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IMDA eNews

Code of Ethics

AdvaMed – the association for medical device manufacturers – has written a new "Code of Ethics On Interactions With U.S. Health Care Professionals," with a recommended effective date of January 1, 2020. IMDA members should pay attention, as the new code requires the AdvaMed member to communicate the code's provisions "to its employees, agents, dealers and distributors, with the expectation that they will adhere to the Code." The code runs the gamut, from properly conducting company-conducted meetings, to providing technical support in the clinical setting, and gift-giving. Re gifts: "A company may occasionally provide modest, appropriate educational items to healthcare professionals that benefit patients or serve a genuine educational function for healthcare professionals." No more office supplies, mobile devices, pens, mugs, cookies or flowers. Nor may a company raffle or give away an item that it would not otherwise give a healthcare professional under the code.

Saving kids' lives in disaster situations

Treating children who have been exposed to infectious diseases, trauma and other hazards calls for specialized equipment, supplies and equipment, according to the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. ASPR will issue a Funding Opportunity Announcement in the coming months to address the first phase of the National Disaster Pediatric Initiative, with a pilot project for two Pediatric Disaster Care Centers of Excellence. The two centers will allow for strategically and geographically placed facilities to ensure the most vulnerable population receives consistent and reliable care during times of disasters and other emergencies. Submissions should include information on specialty equipment necessary to meet the unique healthcare needs of saving the lives of pediatric patients in disasters.

Outcomes on the line

Medtronic and Blue Cross and Blue Shield of Minnesota have agreed to an outcomes-based arrangement for Medtronic's continuous glucose monitor which ties payments to the amount of time a patient's blood sugar stays in a healthy range, reports MedTech Dive. It's not the first such agreement for Medtronic, which last year signed a deal with UnitedHealthcare for users of its insulin pumps, and another with Aetna that tied part of Medtronics' reimbursement to meeting clinical goals for patients who switched to Medtronic insulin pumps.

EtO facility shutdown affects tracheostomy tubes

Last month the FDA issued an alert about the potential for medical device shortages arising from the closure of a large ethylene oxide sterilization facility in Willowbrook, Illinois, and the future planned closure of a similar facility in Michigan. The agency has since identified Smiths Medical's Bivona tracheostomy tubes as such a device. Although the Bivona tubes are indicated for use in both adult and pediatric patients, the temporary shortage is more likely to impact pediatric patients because supply of alternative tubes with similar functionality is limited, says FDA. The Bivona tube is made from a flexible silicone material, which is said to make it easier to insert in the stoma of pediatric patients. The good news: Smiths Medical is using an alternative facility to sterilize its devices. FDA says it is "working closely with Smiths Medical to expedite release of sterilized tubes that still meet the FDA's standards for safety and effectiveness and expect new tubes to be available within the next few weeks."

Reclassification of medical devices

The FDA has reclassified eight types of medical device accessories to class I, effective May 13, reports the Regulatory Affairs Professionals Society. They are: 1) gastroenterology-urology accessories to a biopsy instrument; 2) penile implant surgical accessories; 3) ureteral stent accessories; 4) biliary stent, drain and dilator accessories; 5) suprapubic catheter accessories; 6) implanted mechanical/hydraulic urinary continence device surgical accessories; 7) air-handling apparatus accessory; and 8) corneal inlay inserter handle.

Who can afford innovation anymore?

Can hospitals afford to keep pace with innovation? Yes, though it won't be easy, says GPO Vizient. Data compiled by Vizient indicate that price premiums for innovative devices range from two to 10 times those of predicate therapies. "Payers are slow to adjust their reimbursement models to accommodate these higher-cost procedures, creating a gap between device cost per episode of care and reimbursement. This gap will continue to challenge healthcare organizations as they consider adoption of new technologies, taking into account the financial impact, which may be looked at independently of improved outcomes and quality of life."

Value – any way you look at it

How do providers define value? Come to this summer's IMDA/HIRA conference and find out. And take the opportunity to offer your own perspective on the matter. Speaking about value will be: Mike Schiller, former senior director of the Association for Healthcare Resource & Materials Management; Denise Downing, a perioperative informatics nurse; Dee Donatelli, past president of the Association of Healthcare Value

Analysis Professionals and chair-elect of AHRMM; and Richard Priore, who has served as the CEO of several investor-owned hospitals. Don't miss the conversation, at "The Many Facets of Value," the IMDA/HIRA Annual Conference, to be held July 21-23 in suburban Chicago. For more information, go to www.imda.org or www.hira.org.