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Glossary: Medical Devices

Medical devices are an industry with many parallels to pharmaceuticals. Like drugs, devices are regulated by the FDA; tremendous innovation has helped patients lead longer, healthier lives but inadequate oversight and hidden pricing of devices may be contributing to cost growth and safety concerns. This glossary of terms may help advocates, policymakers and others navigate this important topic. For more: healthcarevaluehub.org/Medical-Devices

Term	Acronym	Definition
510(k) Pathway		Expedited FDA approval process for medical devices whereby manufacturers have to prove new products are substantially equivalent to ones already on the market
Anti-Kickback Statute	AKS	The federal criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business.
AdvaMed		The American medical device trade association.
Bundled Payment for Care Improvement	BPCI	A program developed by the Centers for Medicare and Medicaid Services (CMS) to link payments for services beneficiaries receive during an episode of care to outcomes.
Comprehensive Care for Joint Replacement	CJR	A model implemented by CMS to bundle payment and quality measurement for an episode of care associated with hip and knee replacements with the goal of encouraging hospitals, physicians, and care providers to work together to improve the quality of care coordination.
Durable medical equipment	DME	Equipment that is primarily and customarily used for medical purposes and which can withstand repeated use (canes, pumps, etc). A subset of medical devices.
Durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies	DMEPOS	Devices that provide therapeutic benefits to a patient because of certain medical conditions and/or illness, function as an artificial body part, or are used to support, align, prevent or correct the function of movable parts of the body.
Food and Drug Administration	FDA	The federal agency, part of the Department of Health and Human Services, that regulates pharmaceutical drugs, food, tobacco products and medical devices. The agency is responsible for protecting and promoting public health.
General Controls		The basic provisions that allow the FDA to monitor and regulate certain classes of devices. They include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records

		and reports; restricted devices; and good manufacturing practices.[1]
Implantable Medical Devices	IMD	Devices that are inserted into the human body to replace a missing body part, support a damaged body part, or modify an important body function.
Medical technology		Applications of knowledge to practical medical problems but often encompassing *medical* drugs and devices, and health information technology (HIT).
National Evaluation System for health Technology	NEST	An FDA system under development to more efficiently generate evidence for medical device evaluation and regulatory decision. NEST will leverage real-world evidence and tailored analytics across the product life-cycles of medical devices.[2]
Premarket Approval		The FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices before they come to market.
Safe Harbor		The "safe harbor" regulations describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute.
Special Controls		Applicable to Class II medical devices, these FDA controls are usually device-specific and include: performance standards, post-market surveillance, patient registries, special labeling requirements, premarket data requirements and guidelines.
Supplement Pathway		Manufacturers seeking approval for updates or changes to devices they already have on the market submit amendments or supplements to the original Premarket Approval (PMA) submission to the FDA. Depending on the type of changes a manufacturer wants to make, devices face differing evidentiary burdens. Supplements fall into five approval tracks: panel-track, 180-day, real-time, special and 30-day notice

www.HealthcareValueHub.org/Medical-Devices

[1] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm
[2] https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.htm