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Medical Device Data Systems Dodge FDA Regulation

The U.S. FDA has decided not to regulate most devices used to store patient data, saying systems that perform tasks such as storing and transmitting medical images pose a low risk to public health.

The new policy, outlined in final guidance published Feb. 9, completes a gradual deregulation of medical device data systems that began in 2011 when the FDA placed them all in Class I. Before that, MDDS were assigned the same classification as their corresponding device.

Data-collection technologies that fall under the guidance include software used to transfer information from a device to medical records, store information for later review, reformat medical data for printing or display data previously collected, such as an electrocardiogram. The MDDS may take any form, provided it is only serving these purposes.

Narrow Definition

For example, an MDDS can be an assembly of network components that includes specialized hardware or software, software labeled by the manufacturer as an MDDS, custom software developed by a hospital that directly connects to a medical device or modified portions of an underlying IT infrastructure.

If the functions of the device extend beyond those listed in the guidance, however, it doesn't qualify as an MDDS.

This means that an MDDS can't modify data or control the function of any connected device. The FDA stresses that devices meant for active patient monitoring are not MDDS. Data-gathering devices that require an immediate response — for example, hospital patient monitoring technology, or blood glucose monitors for diabetics — will still be FDA-regulated under the new guidance.

The FDA also updated its guidance on mobile medical apps to make clear that apps that perform the same functions as an MDDS are not regulated.

View the guidance at www.fdanews.com/02-16-15-data.pdf.
— Elizabeth Orr

China to Revise GMPs for Sterile, Implantable Devices

The China Food and Drug Administration plans to revise its device good manufacturing practices to include specific GMPs for sterile and implantable devices.

The revisions, outlined in Feb. 9 draft guidance, aim to bring GMPs for these products up to par with international standards, Seth Goldenberg, director of global regulatory strategy at NAMSA, tells *IDDM.*

Several parts of China's device GMPs lack details for sterile and implantable devices, and the revisions should help domestic companies that don't have a lot of historical experience with quality systems compliance, Goldenberg adds, noting local devicemakers are often confused about what is sufficient in terms of GMPs. The proposed requirements will hopefully clarify these concerns, he says.

Multinational firms should have no problem meeting these requirements, Goldenberg says. For example, the proposed cleanroom requirements are lifted from ISO 14644-1 on cleanrooms and associated controlled environments and Federal Standard 209E on airborne particulate cleanliness classes in cleanrooms and cleanzones.

Goldenberg doesn't think companies will have much trouble complying with the implantable device GMPs, but some domestic firms, such as makers of single-use sterile devices, could be challenged by the sterile product GMPs.

Still, the category-specific GMPs remove any gray area regarding what companies are expected to do and will make it easier for regulators to enforce quality regulations, he says. "Companies can't sneak by due to ambiguous language anymore."

The proposed GMPs follow CFDA plans to beef up its inspections system for devicemakers (*IDDM,* Feb. 9).

CFDA is taking comments on the sterile and implantable device GMPs. Download the drafts, in Chinese, at www.sfda.gov.cn/WS01/CL0779/114065.html. — Kellen Owings

Industry: U.S. Implementation Of ICD-10 Should Stay on Track

Devicemakers are urging the U.S. Congress not to delay ICD-10 implementation again, saying the new diagnostic codes are more precise and will allow healthcare providers to better track patient outcomes — resulting in savings for the Medicare payment program.

The Centers for Medicare & Medicaid Services has set an Oct. 1 deadline for providers to begin submitting claims that use the updated codes. The deadline, originally set for Oct. 1, 2013, has been pushed back twice.

The U.S. is one of a handful of developed nations still using the 36-year-old ICD-9 system, witnesses told a Wednesday hearing of the House Energy & Commerce Committee's health subcommittee.

Delays Are Costly

Kristi Matus, chief financial and administrative officer at athenahealth, said sticking with this year's deadline is critical to vendor readiness. "Delays make it easier to doubt future deadlines, which allows vendors to delay preparations," she said, adding she believes providers and vendors would be able to adjust easily to any disruption.

The majority of the healthcare industry is ready for ICD-10, and plentiful resources are available to help those who aren't, said Richard Averill, director of public policy for 3M Health Information Systems. According to Averill, the most recent delay cost the healthcare sector $6.5 billion and future delays will only be costlier due to the long lead times of transitioning major software systems.

Among those asking lawmakers to again delay implementation was William Terry, an Alabama urologist, who said ICD-10's more complex coding guidelines would increase physicians' paperwork burden without benefiting patient care. He urged Congress to perform a risk-benefit

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analysis on the ICD-10 codes or allow doctors to use both systems for the time being.

