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IMDA UPDATE
The nation's premier providers of specialty medical sales, service and education

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Save the date!
IMDA 2013 Conference & Manufacturers Forum will be held June 9-11 at Loews Royal Pacific Resort, Orlando, Florida.

FDA wants to keep tabs on devices *after* they hit the market. Since at least 2004, the Food and Drug Administration has wrestled with a vexing problem: After a drug or medical device has been cleared for marketing, who is responsible for ensuring the safety of that product in use? It's called postmarket surveillance.

Vendor credentialing signs of progress

Summit shows signs that suppliers and providers may be moving in step with each other.

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This new attitude may become formalized with the launch of an industrywide group focused on vendor credentialing -- the Coalition for Best Practices in HCIR Requirements (where "HCIR" stands for "healthcare industry representative"). IMDA Past President Shawn Walker has been involved in discussions regarding the Coalition, and is a steering committee member.

Feels like progress

Sponsored by a number of manufacturers, distributors and supply-chain-related organizations, including the Health Industry Distributors Association, the Summit was the third annual such event. Held July 31 to Aug. 1, in Alexandria, Va., it featured seminars, breakouts and some booths.

"People feel there's hope," says Rhett Suhre, chair of the Advanced Medical Technology (AdvaMed) working group on HCIR credentialing and director, HCIR credentialing, Abbott. "At the first Summit, there was confusion, misunderstanding and frustration. At the second Summit, the attendees discussed what requirements were the most appropriate. At this year's Summit, we discussed the work that had been done to arrive at a draft 'best practices' document, and spent the majority of the meeting sharing best practices and working toward how to best meet the requirements."

"The tenor and tone of Summit has changed," says Doug Cones, director, sales operations, Cardinal Health, who has attended all three Summits held since 2010. "People are listening to all sides to make sure this process is efficient for everyone. We want to make sure there is awareness across the three constituencies -- hospitals, vendors and the vendor credentialing companies -- that the primary focus is patient safety, privacy, and making sure reps are adequately trained."

Shawn Walker agrees, with qualifications. "Overall, there's an acceptance that credentialing is here to stay," she says. This is especially true among the largest suppliers, who have devoted the resources necessary to comply with providers' requests. But smaller suppliers face more difficulties, partly due to the cost of credentialing.

IMDA Announcement

Recruit!

The Manufacturers Forum is the industry's only venue where innovative manufacturers can meet the market-makers, that is, the members of IMDA.

Talk to your manufacturer partners -- and potential partners -- today about exhibiting at the 2013 Forum, to be held in conjunction with 2013 Annual Conference, June 2013 in Orlando, Fla.

Call IMDA Executive Director Katie Keel for more details, at (269) 532-1146. Or pass this note to your suppliers.

Manufacturers need specialty distribution, and IMDA needs a strong showing at the Forum. It's a perfect fit.

One also has to consider the "genetics" of many small companies, she says. "[Credentialing] chafes against the personalities of the types of organizations they are. They're independent, in many cases, because they don't want to be told what to do. And they don't like paperwork. So I would say it continues to be a struggle, especially at the independent rep level."

"The expense of credentialing wasn't the concern [of suppliers at the Summit] as much as the disparate requirements," says Kevin Connor, president and CEO of credentialing firm VeriREP, and a key figure in organizing the first Summit, held two years ago in Niagara Falls. "We heard more complaints about, 'This company makes me do this, this one makes me do that.'"

Progress is being made on industry standards, however, says Connor. "Mayo Clinic has recently adopted the Indiana Hospital Association's best practices guidelines, and in general, people think that's a good start."

Managing providers' expectations

Five or six years ago, multiple credentialing platforms arose, so that in a busy metro area, a rep could have four or five different subscriptions, recalls Connor. "Hospitals would tell the vendor credentialing company what they wanted, and the vendor credentialing company would do it." The result was confusion and cost.

But over time, as vendor credentialing companies have become more embedded in the supply chain, they are approaching hospitals with suggestions on what they consider to be important information to capture in the credentialing process, and what they consider to be irrelevant.

"We have to be competitive and support our customers' requirements," says Connor. "But if we can help them manage expectations, that's great."

