include only the MBAN coordinator's actual costs for such consultation services. The amount of the payment to the AMT coordinator should be determined by agreement between the AMT and MBAN coordinators, and would be incorporated into the overall coordination fee that an MBAN user incurs. We have entrusted the AMT coordinator with a special role in the management of AMT spectrum use, and we expect it to bring the same principles of non-discrimination and fair play into its MBAN coordination activities. As such, we expect the AMT coordinator to pass on only its actual coordination costs, on a not-for-profit basis, to the MBAN coordinator. This cost may

¹⁵⁴ Philips/GE Comments at 6; AFTRCC Comments at 5; ASHE Comments at note 9.

¹⁵⁵ *Further Notice* at 6459-60, para. 83.

¹⁵⁶ Philips/GE Comments at 6; ASHE Comments at note 9; AFTRCC Comments at 5.

¹⁵⁷ Further Notice at 6460, para. 84.

¹⁵⁸ Philips/GE Comments at 6; AFTRCC Comments at 5.

¹⁵⁹ ASHE Reply at 4: AFTRCC Comments at 6: *See also* Philips/GE Comments at 6.

¹⁶⁰ The MBAN coordinator may delegate the collection of registration and coordination fees to a third party technical consultant.

include the actual cost to the AMT coordinator of coordinating Federal AMT operations, but may not include charges for work performed by Federal employees such as the Federal Government Area Frequency Coordinators. Because the costs incurred by the AMT coordinator will be charged to the MBAN user as part of the registration and coordination fees paid to the MBAN coordinator, there is no need to place a requirement in our rules that the MBAN user bear direct responsibility for the AMT coordinator's cost as suggested by Philips/GE, AFRTRCC, and ASHE. 161

- In the Further Notice, the Commission also sought comment on how reasonable costs should be evaluated and what oversight the Commission should exercise over AMT-MBAN coordination fees. 162 The Commission's experience with other registration regimes such as WMTS is that the fees have been reasonable and we expect a similar outcome for MBAN coordination. We recognize that there are additional actions we could take – such as setting specific cost schedules or choosing multiple MBAN coordinators - that might be beneficial in assuring that costs remain reasonable. However, we conclude that the costs of such actions – the added administrative complexity and increased overall coordination cost overhead that would have to be borne by a relatively small user community, for example – outweigh any such benefits. In addition, we observe that, as another safeguard, the Bureau has the authority to investigate the reasonableness of the MBAN registration and coordination fees, and it will do so as appropriate, either in response to complaints or on its own motion. 163 The MBAN coordinator will be required to provide the Bureau with any information it requests in the course of conducting such an investigation. In judging the reasonableness of MBAN registration and coordination fees the Bureau should consider the customary practices in other bands where registration or coordination is required under the Commission's rules. We will also require the MBAN coordinator to provide the Bureau with its fee schedule upon request. 164 This fee notification requirement coupled with the ability to investigate the reasonableness of fees will provide a necessary incentive for the MBAN and AMT coordinators to maintain the fee structure for MBAN registration and coordination at a reasonable level.
- MBAN Coordinator Selection. In the Further Notice, the Commission proposed that the Bureau, acting under delegated authority, select the MBAN coordinator using the same procedures that were implemented for selecting the WMTS coordinator. Under the Commission's rules, the Bureau has delegated authority to certify frequency coordinators for the services that it administers, including the MedRadio Service under Part 95 of the Commission's rules. Both ASHE and Philips/GE support this proposal. Philips/GE further suggests that the MBAN coordinator commit to immediately engaging AFTRCC in discussions on a coordination agreement and report to the Commission that an agreement has been reached within 90 days. If no agreement is reached Philips/GE suggests the MBAN coordinator be required to make monthly reports and that the Commission initiate a meeting with the coordinators to consider necessary action if no agreement is reached within six months of designation of the MBAN

¹⁶¹ Joint Parties and ASHE ex parte, filed January 30, 2012, at Appendix § 95.1615 (g)(I).

¹⁶² Further Notice at 6460, para, 84.

