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IN THIS ISSUE

Industry Pushes to Modernize Anti-Kickback Statute to Advance Value-Based Care

AdvaMed is paying close attention to an initiative by HHS that could impact pricing arrangements for medical devices by adding safe harbors to the federal anti-kickback statute.

HHS last week issued a Request for Information on barriers to coordinated care as part of a broader effort to shift away from fee-for-service and toward value-based care.

The RFI would provide information needed to modernize the anti-kickback statute.

The HHS Office of Inspector General is looking at ways to modify or add safe harbors to the anti-kickback statute to foster arrangements that would promote care coordination while also protecting against fraud and abuse.

(See **Anti-Kickback**, *Page 2)*

FDA Warns Zimmer Biomet For Quality Violations

Zimmer Biomet's Warsaw, Indiana orthopedic implant manufacturing facility drew a warning from the FDA for quality violations dating back to 2016 after an April inspection revealed ongoing problems.

In its Aug. 24 warning letter, the FDA noted the facility implemented "numerous interim controls" in response to the 2016 inspection findings but that the spring inspection revealed "continuing, significant violations."

The agency was not fully satisfied with the company's response to the Form 483 report issued on April 24 or with a July 31 status update.

Three separate CAPAs reviewed during the April inspection revealed that the firm did not demonstrate that the CAPAs were effective in ensuring that the distributed devices met finished product specifications. The investigators noted one instance where the data didn't show that the cleaning process was capable of meeting the cleanliness specification for the devices.

(See **Zimmer**, *Page 4)*

Anti-Kickback, *from Page 1*

The medtech industry has been working with HHS to "remove these archaic roadblocks through AKS modernization," noted AdvaMed President Scott Whittaker.

Currently, the anti-kickback statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under federal healthcare programs.

The concern is that because the statute was written so broadly, some innocuous and potentially beneficial arrangements could be subject to criminal prosecution.

The agency is accepting comments from industry on the safe harbors to the anti-kickback statute. Civil monetary penalties could be imposed under the act on anyone who offers remuneration to a Medicare or state healthcare program provider that could influence the provider or supplier.

Waivers

Remuneration could include waivers of copayments and deductible amounts and transfers of items or services. However, in a system that is quickly moving toward a more value-based and coordinated care model, stakeholders are pushing HHS to modify existing safe harbors to reduce regulatory impediments to the value-based arrangements.

"Congress intended the safe harbors to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the healthcare industry," the RFI says.

The RFI notes that healthcare providers and others "may voluntarily comply with safe harbors in an effort to ensure that their business practices will not be subject to criminal prosecution under the anti-kickback statute, the imposition of civil monetary penalties (CMPs)," program expulsion and liability under the False Claims Act.

"When we think about coordinated care, we think about a healthcare system in which all participants are invested in good patient outcomes. But there remain significant regulatory roadblocks that stand in the way of the medtech industry's full participation," AdvaMed said in its comments.

Device manufacturers can be key players in coordinated care by leveraging their clinical and economic expertise, supply chain management capability and data analytics proficiency, the association said, adding that "these capabilities can facilitate clinical guarantees — and intelligent bundling of services, information technology and life-changing medical technology — to help achieve better outcomes, lower costs and an improved patient experience."

New Safe Harbors

AdvaMed said devicemakers want to help "drive comprehensive solutions to detect, treat, and manage disease, and share accountability for achieving better outcomes as well as managing costs. But the existing AKS and its narrow and outdated regulatory safe harbors deter medtech companies from participating in these value-based arrangements."

AdvaMed has been working with the OIG and other stakeholders to advance proposals for two new AKS safe harbors — one to protect value-based pricing arrangements and another to protect value-based warranties.

"These proposals are intended to allow for clinical performance incentive payments and results-based contracts — between providers, between providers and manufacturers, and between manufacturers and payers — that focus on optimizing patients' clinical outcomes and fostering efficient and cost-effective delivery of care through shared accountability. And, they will facilitate medtech company competition based on outcomes, all for the benefit of patients," AdvaMed said.

Read the HHS Request for Information here: www.fdanews.com/08-29-18-Antikickback.pdf.

BRIEFS

Cyber Vulnerabilities Reported in Becton Dickinson's Alaris Plus Syringe Pumps

The Department of Homeland Security warned that Becton Dickinson's Alaris Plus medical syringe pump is vulnerable to a remote attacker gaining unauthorized access and gaining control of the pump when it's connected to a terminal server via the serial port.

BD reported that the affected pumps are sold in the European Union. The vulnerable pumps include the Alaris GS, Alaris GH, Alaris CC, and the Alaris TIVA.

