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Federal Communications Commission  
Office of the Secretary

Before the  
**FEDERAL COMMUNICATIONS COMMISSION**  
Washington, D.C. 20554

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Federal Communications Commission  
Office of the Secretary

In the Matter of )

**BEN BARTLETT** )

Petition for Rulemaking for the Allocation of MBAN )  
Frequency in the TV White Space Spectrum )

ET Docket No. 08-59

**PETITION FOR RULEMAKING BY BEN BARTLETT**

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January 1, 2013

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**PETITION FOR RULEMAKING**

Pursuant to § 254 (c)(1) of the Telecommunications Act of 1996, I urge the Federal Communication Commission (“ FCC”) to take an important step towards improving the state of health care delivery by undertaking a rulemaking to allocate frequency in the TV White Space spectrum for Medical Body Area Networks (“MBAN’s”). I propose that only those persons who meet the Food and Drug Administration (“FDA”) standards for wireless telemedicine devices be granted spectrum. As detailed below, this new allocation would serve the public interest, convenience, and necessity.

**I. INTRODUCTION AND SUMMARY**

I am a second year law student at the University of California, Hastings College of the Law studying teleHealth applications. This petition for rulemaking encourages the allocation of new MBAN frequencies and proposes a methodology for their sustainable deployment. The current allocations in traditional wireless space are limiting and present hazardous interference challenges, thus threatening the policy goals set forth in the National Broadband Plan regarding Universal Access and Health. Furthermore, the current system of approval of MBAN devices is unclear and subject to liability. The proposed “Bartlett rule” can both fulfill FCC policy goals by increasing telehealth coverage and encourage industry participation by streamlining the MBAN

approval process. FCC has the power to enact the Bartlett rule according to statute, ancillary enhanced jurisdiction, and Chevron deferential jurisdiction.

## **II. BACKGROUND**

### **A. Utility of Telehealth/MBAN Technology**

The U.S. spends 17% of its GDP on medical costs. Much of this cost can be defrayed by the deployment of Telehealth and MBAN technology<sup>1</sup>. Telehealth is the use of telecommunications and information technologies to meet healthcare needs in diverse areas such as medical intervention, prevention, care management, education, administrative tasks, records, imaging and prescriptions. Some applications include Real Time Video Consultations, Medical Imaging and Remote Patient Monitoring. Telecommunications technology is facilitating an unprecedented exchange of diagnostic information between health care practitioners and patients<sup>2</sup>.

The Telehealth industry is driven by the need for providers and insurers to reduce costs, improve care and increase coverage for low income people. At this point there are more than 200 telehealth networks in the United States, connecting more than 2000 medical institutions. The FCC has recognized the benefits of the telehealth trend and has become a partner in its development. The FCC has dedicated over 400 million dollars for the creation of sixty nine regional telehealth networks across forty two states under its Rural Health Program<sup>3</sup>. Adoption is

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<sup>1</sup> <http://manhattanresearch.com/Infographic-Images/data-snapshot-taking-the-pulse-us-image>

<sup>2</sup> *High Blood Pressure Patients Advised to Use Home Monitors*. The American Heart Association. <http://americanheart.mediaroom.com/index.php?s=43&item=425>. 5/22/08)

<sup>3</sup> [apps.fcc.gov/ecfs/comment/view?id=6017041412](http://apps.fcc.gov/ecfs/comment/view?id=6017041412)

happening as indicated by the fact that seventy five million people used their mobile phones for health information and tools so far this year<sup>4</sup>.

In recognition of this trend, FCC has embraced the next frontier in lifesaving technologies by creating Medical Body Area Networks or MBAN's. On May 24, 2012 the FCC announced that it was adopting rules to enable the allocation of bandwidth spectrum for MBAN technology. The FCC laid bare its motivations: "This platform will enhance patient safety, care and comfort by reducing the need to physically connect sensors to essential monitoring equipment by cables and wires....As the numbers and types of medical radio devices continue to expand, these technologies offer tremendous power to improve the state of health care in the United States<sup>5</sup>."

Medical Body Area Network is a term used to describe the medical application of wearable computing devices. Recent technological advances have resulted in the feasibility of low power physiological sensors that can operate from inside the human body. The sensors may be implanted, worn outside the body or ingested in the form of a pill. Once there, the sensors' signals can be integrated into a wireless Medical Body Area Network from which they will send and receive medical information around the world, seamlessly and in real time. Potential applications include: controlling of heart rhythms, monitoring hypertension, providing functional electrical stimulation of nerves for stroke and paralysis victims, operating as glaucoma sensors, monitoring bladder and cranial pressure, monitoring vital signs, assisting the movement of

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<sup>4</sup> *Manhattan Research's Cybercitizen Health® U.S. 2012 study*  
<http://manhattanresearch.com/News-and-Events/Press-Releases/multiscreen-health-activity> )

<sup>5</sup> ET Docket No. 08-59 Spectrum for the Operation of Medical Body Area Networks

artificial limbs, drug delivery, in-home EEG readings and cell phone based insulin measurement and delivery. MBAN applications are limited only by the imagination<sup>6</sup>.