¹⁶³ Under our rules, the Bureau is authorized to engage "in oversight of coordinator actions and practices." 47 C.F.R. § 0.131(m).

¹⁶⁴ We direct the Bureau to incorporate the requirement that the MBAN coordinator provide the Bureau with information during investigations and provide the fee schedule upon request into the MOU between the MBAN coordinator and the Commission.

¹⁶⁵ Further Notice at 6460, para. 85.

¹⁶⁶ 47 C.F.R. § 0.131(m) (stating that the Wireless Telecommunications Bureau "[c]ertifies frequency coordinators; considers petitions seeking review of coordinator actions; and engages in oversight of coordinator actions and practices").

¹⁶⁷ ASHE Comments at 9; Philips/GE Comments at 6.

¹⁶⁸ Phillips/GE Comments at 7.

coordinator. AFTRCC asks that the Commission's selection of the MBAN coordinator be contingent on the MBAN coordinator reaching a coordination agreement with AFTRCC. 169

- 80. We adopt the proposal in the *Further Notice* and direct the Bureau to select the MBAN coordinator. Because the procedures the Bureau used in selecting the WMTS coordinator were successful, we direct it to employ a similar process to select the MBAN coordinator, including releasing a Public Notice to announce procedures for interested parties to submit applications for consideration as an MBAN coordinator, ¹⁷⁰ issuing an Order to designate the MBAN coordinator, and executing a MOU on behalf of the Commission with the selected coordinator that will set forth the coordinator's authority and responsibilities. ¹⁷¹ We anticipate that the MBAN coordinator would assume its duties upon the execution of this MOU.
- 81. We agree with Philips/GE that the MBAN coordinator and AMT coordinator should quickly reach agreement on mutually agreeable procedures to create coordination agreements. Until such procedures are in place, no registered MBAN system can be deployed. Hence, we will require the selected MBAN coordinator to report to the Commission when it has procedures in place with the AMT coordinator allowing coordination agreements for MBAN systems to be made. If no such report is made within six months of selection of the MBAN coordinator, we direct the Bureau to take all necessary action to promote such an agreement.
- 82. We decline to adopt AFTRCC's suggestion that selection of the MBAN coordinator be contingent on executing a coordination agreement with AFTRCC. In the *Report and Order*, the Commission established the rules and procedures that will allow MBAN and AMT use in the band. While it also recognized that the MBAN and AMT coordinators will have to agree on the procedures used to determine when coordination is required and how it is done, ¹⁷³ it did not suggest that AFTRCC be given a special role in selecting the MBAN coordinator. However, making selection of an MBAN coordinator contingent on executing a coordination agreement with AFTRCC would effectively allow AFTRCC to second-guess the Bureau's selection or even restrict the pool of candidates, and would not be consistent with the Commission's intent. Instead, we emphasize that it is the responsibility of both the selected MBAN coordinator and AFTRCC to cooperate in good faith in developing procedures for MBAN coordination.
- 83. <u>Petition for Rulemaking.</u> Finally, Ben Bartlett, who identifies himself as a law student at the University of California Hastings College of Law, filed a Petition for Rulemaking requesting that we allocate spectrum for MBAN use in an unused portion of the television frequency bands. ¹⁷⁴ Bartlett claims that the 2360-2400 MHz band is unsuitable for MBAN use because interference between MBAN systems and the AMT and amateur services will put patients at risk and interfere with the operation of

¹⁶⁹ AFTRCC Comments at 4.

¹⁷⁰ See, e.g., Wireless Telecommunications Bureau Opens Filing Window for Requests to Be a Frequency Coordinator in the Wireless Medical Telemetry Service, *Public Notice*, 15 FCC Rcd 19038 (2000).

¹⁷¹ WMTS Designation Order at 4551, para. 26.

¹⁷² As we stated in the *Further Notice*, "We recognize that the MBAN and AMT coordinators will have to agree to the procedures they will use to determine when coordination is required and how it is done, but we also are confident that the coordinators will be technically competent and will fully cooperate to develop mutually agreeable procedures to create coordination agreements." *Further Notice* at 6454, para. 69.