The cybersecurity firm CyberMDX discovered the vulnerability, and BD reported it to the DHS Industrial Control Systems Cyber Emergency Response Team. BD said the vulnerability can't be accessed if the device is connected to the Alaris Gateway workstation docking station and an attacker can't switch the device on remotely.

The attack uses a known vulnerability in terminal servers, the devicemaker said, and users should understand that the device does not support terminal server use. To mitigate risk, users should ensure they are operating the devices in a segmented network environment or as a standalone device, BD said.

The National Cybersecurity and Communications Integration Center recommended the following defensive measures to minimize risk:

- Minimize network exposure for all control system devices and systems and ensure that they are not accessible to the internet;
- Locate control system networks and remote devices behind firewalls, and isolate them from the business network; and
- When remote access is required, use secure methods, such as virtual private networks (VPNs), recognizing that VPNs may have vulnerabilities and should be updated to the most current version available. Also recognize that VPN is only as secure as the connected devices.

India's CDSCO Releases Guidance On Evaluating IVDs

Manufacturers of in vitro diagnostic devices in India must submit performance reports issued by central medical device testing laboratories with their Class B, Class C and Class D IVD applications, India's Central Drugs Standard Control Organization said.

Under new medical device rules that became effective Jan. 1, laboratories that test medical devices and in vitro diagnostics must register with the agency.

The registrations will allow CDSCO and other government agencies to maintain updated information on all laboratories involved in testing of medical devices and IVDs. No laboratory may be designated without first being accredited by the National Accreditation Board for Testing and Calibration Laboratories.

Laboratories that go through the accreditation process will need to inform CDSCO about which IVDs can be tested at their facilities, as well as the persons involved in the testing.

The CDSCO notice lists specific labs for specific tests. It notes that laboratories must be accredited by the National Accreditation Board for Testing and Calibration Laboratories, the National Accreditation Board for Hospitals and Healthcare Providers, the Central Government or State Government laboratory or the Central Licensing Authority.

Egypt Rolls Out Broader Device Regulations

Egypt's Central Administration for Pharmaceutical Affairs is now requiring all medical devices to be registered.

Devicemakers should consult with the agency to see what documentation is required to review their technical files and re-register their devices. The agency said that if devices meet requirements they can remain in circulation, but devices that fail to meet requirements will be pulled from the market.

Previously, only sterile devices needed to be registered with the Egyptian regulator.

Zimmer, *from Page 1*

"We are concerned about your firm's ability to verify the effectiveness of the corrective actions included in this CAPA, when errors are not being identified in your interim processes," said Joseph Matrisciano, Jr., program division director of the FDA's Office of Medical Device and Radiological Health Division.

Matrisciano also called on the company to say what steps it is taking for "products that are currently in distribution and may require additional remediation." He did not call for the withdrawal of any products from the marketplace but said failure to promptly correct the violations may result in regulatory action.

The FDA said the company failed to:

- Check that the results of a process can be validated with a high degree of assurance;
- Develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications;
- Establish and maintain design validation procedures to ensure proper risk analysis is completed;
- Establish and maintain procedures to adequately control environmental conditions; and
- Maintain procedures for implementing corrective and preventive actions in order to identify existing and potential causes of nonconforming product.

Read the warning letter here: www.fdanews.com/08-31-18-ZimmerBiomet.pdf.

— Tiffany Winters

Advantages of Internal Audits

U.S., European and other regulators require drug- and devicemakers to review their operations with some degree of regularity to ensure compliance with GMP rules. Companies are free to determine exactly when, where and how these audits are carried out; still, they often look upon them as yet another burdensome regulatory requirement. But internal audits also offer a keen tool that can pare away not only noncompliant operations, but also inefficient or costly procedures.

When designing an internal audit system, as well as when actually conducting the audits, companies should look at the process in terms of the benefits it can yield. In regulatory and product quality terms, of course, an appropriately designed and implemented internal audit program can let companies identify any GMP or quality system issues before a regulator or client inspection or — even better — provide valuable information that helps to prevent issues from developing in the first place.

Wherever any corrective actions are needed, these can be put in place well before the FDA or other regulator knocks on the door, or before a client asks to review the operations of a drug or devicemaker performing contract manufacturing or providing contract laboratory services.

Then, when an inspection—regulatory or client—occurs and a particular issue is noted, the company can say that it has already identified that problem and is in the process of correcting it or, better yet, has already corrected it.