### **III. PROBLEMS WITH THE CURRENT MBAN ALLOCATION**

With more than four billion cell phone users, ubiquitous Broadband 3G, state of the Art sensors, smartphones and pervasive connectivity, the conditions are ripe for a health revolution of historic proportions. However, for the benefits of telehealth to be realized, it is critical that the FCC make more spectrum. By limiting the MBAN frequencies to the Broadband spectrum, the FCC has created impediments to the program's growth and exposed participants and providers to undue risk. Broadband has small frequency waves that may be interrupted in transit. Further, the MBAN frequencies are located next to experimental which may result in dangerous interference.

#### **A. The Existing MBAN Spectrum Allocation Is Inadequate**

The FCC has allocated 40 MHz of spectrum in 2360 –2400 MHz. All MBAN use of the 2360-2390 MHz band will be restricted to indoor operation at healthcare facilities; while use of the MBAN devices that operate in the 2390-2400 MHz will be available for use outdoors and in residences<sup>7</sup>. FCC efforts to find available space within the Broadband spectrum were stymied by the overall lack of available bandwidth. The limited capacity and narrow range of frequency is likely to have adverse consequences for the future of MBAN. The MBAN technology is geared to fundamentally transform multiple sectors of society, even beyond medicine. The FCC stated as much in its ruling when it said that the MBAN order “is intended to spur development in other

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<sup>6</sup> *ET Docket No. 08-59 Spectrum for the Operation of Medical Body Area Networks*

<sup>7</sup> <http://www.healthcare-informatics.com/news-item/fcc-dedicates-spectrum-wireless-monitoring-devices>

industries.”<sup>8</sup> The spectrum limitations are evident when one considers that the present penetration of medical facilities is minimal and is likely to grow exponentially as cost savings are realized. Even more alarming is the fact that residential use has only been allocated a maximum 10 MHz of frequency. At the time of the ruling, residential MBAN use was virtually nonexistent. But again, as cost savings and better delivery of care are realized, the rate of adoption by citizens should grow rapidly. Insurance carriers will incentivize the in-home use of MBAN technology in order to reduce hospital visits. Also, in light of the notable shortage of doctors,<sup>9</sup> MBAN will lead to the widespread practice of remote patient monitoring via a telecommunication interface. FCC is not serious in presuming that 10 MHz will be able to accommodate the potential user base represented in the United States 350 million plus population. If the spectrum for MBAN use remains this narrow, growth be hampered and the entire MBAN project may suffer extraordinary setbacks. When the available spectrum reaches capacity the FCC will be forced to attempt to locate more frequency in an already crowded spectral environment. Such a move would require the industry to reset its practices after significant investment; potentially hobbling efforts to deliver innovative and affordable care.

#### **B. Broadband Frequencies Have Limited Reach**

Broadband networks can be unstable. Broadband has small frequency waves, thus limiting the geographical and temporal reach of the MBAN devices. Wireless reception may be impaired by a number of factors. Signal attenuation may occur from long distance communication. Interference from other wireless networks may disrupt signals. Further, trees and terrain pose obstacles to the Broadband frequencies<sup>10</sup>. These disruptive effects are similar to the "black spots" experienced by cell phone users where coverage lapses. Such outages of

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<sup>8</sup> Id.

<sup>9</sup> <http://www.ama-assn.org/amednews/2012/10/08/pr111008.htm>

<sup>10</sup> [http://transition.fcc.gov/stage/pdf/Berkman\\_Center\\_Broadband\\_Study\\_13Oct09.pdf](http://transition.fcc.gov/stage/pdf/Berkman_Center_Broadband_Study_13Oct09.pdf)

coverage can be frightening when dealing with health issues. The prospect of an MBAN connected pacemaker experiencing a loss of signal while the patient is driving alongside a mountain is a chilling prospect. The inevitable tragedies that will occur as a result of Broadband signal limitations may result in prohibitively high insurance rates and costly litigation. Also consumer adoption of MBAN technology may be slowed due to inconvenience. In order to prevent distance disruption of their life saving signals, patients would have to remain within feet of router like hubs at all times.

### **C. Placing The MBAN Frequency At The Current Range May Result In Hazardous Signal Interference**

The FCC has created potential liabilities by placing MBAN frequencies next to aircraft frequencies. Interference is any unwanted radio frequency signal that prevents a signal from being received and/or communicated. Interference may prevent reception altogether or may cause only a temporary loss of a signal. In its most benign form, interference affects the quality of image on a television or the sound on a radio. It may cause garage door openers to malfunction or distort cordless phone reception<sup>11</sup>. More alarmingly, interference may result in catastrophic events like planes losing contact with air traffic control towers.