¹⁷³ First Report and Order at 6454, para. 69.

¹⁷⁴ Petition for Rulemaking by Ben Bartlett, ET Docket No. 08-59, filed Jan. 1, 2013 (*Bartlett Petition*). The unused portion of the television band that Bartlett identifies is popularly known as "TV white space" spectrum. On July 29, 2013, Bartlett re-filed his petition in ET Docket 04-186. We specify that our analysis and decision herein applies to both filings.

these services, ¹⁷⁵ that the amount of spectrum available for MBAN operations is not sufficient to meet the future demand for medical applications, ¹⁷⁶ and that the current MBAN frequencies have limited propagation characteristics compared to the TV bands. ¹⁷⁷ He envisions an expanded role for MBAN devices where patients will not be tied to a hub because the wireless link will be able to traverse long distances and pass through buildings and other obstacles. ¹⁷⁸

We conclude that the petition does not warrant further consideration at this time and dismiss it without prejudice. First, MBAN systems are designed to provide wireless monitoring of patients over short distances to provide patients with mobility in hospitals and other health care facilities. In the First Report and Order, the Commission concluded that the 2360-2400 MHz band is well suited for this purpose given the ability of MBAN devices to share with spectrum with the incumbent users. 179 Nothing in the petition gives us reason to question this conclusion. 180 Second, although the petition also asserts that the amount of spectrum we have allocated for MBAN use will not be sufficient to meet future demand, we find this claim to be speculative at best, particularly given that no MBAN devices have been deployed. Finally, the petition does not provide the technical details necessary to draw conclusions as to the feasibility of the long-range medical wireless devices that Bartlett envisions. Deployment of these types of devices may be possible under our existing rules in other frequency bands. To the extent that such devices cannot already be designed within our existing rules, the recently expanded experimental licensing process is a more suitable method for addressing the difficult engineering challenges of designing wireless links for medical applications that require high reliability and function over long distances – challenges that the petition does not address. ¹⁸¹ Also, as a practical matter, the frequencies identified in the petition are subject to our ongoing broadcast television spectrum incentive auction rulemaking proceeding. It would not serve the public interest to further complicate that complex undertaking with a proposal to expand the scope and location of MBAN operations. 182

¹⁷⁵ *Bartlett Petition* at 8-11.

¹⁷⁶ *Id*. at 6-7.

¹⁷⁷ *Id.* at 7, 12-13. The TV bands extend from 54-72 MHz, 76-88 MHz, 174-216 MHz and 470-806 MHz.

¹⁷⁸ *Id.* at 12-13.

¹⁷⁹ First Report and Order at 6430, para. 14.

¹⁸⁰ The Commission addressed the potential for harmful interference when it decided that the 2360-2400 MHz band would be suitable for short-distance communications under the MBAN concept. For example, it determined that the registration and coordination procedures put in place by the MBAN rules will minimize interference to the AMT service, and recognized that MBAN device manufacturers will "need to build robust products in order to satisfy FDA requirements and to ensure customer acceptance." *First Report and Order* at 6433, para. 19.

¹⁸¹ See Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules, ET Docket No. 10-236; 2006 Biennial Review of Telecommunications Regulations – Part 2 Administered by the Office of Engineering and Technology (OET), ET Docket No. 06-155; Report and Order, 28 FCC Rcd 758 (2013); Erratum, 28 FCC Rcd 3096 (2013), Order on Reconsideration, FCC 13-76, rel. May 29. 2013.

¹⁸² Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, GN Docket No. 12-268, *Notice of Proposed Rulemaking*, 27 FCC Rcd 12357, 12358-59, 12368, paras. 3-5, 27 (2012); *Report and Order*, FCC 14-50 (rel. Jun. 2, 2014). *See also* Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. No. 112-96, § 6403 (2012).