Maintaining Reputation

And it's important to remember issues identified during an internal audit are confidential, whereas corrective actions are not. The confidential information includes the way in which the issue was identified and probably some of the ugliness of it under the internal audit. Some of what is uncovered during an internal audit could be things like insufficient SOPs, failure to follow critical SOPs or problems with equipment or manufacturing facilities, all things that can make a drug- or devicemaker look bad.

Corrective actions, on the other hand, should show proactive steps taken to deal with a problem or potential problem. That adds an element of robustness to your quality system. In terms of what regulators, healthcare providers, clients and the public see, the corrective actions simply show that a problem was identified quickly and addressed promptly and thoroughly, which can raise a company's profile.

Excerpted from the FDAnews management report: *Quality Management Essentials — Expert Advice on Building a Compliant System*.

China Simplifies Device Registration Requirements

China's National Drug Administration is loosening some documentation requirements for registration renewals and clinical trials to simplify compliance.

According to a recent CNDA notice, only summary information will be required for device and IVD renewals. This means devicemakers will no longer need to submit sales data and post-market inspection reports.

However, devicemakers should continue to report adverse events and complaints as these requirements have not been relaxed, Ropes & Gray attorney Katherine Wang told *FDAnews*.

To simplify filings for clinical trials, foreign manufacturers won't have to provide proof of home country approval in their clinical trial applications.

Ethics Committees

"This is a move to simplify compliance and [ease the] burden on applicants," Wang said. "For example, previously applicants needed to submit [Ethics Committee] approvals from all sites to apply for clinical trial authorizations. The recent notice will allow applicants to only submit the approval from the lead site, and this will significantly shorten the preparation timeline."

With recent policy moves to enhance enforcement efficiency and consistency, CNDA officials will have access to databases and enforcement records that earlier may have been siloed in different regulatory bodies. This means it will likely be easier for enforcement teams to share information and better coordinate enforcement efforts (*IDDM*, April 9).

Previously, lower-risk devices were reviewed by local authorities. The national administration will now have wider authority to review and approve lower-risk products as regulatory authority is transferred from provincial authorities and consolidated within the new national drug administration.

A draft amendment calls for joint inspections with the national authority, the provincial authorities and local authorities for GCP, GMP and GSP inspections, but the national authority would be responsible for overseas inspections.

"The CNDA requires medical devices to comply with China's mandatory technical standards, which are not always consistent with the latest ISO standards," Wang said in a research note.

"Manufacturers of imported medical devices might have taken an opportunistic approach in the past, creating product technical requirements that could conform to the mandatory standards on paper, but deviate from the actual product specifications in reality."

These nonconforming products will be deemed as "disguised devices" under the draft amendment, and foreign manufacturers as well as their Chinese legal agents will face serious penalties, she said.

The significant increase in fines — up from 20 times to 30 times of sales value — and personal liabilities imposed on individual managers will incentivize companies to "thoroughly review their quality management systems and close potential gaps as soon as possible," Wang said.

UDI Required

The amendment would prohibit importation and distribution of used devices, and it also requires that all medical devices bear a unique device identifier (*IDDM*, July 9).

The recent move follows a string of updates to China's device regulations that are aimed at bringing China's regulations more in line with those of international regulatory authorities and the country has been more active in the International Medical Device Manufacturers Forum.

One of the biggest changes is that CNDA will accept foreign clinical trial data, and local trials may not be required. However, local trials may be required for higher-risk devices. In addition, clinical trials can begin 60 days after an IDE is filed if the manufacturer does not hear otherwise from the agency.

Profile: All Eyes on First Approved AI Diagnostic Tool

The doctor behind the first autonomous artificial intelligence-driven diagnostic system to win approval from the FDA is showing his work.

Michael Abramoff, a University of Iowa ophthalmologist and professor, and his colleagues spent more than three decades developing the IDx-DR, an AI-driven tool designed to diagnose degeneration in the eye.

The FDA earlier this year approved IDx-DR to detect retinopathy caused by diabetes, the first time such a technology was OK'd in any field in medicine. And now the researchers have published the clinical data behind IDx-DR's success.

So how did they do it?

Abramoff tells *FDAnews* he began studying AI 30 years ago and a few years later started working on the algorithms that would become IDx-DR 22. He founded the company that now owns the marketing rights to IDx-DR in 2007 but was in discussions with the FDA for eight years before getting the go-ahead for a clinical trial last year.

The FDA designated IDx-DR as a breakthrough device and "provided intensive interaction and guidance to the company on efficient device development, to expedite development, to expedite evidence generation and the agency's review of the device," he says.

