

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

In the Matter of)	
)	
Amendment of Parts 2 and 95 of)	ET Docket No. 99-255
the Commission's Rules to Create a)	
Wireless Medical Telemetry Service)	

**REPLY COMMENTS OF THE
AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY**

**AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY**

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SUMMARY

The American Hospital Association Task Force on Medical Telemetry (“the Task Force”) reaffirms its strong support for the Commission’s proposal to allocate at least 14 MHz of spectrum to a new Wireless Medical Telemetry Service (“WMTS”) with primary or co-primary status in both lower and upper band allocations. Because WMTS will not be a high power service, WMTS generally will not interfere with other services, but other services may interfere with WMTS. It is undisputed that the interference with medical telemetry device signals has the potential to result in serious injury or death to a patient whose monitoring is interrupted or otherwise disrupted. No party opposed the allocation of at least some spectrum to WMTS on a primary or co-primary basis.

Contrary to the claims of some commenters, the Commission’s proposal to allocate WMTS a minimum of 14 MHz is fully supported in the record. The Task Force’s recommendation of a minimum of 12 MHz of spectrum was based on a study it conducted surveying more than a half dozen clinical professional organizations and fourteen geographically dispersed hospital systems of various sizes in both metropolitan and suburban areas. The study results were interpreted in a very conservative manner so as not to overstate the current spectrum requirements of medical telemetry devices. The Task Force’s estimate of WMTS spectrum required to satisfy longer term needs is similarly conservative.

All parties who addressed the issue, including the representative of the radio astronomy community, supported the Commission’s proposal for a lower band allocation to WMTS of the 608-614 MHz band (TV Channel 37) with co-primary status with radio astronomy. This 6 MHz lower band allocation, however is not sufficient by itself to support WMTS even in the short term because this band cannot be used in the vicinity of radio astronomy “quiet zones” and where broadcasters’ use of TV Channels 36 or 38 encroach upon the amount of TV Channel 37 spectrum that can be used effectively for WMTS.

The Task Force affirms its support for FCC proposed Option 1 as the optimal upper band WMTS spectrum allocation, even though its adoption likely will preclude use by Little LEO operators of the 1429-1432 MHz band for feeder downlinks, unless they modify their transmission parameters. In deciding which of two conflicting uses should be allocated spectrum, the Commission must decide in favor of WMTS, the service with a substantial and current need.

The Commission should reject the proposals to modify the service definitions it proposed in the Notice. In particular, the issue whether to authorize deployment of WMTS devices for in-home or mobile uses should be deferred to subsequent proceedings after some experience is gained under the new WMTS rules. The Task Force also opposes the recommendation that bi-directional uses of WMTS systems be treated as secondary. Bi-directional capabilities such as

telecommand, power control and re-transmission functions already are widely deployed in the ISM bands to the benefit of monitored patients, and these benefits should be extended to patients using new WMTS systems.

Although the Task Force does not oppose in theory LMCC's proposal to create a medical telemetry database for the 450-470 MHz band, it considers the proposal unworkable. Prior efforts to maintain such a database proved unsuccessful and were abandoned by the Commission in 1992. Nevertheless, the Task Force is open to considering this issue further if LMCC desires to develop a practical, cost-effective proposal to create a medical telemetry database for the 450-470 MHz band.

Contrary to the proposal of PCTEST Engineering Laboratory, Inc., WMTS systems should be subject to Declaration of Conformity (DoC) equipment authorization procedures and should be categorically excluded from environmental processing. Indeed, wireless devices of similar power to WMTS and using similar frequencies already are categorically excluded. Moreover, because the safety and effectiveness of all medical devices are reviewed by the FDA as part of its clearance and approval processes, it is unnecessary for the FCC to duplicate the FDA's safety review.

Finally, the Commission should reject the proposals to shorten the transition periods and to eviscerate the grandfathering proposals for medical telemetry systems in existing bands. In particular, an abbreviated transition period for the 460-470 MHz band is not feasible. Sufficient spectrum for current users to migrate to is not immediately available in all locations, and replacement costs for equipment and infrastructure cannot be absorbed by health care facilities over a transition period shorter than five years. Moreover, it is not clear that manufacturers have the resources to migrate all types of medical telemetry systems to the new WMTS bands in anything less than five years. For similar reasons, the Commission should reject proposals that the Commission (1) prohibit any new medical telemetry devices from initiating operations in the 460-470 MHz band and (2) eliminate the grandfathering of health care facilities' existing medical telemetry systems. Instead, the Commission should authorize the use and manufacture of existing devices in the 460-470 MHz band (as well as Part 15 devices operating in the 608-614 MHz band) until health care providers decide the devices no longer are in acceptable working order or until they become subject to objectionable interference from primary users of the band after the expiration of a five-year transition period.