V. PROCEDURAL MATTERS

- 85. <u>Final Regulatory Flexibility Certification</u>. The Regulatory Flexibility Act of 1980, as amended (RFA)¹⁸³ requires that a regulatory flexibility analysis be prepared for rulemaking proceedings, unless the agency certifies that "the rule will not have a significant economic impact on a substantial number of small entities."¹⁸⁴ The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."¹⁸⁵ In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.¹⁸⁶ A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).¹⁸⁷
- In this Order on Reconsideration and Second Report and Order, the Commission addresses a number of issues related to designating the MBAN coordinator for the 2360-2390 MHz band. Among other actions, the Commission concludes to only designate one MBAN coordinator, but delegates to the Wireless Telecommunication Bureau (Bureau) the authority to possibly designate more than one coordinator at a later date. The Commission adopts a number of qualifying criteria to guide the Bureau in selecting the coordinator, such as the ability to register and maintain a database of MBAN transmitter locations, knowledge of wireless systems in healthcare facilities and of AMT operations, and the ability to calculate and measure interference potential between MBAN and AMT operations. The Commission also adopts a rule requiring that the MBAN coordinator provide registration and coordination to all eligible healthcare facilities on a non-discriminatory basis, provide the registration and coordination services on a not-for-profit basis, notify the Commission six months prior to ceasing to perform the functions of frequency coordinator, and transmit the MBAN registration data in a usable form to another coordinator designated by the Commission if it ceases to be the frequency coordinator. While the decisions made and rules adopted in the Order on Reconsideration and Second Report and Order could have a significant economic impact on the MBAN coordinator, the Commission has decided to designate only one MBAN coordinator. Although the Commission does allow the Bureau to possibly designate multiple coordinators at a later date, we do not foresee there ever being more than a couple of MBAN coordinators.
- 87. The Commission also addresses several issues related to MBAN users. First, the revisions to the authorized location rule will not increase the number of health care facilities that can use the 2360-2390 MHz band, and therefore will not impose regulatory burdens on any new small entities. Second, in the Report and Order, the Commission originally declined to require registration for the 2390-2400 MHz band users because it concluded that such a requirement "would unnecessarily burden hospitals that do not need assistance from the MBAN coordination." Under the revised registration requirement we are adopting, the scope is narrower and it targets only those hospitals that may eventually need to interact with MBAN coordinator. We find that the benefit of providing the MBAN coordinator

The RFA, *see* § 5 U.S.C. S 601 *et. seq.*, has been amended by the Contract With America Advancement Act of 1996, Pub. L. No. 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

¹⁸⁴ 5 U.S.C. § 605(b).

¹⁸⁵ 5 U.S.C. § 601(6).

¹⁸⁶ 5 U.S.C. § 601(3) (incorporating by reference the definition of "small business concern" in Small Business Act, 15 U.S.C. S § 632). Pursuant to 5 U.S.C. § 601(3), the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register."

¹⁸⁷ Small Business Act, § 15 U.S.C. S 632.

with this additional information outweighs the slight increase in registration costs for this limited number of MBAN operators. In addition, we find that the increase in registration costs is minor, and therefore will not have a significant economic impact on a substantial number of small entities. Lastly, the remaining revisions to Section 95.1223 do not change the regulatory burden on small business health care facilities; they merely clarify the rules and do not have a significant economic impact on any new small entities.

- 88. Therefore, we certify that the requirements of this *Order on Reconsideration and Second Report and Order* will not have a significant economic impact on a substantial number of small entities. The Commission will send a copy of the *Order on Reconsideration and Second Report and Order* including a copy of this final certification, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, *see* 5 U.S.C. § 801(a)(1)(A). In addition, the *Order on Reconsideration and Second Report and Order* and this certification will be sent to the Chief Counsel for Advocacy of the Small Business Administration, and will be published in the Federal Register. *See* 5 U.S.C. § 605(b).
- 89. <u>Congressional Review Act.</u> The Commission will send a copy of this Order on Reconsideration and Second Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).
- 90. <u>Paperwork Reduction Act.</u> This document contains new and modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. The requirements will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. The Commission will publish a separate notice in the Federal Register inviting comment on the new or revised information collection requirements adopted in this document. The requirements will not go into effect until OMB has approved them and the Commission has published a notice announcing the effective date of the information collection requirements.
- 91. <u>Further Information.</u> For further information, contact Jamison Prime, Office of Engineering and Technology, at (202) 418-7474, or Brian Butler, Office of Engineering and Technology, at (202) 418-2702, Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554; or via the Internet at Jamison.Prime@fcc.gov or Brian.Butler@fcc.gov, respectively.