When the trial was finally greenlighted, researchers recruited 900 people with diabetes at risk for retinal decline at 10 eye clinics around the country. Over six months, clinic staff visually examined participants' eyes, scanned them with IDx-DR and, finally, trained retinal photographers took pictures of their eyes using fundus imaging and optical coherence tomography, considered the "gold standard" for retinal imaging.

All but 80 volunteers completed all three procedures during the trial. Of those, 198 showed signs of retinal decay. The IDx-DR system diagnosed 173 correctly, a success rate of more than 87 percent.

Nearly 24,000 Americans suffer diabetes-related blindness each year, according to the CDC. But nearly half of diabetics in the U.S. skip recommended annual eye exams, the FDA noted in approving IDx-DR. Among the major reasons cited for skipping exams were cost and lack of access to advanced eye care — hurdles Abramoff believes IDx-DR can help overcome.

More Potential

The IDx-DR has two algorithms at its core. One focuses on image quality and the other on diagnostics. The image algorithm takes four rapid-fire photos of the retina to determine whether there's sufficient area, focus, color balance and exposure to make a diagnosis.

IDx-DR was developed specifically for diabetic retinopathy. But Abramoff believes it has potential to do a lot more. In fact, he and his team are working on sister devices that they hope will help diagnose other eye disorders such as glaucoma. — Bill Myers

Australian Wheelchair Manufacturer Failed to Report Product Defects

Magic Mobility was called out by the FDA and issued a Form 483 over MDR reporting and complaint handling practices at its Melbourne facility, including a failure to report a serious wheelchair malfunction.

The investigator, who inspected the facility in late October, found that the firm had no MDR procedures. Despite receiving information that warranted an MDR report, the firm did not submit one within the 30 day deadline. Specifically, it received a claim that its Extreme X8 wheelchair emitted a burning smell and smoke from under the seat while being driven, launching the user out of the chair when the joystick wire flared up.

The agency also found the firm did not have a proper complaint procedure to describe how to routinely and quickly process complaints, maintain complaint files, receive, review and evaluate complaints and evaluate the reportability of complaints.

One complaint about a faulty limit switch had no form of identification, including the device model or serial number. It also lacked complaint details and information about the investigation. Another complaint about a circuit board's soldering lacked the same details, while a wheelchair complaint lacked the date of the event and other information.

The investigator also noted that the firm had no records to prove that it implemented corrective actions for poor weld penetration on a wheelchair hanger mount. The parts were supposedly collected, visually inspected and destroyed if they did not pass, but the firm did not have records to support the claim.

Read the Magic Mobility 483 here: www.fdanews.com/08-30-18-magicmobility483.pdf. — James Miessler

APPROVALS

FDA Clears TechLab's Gastrointestinal Diagnostic Tests

The FDA granted 510(k) clearance for two TechLab gastrointestinal disease diagnostic tests, the H. pylori Chek and QuikChek tests.

Both tests are designed to help in the diagnosis of Helicobacter pylori infection, a bacterial infection linked to peptic ulcers.

The QuikChek test can diagnose infection in 30 minutes, while the Chek test is a 96-well plate format diagnostic used in laboratories for diagnosing large numbers of specimens in an hour.

UVision360's Hysteroscopy System Receives 510(k) Clearance

UVision360's Luminelle DTx system, a hysteroscopy device, received 510(k) clearance by the FDA for use in hysteroscopy and cystoscopy procedures.

The device allows physicians to examine the internal lining of the uterus and identify suspicious tissue, in addition to allowing biopsies under visualization.

The system is similar to operating room equipment but can be used by physicians to perform the procedures in their offices.

Gore Gets 510(k) Clearance Of Molding and Occlusion Balloon

The FDA cleared Gore's molding and occlusion balloon device, a compliant polyurethane balloon catheter.

The device meets all endovascular aortic repair procedural requirements, from 10 to 37 mm device sizes, and consists of a single balloon, removing the need for multiple molding and occlusion balloons.

It comes in a single catheter length of 90 mm for use with Gore Excluder devices and is designed to help clinicians with the expansion

(See **Approvals**, *Page 8)*

Approvals, *from Page 7*

of self-expanding stent grafts and the temporary occlusion of large-diameter vessels. It is also compatible with 108 cm length guidewire.

FDA Clears Gynesonics' Sonata System for Treating Uterine Fibroids

The FDA granted 510(k) approval for Gynesonics' Sonata system, a sonography-guided transcervical fibroid ablation device.

The device uses intrauterine ultrasound technology with a radiofrequency ablation device to treat uterine fibroids.

The Sonata system provides women with a transcervical treatment for uterine fibroids that requires no incisions.