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The American Hospital Association Task Force on Medical Telemetry (“the AHA Task Force” or “Task Force”), by its attorneys and pursuant to Section 1.415 of the Commission’s Rules, hereby files its reply to the initial comments filed by other parties on the Notice of Proposed Rulemaking released July 16, 1999, FCC 99-182 (“Notice”) in the above-captioned proceeding.¹

The Task Force reaffirms its strong support for the Commission’s proposal to allocate at least 14 MHz of spectrum to a new Wireless Medical Telemetry Service (“WMTS”) with primary or-co-primary status in both lower and upper band allocations. The Task Force refutes any suggestion that the proposed allocation to WMTS of 14 MHz of spectrum has not been adequately justified. Additionally, the Task Force opposes commenters proposing to shorten the proposed transitional period or to eviscerate the “grandfathering” rules necessary to facilitate an orderly migration to WMTS spectrum. In this regard, the Commission must focus on patient safety first and

¹For the sake of brevity, the Task Force will cite initial comments by the name of the commenting party and the relevant page number(s), for example “Task Force at 4-6.”

ensure that health care facilities have access at all times to adequate spectrum for the effective operation of medical telemetry systems.

I. THE COMMISSION’S PROPOSED ALLOCATION OF AT LEAST 14 MHz OF SPECTRUM TO WMTS IS FULLY SUPPORTED BY THE RECORD.

The Commission’s proposal to establish WMTS as a new service under Part 95 of the Commission’s rules and to allocate spectrum to WMTS with primary or co-primary status in order to avoid interference to medical telemetry operations received no opposition. No party disputed the health and safety benefits of medical telemetry equipment or the need for such equipment to operate now and in the future protected from harmful interference from other licensed and unlicensed devices.

A very few parties, however, question the need for an allocation to WMTS of 6 MHz of spectrum in the near-term and an additional 8 MHz or more in the medium and long term, for a total of at least 14 MHz.² For example, Final Analysis Communication Services, Inc. (“Final Analysis” or “the Little LEO representative”), a Little LEO licensee in the Non-Voice Non-Geostationary Mobile Satellite Service, characterized the Commission’s proposal to allocate WMTS 14 MHz as “wasteful and unwarranted.”³

Notwithstanding the claims of Final Analysis and the other challengers, the Commission’s proposal to allocate WMTS a minimum of 14 MHz is fully supported in the record. It is essential that a sufficient amount of spectrum is allocated so that WMTS systems can be operated without harmful interference from each other and from other licensed or unlicensed services. It is

²Personal Communications Industry Association (“PCIA”) at 3-4; American Mobile Telecommunications Association, Inc. (“AMTA”) at 4 n.6.

³Final Analysis at ii.

undisputed that the degradation of medical telemetry device signals has the potential to result in serious injury or death to a patient whose monitoring is interrupted or otherwise disrupted. The Commission has noted the instance when a television station in Dallas, Texas began test transmissions on a previously unused channel and those transmissions caused severe interference to the operation of medical telemetry equipment at nearby Baylor University Medical Center, rendering the equipment temporarily unusable.⁴ The Commission correctly concluded that all necessary measures must be taken to prevent the repetition of such instances, when patient safety was in jeopardy due to interference to medical telemetry devices.

The AHA Task Force's specific recommendation for the amount of spectrum to be allocated to WMTS was based on a study conducted by a Workgroup of the Task Force in order to determine the reasonable bandwidth requirements of medical telemetry. The study was conducted on an expedited basis at the request of the staffs of both the Commission and the Food and Drug Administration ("FDA") because of the urgency of the potential interference problems which would have a direct adverse impact on patient safety. The Task Force's study included a survey of fourteen geographically dispersed hospital systems of various sizes in both metropolitan and suburban areas. (In effect, more than fourteen facilities were surveyed because some of the individual hospital systems included affiliated facilities consisting of both large urban hospitals and smaller suburban health care facilities.) The survey also included input from more than a half dozen clinical professional organizations.⁵ It must be noted that no party has challenged the

⁴Notice at para. 8.

⁵Those professional groups included the American Association of Critical Care Nurses, the American College of Cardiology, the Society of Critical Care Medicine, the American Medical Association, the American Association of Respiratory Care, the American Academy of Neurology, and the American Association of Cardiovascular and Pulmonary Rehab.

survey's conclusions regarding the estimated number of patients using medical telemetry equipment concurrently or the required bandwidth per physiologic parameter monitored.