VI. ORDERING CLAUSES

- 92. Accordingly, IT IS ORDERED that, pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 301, 302a, 303(e), 303(f), 303(r), and 307(e), this Order on Reconsideration and Second Report and Order IS ADOPTED.
- 93. IT IS FURTHER ORDERED that the rules and requirements adopted herein WILL BECOME EFFECTIVE [thirty days after the date of publication in the Federal Register], except for 47 C.F.R. § 95.1225(c), which includes new or modified information collection requirements that require approval by OMB under the PRA and WILL BECOME EFFECTIVE after such approval, on the effective date specified in a notice that the Commission publishes in the Federal Register announcing such approval and effective date.
- 94. IT IS FURTHER ORDERED that pursuant to the authority of Section 5(c) of the Communications Act of 1934, as amended, 47 U.S.C. Section 155(c), we delegate authority to the Wireless Telecommunications Bureau as set forth in this Second Report and Order.
- 95. IT IS FURTHER ORDERED that the Petition for Rulemaking filed by Ben Bartlett in ET Docket Nos. 08-59 and 04-186 is DENIED.
- 96. IT IS FURTHER ORDERED that the Joint Petition for Reconsideration of GE Healthcare, Phillips Healthcare, and the Aerospace and the Flight Test Radio Coordinating Council is GRANTED IN PART and DENIED IN PART.

- 97. IT IS FURTHER ORDERED that the Petition for Reconsideration of The American Society for Healthcare Engineering of the American Hospital Association is GRANTED.
- 98. IT IS FURTHER ORDERED that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this *Order on Reconsideration and Second Report and Order*, including the Final Regulatory Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch Secretary

APPENDIX

Final Rules

PART 95 – PERSONAL RADIO SERVICES

SUBPART E – TECHNICAL REGULATIONS

1. The authority citation for Part 95 is revised to read as follows:

Authority: 47 U.S.C. 154, 301, 302(a), 303, and 307(e).

2. Section 95.628 of the rules is amended by revising paragraph (c) as follows:

§ 95.628 MedRadio transmitters in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz and 2360-2400 MHz bands.

* * * * *

(c) A MedRadio programmer/control transmitter and its associated medical body-worn transmitters shall not commence operating in, and shall automatically cease operating in, the 2360-2390 MHz band if the programmer/control transmitter does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation. Medical body-worn transmitters shall cease operating in 2360-2390 MHz if they lose communication with their associated programmer/control transmitter. Additionally, a MedRadio programmer/control transmitter and its associated medical body-worn transmitters operating in the 2360-2390 MHz band shall comply with a control message that notifies the devices to limit transmissions to segments of the 2360-2390 MHz band or to cease operation in the band.

* * * * *

3. Appendix 1 is amended by modifying the definition "Medical Body Network" as follows:

Appendix 1 to Subpart E of Part 95—Glossary of Terms

Medical Body Area Network (MBAN). An MBAN is a low power network consisting of a MedRadio programmer/control transmitter and one or more multiple medical body-worn devices all of which transmit or receive non-voice data or related device control commands for the purpose of measuring and recording physiological parameters and other patient information or performing diagnostic or therapeutic functions via radiated bi- or uni-directional electromagnetic signals.

SUBPART I – MEDICAL DEVICE RADIOCOMMUNICATIONS SERVICE (MEDRADIO)

4. Section 95.1203 of the Rules is amended as follows:

§95.1203 Authorized locations.

