Health Watch USA[sm]

Member of the National Quality Forum and a designated "Community Leader" for Value-Driven Healthcare by the U.S. Dept. of Health and Human Services

www.healthwatchusa.org, www.healthconference.org

Kate Goodrich, MD

Director & CMS Chief Medical Officer

Centers for Medicare & Medicaid Services

Dec. 17, 2019

Dear Dr. Goodrich:

Health Watch USA[sm] would like to request the addition of a new Condition of Participation (COP) for Medicaid and Medicare concerning recipients of implantable medical devices. We propose that it is made mandatory for a patient to receive information about their implanted device, including the Unique Device Identifier (UDI).

Informed and engaged patients are an important part of safety in healthcare, and patients should be informed about their implanted medical devices. However, in current practice too many patients do not know the name or manufacturer of their device. The FDA requires that many medical devices contain a unique device identifier (UDI) placed directly on the device. However, implantable devices are exempted. Health Watch USA[sm] feels this creates a significant risk to patient safety which can be lessened by informing the patient and providing them with written information regarding the device and the device's UDI.

An implantable device may fail or be recalled many years after implantation. Identification of patients at risk for device failure and even identification of the device after explantation can be difficult. The latter is important for implant epidemiological studies and to determine the reasons for failure.

Compounding this problem are shortcomings in the fragmented tracking and recordkeeping systems in the healthcare industry. For example:

1. Electronic Medical Record (EMR) information is not always available. Patients may change providers or move to a different location. The lack of portability of EMR data between different healthcare systems greatly impedes access to this necessary information.

2. In addition, healthcare providers may change to a different EMR company and system. The portability of data to the new EMR can be a significant challenge and old data can become lost.
3. States vary on hospital record retention requirements. There is not a set standard. Of the 50 states, District of Columbia and Puerto Rico, only 2 States require record retention for thirty years or greater, the remainder require record retention for 11 years or less with seven states having no record retention requirements – See Figure to the right. Doctors have even less rigorous requirements and the FDA does not require manufacturers to keep their records after device failure, explantation or patient death (USC 21 Part 821.60 Retention of Records).

Years required to retain hospital records, by state

no mandate	5	6	7	8	9	10	11	30 years
DE	AL	AZ	AK			AR	NC	MA
ID	GA	NY	CA			CO		MI
IA	KY		FL			CT		
OH	MD		HI			DC		
PR	NV		IN			IL		
WV	OK		ME			KS		
WY	RI		NH			LA		
	VA		PA			MS		
	WI		UT			MT		
						NE		
						NJ		
						NM		
						ND		
						OR		
						SC		
						SD		
						TN		
						TX		
						VT		
						WA		

4. It is also critically important to study implants that fail and are removed from patients, making it is imperative that their make, model and manufacturer is known. However, this information may not be available, since UDI markings are not required on implants and the FDA does not require retention of UDI records after the implant has been removed or the patient has died (USC 21 Part 821.60 Retention of Records). In these cases, a patient's record would be invaluable.

Thus, Health Watch USA[sm] recommends that the following information be provided to the patient, patient's family or designated patient representative (45 CFR 164.502(g)) during the perioperative period that a medical device is implanted:

1. Device Name.
2. Date the device is manufactured.
3. Manufacturer Name.
4. UDI in writing and Barcode.
5. Presence or absence of a manufacturer's warranty. If the warranty includes device replacement and/or medical expenses. The length of time the warranty is in effect.
6. Expected length of device functioning.
7. Signs and symptoms of complications which may occur.

It should be noted that these informational items for medical devices are very similar to the information given to consumers for almost all products which they purchase. Certainly, they should be given for implantable medical devices.

Implementation: Health Watch USA[sm] considers the facility or entity which purchases the implant should be ultimately responsible for implementation of this initiative. We would like to request that the Centers for Medicare & Medicaid Services (CMS) require the provision of the above medical device information, including the UDI, to the patient or patient's representative as a facility level requirement for Conditions of Participation (COP) in Medicare and Medicaid. In addition, we feel that CMS should withhold payment for the device, if this information is not provided.

Medical Device information provided to patients is of utmost importance. An importance augmented by non-standardized EMR systems and loopholes for record retention. Occasionally patients may lose this information and healthcare literacy can vary. However, information given to patients should be viewed as a vital supplement to current recordkeeping systems and is not only important for patient empowerment but should be viewed for a basic patient right.

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