"From the vendor/supplier side, we have to figure out the best, most efficient way, to ensure that our representatives are able to meet the requirements of our customers," says Suhre, who is on the steering committee of the Coalition. "From the provider side, I think they understand they need to align their requirements on the things that are the most important. There are certain documents reps aren't authorized to sign, so it's better if they are able to get those documents to the authorized person in the company. Credentialing provides that mechanism.

Best practices

Vendor credentialing companies are committed to bringing order to the credentialing process, according to those who attended the Summit. In a panel discussion, representatives from VeriREP, IntelliCentrics, Vendormate and Vendor Credentialing Service stated that aligning on a set of requirements or best practices made sense, says Suhre.

One idea floated at the Summit was that, if the industry can agree on "best practices," vendor credentialing companies could offer their customers a "best practices option," says Suhre. The system would be good for vendors, as it would move the industry toward standard requirements. But it would also help hospitals that are new to credentialing, and who have yet to put a process in place, he suggests.

In fact, organizers of the Coalition for Best Practices in HCIR Requirements have circulated a draft of recommended best practices for vendor credentialing. Borrowing from concepts proposed by the Indiana Hospital Association as well as Mayo Clinic Vice Chair, Supply Chain Operations Bruce Mairose, the committee sent the draft to various organizations for vetting, including the American Hospital Association, American College of Surgeons, Association of periOperative Registered Nurses and the American College of Cardiology, among others.

"Our goal is to have a final document that we will ask people to endorse," says Suhre. But those recommended best practices will be a "living document," he says, that is, subject to modification as circumstances dictate.

There would be certain expectations of those who endorsed the final document, he says. "If you were a supplier, you would do everything you need to do to ensure your representatives meet the recommendations. As a provider, you would be asked to align yourself with the best practices. And if you were a professional organization, such as the American College of Surgeons, you would advocate among your peer group that they follow the best practices recommendations."

"The idea [behind the Coalition] is to streamline the credentialing process, reinforcing that we believe in patient safety and confidentiality and that we are committed to continue building a bridge between vendors and the supply chain through dialogue and collaboration, and ensure continuing access to medical technology," says Shawn Walker. "We want to give people a place where they can participate, spread the word that the industry now has an umbrella we can all sit under."

The Coalition will put more definition around, and focus on, credentialing, adds Cones, who also is on its steering committee. "It will allow us to continue with the common discussion, bring more hospitals to the table, help [providers] understand our perspective, and help [vendors] understand theirs."

The Coalition can lead to tangible benefits for all supply chain players, large and small, adds Suhre. One example is the development and dissemination of training modules on, for example, fire safety. "One of our goals is to take a training module that we all agree is appropriate, and make it available to everyone in the industry," he says. "We keep costs down and we're consistent, so that every rep calling on hospitals is receiving the same training.

"We're really trying to work collaboratively to solve this," he says. "We want to figure out what makes sense. If people understand that, we can begin to have that discussion."

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Medical device excise tax: Calm before the storm?

Despite the national clamor surrounding the impending 2.3 percent medical device tax, things seem relatively subdued among IMDA members and their manufacturer partners, at least for now, according to IMDA members who responded to a question from *IMDA Update*.

As part of the Affordable Care Act, manufacturers or importers of medical devices will be required to pay a 2.3 percent tax on the sale of medical devices (excluding those purchased over-the-counter at retail locations), beginning Jan. 1, 2013.

The tax has been front and center for many in the medical device industry. Welch Allyn, for example, recently announced it would cut 10 percent of its workforce, at least partly because of the tax. Cook Medical blamed the tax for its decision to kill plans to build five manufacturing plants in the United States.

"Most of our manufacturers are too small to [experience] a very large impact from the tax," said one IMDA member. At the same time, though, "it will definitely affect their ability to grow and add new people or marketing money," he said.

According to another member, "One of our major suppliers says they are not adding any new pricing to cover the 2.3-percent device tax. Another of our major suppliers has still not decided what to do; they think they will probably do a pricing increase, but it's still pending. We expect to add a price increase to the products we import to help defray the tax."

"I have [a manufacturer] who sent a letter stating that after Jan. 1, the 2.3 percent excise tax would appear as a separate line item at the bottom of invoices to dealer," said one member.

Still another answered, "We have heard nothing from our suppliers."

