Published on *The National Law Review* https://natlawreview.com

Seeking FCC Flexibility on the Sale of Wireless Medical Devices During COVID-19

Article By:

Laura A. Stefani

We've written previously about the role of the Federal Communications Commission (FCC) in regulating wireless medical devices, chiefly in determining the operating frequency and certain technical rules that ensure co-existence with other devices and wireless users. As part of that process, manufacturers must submit prototypes of new devices for testing and review by independent third party test labs and certification bodies (TCBs). The FCC prohibits responsible parties, such as manufacturers and resellers, from importing, marketing, or selling any device subject to this equipment approval process prior to obtaining approval from a TCB, which comes in the form of a grant of equipment certification.

Generally, once a device is ready for market, the process of undergoing the required testing and then approval from the TCB can be completed within a month or so. However, the COVID-19 crisis has disrupted the workflow of both the test labs and the TCBs, which are now limited in their ability to have sufficient numbers of staff present at their facilities to perform all of the necessary testing and review. This has resulted in delays in approvals of new technologies over the last month.

GE Healthcare, a large producer of medical devices, is now seeking a waiver of the FCC marketing rules to allow it to sell certain medical devices used in the fight against COVID-19 prior to obtaining equipment certification. GE cites two compelling reasons for this waiver: (1) the delays at the test labs and TCBs; and (2) the need to rely on new suppliers to meet the rising demand for certain products. (Design changes due to the use of different components in a wireless device can require additional testing and either new approvals or certain FCC filing requirements.) For these reasons, GE suggests that the FCC should grant it an 18-month waiver so that it may more rapidly place devices into the marketplace, after which it would either seek return or disposal of the uncertified devices or ensure that they are appropriately authorized.

The timing of potential FCC action on GE's request is unclear. While the FCC has moved expeditiously in handling many COVID-19 related matters, such as the grant of telehealth funds, the agency also is extremely busy handling ongoing work, including acting on decisions related to expediting the rollout of 5G technologies. Nonetheless, GE's request is compelling, given its long-standing experience, its assurance that it will conduct self-testing to ensure compliance with the FCC's rules, and its proposed limitation on where the devices may be used, among other suggested conditions. The FCC is likely to act fairly quickly on the request, although its decision would apply

only to GE unless the FCC acts on its own accord to broaden the proposal. Other manufacturers in similar situations would need to request their own waivers from the FCC.

National Law Review, Volume X, Number 113