Contrary to the claims of the Little LEO representative, the Task Force's study is not "inherently biased toward the inflation" of estimated medical telemetry demand.⁶ Review of the study documentation submitted by the Task Force reveals quite the opposite. In fact, the study results were interpreted in a very conservative manner that understated the current spectrum requirements of medical telemetry devices. For example, the survey data revealed a very broad interest in voice and in real-time diagnostic ECG monitoring (requiring the highest data rate for physiological parameters). In recognition that other potential means exist for supporting these functions, however, the Workgroup conducting the Task Force study excluded the spectrum requirements for these uses from the near-term analysis.⁷

The Workgroup conducting the study also deliberately understated near-term demand in its analysis by recognizing that some of the hospitals responding to the survey would not implement all of the requested parameters immediately, even if sufficient spectrum were provided, because of the required capital investment to purchase the necessary equipment.⁸ Additionally, in order to avoid any potential bias toward inflated demand estimates, data from one hospital system that responded with uniquely large estimates of demand for certain parameters were totally excluded

⁶Final Analysis at 16.

⁷Final Report of the Physiologic Parameters Workgroup to the American Hospital Association Taskforce on Medical Telemetry, December 17, 1998, ("Workgroup Report") at Section 6.

⁸Id.

from the analysis.⁹

Moreover, the bandwidth calculations that underlie the estimated spectrum requirement intentionally utilized a better utilization than medical telemetry technology currently affords.¹⁰ The Task Force calculations were based on a spectral efficiency of 0.8 bits per second per Hertz, a standard that was chosen because it is approximately the same spectral efficiency as the Commission requires in Part 90 of its rules.¹¹ If actual current spectral efficiencies were used, the estimated bandwidth required to satisfy near-term demand for the same number of concurrent patients and parameters being monitored would have been considerably higher than the 6 MHz of spectrum recommended by the Task Force. Nevertheless, the Task Force chose this conservative approach in anticipation of advanced technologies that would achieve this improved efficiency.

The Task Force's estimate of 12 MHz of spectrum needed for longer term needs is similarly conservative when it is considered that in medium to large hospitals the number of concurrent uses of patient-connected transmitting devices is estimated to increase over a ten-year period from approximately 300 to an average of 1,000, as these devices serve more types of acute patients and monitor additional vital signs measurements.¹² The Task Force Report described

⁹Id.

¹⁰Id.

¹¹Id. See also Notice at para. 12.

¹²Report of the American Hospital Association Task Force on Medical Telemetry, April 16, 1999 (“AHA Task Force Report”), at 7. In urban areas, the AHA generally classifies “medium” hospitals as those with 101-299 beds and “large” hospitals as those with 300 + beds (see A Profile of Metropolitan Hospitals 1994 - 1997) ; in rural areas it classifies “medium” hospitals as those with 50-99 beds and “large” hospitals as those with 100 + beds (see A Profile of Non-Metropolitan Hospitals 1994 - 1997).

briefly the trends that undergird its estimate of future growth in WMTS spectrum requirements.¹³ For example, the typical patient entering a hospital is of greater acuity (that is, more ill) than in past years; these patients require a level of monitoring in general nursing units which previously was available only in the intensive care ward. Moreover, one of the methods increasingly used to accelerate patient recovery is to encourage earlier ambulation while continuing to monitor the patient, a trend that is being extended increasingly to the obstetrical environment. The aging of the baby boom generation undoubtedly will lead to growing concurrent demand for wireless medical telemetry monitoring at the same time that medical and technological advances likely will call for an increased number of physiological parameters to be measured.

Indeed, the Workgroup concluded that the need for WMTS spectrum likely will exceed 12 MHz in ten years, but declined to make projections of growth beyond this period on the basis of its expedited study.¹⁴ The Commission should be applauded for recognizing the likely long-term need for additional WMTS spectrum beyond 12 MHz and proposing a minimum of 14 MHz in both of the allocation options presented in the Notice. Because the Commission's proposal for

¹³Workgroup Report at Section 5.

¹⁴Id. at Section 7.

this spectrum allocation is fully supported by the record, it should be adopted and implemented promptly.

II. THE TASK FORCE CONTINUES TO FAVOR THE FCC'S PROPOSED OPTION 1 SPECTRUM ALLOCATION ALTERNATIVE

All parties who commented on which frequency bands to allocate to WMTS support the Commission's proposal to adopt the Task Force's recommendation for a lower band allocation of 608-614 MHz (TV Channel 37) with co-primary status with radio astronomy.¹⁵ Significantly, the representative of the radio astronomy community, the National Academies, through the National Research Council's Committee on Radio Frequencies ("CORF"), supports the allocation of the 608-614 MHz band to WMTS with co-primary status.¹⁶ As the Task Force noted in its initial comments, however, the 6 MHz lower band allocation is not sufficient bandwidth by itself to support WMTS even in the short term. An upper band allocation in addition to 608-614 MHz is required immediately for locations in the vicinity of radio astronomy "quiet zones" and where broadcasters' use of TV Channels 36 or 38 may encroach upon the amount of TV Channel 37 spectrum that can be effectively used for WMTS.¹⁷

The upper band allocations in the 1.4 GHz band that had been proposed either by the Task

¹⁵See, e.g., Motorola at 3; IIT Research Institute at 2.