Lawmakers seemed largely in favor of allowing ICD-10 to go forward, but not without some dissent. Congressman Michael Burgess (R-Texas) questioned whether CMS would be able to stage the rollout effectively. But panel chairman Joe Pitts (R-Pa.) advocated for the switch, saying, "we need to end this uncertainty." — Elizabeth Orr

Study Points to Trial Length as New Target for Policy Changes

The U.S. FDA needs to work with devicemakers and Congress to understand why clinical development takes longer here than in other countries and then implement changes to speed up the process, a new study concludes.

Changes could include the FDA's recent expedited access PMA proposal, which would allow approval of some innovative devices after smaller or shorter clinical trials. Under such a program, the agency could have granted earlier approvals for innovative products looked at in the study, according to Joshua Rising and Ben Moscovitch of the Pew Charitable Trusts.

In a first-of-its-kind study, Rising and Moscovitch analyzed public data on clinical trials and premarket reviews for devices intended to fill an unmet need. The study, published Feb. 4 in *PLOS One*, looked at pivotal trial length, primary endpoint, FDA review, the number of trial patients and country of first approval.

Of 27 approved priority review devices from January 2006 through August 2013, most were available in other countries before they got U.S. approval, the authors note. And while FDA reviews can take years, pivotal clinical trials were responsible for more of the development timeline and delays getting to market.

The median length of pivotal trials was three years, with some taking as long as seven years. Trials had a median primary outcome measure evaluation time of one year and a median enrollment of 297 participants. Meanwhile, median FDA review time for the devices in the study was one year and three months.

Many efforts to speed device innovation focus on FDA reviews, but this study shows that reduction of clinical trial time should be another key target for new policies, the authors say. These should address not only the length of clinical trials but also contributing factors like primary outcome measures and enrollment. They urge the FDA to work with manufacturers, researchers and federal agencies to narrow the gap between primary outcome completion and overall trial length.

The study also found that about one-quarter of priority review applications received during the time frame were not approved. "This indicates that devices considered to be innovative advances were not able to meet FDA's standards for safety and/or effectiveness," the authors write.

Had those devices been approved under the early access process, postmarket data may have shown they did not meet FDA standards. For the process to work, the FDA must have strict postmarket controls, the authors stress. The agency also needs authority to remove products from market soon after finding they fall short of FDA standards.

The article is available at www.fdanews.com/02-12-15-PLOS.pdf. — April Hollis

South Korea Updates GMPs For Medical Devices, IVDs

Devicemakers seeking to register products in South Korea say new regulations requiring them to first obtain a Korean good manufacturing practice certificate could delay product launches.

The new rules, which take effect Jan. 29, 2016, add an additional step to the process of getting a device on the market, says Jon Dobson, spokesman for U.S. industry group AdvaMed. Currently, companies register a product first and

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then get a KGMP certificate and reimbursement concurrently. Under the new rules, the process will entail getting KGMP, then registration and then reimbursement.

The Ministry of Food and Drug Safety has also set KGMP compliance deadlines for in vitro diagnostic devices. Higher-risk Class 3 and 4 IVDs must meet KGMPs by Nov. 10, while Class 2 IVDs have until Nov. 11, 2016.

Stewart Eisenhart, senior regulatory analyst with Emergo Group, says affected manufacturers should apply for KGMP certification at least 10 months ahead of the deadlines, as the certification process involves multiple steps.

Read the KGMP regulation, in Korean, at www.fdanews.com/02-15-Korea-GMP.pdf. An English translation of the IVD regulation is at www.fdanews.com/02-15-Korea-IVD.pdf.
— Jonathon Shacat

AdvaMed Calls for FDA-CMS Joint Breakthrough Pathway

U.S. devicemakers are pushing for a breakthrough pathway to bring true medtech innovations to market more quickly.

The pathway would require the Centers for Medicare & Medicaid Services to cover innovative devices that have been FDA-approved, helping breakthrough technologies reach patients more quickly, AdvaMed President Stephen Ubl said Wednesday. The proposal — part of a larger effort to restructure CMS' coverage and payment processes — builds on the existing FDA-CMS parallel review process.

To date, only two devices have benefited from parallel review, and the program is limited to six devices per year. By contrast, AdvaMed's proposal could accommodate about a dozen devices annually, the group says.

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A similar proposal is included in the 21st Century Cures bill now being floated in the House of Representatives.

Ubl sees the proposed pathway as part of a broader CMS initiative to prioritize support for new technologies. This might include automatically covering devices used in FDA-approved clinical trials, which would bring parity to drug and device trials. AdvaMed also wants to see broader coverage of telehealth.

