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Practice Resource

A Provider's Guide to Managing a Medical Device Recall

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What is the issue? Health care providers are often in the best position to notify their patients about medical device recalls. The process of adequately informing affected patients can, however, be burdensome and challenging.

What is at stake? Without an effective recall system at the provider level, hospitals and physicians can expose themselves to liability and be in violation of federal Medicare billing regulations.

What do you need to know? Creating an effective recall system requires establishing a multidisciplinary approach when drafting policies and procedures, providing regular training for staff, maintaining quality communication with patients when a recall occurs, and staying informed about recalls of FDA-regulated medical devices.

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Healy, Braender, Zalewski: Medical Device Recall

CONTENTS

Introduction

The recall rate of medical devices nearly doubled between 2003 and 2012.[1] Innovations in medical technology together with improvements in device tracking and data collection and pressure on the Food and Drug Administration (FDA) to expedite the review of breakthrough technologies suggests that the trend will continue upward.[2] In many instances, a medical device will have been stocked and used to treat patients before a safety concern is identified, leaving hospitals and physicians with the burden of managing recalled inventory and communicating with patients about the recall's impact and an appropriate treatment course. An effective recall system at the provider level, marked by preparedness, infrastructure, and collaboration between staff, manufacturers, regulators, and payers, is essential to ensuring patient safety and avoiding potential provider liability in the almost inevitable event of a recall.

Regulatory Landscape

The medical device industry is heavily regulated, mainly governed by the FDA's efforts to ensure that potential harm to individuals from defective products or misleading advertising is avoided or at least minimized. A federal law, the Food, Drug, and Cosmetic Act (FDCA) provides guidance for medical device manufacturers, distributors, suppliers, and providers on recalls and how to initiate and implement a recall.

When is a medical device subject to recall?

When an FDA-regulated medical device is defective, potentially harmful, fails to meet the requirements of an established performance standard, or has false or misleading labeling, it is in violation of the FDCA and potentially subject to recall. As defined under the FDCA, a "medical device" includes an expansive

1 Department of Health and Human Services, Office of Inspector General, Shortcomings of Device Claims Data Complicate And Potentially Increase Medicare Costs For Recalled And Prematurely Failed Devices, n.1 (Sept. 2017), *available at* https://oig.hhs.gov/oas/reports/region1/11500504.pdf.

2 Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Recall Report: FY2003 to FY2012 (2014).

list of products, ranging from simple items such as disposable gloves to more complex devices such as electronic implantable products.[3] Accessories to products that meet the FDCA's definition of device—including "software as medical device" (SaMD) products (i.e., software products that compute or analyze data input for the purpose of providing output to facilitate diagnosis or treatment)—are regulated in the same way as medical devices.[4]

How are recalls initiated?

"Recall" is defined as the removal or correction of a marketed product that the FDA considers to be in violation of the FDCA as an alternative to an FDA-initiated court action to compel the removal of the product from the market.[5] It does not, however, include market withdrawals or stock recoveries that cover circumstances in which the manufacturer issues a notification or removes or corrects a product because of a minor violation that would not otherwise be subject to legal action by the FDA. The FDA has the authority to compel a recall, but it views the process of "voluntary recall" as affording greater protection to the public than a seizure or mandatory recall.[6]

When a manufacturer voluntarily initiates a recall to remove or correct a product, it immediately notifies the FDA of its decision and submits a proposed recall process.[7] The FDA identifies the manufacturer's recall classification, reviews the proposed process, and provides comments.[8] In circumstances where the FDA determines that a product presents a risk of illness, injury, or gross consumer deception, and a manufacturer has not initiated a recall of the product, the FDA will request that the manufacturer implement a recall. In instances where the FDA finds reasonable probability that a device would cause

3 21 U.S.C. § USC 321(*h*).
4 FDA, Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types: Guidance for Industry and Food and Drug Administration Staff (2016), *available at* www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429672.pdf.
5 21 C.F.R. § 7.3(g).
6 21 C.F.R. § 7.40.
7 *Guidance for Industry: Product Recalls, Including Removals and Corrections*, FDA, www.fda.gov/safety/recalls/industryguidance/ucm129259.htm (last visited Nov. 27, 2017).
8 21 C.F.R. § 7.46.

serious, adverse health consequences or death and the manufacturer has not implemented a recall, the FDA will order that distribution of the defective device be immediately discontinued and the public be notified of the FDA's order. It is important to note, however, that the FDA rarely exercises its mandatory recall authority and instead generally relies on cooperation from regulated device manufacturers, distributors, or other responsible parties to conduct voluntary recalls of consumer products that present a risk to public safety.