¹⁶CORF at 1, 3.

¹⁷Task Force members have identified 120 locations where either TV channel 36 or 38 has been assigned for digital TV transmissions. In at least ten of the locations, both TV Channels 36 and 38 have been assigned, thereby exacerbating the potential encroachment on WMTS use of TV Channel 37. At least 122 hospitals and over 32,100 beds will be affected in these ten locations alone. Moreover, as discussed in the Task Force's initial comments at 8-9, health care facilities in approximately ten mid-size cities would be precluded from using the TV Channel 37 band for WMTS, due to their proximity to "quiet zones," in the absence of the concurrence of the director of the local radio astronomy observatory.

Force or the Commission are as follows:

Upper Band Allocation Alternatives

Task Force April 1999 Recommendation	FCC Option 1	FCC Option 2	Task Force September 1999 Alternative
1385-1390 MHz	1395-1400 MHz	1391-1400 MHz	1394-1400 MHz
1432-1435 MHz	1429-1432 MHz		1427-1429 MHz

The issue of which upper band frequencies to allocate to WMTS was subject to significant dispute in the initial comments. Because WMTS will not be a high power service, WMTS generally will not interfere with other services, but other services may interfere with WMTS. Upon consideration of the various relevant factors, the Task Force recommended adoption of the FCC's proposed Option 1. The Little LEO representative, Final Analysis, on the other hand, vigorously opposed adoption of either FCC Option 1 or Option 2 in recognition that WMTS and Little LEO satellite operators likely could not share spectrum.¹⁸ Final Analysis confirms the Task Force's preliminary conclusion that sharing by WMTS of an upper band allocation with Little LEO operators likely will be very difficult and perhaps impossible.

The Little LEO representative notes that dedicated feeder uplinks in the 1390-1393 MHz band may cause harmful interference to WMTS services operating in overlapping bands under FCC Option 2.¹⁹ It states that satellite tracking to elevations as low as 5 degrees could cause power levels at the horizon that interfere with medical telemetry operations, especially when

¹⁸Final Analysis at 27-32.

¹⁹Id. at 27-28.

atmospheric ducting is considered in the L-band.²⁰ The Little LEO representative also concludes that it is not possible to protect medical telemetry from interference from Little LEO feeder downlinks if spectrum in the 1429-1432 MHz band is to be shared by WMTS and Little LEOs, as under FCC proposed Option 1.²¹ Based on the preliminary information that has been exchanged so far, the Task Force agrees, especially since buildings will not effectively shield WMTS devices from Little LEO downlinks. WMTS devices often will be operating near windows and/or used to monitor ambulatory patients on the grounds of a health care facility but outside of a building.

Itron, Inc. addressed the upper band spectrum included within the Task Force’s alternative proposal of 1394-1400 MHz and 1427-1429 MHz (the Task Force offered this alternative for the Commission’s consideration in case the Commission wanted to avoid the spectrum being investigated by the Little LEO operators). Itron claims that WMTS cannot be accommodated within the 1427-1432 MHz band without jeopardizing the continued operations of its meter-reading services that operate in that band with secondary status.²² Itron states that because its users deploy meter-reading devices ubiquitously within their service areas, Itron’s service cannot be “operated around.”²³

Upon review of the initial comments, the Task Force reaffirms its support for FCC proposed Option 1 as the optimal WMTS spectrum allocation. The Task Force recognizes that Commission adoption of Option 1 likely will preclude use by Little LEO operators of the 1429-

²⁰Id. at 28.

²¹Id. at 30.

²²Itron at 3. Stations operating in a secondary service cannot claim protection from harmful interference from stations of a primary service. See 47 C.F.R. § 2.105(c)(3) (1998).

²³Itron at 3.

1432 MHz band for feeder downlinks, unless the Little LEOs modify their transmission parameters. It is undisputed, however, that WMTS has a current and real need for effective useable spectrum that must be accommodated now. As described by Final Analysis, there has been historical opposition to international allocations to the Little LEO industry, and the Little LEOs have been unsuccessful in seeking an international allocation of spectrum around 1.4 GHz for feeder links for a number of years.²⁴ The Little LEOs cannot guarantee that the international allocation that they claim is necessary for their operation ever will be received. In deciding which of two conflicting uses should be allocated spectrum, therefore, the Commission must decide in favor of WMTS, the service with a substantiated and current need.