Ubl praised recent improvements in FDA performance indicators, but said the device approval process remains overly time-consuming, inefficient and inconsistent. Most companies still elect to do their first clinical trials overseas due to the agency's cumbersome process, he added.

AdvaMed's 2015 work agenda also includes a continued push for repeal of the 2.3 percent medical device excise tax as part of a broader press for tax reforms that promote innovation. Ubl said the excise tax is partially responsible for the 75 percent drop in first-time venture capital funding for medtech businesses since 2008. The group didn't offer a specific offset to recoup revenue that would be lost if the device tax were repealed.

Other priorities include streamlining the FDA's regulatory processes, supporting growth in U.S.-based R&D through increased funding for the National Institutes of Health and National Science Foundation and improving access to international markets and enhanced regulatory and payment policies (*see story, page 6*). — Elizabeth Orr

Customed Warned Over Warehouse Conditions

Customed, a Puerto Rican maker of convenience packs for surgical procedures, received a U.S. FDA warning letter for unacceptable warehouse conditions and other GMP issues.

In the finished goods warehouse, an investigator saw black and brown stains in the finished product area that appeared to be mold, as well as open windows and doors that lacked screens to keep bugs out. The FDA also saw expired products that were not segregated from products set for distribution, according to the Dec. 9 letter posted online Tuesday.

In the incoming and raw materials warehouse, the company stored product with "visible signs of deterioration" and no expiration dates, and again had open windows and doors without screens, the letter says.

Meanwhile, there were inadequate gowning requirements for the manufacture of finished product and employees were seen assembling sterile and nonsterile convenience kits without wearing gloves.

The FDA also dinged Customed's performance requalification study, which lacked post-sterilization inspections to check whether the sterilization process would impact product function or package integrity. According to a final report, no physical inspection was ever conducted.

Poor Sterility Controls

Customed also failed to adequately demonstrate that the terminally sterile medical packaging and product can make it through transit, handling and storage without negative effects on sterility.

During the July 14-31, 2014, inspection of Customed's Fajada, P.R., facility, the devicemaker provided shipping validation documents from 2006 for convenience packs intended for cardiovascular and ophthalmic surgeries. An FDA review of the company's shipping validation protocol found it performed ethylene oxide validation using the outside cardboard shipping containers, but did not perform validation of the inside convenience packages following the EtO sterilization process.

Another sterilization-related citation involved a corrective and preventive action plan that was opened after a complaint related to saline bottles. The company decided to remedy the issue with a substitute item, but did not retrospectively review all components that had gone through the sterilization cycle to check compatibility with sterilization cycle parameters.

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Customed was also rapped for failing to validate software it used to track product inventory, such as incoming materials, finished and released products and quarantine items. Further, the status of lots of finished products and incoming materials in the warehouse didn't match the system inventory, according to the warning letter.

The FDA also chided Customed for its medical device reporting procedure, which lacked adequate systems for identifying and evaluating events. The procedure did not ensure timely transmission of complete MDRs or describe how the company will meet documentation and recordkeeping requirements.

Customed did not respond to a request for comment by press time. The warning letter is available at www.fdanews.com/02-10-15-Customed.pdf. — April Hollis

Industry Urging Japan to Address Reimbursement

Japan could stimulate more foreign direct investment and a more robust domestic medical technology industry if it switched to a market-based reimbursement system, says U.S. industry group AdvaMed.

Japan should eliminate its nonmarket-based foreign average pricing system, which is redundant and unnecessary, and simply rely on its market-based reasonable-zone system to make determinations for medical devices, says Phil Agress, the group's senior vice president of global strategy and analysis.

In the meantime, AdvaMed has asked government officials not to make any unfavorable revisions to the FAP rules on reimbursement determinations, he tells *IDDM*.

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R-zone sets reimbursement prices for most medical devices, other than in vitro diagnostics and capital equipment, while FAP is an overlapping system that Japan uses on a subset of R-zone products. For categories that are reviewed under both R-zone and FAP, Japan calculates reimburses at the lower of the two amounts.

To determine FAP, the government looks at prices in the U.S., UK, France, Germany and Australia and uses a formula to set prices in Japan.

Conditions in other countries aren't relevant to what prices should be in Japan, Agress argues, citing a much higher cost of doing business there. On the bright side, the recent addition of a legal framework specific for devices is helping to speed approvals and simplify the regulatory environment, he adds. — Jonathon Shacat

Public Health Expert to Lead CDRH Surveillance Efforts

The U.S. FDA has chosen a veteran public health officer to spearhead its device postmarket surveillance programs.