How is a medical device recall implemented?

The degree of hazard and the extent of distribution of the defective product dictate the overall recall strategy developed by the manufacturer and the FDA. The FDA assigns a product recall classification that indicates the degree of hazard presented to the public health. Those classifications are:

- Class I Recall: There is reasonable probability that the use of, or exposure to, the product will cause serious adverse health consequences or death.
- Class II Recall: The use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences. The probability of serious adverse health consequences is remote.
- Class III Recall: The use of, or exposure to, the product is not likely to cause adverse health consequences.[9]

The recall plan sets forth the depth of the recall, the need for public warnings, and the types of effectiveness checks employed.[10] The *strategy* for alerting health care providers, and sometimes the general public, may require mailings, telephone communication, or in-person correspondence such as through sales representatives. Notices to providers will list the products or components of the products that are subject to the recall, an analysis of the issue, and recommendations for a course of action regarding the recall. The *action* required by the recall plan depends on the recall classification and does not necessarily

9 21 C.F.R. § 7.3(m).
10 *Id.* §§ 7.46 (firm-initiated recalls), 7.42 (recalls including product corrections).

direct providers to stop using, quarantine, or return the recalled device. A recall initiated due to incorrect labeling, for example, may only require a correction to the product.[11] In other instances, a device may only require an adjustment or an update. For example, the FDA's first recall due to a cybersecurity breach occurred in August 2017 with the FDA recalling an implantable pacemaker due to the potential for exploitation of cybersecurity vulnerabilities in the software embedded in the hardware of the device.[12] Instead of recommending that health care providers remove or replace the affected device, the FDA suggested updating the software. When an implanted device has the potential to fail unexpectedly, the established recall plan may direct physicians to contact affected patients to discuss the risk of removing the device compared to the risk of leaving it in place, thereby deferring the course of action to the judgment of the physician and the patient's preference.[13]

Considerations for Health Care Providers

The health care provider is often in the best position to directly inform his or her patients about a medical device recall, but the process of warning and informing all affected patients can be challenging, from tracking the device at issue to billing for services and products associated with a recall.

Managing provider liability risks

While the manufacturer is expected to identify the need for a device recall, health care providers are in a better position to identify and notify affected patients and quarantine identified devices. The provider may therefore be legally obligated to take those actions. A device manufacturer is responsible for any negligent actions relating to the manufacture or performance of a defective

11 *Class 3 Device Recall Acumedia Urea Base Agar*, FDA, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=155596 (last visited Nov. 27, 2017).

12 *Firmware Update to Address Cybersecurity Vulnerabilities Identified in Abbott's (formerly St. Jude Medical's) Implantable Cardiac Pacemakers: FDA Safety Communication*, FDA, www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm573669.htm (last visited Nov. 27, 2017).

13 *What is a Medical Device Recall?*, FDA, www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm (last visited Nov. 27, 2017).

device, and in most cases, any product liability claim related to a recalled device would be brought against the manufacturer of the product; however, a health care provider may be exposed to liability in the event he or she fails to adequately respond to a recall action, remove a defective product from inventory, or notify affected patients.