FCC Option 1 also received strong support from CORF, which represents the interests of the scientific users of the radio spectrum, including users of the Radio Astronomy Service and the Earth-Exploration Satellite Service. CORF concludes that WMTS would be a “good neighbor” in the upper band allocation because it would be unlikely to cause interference to passive scientific observations in the 1.4 GHz band.²⁵ One of the benefits noted by CORF resulting from Commission adoption of Option 1 is the reduction or elimination of potentially

²⁴Final Analysis at 11-12.

²⁵CORF at 3.

substantial interference to radio astronomy observations in the 1429-1432 MHz band from Little LEO downlinks.²⁶

The Task Force also would support adoption of any part of its initial upper band recommendation (1385-1390 MHz, 1432-1435 MHz), as proposed in the alternative by Final Analysis,²⁷ if it can be determined (1) that Congress no longer is considering legislation authorizing the U.S. government to take back the 1385-1390 MHz band²⁸ and/or (2) that the National Telecommunications and Information Administration (“NTIA”) now agrees with the Task Force’s prior analysis (and the comments of Final Analysis) that the frequencies in the 1385-1390 MHz and 1432-1435 MHz bands may be allocated immediately to WMTS without being subject to competitive bidding.²⁹ The Commission should not allocate either the 1385-1390 MHz or the 1432-1435 MHz bands to WMTS, however, unless both of these issues have been resolved conclusively in favor of an allocation to WMTS.

III. THE COMMISSION SHOULD REJECT MOST OF THE SERVICE RULE CHANGES SUGGESTED BY OTHER PARTIES

A. Proposed Changes To Definitions and Service Regulations

Final Analysis Communication Services suggests revisions to the proposed definitions to “medical telemetry,” “health care facility,” and “authorized health care provider” to exclude voice and video transmissions from the scope of WMTS, to bar in-home uses of WMTS devices, and to

²⁶Id. at 4.

²⁷Final Analysis at 21.

²⁸See Task Force Comments at 8 (describing the recent consideration by Congress of a bill authorizing the take-back of the 1385-1390 MHz band).

²⁹AHA Task Force Report at 14-16; Final Analysis at 21-25.

limit the number of health care facilities eligible to deploy WMTS equipment.³⁰ The purpose underlying most of these suggested changes by Final Analysis is clearly self-serving. The Little LEO representative evidently seeks to suppress the utility and/or availability of WMTS systems in order to support its argument that WMTS does not require a spectrum allocation of 6 MHz or more in the 1.4 GHz band.

The Commission should reject the Final Analysis proposals as they seek inappropriately (1) to impose restrictions that Final Analysis apparently wants to apply to WMTS upper band frequencies to the entire WMTS spectrum allocation and (2) to adopt usage restrictions which, if warranted, should be set forth in service regulations rather than in definitions. For example, Final Analysis inappropriately proposes to substitute its judgment for those of licensed medical practitioners when it attempts to analyze the medical feasibility of WMTS devices being deployed for in-home uses, a complex subject matter which members of the AHA Task Force propose to leave open for future evaluation as experience is gained under the new WMTS rules.³¹ Similarly, although the Task Force supports the Commission's proposal not to authorize video and voice communications for WMTS systems for the time being, the Task Force does not agree with Final Analysis that it is reasonable to incorporate a blanket prohibition of such uses into the definition of "medical telemetry." The Task Force also opposes Final Analysis's proposal to add the phrase "accredited under state or federal law" to the definition of "health care facility." Not only do hospitals operate without accreditation, but accreditation is provided by private organizations not

³⁰Final Analysis at 33-34.

³¹Task Force at 16-17. See also letter from Dena S. Paskin, Director, Office for the Advancement of Telehealth, Department of Health and Human Services ("HHS") to William E. Kennard, Chairman, FCC, September 2, 1999, at 2 (supporting home health care monitoring).

“under state or federal law.” Additionally, Final Analysis’s proposed last sentence in the definition of “authorized health care provider”³² would need to be clarified to allow the use of WMTS devices to monitor ambulatory patients on the grounds of a health care facility but outside of a building, a need that even Final Analysis elsewhere recognizes as typical.³³

The Commission also should reject the Little LEO representative’s recommendation that bi-directional uses of WMTS systems be secondary. When Final Analysis claims that bi-directional operations are not a priority,³⁴ its opinion should be accorded little weight as it has no demonstrated expertise in the field of medical telemetry parameters and requirements. In fact, bi-directional capabilities such as telecommand, power control, and re-transmission functions already are widely deployed in the ISM bands to the benefit of the monitored patients. Because these bi-directional functions will promote the most efficient and cost-effective use of the new WMTS spectrum and advance the development of higher quality WMTS systems, they should

³²Final Analysis at 35.

