510(k) Coalition - Short Comment Regarding a Proposed Exemption
Under 17 U.S.C. 1201; Docket No. 2014-07
Proposed Class 27: Software – Networked Medical Devices

Item 1. Commenter Information

The 510(k) Coalition is a group of medical device companies dedicated to patient health and to the promotion of efficient, rational regulation of medical devices. The Coalition appreciates the opportunity to provide comments on the proposed exemption for software networked medical devices (the "Proposed Exemption"). The 510(k) Coalition; Ralph Hall, Partner, Leavitt Partners; 1050 K Street, NW, Suite 310; Washington, DC 20001-4448; Ralph.Hall@leavittpartners.com.

Item 2. Proposed Class Addressed

These comments concern Proposed Class 27: Software – Networked Medical Devices.

Item 3. Statement Regarding Proposed Exemption

The Coalition supports the comments on this Proposed Exemption previously submitted by the Advanced Medical Technology Association (the "AdvaMed Comments"). A summary of the main points stated in the AdvaMed Comments is included below. For the following reasons and the reasons listed in the AdvaMed Comments, we respectfully request that the Copyright Office oppose the inclusion of medical devices in an exemption under Proposed Class 27.

- The unauthorized circumvention of technological protection measures ("TPMs") under the Proposed Exemption lacks the necessary protections for patient safety and privacy, will place safety and privacy at risk, and would create incentives to misuse devices.
- There is a risk that circumvention activities could cause a device to malfunction and unnecessarily jeopardize patient safety. Tampering with any implanted devices presents an unnecessarily high risk to patient safety due to the malfunction, degradation, and/or damage that may result from unauthorized circumvention activity within those devices.
- Where unauthorized circumvention activity is utilized to access the monitoring system of an implanted or attached device, or its associated networked systems, patient personally identifiable ("PII") or protected health information ("PHI") of other patients may be compromised. In certain instances, networked devices could be used to access information which third parties should not be able to access and/or monitor.
- The Proposed Exemption purports to address an issue which, in fact, is already being widely worked on by industry. Robust medical device security research is already ongoing under a framework that includes the necessary protections for patient privacy, patient safety, and intellectual property.
- The Proposed Exemption may directly conflict with FDA regulations and creates jurisdictional questions. FDA should retain regulatory supremacy over device operations because circumvention activity without oversight by FDA and without a manufacturer's consultation will endanger patients.
- The Proposed Exemption is overly broad and may include many more devices other than those specified. With the broad spectrum of devices potentially included within the exemption, it is difficult to anticipate the full scope of risks likely to be created.