The FCC has allocated MBAN spectrum bandwidth in the 2,360MHz to 2,400MHz range. This spectrum, previously reserved for commercial test pilots, will now be used in hospitals, clinics and doctors' offices. Inexplicably, the FCC has placed the test pilot frequency at the adjoining band so that the two frequencies now abut one another<sup>12</sup>. Title 47 of the Code of Federal Regulations contains a general provision that devices may not cause interference. It also prohibits the operation of devices once the operator is notified by the FCC that the device is

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<sup>11</sup> <http://www.fcc.gov/guides/interference-defining-source>

<sup>12</sup> *Genachowski in his remarks at George Washington University.* <http://www.eweek.com/c/a/Health-Care-IT/FCC-Proposes-New-Wireless-Spectrum-for-Medical-Monitoring-898301>

causing interference<sup>13</sup>. Specifically, it states: “(b) Operation of an intentional, unintentional, or incidental radiator is subject to the conditions that no harmful interference is caused . . . (c) The operator of a radio frequency device shall be required to cease operating the device upon notification by a Commission representative that the device is causing harmful interference.”<sup>14</sup> Title 47 Operation shall not resume until the condition causing the harmful interference has been corrected.

Placing the MBAN frequency next to the frequency used by pilots is likely to result in violating the rules against Interference. The MBAN will be subject to the requirements of section (b) of the CFR. MBAN devices may only operate "subject to the condition that no harmful interference is caused. If an insulin device was demonstrated to interfere with an adjoining frequency, it would be necessarily be in violation of the code. Further, section (c) would require the insulin injecting device *to cease operation*. This turn of events would imperil dependent users of the technology. Also, if the MBAN signal was to cause the downing of a plane, the result would not only contribute to large scale loss of life and capital investment by providers; it would place the entire MBAN project in jeopardy. Such a scenario is entirely plausible as evidenced FCC’s recently levied fine against AT&T. AT&T was found to be in violation of C.F.R. section 15 (b) and (c) by operating a Wi-Fi device that caused interference with an airport radar station in Puerto Rico. AT&T was fined \$25,000 and ordered to cease transmission<sup>15</sup>.

Before creating MBAN, FCC fielded comments from numerous concerned parties within the aerospace industry. The Aerospace and Flight Test Radio Coordinating Council (“AFTRCC”) feared that MBAN devices would be unable to share the bandwidth with existing

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<sup>13</sup> 47 C.F.R. 15.5d

<sup>14</sup> Id.

<sup>15</sup> <http://www.commlawblog.com>

primary Aerospace Mobile Telemetry (“AMT”) operations<sup>16</sup>. Additionally, Boeing Company<sup>17</sup> and Cessna Aircraft Company expressed serious concerns about the impact of MBAN operation on aircraft<sup>18</sup>. In all the FCC received twenty nine comments regarding the MBAN allocation. The National Association for Amateur Radio (“ARRL”) claimed that MBAN operations could be Incompatible with incumbent amateur licensee use<sup>19</sup>, and several parties questioned whether the MBAN spectrum proposal would inhibit Wi-Fi, Bluetooth and other unlicensed devices that currently enjoy widespread, popular use<sup>20, 21, 22, 23</sup>.

After much discussion, the Aerospace companies agreed to the MBAN project on the condition that MBAN users agree to register and coordinate use of the spectrum. The amateur radio enthusiasts had to accept a new level of interference as the FCC ruled that the public interest in health outweighed their concerns. The FCC did not, however, address the other stated concerns regarding Bluetooth and Wi-Fi<sup>24</sup>.

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<sup>16</sup> <http://apps.fcc.gov/ecfs/comment/view?id=6017091328>

<sup>17</sup> See e.g., Comments of AFTRCC, filed October 5, 2009, at i-ii (AFTRCC Comments); Comments of the Boeing Company, filed October 5, 2009, at ii-iii (Boeing Comments).

<sup>18</sup> Boeing Company ex parte, filed May 24, 2011; Cessna Aircraft Company ex parte, filed June 9, 2011.

<sup>19</sup> Comments of IEEE 802 Local and Metropolitan Area Networks Standards Committee, filed July 27, 2009.

<sup>20</sup> Specifically, ARRL was opposed to MBAN operation in the 2300-2305 MHz, 2390-2400 MHz, 2400-2402 MHz, and 2402-2417 MHz bands. See Comments of ARRL, the National Association for Amateur Radio, filed October 5, 2009 (ARRL Comments).

<sup>21</sup> See Comments of the Wi-Fi Alliance, filed October 2, 2009 (Wi-Fi Alliance Comments) and Comments of the Blue Tooth Special Interest Group filed August 31, 2009 (listed as "Mike Foley" in the ECFS).

<sup>23</sup> See Comments of the Telecommunications Industry Association, filed October 5, 2009 (stating that the proposed MBAN use of the 2360-2400 MHz band should not go forward absent extensive interference tests.