³³Final Analysis at 30. The Task Force recognizes that it included a proposed definition of “authorized health care professional” in the AHA Task Force Report but recommends that the entity licensed by rule and subject to frequency coordination be a “health care facility,” rather than an “authorized health care provider.” If the Commission adopts this recommendation, the definition of “authorized health care provider” is surplusage and may be deleted from the proposed WMTS regulations. If the Commission decides to retain the definition of “authorized health care provider,” however, the Task Force still opposes the changes proposed by Final Analysis.

³⁴Final Analysis at 36.

not be relegated to secondary status. Instead, two-way WMTS capabilities should be encouraged and fostered through an upper band allocation of non-contiguous (split) frequencies.

The International Association of Fire Chiefs, Inc. and International Municipal Signal Association (“IAFC/IMSA”) and HHS suggest that WMTS systems should be authorized for mobile operations in ambulances.³⁵ The Task Force recognizes that this capability has significant potential benefit but submits that further analysis and experience with the WMTS database are required before mobile operations can be authorized for WMTS. The Task Force, therefore, requests that use of WMTS for mobile operations be considered in a subsequent or separate proceeding if and when such applications are developed.

B. WMTS Database Proposals

The Task Force does not support the proposal of IAFC/IMSA to establish a five year renewal requirement for WMTS registrations.³⁶ As discussed in its initial comments,³⁷ the Task Force agrees with the Commission that such a renewal requirement is unduly burdensome and should not be adopted.³⁸ For similar reasons, the Task Force opposes the IIT Research Institute’s recommendation that additional information on WMTS equipment and usage be collected for the WMTS database.³⁹ Because the collection of this additional information is not necessary for the

³⁵IAFC/IMSA at 3; HHS at 1.

³⁶IAFC/IMSA at 7.

³⁷Task Force at 17-18.

³⁸See Notice at para. 32.

³⁹IIT Research Institute at 5-6.

frequency coordination function, it should not be required.⁴⁰

Although the Task Force does not oppose the concept, the Task Force considers LMCC's proposal to create a database for the 450-470 MHz band unworkable.⁴¹ Prior efforts to maintain a database for the licensing and coordination of low power medical telemetry users in this band have proven unsuccessful and were abandoned by the Commission in 1992.⁴² As a result, manufacturers and health care facilities have limited records on the use of medical telemetry devices in this band. It would be impossible, or at least not cost-effective (especially if health care facilities are intended to fund the database), to create a comprehensive database for a use of the 450-470 MHz band which is intended to be phased out over a five year period — by the time the data were collected and input, it would be out-dated and, therefore, of minimal use. A non-comprehensive database, on the other hand, will be of little use for frequency coordination or other purposes. Notwithstanding its skepticism, however, the Task Force is open to considering

⁴⁰Additionally, the Task Force does not support IAFC/IMSA's proposal to bar disclosure of user identification and contact information from the WMTS database to third parties. This proposal intended to protect patients' privacy is not necessary because patient identification information will not be collected by the WMTS frequency coordinator and, thus, will not be subject to routine disclosure. Moreover, it is highly unlikely that the fraudulent interception of WMTS signals could be used successfully to identify a particular patient. The low power of WMTS signals, the large number of concurrent uses, and the fact that the devices used by a particular patient will change from day to day or even from hour to hour as the patient moves floors and his or her treatment changes all work against any successful attempt to intercept WMTS signals for the purpose of unauthorized patient identification.

⁴¹LMCC at 11.

⁴²Licensing of Low-Power Medical Devices in the 450 - 470 MHz Band, 7 FCC Rcd 5464 (1992).

this issue further if LMCC desires to develop a practical, cost-effective proposal to create a database for the 450-470 MHz band.

Finally, the Task Force notes that several parties, including Comsearch, the IIT Research Institute, IAFC/IMSA and the Personal Communications Industry Association, each propose that it be designated as the frequency coordinator of WMTS. As discussed in the Task Force's initial comments, the American Hospital Association would be qualified to serve as the sole frequency coordinator for WMTS because of its experience in resolving issues among health care facilities and its close ties to, and undivided focus on the needs of, the constituent WMTS users.