Some lawmakers have vowed to fight the tax. Last year, for example, Sen. Orrin Hatch (R-Utah) introduced the "Medical Device Access and Innovation Protection Act" (S.17), which would repeal the tax. That bill is still pending. A related bill, H.R. 436 ("Health Care Cost Reduction Act of 2012"), introduced by Rep. Erik Paulsen (R-Minn.) would do the same thing.

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More than 1,300 strong

More than 1,300 people are now members of IMDA's LinkedIn group. Shouldn't you be too?

Go to www.imda.org and click on the LinkedIn graphic. You'll be connected to 1,300+ people with an interest in specialty sales and marketing. Share ideas. Learn about new lines. Get yourself out there. Check in with LinkedIn every day.

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Licensed to sell?

By now, most IMDA members are well-prepared to answer this question from their customers: "Have you signed up with our vendor credentialing firm?" But increasingly, they're being asked yet another question: "Are you licensed to sell medical devices in our state?" That one is reportedly catching some members by surprise.

Approximately 20 states require distributors of medical devices to be licensed to sell medical devices, says Frank Fazio, a pharmacist and an attorney with Porzio, Bromberg & Newman P.C., Morristown, N.J. More than twice that number require licensure for companies shipping prescription drugs. And while the number of states requiring such licensure has been relatively stable over the past several years, more attention is being paid to the issue.

"These laws were originally put into place for the purpose of preventing diversion," explains Fazio, who is a principal with the law firm, and also vice president of distribution and licensing for a subsidiary company, Porzio Life Sciences LLC, which focuses on helping companies remain compliant with federal and state regulations governing distribution licensing, marketing and sales in the life sciences industry. In many cases, states are interested primarily in preventing the diversion -- or gray market sales -- of prescription drugs. But some states have opted to include medical devices into the mix. Approximately 14 states have developed a separate set of more stringent criteria for wholesalers, as opposed to manufacturers.

IMDA announcement

Spread the word about IMDA

At the next clinical meeting you attend, let other specialty distributors and reps know about your association. IMDA has prepared a simple, one-page flyer describing five benefits of joining the association. Before your next clinical meeting, print out a few, then hand them out to prospective members. Go to "Let Others Know about IMDA" in the "Members Only" section of imda.org.

Remember: IMDA's strength lies in numbers. Help us keep them up, and keep us strong.

"Many of these laws were designed with small distributorships in mind," notes Fazio. Lawmakers demand personal information, such as social security numbers, fingerprints, background checks, etc., to prevent such companies from closing shop, then opening up under another name weeks later.

Some states have more active enforcement procedures in place than others, notes Fazio. In those states, IMDA members might be more prone to get asked by their customers to show proof of licensure. That's because, in those states, not only is it a violation to sell products without a license, it's also a violation to buy from a company that doesn't have one, he says. On the other end, manufacturers may also ask the distributor for proof of licensure, because it is also a violation to sell products to a distributor that doesn't have a license.

Bigger medical device manufacturers are getting onboard with these state requirements, says Fazio. And as the big companies roll out their programs, there may be a trickle-down effect, so that smaller manufacturers -- that is, those with whom IMDA members frequently deal -- will likely begin doing the same.

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FDA wants to keep tabs on devices *after* they hit the market

Since at least 2004, the Food and Drug Administration has wrestled with a vexing problem: After a drug or medical device has been cleared for marketing, who is responsible for ensuring the safety of that product in use? It's called postmarket surveillance.

The issue came to a head in 2004 when Merck & Co.'s Vioxx painkiller was withdrawn from the market following its linkage to heart attacks. Two previous incidents drew attention as well: 1) the withdrawal from the market in 2001 of the cholesterol drug Baycol (cerivastatin) by Bayer AG over concerns that the drug caused serious muscle conditions; and 2) GlaxoSmithKline's failure to report studies linking its anti-depressant Paxil with incidences of suicide among children and teenagers.

Legislators and clinicians demanded that FDA improve its postmarket surveillance activities for both drugs and medical devices.

This month, the agency issued a set of proposals to do just that, in a report titled "Strengthening Our National System for Medical Device Postmarket Surveillance." The report provides an overview of the current U.S. medical device postmarket surveillance system, and proposes four specific actions to improve it.