Courts have held that a health care provider can be liable for failing to make reasonable efforts to warn an affected patient of a recall where the provider receives notice of such recall and is instructed as part of the FDA established recall plan to notify patients.[14] In one such case, a patient who received a dental implant that was subsequently recalled filed a lawsuit against her oral surgeon for failing to notify her of the recall under a theory of ordinary negligence (as opposed to medical malpractice). Once the patient established that the doctor was aware of the recall and that she was not notified of the recall, the court shifted the burden to the implanting doctor to explain the steps taken to attempt to notify the patient, or to explain why no steps were taken.[15] The duty to warn and the adequacy of the warning were determined to be questions of fact for a jury. It has also been established that a provider can be held accountable, under a theory of ordinary negligence, when the provider's failure to have policies and procedures in place to ensure a recalled product is promptly removed from inventory results in patient injury.[16] Health care providers therefore have both an ethical duty and a legal duty to maintain policies and procedures and a system of health information that allows the provider to promptly respond to a recall and to advise affected patients.

Challenges in tracking devices and notifying patients

Identifying the universe of patients who have been treated with a defective device can be burdensome and absorb tremendous resources, particularly if necessary data is not fully integrated into the provider's clinical and administrative practice management systems. Even if a provider uses an electronic

14 Bush v. Thoratec Corp., 13 F. Supp. 3d 554 (E.D. La. 2014); Cox v. Paul, 828 N.E.2d 907 (Ind. 2005) [hereinafter *Cox*].
15 *Cox*.
16 Holmes Reg'l Med. Ctr., Inc. v. Dumigan, 151 So. 3d 1282 (Fla. Dist. Ct. App. 5th Dist. 2014).

health record versus paper charts, each record must be manually reviewed to identify patients and the specific device if the electronic health record is not maintained in a manner that allows it to be queried for the pertinent data.

Traceability of medical devices down to the component part level is critical to implementing an effective recall. Historically, medical devices did not have standardized barcodes and were tracked by hospitals through manual data entry. Clinical systems often lack the ability to link medical device information with patient information in a way that allows a provider to query which patients have been treated with a particular device in the event of a recall. On September 4, 2013, the FDA published a final rule, mandated by the Food and Drug Administration Amendments Act of 2007, which established a unique device identifier (UDI) system to identify devices through distribution and use.[17] The UDI mandate, which is being implemented in phases through 2020, requires device labels to include a unique device identifier in human and machine readable forms that can be scanned and recorded and cross-referenced with an FDA-maintained database that serves as a reference catalog of information about every device that has a UDI. Although hospitals have the discretion to decide whether to track UDIs and what type of technology they will use to capture data, the FDA is working to develop a roadmap for the adoption and implementation of UDI throughout health care systems. The Centers for Medicare and Medicaid Services (CMS) has published a final rule that will require UDI integration for some electronic health record incentive payments.[18] While the effectiveness of the UDI depends on a provider's ability to integrate UDIs into electronic health records and other administrative systems such that providers can identify defective devices and component parts and associate them with patients using minimal resources, the UDI

17 Unique Device Identification System, 78 Fed. Reg. 58786 (Sept. 24, 2013) (to be codified at 21 C.F.R. pts. 16 801, 803, 806, 810, 814, 820, 821, 822, & 830), *available at* www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf.

18 Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62762 (Oct. 16, 2015) (to be codified at 42 C.F.R. pts. 412 & 495), *available at* www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf.

system offers the potential for real time surveillance and tracking and provides a tool for quickly responding to safety concerns related to medical devices.[19]

Billing for services and products associated with a recall

In addition to identifying and notifying affected patients, a provider is responsible for discussing the risks and benefits of increased monitoring, imaging, medical intervention, or other course of action in response to the recall. A patient's options will depend on a variety of factors, but underlying the discussion will usually be the question of who will pay for the additional costs attributable to the recall. In many instances, manufacturers will cover the cost of the device and at least a portion of the hospital and physician charges directly related to the recall. The more likely scenario, however, is that the patient or the patient's insurer will bear the medical costs unless the patient brings the matter to litigation.