MedRadio operation is authorized anywhere CB station operation is authorized under §95.405, except that use of Medical Body Area Network devices in the 2360-2390 MHz band is restricted to indoor operation within a health care facility registered with the MBAN coordinator under §95.1225. For the purposes of this subpart, health care facilities are limited to hospitals and other establishments, both Federal and non-Federal, that offer services, facilities and beds for use beyond a 24 hour period in rendering medical treatment.

5. Section 95.1209 is amended by revising paragraph (g) as follows:

§ 95.1209 Permissible communications.

* * * * *

(g) Medical body-worn transmitters may relay only information in the 2360-2400 MHz band to a MedRadio programmer/control transmitter or another medical body-worn transmitter device that is part of the same Medical Body Area Network (MBAN). A MedRadio programmer/control transmitter may not be used to relay information in the 2360-2400 MHz band to other MedRadio programmer/controller transmitters. Wireless retransmission of all other information from an MBAN transmitter to a receiver that is not part of the same MBAN shall be performed using other radio services that operate in spectrum outside of the 2360-2400 MHz band. Notwithstanding the above restriction, a MedRadio programmer/control transmitter in the 2360-2400 MHz band may communicate with another MedRadio programmer/control transmitter in the 2360-2400 MHz band to coordinate transmissions so as to avoid interference between the two Medical Body Area Networks.

* * * * *

6. Section 95.1213 is revised as follows:

§ 95.1213 Antennas

- (a) An antenna for a MedRadio transmitter shall not be configured for permanent outdoor use.
- (b) Any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.
- (c) Paragraphs (a) and (b) of this Section do not apply to MedRadio operations in the 2390-2400 MHz band.
- 7. Section 95.1223 is amended by revising the section title, introductory language in paragraph (a), and paragraphs (a)(3), (a)(5), and (b) to read as follows:

§ 95.1223 Registration and Frequency Coordination

(a) Prior to operating MBAN devices that are capable of operation in the 2360-2390 MHz band, a health care facility, as defined by § 95.1203, must register with a frequency coordinator designated under § 95.1225 of this chapter. Operation of MBAN devices in the 2360-2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that registration and coordination (to the extent coordination is required under paragraph (c)) is complete. The registration must include the following information:

* * * * *

(3) Number of MedRadio programmer/control transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;

* * * * *

(5) Location of MedRadio programmer/control transmitters (*e.g.*, geographic coordinates, street address, building);

* * * * *

(b) *Notification*. A health care facility shall notify the frequency coordinator whenever an MBAN programmer/control transmitter in the 2360-2390 MHz band is permanently taken out of service, unless it is replaced with transmitter(s) using the same technical characteristics and locations as those reported on

the health care facility's registration which will cover the replacement transmitter(s). A health care facility shall keep the information contained in each registration current and shall notify the frequency coordinator of any material change to the MBAN's location or operating parameters. In the event that the health care facility proposes to change the MBAN's location or operating parameters, the MBAN coordinator must first evaluate the proposed changes and comply with paragraph (c) of this Section, as appropriate, before the health care facility may operate the MBAN in the 2360-2390 MHz band under changed operating parameters.

* * * * *

8. Section 95.1225 is amended by revising paragraphs (a) and (b)(1) and adding new paragraph (c) as follows:

§ 95.1225 Frequency coordinator.

- (a) The Commission will designate a frequency coordinator(s) to manage the operation of medical body area networks by eligible health care facilities.
- (b) The frequency coordinator shall perform the following functions:
 - (1) Register health care facilities that operate MBAN transmitters, maintain a database of these MBAN transmitter locations and operational parameters, and provide the Commission with information contained in the database upon request;

* * * * *

- (c) The frequency coordinator shall:
- (1) Provide registration and coordination of MBAN operations to all eligible health care facilities on a non-discriminatory basis;
 - (2) Provide MBAN registration and coordination services on a not-for-profit basis;
- (3) Notify the Commission of its intent to no longer serve as frequency coordinator six months prior to ceasing to perform these functions; and
- (4) Transfer the MBAN registration data in usable form to a frequency coordinator designated by the Commission if it ceases to be the frequency coordinator.