Current state

Medical device postmarket surveillance presents unique challenges compared to drugs and biologics due to "the great diversity and complexity of medical devices, the iterative nature of medical device product development, the learning curve associated with technology adoption, and the relatively short product life cycle," notes the FDA in the report.

Currently, the U.S. medical device postmarket surveillance system depends primarily upon six tools to identify potential safety problems of approved devices:

1. Medical Device Reporting (MDR). Each year, the FDA receives several hundred thousand medical device reports of confirmed or possible device-associated serious injuries, deaths and malfunctions. But being a voluntary system, MDR leads to "submission of incomplete or inaccurate, data, under-reporting of events, lack of denominator (exposure) data, and the lack of report timeliness."
2. Medical Product Safety Network (MedSun), which is an enhanced surveillance network comprised of approximately 280 hospitals nationwide, who work with the FDA to better understand and report on device use and adverse outcomes in the real-world clinical environment. "The overall quality of the approximately 5,000 reports received annually via MedSun is significantly higher than those received via MDR," says the agency.
3. Post-approval studies. The FDA may order a post-approval study as a condition of approval for a device approved under a premarket approval (PMA) order. Typically, post-approval studies are used to assess device safety, effectiveness, and/or reliability including longer-term, real-world device performance.

IMDA Announcement

What do you need to know when signing contracts with hospitals and IDNs?

IMDA legal counsel Mitchell Kramer has it all spelled out for you. Go to www.imda.org and click on the third item in "What's New."

Take care of yourself and your company. Read this article. Sign

good contracts. And for heaven's sake, *read the addendums!*

4. Postmarket surveillance studies. The FDA may order a manufacturer of certain Class II or Class III devices to conduct postmarket surveillance studies (often referred to as "522 studies"). Study approaches vary widely and may include non-clinical device testing, analysis of existing clinical databases, observational studies, and, rarely, randomized controlled trials.

5. FDA discretionary studies. The FDA conducts its own research to monitor device performance, investigate adverse event signals and characterize device-associated benefits and risks.

6. Other tools.

Future

In May 2008, the FDA announced the Sentinel Initiative, a long-term effort to create a national electronic system for monitoring FDA-regulated medical product safety. The Initiative requires the FDA to collaborate with public, academic and private entities to develop methods for obtaining access to disparate health data sources. The Food and Drug Administration Safety and Innovation Act of 2012 requires expansion of the Sentinel System to include medical devices.

The agency envisions creation of a national system that 1) conducts active surveillance in near real-time using routinely collected electronic health information containing unique device identifiers, 2) quickly identifies poorly performing devices, 3) accurately characterizes the real-world clinical benefits and risks of marketed devices, and 4) facilitates the development of new devices.

Specifically, the agency believes four steps are needed to strengthen medical device postmarket surveillance:

1. Establish a unique device identification (UDI) system and promote its incorporation into electronic health information. In July 2012, the FDA issued a proposed rule for a UDI system. A UDI may contain two types of information: a unique numeric or alphanumeric code, specific to a device model, and an identifier that includes the production information for that specific device, such as the manufacturing lot or batch number, the serial number, manufacturing date and expiration date. UDIs will enhance postmarket surveillance activities by providing a standard and unambiguous way to document device use in EHRs, clinical information systems, and claims data sources, says the agency.

2. Promote the development of national and international device registries for selected products. A registry is a system that collects and maintains structured records on a specific disease, condition, procedure or medical product for a specified time period and population, says the agency. Product registries include patients who have been exposed to a specific medical device, biologic or drug product. The FDA isn't seeking to develop a centralized repository of registry data. Rather, each registry would retain physical and operational control over its own data.

3. Modernize adverse-event reporting and analysis. Several ongoing or proposed activities -- many revolving around automated collection and dissemination of information -- would significantly enhance the FDA's surveillance capabilities, says the agency, including: development of automated adverse-event reporting systems; the development of a mobile application for adverse event reporting; modernization of the medical-device adverse-event database; and identification of so-called "safety signals," using automated, computerized statistical methods to discover patterns of unexpected occurrences in large databases.

4. Develop and use new methods for evidence generation, synthesis and appraisal. "The evolution of health-related electronic records, registries and adverse-event reporting, as well as the increasingly global nature of product development and marketing, demands the strategic development of innovative methodological approaches for evidence generation, synthesis and appraisal," according to the FDA.

The full report may be viewed here.

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