<sup>24</sup> <http://www.gyvernetworks.com/TechBlog/tag/fcc/>

The FCC claims that its priority is to ensure that wireless medical devices, like all other radio frequency devices, operate compatibly with other spectrum users. To that end, FCC allocates space along the spectrum accordingly, taking care to avoid signal conflicts<sup>25, 26</sup>.

However, by placing the MBAN frequencies at 2,360MHz to 2,400MHz, FCC has placed the MBAN bandwidth signal in conflict with aeronautical channels. This puts planes, passengers and people on the ground in danger. It also puts our most vulnerable, the infirmed, in peril. Bandwidth conflicts here, could result in the discrediting of the MBAN project, and ruin this multi-billion dollar market. To assume that the signals will not interfere with one another, or that if they do, it will be minor, is to court disaster.

FCC should allocate alternative spectrum for MBAN technology. The viability of MBAN depends on its allotted spectrum to not prematurely reach capacity and for MBAN signals to not disrupt air traffic.

#### **IV. TV WHITE SPACE SPECTRUM IS AN OPTIMUM ALTERNATIVE TO BROADBAND MBAN SPECTRUM**

TV White Space provides an acceptable alternative forum for MBAN because it does not have many of the inherent limitations and risks of traditional Broadband.

##### **A. TV White Space Background**

TV White Space refers to frequencies allocated to a broadcasting service but not used locally. Specifically, they are the space between channels and are meant to act as buffers between channels to prevent destructive interference. In particular, the historic switchover to digital television has freed up large areas of spectrum between 50 MHz and 700 MHz. It is in these open "White Spaces" that the FCC should create an MBAN frequency.

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<sup>25</sup> <http://www.fcc.gov/document/medical-body-area-networks-first-report-and-order>

<sup>26</sup> <http://www.eweek.com/c/a/Health-Care-IT/FCC-Proposes-New-Wireless-Spectrum-for-Medical-Monitoring>

The rules governing the use of unlicensed devices in TV White Spaces went into effect Jan. 5, 2011. These rules, adopted by FCC allow unused TV airwaves to be used for wireless broadband<sup>27</sup>.

The FCC created the TV White Space spectrum in order to spur development. "This type of "opportunistic use" of spectrum has great potential for enabling access to other spectrum bands and improving spectrum efficiency. The Commission's actions here are expected to spur investment and innovation in applications and devices that will be used not only in the TV band but eventually in other frequency bands as well<sup>28</sup>."

## **B. Advantages of TV White Space**

TV White Space offers significant advantages to traditional Broadband in the areas of growth, reliability, capacity, interference, and policy.

### **i. Growth**

TV White Space has near unlimited potential for growth as a result of the abundance of channels made available after the switch from analog to digital. This addresses the problem that MBAN faces in Broadband regarding restraints on growth.

### **ii. Reliability**

TV White Space frequency is an ultra-low bandwidth so its waves are stronger and maintain their integrity without degrading despite traveling long distances. They also are able to pass through obstacles like trees, buildings and mountains. Medical data will be able flow unimpeded, irrespective of barriers and weather. Patients will have total mobility and need not be

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<sup>27</sup> <http://www.scribd.com/doc/89730748/IEEE-802-22-Standard-Approved-for-White-Space-Development>

<sup>28</sup> From the federal register Federal Communications Commission 47 CFR Parts 0 and 15 Unlicensed Operation in the TV Broadcast Bands; Final Rule.

tied to a hub. This notable advantage over Broadband will allow for greater reliability of life saving services and will afford more freedom to the end user.

### **iii. Capacity**

The TV White Space low frequency waves are able to carry more information than broadband waves. This capability will allow for the adoption of more adventurous applications such as the signal relays to make paralyzed muscles move again, or remote stroke diagnosis and treatment.

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#### **iv. Interference**

Initial fears that TV White Space frequencies would interfere with certain frequencies such as the one for wireless microphones have been shown to not be of concern. Technical studies<sup>29</sup> show that properly controlled unlicensed devices can use these channels without causing interference to TV operation and other authorized users, including wireless microphones<sup>30</sup>. FCC detailed new operating guidelines intended to alleviate risks of interference<sup>31, 32</sup>.

#### **v. Policy**

TV White Space signals will serve FCC objectives as laid out in the Rural Health Care Plan<sup>33</sup>. The extensive geographic reach of the TV White Space signals would allow rural populations to engage with a wide spectrum of medical services from more developed parts of the country, thus helping to mitigate regional healthcare disparities<sup>34</sup>.

