

# RFID use in health care raises privacy questions

Newly developed technology enables doctors to monitor patients wirelessly in several ways but is raising questions related to privacy protection.

Consumers may be familiar with radio frequency identification devices because they are used in highway toll passes and gas station payment fobs. The utility of RFID is limited because the information contained in the RFID transmitter is generally unchanged once it is imprinted in the device.

Recently, the FCC proposed to modify its rules to accommodate the further development and use of medical devices that use more active wireless technology. The proposed rules would foster the production of additional body-worn devices that would sense body functions and conditions and transmit that information to a device that records the information or passes it along to an external device. While these devices are already permitted by FCC regulations, the new rules would create more capacity for wireless medical transmissions.

If the wireless device is to be marketed with claims of medical utility, such as to provide access to medical information to assist medical personnel in diagnosing or treating an injury, illness or condition, it is treated as a medical device and will be subject to premarket review or approval by the FDA.

One of the first FDA-approved uses of radio frequency signal transmitters and receivers is the transmission of a patient's physiological signals such as electrocardiographs and other vital signs over the telephone lines to a health care provider. Subsequently, the FDA cleared an RFID tag that is placed on a patient's skin prior to surgery to minimize the likelihood of errors.

Access, use and disclosure of medical information is presently governed at the federal level by the Health Insurance Portability and Accountability Act of 1996 and by state privacy laws

that may be stricter than HIPAA.

An RFID chip containing an identifier that leads to a file in a database appears to fit within the existing regulatory scheme. In this instance, it is the database that contains personal health information, not the chip, and the access, use and disclosure of the database information as well as its security would be governed by HIPAA. The risk of inappropriate access to the database

does not appear to differ from the risk of inappropriate access to a conventional paper or electronic medical record system. If the database associated with an RFID identifier or any other wireless transmission device was compliant with HIPAA, there would be appropriate access controls to ensure that more than a unique ID was necessary to enter the database.

It is unclear how an RFID chip or a medical device that broadcast real time PHI might fit within the existing legal framework. This type of system would present unique issues such as a traveling patient, being subject to different state privacy laws as he or she moves from state to state. It is not clear whether personal health information in the possession of someone who is not a covered entity would be subject to HIPAA protections at all. Of greater concern is whether access to such a system could be monitored to prevent inappropriate use of a patient's information or punish violators. Could anyone with a reader/transceiver access the information?

The choice of using technology may require a risk-benefit analysis and a calculation of whether the privacy risks are outweighed by the benefits in a patient's particular situation.

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