Philips' Ultrasound Systems Cleared by FDA

Two of Philips' cardiovascular ultrasound devices have gained 510(k) clearance from the FDA for performing diagnostic, pediatric and interventional echocardiography.

The Epiq CVx device helps clinicians in their inspections of the heart by offering improved image quality, while the Epiq CVxi offers a tool to improve communications between interventional cardiologists and echocardiographers.

The Epiq CVxi combines live ultrasound and X-rays into a single view.

Dthera's Digital Alzheimer's Treatment Granted Breakthrough Designation

The FDA granted Dthera Sciences breakthrough designation for its digital Alzheimer's treatment, one of the first digital therapeutic products to receive the designation.

The digital device uses a custom-built tablet, equipped with a camera, to display memories relevant to the patient, such as photos of loved ones.

Artificial intelligence built into the device gauges the patient's reaction to the displayed memories and adjusts content on the screen to guide the patient's emotions.

FDA Clears Ceterix's Suture Cartridge

The FDA granted 510(k) clearance for an additional feature of Ceterix Orthopaedics' NovoStitch Pro Meniscal Repair System, a device used in repairing meniscal tears.

The device is used to place stitches arthroscopically within tight joint areas and allows surgeons to work on meniscal tears that previously responded poorly to repairs.

The cleared feature, a size zero suture cartridge, gives surgeons expanded options in suture size and enables them to pass a complete stitch in the knee joint without having to remove the device to reload a suture.

iVWatch Gains CE Mark For IV Surveillance Device

iVWatch received the CE Mark for its iVWatch Model 400, a continuous monitoring device for detecting intravenous infiltrations and the leakage of fluids.

The device, which has been cleared by the FDA, provides a measure of security for standard, unmonitored peripheral IVs.

It enables early detection of fluid leaks and notifications of infiltration, improving patient outcomes during IV therapy by identifying potential complications.

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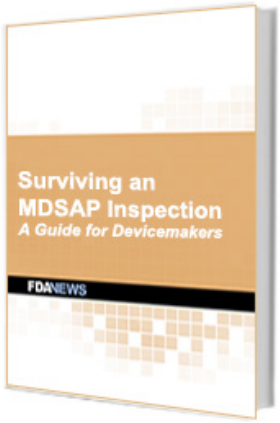

Surviving an MDSAP Inspection: *A Guide for Devicemakers*

Currently, Australia, Brazil, Canada, Japan and the United States are participating in the MDSAP program. If you pass one MDSAP inspection you'll be ready to pursue marketing authorization in five separate countries.

But, if you're going through MDSAP for the first time your experience will be very different from regulatory inspections you've gone through in the past.

- You'll know exactly when and how often to expect an audit
- You'll know exactly how long the audit will be
- You'll know exactly what questions the auditor will ask

The prescriptive nature of the MDSAP model makes it relatively easy to prepare for an audit — if you know what to expect. **Surviving an MDSAP Inspection** provides all the information you'll need to understand the MDSAP model. You'll learn:

- The standard schedule for and duration of audits
- Specific areas auditors will examine and questions they will ask
- Different types of audits involved, such as initial certification, surveillance, desk and site audits
- How to create a checklist to make sure all your bases are covered
- The MDSAP grading system and how nonconformance issues can be escalated — and consequences of getting a bad grade

The management report also includes a copy of the MDSAP Companion document — the official guide — auditors will follow.

Order your copy of **Surviving an MDSAP Inspection: *A Guide for Devicemakers*** and know what to expect from an MDSAP audit and how to prepare for it.

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EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements*

The new EU Medical Device Regulation is massive… complex… and confusing… and you must be ready to comply by May 26, 2020.

When the European Union revised its system of rules for medical device manufacturers in 2017, it replaced a longstanding set of directives on specific topics with one large document that covers all aspects of making devices in EU countries.

Not only did they consolidate all the rules, they gave them greater weight. Previously, medical device directives provided guidance but did not have the force of law. The new MDR, however, contains mandates that are legally enforceable by EU member countries.

The FDAnews report **EU MDR Compliance** can help. Our editors have combed through the regulations, picking out the most minute compliance points and building them into a checklist of 200+ requirements you can use to confirm that you are satisfying all the EU mandates for device manufacturing. The report provides:

- Definitions of key terms in the EU MDR
- Knowing where to find specific requirements in the 150+ page regulation
- Checklists that walk you through every aspect of manufacturing, safety and performance requirements
- A training tool for employees new to the regulations

EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements* is the tool that collects all the requirements, explains them and itemized them in an easy-to-use form to ensure compliance.

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