#### **C. TV White Space TeleHealth Feasibility Has Been Demonstrated**

Telehealth applied to TV White Space has already been successfully demonstrated. Google<sup>35</sup> and Spectrum Bridge participated in a joint demonstration project at the Hocking Valley Medical Center in Logan, Ohio. They set up a TV White Space broadband network for the twenty five bed medical facility. The project seamlessly connected data transmissions between first responder emergency medical services and the hospital campus. It created indoor broadband access throughout the hospital, linking patient rooms, waiting areas, meeting rooms

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<sup>29</sup> <http://www.businesswire.com/news/home/20100914005980/en/TV-White-Spaces-Delivering-Enhanced-Broadband-Access>

<sup>30</sup> 33 Federal Register / Vol. 77, No. 96 / Thursday, May 17, 2012 / Rules and Regulations

<sup>31</sup> <http://www.commlawblog.com/2012/04/articles/broadcast/fcc-adjusts-white-space-rules/>

<sup>32</sup> <http://whitespaces.spectrumbridge.com/WhiteSpacesSolutions/WirelessMics.aspx>

<sup>33</sup> <http://www.broadband.gov/plan/10-healthcare/>

<sup>34</sup> [http://www.economist.com/blogs/babbage/2010/09/white-space\\_wireless](http://www.economist.com/blogs/babbage/2010/09/white-space_wireless)

<sup>35</sup> <http://mobihealthnews.com/8913/google-eyes-white-space-for-wireless-health/>

and the cafeteria. For the first time, signals were able to be received despite the presence of walls and other obstacles<sup>36</sup>. The TV White Space broadband telemedicine pilot was a success. It resulted in increased efficiency, saving resources and increased capabilities to save lives<sup>37</sup>.

FCC has recognized the success of the Hocking Valley program by announcing plans to allow more parties to enter the TV White Space spectrum<sup>38</sup>. The first White Space Broadband initiative was launched in January 2012 in Hanover, North Carolina<sup>39</sup>.

I propose that FCC bolster this new TV White Space plan with a Telemedicine MBAN frequency ruling.

## **V. THE BARTLETT RULE MUST COMPORT WITH EXISTING INTER-AGENCY REQUIREMENTS**

FCC should create an MBAN frequency in the TV White Space spectrum. In order to ensure the viability of the program, FCC should address the following interagency issues before constructing the parameters of the MBAN telehealth frequencies. FCC should minimize the risk of vendors not being accepted by unifying the permitting process. FCC should establish a permit regime that answers all the interagency issues at once. This is important because providers must have an established protocol and a clear pathway to realize their investments in the technology.

### **A. FCC Should Require FDA Approval For TV White Space MBAN Providers**

Wireless medical devices require both FCC certification and FDA authorization before it can be marketed in the U.S.<sup>40</sup>. FDA's goal is to ensure that all medical devices are safe and

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<sup>36</sup> The technology has allowed for easier transfer of data between walls that had impeded earlier efforts to transmit data, *InformationWeek* reports (Gardner, *InformationWeek*, 9/24).

<sup>37</sup> <http://spectrumbridge.com/ProductsServices/WhiteSpacesSolutions/success-stories/logan.aspx>

<sup>38</sup> <http://www.ihealthbeat.org/articles/2010/9/27/fcc-approval-of-white-spaces-opens-door-for-health-care-wifi-use.aspx#ixzz29bdReyR>

<sup>39</sup> [http://triad.news14.com/content/local\\_news/652981/new-hanover-county-leads-way-in--white-space--technology](http://triad.news14.com/content/local_news/652981/new-hanover-county-leads-way-in--white-space--technology)

effective for use. Included in FDA's definition of medical devices are products directly related to the telehealth sector. Examples include cell phone applications that remind people to take medicine, mobile information networks, medical conferencing, software that is created for telehealth purposes and radiological medical imaging devices<sup>41, 42</sup>.

FDA has created a telehealth device classification scheme that is based on risk. Low risk devices are Class 1 and may be marketed without FDA approval. The Class 1 devices are still subject to overall general requirements such as labeling and quality control<sup>43</sup>.

The next level of review is for Class 2 devices. Here is where the majority of telemedical devices ultimately reside. In order to be allowed into market, the Class 2 devices must be shown to be "substantially equivalent" to another device that is lawfully on the market. Class 3 devices are newer devices, and because of their higher risk, FDA requires proof via clinical trials that the devices are safe and effective.

FDA and the FCC may have divergent views on certain devices. Implementing a successful MBAN plan in the TV White Space will likely involve the introduction of many Class 3 devices. FCC should harmonize its approval process with FDA's so that by the time a vendor has been granted spectrum it may invest with confidence that its FDA mandated safety obligations have been met.

To ease harmonization of FDA and FCC approval regimes FCC should align its processes with the FDA's newly released telehealth standards. In 2007 FDA issued guidance for

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<sup>40</sup> <http://www.telehealthresourcecenter.org/toolbox-module/food-and-drug-administration-and-state-regulations>

<sup>41</sup> Id.