IV. WMTS SYSTEMS SHOULD BE SUBJECT TO DECLARATION OF CONFORMITY EQUIPMENT AUTHORIZATION PROCEDURES AND SHOULD BE CATEGORICALLY EXCLUDED FROM ENVIRONMENTAL PROCESSING

PCTEST Engineering Laboratory, Inc. ("PCTEST Lab") claims that specific absorption rate ("SAR") testing using a representative transmitter operating in the WMTS allocations above 1 GHz reveals that medical telemetry devices may be capable of exceeding the applicable RF radiation standards required for portable RF devices under Section 2.1093 of the Commission's Rules.⁴³ Based on that claim, PCTEST recommends that the Commission require WMTS devices to be evaluated for RF exposure prior to equipment authorization and that WMTS devices be subject to certification, rather than Declaration of Conformity (DoC), equipment authorization procedures.

The Commission should reject PCTEST Lab's recommendations. First, the testing standards for the DoC procedures are identical to the certification procedures so that the only result in adopting PCTEST Lab's recommendation for certification will be delay in bringing

⁴³PCTEST Lab at 1.

compliant WMTS systems to market. The specialized equipment manufacturers in this field are so few and well known to their competitors that no abuses of the DoC procedures likely would be attempted successfully.

Second, wireless devices of similar power to WMTS and using similar frequencies already are categorically excluded from environmental processing.⁴⁴ Based on its experience with these low power services, the Commission should recognize that no problems have arisen with such devices and should categorically exclude WMTS devices from environmental processing also.⁴⁵ In any event, evaluation by the FCC of specific WMTS devices is not necessary because both the safety and effectiveness of all medical devices are reviewed by the FDA as part of its clearance and approval processes.⁴⁶ PCTEST Lab has provided no justification for the Commission to duplicate the FDA's safety review.

Finally, it must be recognized who the operators of WMTS devices will be — health care facilities who will not compromise the safety of their patients, either from SAR or any other controllable factor. With this target market, equipment manufacturers have no incentive to cut any corners and market any devices that threaten a patient's health or otherwise do not comply with the

⁴⁴See OET Bulletin 65, Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields, Supplement C (Edition 97-01). OET Bulletin 65, for example, categorically excludes from environmental processing spread spectrum transmitters operating under 47 C.F.R. § 15.247, the highest average power transmitter available under Part 15 which typically would be used in a portable configuration and whose power typically exceeds that of WMTS devices.

⁴⁵ Evidently, the test on which PCTEST Labs is basing its comments involved holding the dipole next to a head simulator (normally used for performing SAR measurements for portable telephones and similar devices) and directly in the ear. Such a test is not representative for WMTS because body-worn medical telemetry transmitters are normally worn on the chest, which will reduce the SAR.

⁴⁶See 21 U.S.C. § § 360(k), 360c - 360e.

Commission's SAR standards.

V. THE COMMISSION SHOULD ADOPT THE GRANDFATHERING PROVISIONS AND THE FIVE-YEAR TRANSITION PERIOD FOR THE 460-470 MHz BAND AS PROPOSED IN THE TASK FORCE'S INITIAL COMMENTS

Entities representing land mobile radio users of the 450-470 MHz band predictably recommend a much shorter transition period and more restrictive grandfathering provisions for medical telemetry uses of the 450-470 MHz band than proposed either by the Commission or the Task Force in its initial comments. As clarified below, however, the Commission should adopt the grandfathering provisions and the five-year transition period for the 460-470 MHz band as proposed in the Task Force's initial comments.⁴⁷

The Land Mobile Communications Council ("LMCC"), PCIA, AMTA and Motorola each claim generally that the benefits of the FCC's Part 90 "refarming" decision in PR Docket No. 92-235⁴⁸ for the 450-470 MHz band cannot be fully realized until high power operations are authorized on the offset channels currently being utilized by low power wireless medical telemetry devices and until the Commission adopts LMCC's claimed "consensus" Low Power Plan⁴⁹ submitted in that proceeding which proposed designating specific channels in the 450-470 MHz band for the exclusive use of lower power operations. In its comments, LMCC addresses specific portions of its Low Power Plan and requests the Commission to adopt those portions in this

⁴⁷Task Force at 21-25.

⁴⁸Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them, Second Report and Order, 12 FCC Rcd 14307 (1997).

⁴⁹Letter to Dan Phythyon, Acting Chief, Wireless Telecommunication Bureau from Larry Muller, President of the LMCC, June 4, 1997 ("Low Power Plan").

proceeding.⁵⁰

The Task Force notes that mobile units using the lower power offset channels already are pervasive and increasingly cause interference to existing medical telemetry devices. Nevertheless, the specifics of LMCC's claimed consensus Low Power Plan are not appropriate subject matter for decision in this rulemaking proceeding, which focuses on the establishment of, and the allocation of spectrum to, WMTS. The Task Force, however, welcomes LMCC's invitation to work together and, in particular, LMCC's suggestion to develop a plan for economic reimbursements to medical telemetry users in order to facilitate the migration of medical telemetry equipment to the new spectrum allocations.