Gregory Pappas joined the agency this month as associate director for national device surveillance in the Center for Devices and Radiological Health's Office of Surveillance and Biometrics.

In a Feb. 9 staff memo announcing the appointment, OSB Director Tom Gross said Pappas will lead efforts to implement priorities for a robust national postmarket surveillance system laid out in the two recent white papers. These include modernizing adverse event reporting and analysis, developing new ways to generate, synthesize and analyze evidence, integrating unique device identifiers into electronic health records, and promoting development of national and international device registries.

Pappas has worked in the public and private sectors, as well as academia. He served on the executive boards of UNICEF and the Pan American Health Organization, and was on the U.S. delegation to the World Health Assembly.

From 2011 to 2013, Pappas directed the District of Columbia's programs on HIV/AIDS, hepatitis, sexually transmitted diseases and tuberculosis. Prior to that, he was a major architect of President George W. Bush's AIDS policy. Pappas holds an MD and Ph.D. from Case Western Reserve University. — Elizabeth Orr

ANVISA Sets 90-Day Timeline For Most Trial Reviews

Brazilian regulators have set a 90-day timeline for reviewing requests to conduct clinical trials that are also being done in other countries.

This applies to some 60 percent of studies the agency reviews, Anvisa says.

If the agency doesn't respond within the prescribed time frame, the trial may still begin it if has ethics board approval. In such cases, Anvisa will issue a permit for the researcher to import the investigational product.

The timeline for Phase I and II studies conducted only in Brazil is longer. Anvisa plans to review these within 180 days and will not allow studies to begin before they are approved.

The goal, the regulator says, is to bring Brazil in line with international clinical trial standards and speed access to new therapies. — Lena Freund

Medtronic to Pay $2.8M For SubQ False Claims

Irish medical device giant Medtronic will pay the U.S. government $2.8 million to resolve False Claims Act allegations related to subcutaneous chronic pain treatments.

The case stems from claims made by a former Medtronic sales representative that, between 2007 and 2011, the company encouraged dozens of physicians in more than 20 states to submit claims for SubQ stimulation to Medicare and other federal healthcare programs. But the experimental procedure, in which spinal cord stimulation devices are

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placed beneath the skin to alleviate chronic pain, had not been cleared by the FDA.

Despite that, Medtronic reportedly staged physician training programs demonstrating the use of its devices in SubQ stimulation, among other marketing strategies.

Medtronic will also pay the whistleblower $602,000. The investigation was launched in 2010 in a New York federal court.

Company spokesman Justin Ihle says the company has a robust employee compliance program and doesn't believe it acted improperly in this case. The settlement does not include an admission of wrongdoing by Medtronic. — Elizabeth Orr

BRIEFS

FDA Adds Standards on Small Connectors

The FDA has added two standards on small connectors for liquids and gases in healthcare applications to its list of recognized standards. The standards — AAMI/CN3:2014 (PS) and AAMI/CN20:2014 (PS) — establish requirements for connectors for enteral applications and common test methods. In a Wednesday *Federal Register* notice, the agency says the new standards will reduce the risk of unintended connections between enteral and nonenteral devices. A small-bore connector is used to link or join medical devices, components and accessories for the purpose of delivering fluids or gases. Enteral applications are administered via the intestine. View the notice at www.fdanews.com/02-11-15-Enteral.pdf.

WHO Recognizes Global Medtech Alliance

The World Health Organization has recognized the Global Medical Technology Alliance as a nongovernmental organization, making it easier for the group to collaborate with WHO on key global health issues and ensure access to novel technologies. GMTA's 24 members include trade groups in Europe, the U.S., Canada, Japan, Australia and New Zealand.

Sorin Launches Heart Failure Trial

Italian devicemaker Sorin Group is enrolling patients in a clinical trial of its Equila neurostimulation system for treatment of heart failure. The device is implanted under the skin on a patient's chest and stimulates the vagus nerve via a lead in the neck, normalizing an imbalance in the autonomic nervous system that contributes to heart failure. If the trial is successful, Equila may offer an alternative to more invasive cardiac implants such as implantable defibrillators and cardiac resynchronization therapy devices. The first successful implants were performed at the Hôpital Européen Georges Pompidou in Paris.

DePuy Buys Olive Medical

DePuy Synthes acquired Olive Medical, a maker of high-definition visualization systems for minimally invasive surgery, for an undisclosed sum. Olive's HD arthroscopic visualization solutions will complement DePuy's Mitek Sports Medicine arthroscopy line and enable the Johnson & Johnson subsidiary to enter the arthroscopic visualization market for patients with shoulder, knee, hip, and small joint pain or injury, the devicemaker says. DePuy will market the HD technology through its global distribution network.

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