<sup>42</sup> <http://www.americantelemed.org/i4a/pages/index.cfm?pageID=3311>

<sup>43</sup> <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>

manufacturers in the telehealth sector<sup>44</sup>. The eight controlling areas are: Risk Management, Design and Development Verification<sup>45</sup>, Design and Development Validation, Labeling, Purchasing Controls and Acceptance, Corrective and Preventative Action and Servicing<sup>46 47 48 49 50 51</sup>. Each of these eight steps should be integrated into the FCC MBAN TV White Space vendor application.

### **B. FDA Approval Is Required For Centers For Medicaid And Medicare Services (“CMS”) Reimbursement**

In order for telehealth providers to be reimbursed for covering the more than 43 million elderly and low income patients, the MBAN devices must meet certain guidelines. Under section 1862(a)(1) of the Medicare law of 1965, the CMS division of the Department of Health and Human Services must determine that the device provides "reasonable and necessary care". Neither Congressional statute nor case law gives a positive determination of what "reasonable and necessary care" is defined as. However, the Health Care Financing Agency (“HCFA”) may provide guidance.

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<sup>44</sup> Incorporating medical devices - Part 1: Roles, responsibilities and activities  
Electrostatic Discharge Association (ESD Association) ANSI/ESD-S20.20-1999, ESD  
Association Standard for the Development of an Electrostatic.

<sup>45</sup> Future AAMI/IEC 80001-01 1ed., 31-Jul-09 Application of risk management for IT Networks

<sup>46</sup> <http://www.aami.org/> Association for the Advancement of Medical Instrumentation (AAMI)

<sup>47</sup> AAMI TIR No. 18-1997, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers—Part 1: Radiated Radio-Frequency Electromagnetic Energy.

<sup>48</sup> ANSI/AAMI PC69:2000, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators.

<sup>49</sup> ANSI/AAMI/IEC 60601-1-2:2001, Medical Electrical Equipment—Part 1–2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.

<sup>50</sup> ANSI C63.18, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio- Frequency Transmitters.

<sup>51</sup> ANSI C63.19, American National Standard for Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids.

HCFA has promulgated regulations setting forth criteria and procedures for making coverage decisions about health care technology<sup>52</sup>. HCFA has set forth prospective payment limits for health care services including those related to new technology<sup>53</sup>. The regulations define a reasonable and necessary service as one which is safe and effective, cost-effective, appropriate, and not experimental or investigational. A provision of the rule categorizes a medical device that has not been approved by the FDA as being experimental or investigational and hence not reimbursable under the reasonable and necessary standard<sup>54</sup>.

This makes sense in light of the fact that the Medicare law was "designed generally to cover services ordinarily furnished by hospitals, skilled nursing facilities, and physicians"<sup>55, 56, 57</sup>. CMS has also indicated that it views telehealth projects in a favorable light. On July 2, 2011, CMS issued its final rule regarding telemedicine. It allows for hospitals and medical facilities to accept the "credentialing and privileging decisions made by distant-site telemedicine entities" for individual physicians or physician practitioners asked to provide telemedicine services<sup>58</sup>.

FCC can eliminate much of the risk faced by MBAN telemedicine providers by restricting approval of licenses to only those entities that have been approved by FDA. Since CMS bases its determinations of "reasonable and necessary care" on preceding FDA approval,

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<sup>52</sup> Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology." 54 FR 4302.4307. January 30, 1989 and 42 CER s405.380, s405.381, s405.382, and s 405.383 (1989)

<sup>53</sup> See "Medicare: Technology Assessment and Medical Coverage Decisions," GAO Reports, July 21, 1994 and 42 U.S.C. § 1395ww(d).

<sup>54</sup> 42 CFR s 405380(b)(2)(iii)

<sup>55</sup> 54FR430243(04

<sup>56</sup> Practicing Law Institute, "Public Health Care Reimbursement Programs," Health Care Law p.206 (1993).

<sup>57</sup> PROs determine whether health care services provided to Medicare beneficiaries were "of a quality which meets professionally recognized standards of health care," 42 U.S.C. § 1320c-5.

<sup>58</sup> <http://www.healthcarereforminsights.com/2011/05/26/final-rule-streamlines-telemedicine-credentialing-privileging-process/>

MBAN providers under the proposed rule will have an unambiguous means of realizing their investment by meeting CMS reimbursement standards.

Reliance upon FDA approval in making coverage decisions may help avoid additional uncertainty and duplication in a technology assessment system which is already overburdened. Furthermore, the proposed rule permits FCC to make use of FDA expertise, resources and judgments in evaluating the reasonableness and necessity of medical devices. Lastly, tying approval of MBAN providers to FDA approval is most likely to assure reimbursement by CMS<sup>59</sup>.