To facilitate migration of medical telemetry systems when appropriate, the Task Force notes that it already is cooperating with the staffs of the Commission and of the FDA as well as with representatives of the LMCC in developing and distributing a Public Notice which the Commission is preparing in order to determine the number and location of medical telemetry systems operating in the 450-460 MHz band. Once the data are collected and analyzed, and an appropriate migration plan, if possible, is developed for medical telemetry equipment in that band, the Task Force may be able to support the release of another public notice beginning a transition period for deployment of high power private land mobile uses in the 450-460 MHz band.

An abbreviated transition period for the 460-470 MHz band, however, is out of the question. The Task Force's survey indicates that more than 60 percent of the medical telemetry systems in use today operate in the 460-470 MHz band. This represents thousands of devices and millions of dollars in equipment replacement and infrastructure costs to support the new

⁵⁰LMCC at 7-10.

equipment. Realistically, the telemetry infrastructure and cabling of health care facilities must be replaced, and cannot be retrofitted, in order to transition to the new bands. One hospital estimates \$4 million in replacement costs for installation and cabling to support 300 beds using the new spectrum bands, an average of \$13,333 per bed.⁵¹ The health care industry is subject to severe cost containment pressures, and hospital budgets simply cannot absorb such costs over a transition period shorter than five years from the date the Commission makes an allocation of spectrum to WMTS. Nor is it clear that the resources are available in the manufacturing and engineering community to accomplish such a transition reasonably in anything less than five years.

The Commission also should reject LMCC's proposal that the Commission prohibit any new medical telemetry devices from initiating operations in the 460-470 MHz band effective with the date when the Commission releases its order in this proceeding.⁵² Among other things, LMCC's proposal unreasonably would bar the replacement of defective equipment in, or even the addition of one transmitter to, existing systems. Moreover, as discussed previously, effective use by WMTS of the 608-614 MHz band is not available in numerous locations in radio astronomy quiet zones and in areas adjacent to where broadcasters operate on TV Channels 36 or 38. Under LMCC's proposal, therefore, many users would be left without options for new or replacement systems until new equipment is developed for the 1.4 GHz band, a process that may take three to

⁵¹Another hospital system, whose estimate was limited to a single telemetry ward, projects a cost of \$9,300 per bed as of four years ago. Even with mild inflation, the estimated cost today for that ward likely would be in the range of \$11,000 per bed and would be even higher if an estimate for cabling included the whole building.

⁵²LMCC at 12.

five years once an allocation is made.⁵³

Additionally, LMCC's proposal is based on the assumption of an immediate availability and useability of product in the 608-614 MHz band, an assumption which is unsupported. Not all types of telemetry equipment are immediately available in the 608-614 MHz band, nor will they necessarily become available even in the short-or mid-term. To permit a manageable transition for existing UHF telemetry installations, it is imperative that manufacturers be able to provide UHF telemetry systems capable of operation in both the 608-614 MHz and 460-470 MHz bands.

Equally unworkable are the proposals to eliminate the grandfathering of health care facilities' existing medical telemetry systems. Motorola, for example, opposes allowing existing medical telemetry equipment in the 460-470 MHz band to continue operating on a secondary basis after the transition period has ended.⁵⁴ Motorola's proposal especially would harm health care facilities in rural and other less congested areas, without any countervailing public interest benefits. Because the demand for high power private land mobile operations may be low in such areas, existing medical telemetry systems likely could operate on a secondary basis for years without being subject to interference and thus should not be compelled to undertake the costly transition to WMTS spectrum without regard to the actual need to do so. The Commission should authorize the use and manufacture of existing devices in the 460-470 MHz band (and existing Part 15 devices operating in the 608-614 MHz band) until the health care provider decides that they no

⁵³An additional justification for grandfathering use of the 460 - 470 MHz band is that health care facilities in some locations will not be able to use portions of the 1.4 GHz band, due to the time needed for decommissioning of military radar sites, until well after 2004. See NTIA Special Publication 95-32, page 4-7, table 4-2. See also Notice at para 18 ("government operations [in the 1390 - 1400 MHz band] will continue at 17 sites until the year 2004").

⁵⁴Motorola at 6.

longer are in acceptable working order or until they become subject to objectionable interference from primary users of the band after the expiration of the five-year transition period.

VI CONCLUSION

For the foregoing reasons, the Commission should take action consistent with the view's expressed in the initial comments of the American Hospital Association Task Force on Medical Telemetry and these reply comments.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **REPLY COMMENTS OF THE AMERICAN HOSPITAL ASSOCIATION TASKS FORCE ON MEDICAL TELEMETRY** were served this 18th day of October, 1999, via first class mail upon the following:

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