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## FCC SEEKS TO GRANT BROADER EXPERIMENTAL LICENSES;

## TARGETS MEDICAL APPLICATIONS AND NEW RADIO TECHNOLOGIES

Proposed Rulemaking Asks for Comments

Seeking to foster research and innovation in wireless technologies, the Federal Communications Commission has proposed new rules designed to broaden spectrum research and the development of spectrum-efficient wireless technologies. In doing so, it specifically targeted medical services for advances, seeking to "allow medical institutions to innovate and develop new devices that can save lives, have a significant impact on reducing medical costs for consumers, and provide new treatment options for wounded servicemen and women."

The plan was launched in two new proceedings, with the dual goals of promoting investment and the creation of jobs. By leveraging experimental radio licensing, the Commission hopes to accelerate the rate at which new spectrum concepts are developed, tested and ultimately reach the consumer. The Commission targets six areas to achieve this goal:

- 1. New broad research licenses would be issued to universities and other researchers for a wide variety of radio frequency experimentation. Prior authorization to conduct individual experiments would no longer be required; rather, research would be permitted under a broad umbrella license;
- 2. Pre-authorized geographic areas would be designated where spectrum-related testing could be conducted without further authority;
- 3. A new medical experimental authorization would be issued to qualified hospitals, Veteran's Administration (VA) facilities, and other medical institutions to encourage advanced development in radio devices utilized to provide medical services;
- 4. Expanded market trial authority would permit broader pre-grant marketing to better measure consumer acceptance;
- 5. Review, revise, consolidate and streamline existing rules and procedures to make the process more accessible; and
  - 6. Identify and target specific new rules and modifications.

Enthused by past successes in its experimental radio service, the Commission cited achievements that led to the Personal Communications Service ("PCS"), now a mainstay in mobile device communications, and pointed to the Commission-issued experimental license to the Alfred Mann Foundation that led to wirelessly-controlled implantable medical devices.

Under experimental authority, studies are now underway at the University of Maryland to develop new uses and applications of WiMAX and 4G technologies.

The demand for experimental authority in radio technologies has been steadily increasing to the point where broader authority would be useful. The Commission's recent National Broadband Plan recognized that broadband-enabled solutions will be increasingly applied to critical health care service delivery. Last year, the Commission created the Medical Device Radio Communication (Med Radio) Service to authorize body-worn and implanted medical devices. Recognizing the need to ensure the safety and reliability of wireless broadband enabled medical devices, while increasing their availability to consumers and healthcare providers, the Commission believes it has proposed an experimental medical radio license program that will foster cutting-edge test-bed facilities that can try out new wireless medical technologies and assess their operational readiness. The Commission intends for these proposals to shorten the development time with a streamlined approval process.

The Commission asks for comment on a variety of issues, but requests that commenters specifically address these questions:

- Should it restrict licensing to entities that meet specific criteria, such as accreditation by a particular certification body?
- Would it be better to allow any affirmative showing from an applicant that is engaged in a health care field and has sufficient resources and expertise to oversee the tests it intends to conduct under a blanket license?
- What is the best way to include federal medical institutions?
- How should it structure the coordination process between the various federal agencies and governmental institutions in a way to safely expedite the development of new medical devices and delivery of services?
- How should it define the appropriate scope of permissible operations under the medical program experimental radio license, and
- What reporting requirements should be imposed upon researchers?

Presently, Commission rules generally prohibit devices from being marketed or operated prior to receiving a grant of equipment authorization. However, the Commission has acknowledged that there would be great benefit in broader market trials, exploring a greater variety of developing radio technologies. It did so, for example, in the National Broadband Plan and in the Wireless Innovation Notice of Inquiry, recently issued by the Commission. Therefore, the Commission proposes a new subpart permitting two types of trials – product development trials and market trials. These rules would allow experimental programs to evaluate product performance in the conceptual, developmental and design stages, as well as to evaluate product performance and customer acceptability prior to the mass production stage. It would expand marketing opportunities beyond those currently permitted and offer the license to a wider range of eligible entities than is currently permitted.

Comments are due thirty days after publication in the Federal Register. Should you have any questions concerning the contents of this alert, please contact <u>Gregg Skall</u> or a member of the <u>Telecommunications practice group</u>.

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