### **C. The Bartlett Rule Must Comport With HIPAA Security Rules**

To ensure the viability of the MBAN TV White Space project, FCC should adopt the requirements of the HIIPA Security Rule in crafting its licensing regime. The Health Insurance Portability and Accountability Act (“HIPAA”) was enacted in 1996 (Pub. L 104-191). Congress sought to streamline electronic health record systems while protecting patients, improving health care efficiency, and reducing fraud and abuse. Telehealth is a service delivery model. Services rendered through telehealth must comply with the same rules, regulations (federal, state, institutional) and practice stipulations that apply to services delivered in-person. Two major areas to consider when reviewing HIPAA compliance are security and privacy.

HIPAA provisions empower the secretary of Health and Human Services (“HHS”) to issue regulations to define standard electronic formats for common transactions, such as the submission of claims and billing. They also identify the uniform data codes used for diagnoses and medical procedures and set security standards to maintain the confidentiality of health

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<sup>59</sup> DRAFT GUIDANCE FOR THE PUBLIC, INDUSTRY, AND CMS STAFF: FACTORS CMS CONSIDERS IN MAKING A DETERMINATION OF COVERAGE WITH EVIDENCE DEVELOPMENT (April 7, 2002), available at <http://cms.hhs.gov/coverage/download/guidanceced.pdf> )

information. These security standards are meant to guard against unauthorized use, disclosures, and access. Electronic recordings must include a set of unique identifiers for individuals, health care providers, and employers. HIPAA regulations are meant to protect the privacy of client health information and clients' right to gain access to their health information<sup>60</sup>.

The HIPAA security rules specifically apply to electronic protected health information (“e-PHI”). E-PHI is any health information that is created, received, maintained, or transmitted electronically, such as through the internet, CD, magnetic tape, etc. It generally does not apply to paper faxes or voice-to-voice response system. However, it would apply to computer-based faxes or computer based automated voice systems.

The HIPAA security rules also require that administrative, physical, and technical safeguards be established to ensure the security of such information<sup>61</sup>. HIPAA lays out three key areas of compliance for ePHI security. These safeguards are administrative, physical and technical in scope<sup>62</sup>.

#### **i. Administrative Safeguards**

Administrative safeguards “provide management, accountability and oversight structure for covered entities to ensure proper safeguards and policies and procedures are in place” to protect ePHI<sup>63</sup>. The FCC can facilitate compliance with the HIIPA Security Rules by requiring MBAN vendors to commit to a quarterly risk assessment analysis of their network’s devices. Other steps include submitting evidence of staff trainings to handle secured data and establishing

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<sup>60</sup> <http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html>

<sup>61</sup> <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/EducationMaterials/downloads/HIPAA101-1.pdf>

<sup>62</sup> The HIPAA Privacy Rule and Electronic Health Information Exchange in a Networked Environment: Accountability” (2009), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/accountability.pdf>

<sup>63</sup> See CMS Health Information Privacy Security Rule available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html>

a security protocol to retrieve lost data in the event of a breach and enhancing staff awareness of fines etc.

**ii. Physical Safeguards**

Physical safeguards are undertaken by providers to prevent the exposure of ePHI protected health data<sup>64</sup>. FCC should require telehealth vendors to keep a physical copy of MBAN records in the event of loss and to verify in cases of fraud. Mobile devices can be kept in secure places when not in use. Devices can be required to have RFID locator devices in the event they are stolen. The devices can also be equipped with a remote controlled shut off switch to prevent data breaches<sup>65</sup>.

**iii. Technical Safeguards**

Technical safeguards are the “automated processes used to protect data and control access to data<sup>66</sup>.” In order to prevent data breaches FCC should require MBAN vendors to encrypt all data with stringent protective codes. FCC should also require monthly updates of anti-malicious software (“mal ware”). It should apply firewalls between all data and non-vendor related channels. Other options include requiring biometric signatures to access MBAN data; installing cloud back up facilities for data and following the successful technical practices of the banking industry in protecting electronic financial data.

By aligning the FCC approval process for MBAN spectrum in the TV White Space with the HIPAA security measures will allow vendors to proceed in full compliance with that statute.

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<sup>64</sup> Id.

<sup>65</sup> Marisa Torrieri, *Lowering Mobile Device Security Risks for Patients*, Physicians Practice (July 21, 2011), <http://www.physicianspractice.com/mobile-health/content/article/1462168/1911474>.

<sup>66</sup> “HIPAA Security Series: Security 101 for Covered Entities,” (March 2007) available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/security101.pdf>

**VI. THE FCC HAS AUTHORITY TO IMPLEMENT THE PROPOSED BARTLETT RULE UNDER THE PLAIN LANGUAGE OF STATUTE, ANCILLARY JURISDICTION AND CHEVRON GAP FILLING JURISDICTION**

FCC has the authority to implement the proposed MBAN TV White Space rule. The authority is found under the language of existing statute, or alternatively under ancillary jurisdiction or Chevron deferential standard.