Importantly, CMS adopts a prudent buyer principle, which requires providers to seek to economize by refusing to pay more than the going price for an item or service and to seek advantages such as investigating the availability of free replacements or reduced charges under warranties for medical devices. The CMS Provider Reimbursement Manual (PRM) states that Medicare providers are expected to pursue free replacements or reduced charges under warranties.[20] If a provider purchases a device for use in replacing malfunctioning equipment, and does not ask the manufacturer for full or partial credit or payment available under the terms of the warranty, credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment supplied. Federal Medicare regulations require hospitals to report full or partial credit received from manufacturers for medical devices that are replaced because of defects or recalls.[21] In addition, all Medicare

19 *See generally*, *Benefits of a UDI System*, FDA, www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/BenefitsofaUDIsystem/default.htm (last visited Nov. 27, 2017).

20 CMS, Provider Reimbursement Manual, Part I, § 2103.A (Chapter 21), *available at* www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html.

21 42 C.F.R. §§ 412.89, 419.45.

payments to hospitals for services must be based on the reasonable cost of services.[22] CMS will recover overpayment amounts from a provider that is eligible for a credit relating to a recall when the health care provider fails to take adequate steps to minimize its cost. It is therefore incumbent on providers to ensure adequate controls are in place to seek manufacturer credits where appropriate and to properly code for the replacement of recalled devices. Currently, hospitals are only required to report these condition codes if a replacement device is received at no cost or with a cost credit that is fifty percent (50%) or greater of the cost of the device.

Further, CMS has expressed concern regarding expenditures by Medicare due to recalled or defective medical devices and is proactively working to address these costs. In its 2017 Work Plan, the Office of Inspector General (OIG) committed to reviewing Medicare claims to identify costs attributable to additional medical services associated with recalled devices and to recoup overpayments to providers for replacement devices that should have been reimbursed at a reduced rate.[23] In September 2017, the OIG published a report which found that services related to the replacement of seven selected recalled and prematurely failed cardiac devices cost Medicare $1.5 billion during calendar years 2005 through 2014.[24] The report recommended that CMS work with the Accredited Standards Committee X12 (the organization responsible for defining and developing electronic health care forms) to ensure that the Device Identifier (DI), a component of the UDI, is included on the next version of claim forms. The report also recommended requiring hospitals to use condition codes 49 or 50 for reporting a device replacement resulting from a recall or premature failure so that CMS can identify and track Medicare costs associated with replacement of recalled devices. Given the OIG's focus on costs associated with recalls, hospitals should educate staff to ensure modifiers are appropriately used to identify devices furnished without cost or with partial

22 *Id*. § 413.9.

23 HHS OIG, OIG Work Plan (2017), *available at* https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/hhs%20oig%20work%20plan%202017.pdf.

24 HHS OIG, Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices (2017), *available at* https://oig.hhs.gov/oas/reports/region1/11500504.pdf.

credit. As noted by the results of a 2014 OIG investigation, hospitals often do not properly report medical device credits or do not obtain credit for replaced devices despite eligibility under the manufacturer's warranty due to inadequate policies and procedures, lack of awareness of warranties and credit availability, and hospital misapplication of the credit amounts.[25]

What Can Health Care Providers Do To Prepare for a Recall?

Although the risk to patient health and the potential for provider liability increases with the degree of health hazard presented by a defective product, providers should be prepared to act in the event any notice of corrective action is received, even if such notice does not amount to a recall.

Establish multidisciplinary recall policies and procedures

Recall preparedness requires establishing written policies and procedures so staff is ready to act when a recall notice is received. Policies and procedures should not only set forth the steps to be taken in the event of a recall but also should designate specific individuals who will be responsible for each step. Funneling all communication to a designated individual or "recall coordinator" can create efficiencies in the overall recall response. The recall coordinator should work closely with risk management, materials management, and the recalling manufacturer to oversee each aspect of the recall process. Effective policies and procedures will establish a process for identifying, quarantining, and returning recalled devices using technology solutions where possible, and also should involve collaboration with risk management as appropriate. Providers should create a work flow for evaluating the risk of the recall and for developing a strategy to identify and communicate with patients and staff. The recall strategy should include ongoing monitoring of incoming shipments for the recalled product. Importantly, the recall strategy should be capable of activation at all times.

25 HHS OIG, Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits (2014), *available at* https://oig.hhs.gov/oas/reports/region5/51300029.pdf.