**A. The “Bartlett Rule” Comports With the Plain Language of Existing Statute**

The Rule comports with the plain language existing statute. Section 307 E of the Telecommunications Act gives FCC the power to create channels without licenses when doing so serves the public good<sup>67</sup>. The proposed rule is predicated upon the ability to serve healthcare needs by reducing costs and serves to develop new industries and enrich labor markets. Allowing MBAN telehealth projects to operate in the TV White Space spectrum enables efforts to serve the public good. As such they are permitted by 47 U.S.C. § 307(e).

**B. Alternatively The FCC is Authorized Under Enhanced Ancillary Jurisdiction**

Even if the Commission is found to lack the express authority to create the proposed rule under § 307(e), FCC is authorized to adopt it pursuant to its ancillary jurisdiction under § 254 (c)(1) of The Telecommunications Act of 1996.

In the absence of a statute, FCC may use ancillary authority to issue a ruling when, the issue is covered by some other existing statute that falls under FCC authority<sup>68</sup>. In American Library, the Court stated that for FCC to have enhanced jurisdiction it would have to show that (1) the Commission’s general jurisdictional grant covers the regulated subject and (2) the

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<sup>67</sup> 47 U.S.C. § 307(e): “Operation of certain radio stations... if the Commission determines that such authorization serves the public interest, convenience, and necessity, the Commission may by rule authorize the operation of radio stations without individual licenses...”

<sup>68</sup> Am. Library Ass'n. v. F.C.C., 406 F.3d 689, 694 (D.C. Cir. 2005).

regulations are reasonably ancillary to the Commission's effective performance of its statutorily mandated responsibilities<sup>69</sup>.

The Telecommunications Act of 1996 directs FCC to enact policies to create universal access to telecommunications. Section 254 (c)(1) permits FCC to place special consideration on policies that are (a) essential to education, public health, or public safety and (b) are consistent with the public interest, convenience, and necessity.

In following the ancillary authority analysis provided by the court in American Library, FCC can be shown to meet the necessary requirements for the proposed rule. TV White Space MBAN allocation is "essential to public health" because it promotes a cost effective means of ensuring people's health. It is "convenient" because the White Space bandwidth is abundant and the communication waves may connect patients and health care providers over great distance, reducing the burdens and costs associated with travel. The proposed rule is a "necessity" because it serves goals of lowering this country's astronomical health care costs.

### **C. The Proposed "Bartlett Rule" Meets The Chevron Deferential Standard For Statutory Gap Filling**

The proposed rule meets the standard of review requirements for agency delegated authority enunciated by the Supreme Court in Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). When this standard is met, the Court will defer to the FCC's expertise in crafting its rules<sup>70</sup>.

According to the holding in Chevron, the proposed rule would be subject to invalidation only if found to be "arbitrary or capricious" or otherwise inconsistent with statutory authority. Although the "arbitrary and capricious" standard is narrow, it may call for invalidation of the rule

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<sup>69</sup> *Id* at 356, 357.

<sup>70</sup> Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967, 969 (2005)

if the FCC has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view of the product of agency expertise<sup>71</sup>.

The Court in Chevron created a two- step test to determine whether a rule is “arbitrary or capricious”. The first step asks whether the intent of Congress was clearly reflected in the rule. If so then courts must defer to that expressed intent<sup>72</sup>. The second step asks, that in the absence of express consent by Congress; is the rule is tied to an express or implied delegation of authority? And if so, is it reasonable? If these elements are met, courts will defer to the agencies’ expertise in crafting the rule<sup>73</sup>.

While there is no explicit statute granting FCC the power to create TV White Space MBAN frequencies it does reflect the intent of Section 254 (c)(1) of the Telecommunications Act which urges consideration of matters affecting public health. Furthermore, the creation of spectrum to serve the public good suggests that TV White Space spectrum may be used in order to facilitate public health. These two relevant statutes meet the first test for intent under a Chevron analysis. The second test of implied delegation of authority is satisfied by the goals outlined in Chapter 10 of the National Broadband plan. Chapter 10 aims to encourage maximum utilization of TeleHealth solutions. FCC has since applied this directive in the Rural Health Network and the TV White Space telehealth pilot study with Google and Spectrum Bridge. These rules are authorized under the implicit authority of the statute. Also the proposed rule is reasonable because it does not take existing bandwidth, nor does it elevate costs or risks. It

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<sup>71</sup> Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983) cited in St. James Hosp. v. Heckler, 760 F.2d 1460

<sup>72</sup> Id at 842.

<sup>73</sup> Id.

facilitates the public good by meeting health goals. The proposed TV White Space MBAN rule reflects a reasonable application pursuant to FCC's authority under the Communications Act and should be found to be neither arbitrary nor capricious.

#### **IV. CONCLUSION**

Consistent with the recommendations above, we urge the Commission to enact the proposed rule permitting any person who meets the above standards for wireless Telemedicine devices be granted use of spectrum in the TV White Space for MBAN applications.

Respectfully submitted,

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