Monitor billing procedures

The overall recall strategy should include a process for confirming the extent of reimbursement available from the recalling manufacturer, securing such reimbursement, and ensuring recall-related services and devices are properly billed. Some manufacturers will require the credit to be requested while others will automatically issue the credit when a defective device is returned. An effective policy will incorporate cross-departmental workflow of checks and balances, including clinical staff, materials management personnel, and finance personnel, with individuals assigned responsibility at each level.

Educate staff

As soon as notice of a recall is received, pertinent information should be communicated to any impacted areas and to any staff who might receive an inquiry about the recall. It may be helpful to post recall alerts in clinical or staff break areas, or to fax or email such notices throughout the organization. Staff training regarding recall policies and procedures should be ongoing and updated as necessary.

Staff also should be trained about the regulations surrounding a device recall and the terminology used in connection with a recall. For instance, if staff is aware of the different levels of hazard associated with Class I, Class II, and Class III recalls and they understand the meaning of terms such as "safety alert" and "recall," staff will better understand the clinical significance of the recall on patient care and more effectively communicate with affected patients.

Communicate effectively with patients

Health care providers should educate their patients about the risk of complications and potential for defects with devices, particularly with devices that are associated with high rates of incident, as part of the informed consent process before the device is implanted. This proactive discussion may positively affect a patient's response in the event of a recall.

The quality of communication can significantly influence a patient's response in the event of a medical device recall. Communication regarding a recall should be consistent, accurate, honest, timely, and show sensitivity to a patient's circumstance. The method of communication should reflect the severity of the recall. In-person or telephone conversations can be most effective in responding to concerns and easing patient anxiety. Recalling manufacturers will often prepare information packets and materials, including patient letters, which can be helpful resources for communicating with and educating patients. A provider should at minimum follow the instructions and execute the actions in the FDA recall plan.

Stay informed of medical device recalls

While health care providers should receive a notification from the manufacturer in the event of a recall, providers should proactively position themselves to receive recall notices from the FDA. Staff can monitor the FDA's website for alerts or subscribe to FDA listservs for notices regarding medical device recalls and other safety information.

How to Stay Informed About Recent Recalls

The FDA's searchable Medical Device Recall Database includes correction or removal actions initiated by a manufacturer prior to recall classification.

The Center for Biologics Evaluation and Research (CBER) provides information about recalls that may not be included in the FDA's Medical Device Recall Database, such as in vitro diagnostic tests for blood screening and medical devices used for blood collection and processing.

Although not all recalls are announced in the media or on the FDA's website, the FDA frequently posts press releases and other public notices about recalls, market withdrawals, and safety alerts.

The FDA publishes all recalls monitored by the FDA in a weekly enforcement report, which one can receive automatically by subscribing to the enforcement report mailing list or search through the enforcement report database.

Validate recall processes

Recall processes should be internally validated by conducting exercises and training that require staff to respond to simulated recall events. Logistical challenges to implementing a recall plan should be identified in a practice setting, not when a quick response to an actual recall action is required. Going through the motions of a recall while there is no urgency—identifying devices, notifying patients, and removing products from inventory—will give staff the opportunity to ask questions and offer insight on contemplated procedures that may not be practical or effective. The validation process will also ensure that individual staff members are aware of and comfortable with their respective roles and that the process can be activated at any time. Providers should consider validating billing policies and procedures by conducting internal or third party audits of affected claims and addressing any sources of error. Finally, providers should evaluate their recall plans following implementation during an actual recall event to further strengthen procedures. The frequency with which processes should be audited and validated will be dictated by the complexity of the organization.

Conclusion

While medical device manufacturers are generally responsible for initiating recalls through collaboration with the FDA, as a practical matter, much of the burden of implementing a recall falls on health care providers. To ensure patient safety and avoid potential liability, physicians and hospitals should be prepared to effectively track devices and component parts and to promptly notify affected patients by establishing multidisciplinary policies and procedures, cross-departmental checks, and an efficient recordkeeping system. J

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