

# SURGICAL SPOTLIGHT

## SPRING, 2017



## Market News

### ► BI-PARTISAN BILL TO STREAMLINE FDA DEVICE INSPECTION PROCESS

On February 15, 2017, U.S. Senators Michael Bennet, a Democrat from Colorado and Johnny Isakson, a Republican from Georgia, introduced a bipartisan bill (S.404) to modernize the FDA's medical device inspections process.

"FDA inspections are supposed to ensure that companies provide safe and reliable medical devices for patients around the world," Bennet said. "This bill would modernize that process, streamline consistent inspections across regions, and implement recommendations more quickly." The legislation is called, "A bill to amend the Federal Food, Drug, and Cosmetic Act to improve the process for inspections of device establishments for granting export certifications."

"The current device facility inspection process lacks transparency, predictability and consistency between facilities," Isakson said. "This bill is designed to improve communication and consistency in the device facility inspections process, which will allow both FDA and device manufacturers to make more efficient use of resources." **Source: Orthopedics This Week | RRY Publications**

### ► SURGICAL CARE AFFILIATES (SCA), OPTUMCARE TO COMBINE

The combination of SCA with OptumCare, Optum's primary and urgent care delivery services business working with more than 80 health plans, will position the combined organization as a comprehensive provider of ambulatory care services, while continuing expansion of SCA's network of ASCs and surgical hospitals in partnership with leading health systems, medical groups and health payers. The combination builds upon the two companies' successful ASC collaborations and expands OptumCare's capabilities in outpatient surgical procedures. **Source: UnitedHealth Group**

### ► IMPLANT MARKET POSITIONED FOR GROWTH

A Grand View Research report predicts the worldwide market for spinal implants will reach \$19.54 billion by 2024 due to an increasing incidence of obesity, more spinal injuries, expanding adoption of sedentary lifestyles and product advancements. Medtronic, Stryker, NuVasive, Depuy Synthes, Zimmer Biomet, Orthofix International, Globus Medical and LDR are among the key market players. **Source: Becker's Spine Review**



## Regulatory Updates

► Currently CMS approves and reimburses 3,837 procedure codes in the ASC setting. And that number is growing every year. Most recently CMS has approved to add eight spine codes to the list of ASC covered procedures in 2017.

► **Colorado** has adopted changes to its 2017 fee schedule (Rule 18). Implants will no longer be reimbursed separately in outpatient or ASC settings unless they fall under the HCPCS codes: C1822, C2613, C2623, or C2624.

► **Kansas** has adopted changes to its 2017 fee schedule that reimburses implantables for the inpatient hospital setting at 50% for inpatient charges below \$5000 and at cost +25% if above \$5000. Outpatient and ASC charges are reimbursed separately at cost +25% if the following codes are utilized: L8699, C1762 and C1763.

► **Utah** Senate Bill 0216, effective for dates of service May 10, 2016 through July 1, 2018, now allows for reimbursement of covered medical services for inpatient, outpatient, and Ambulatory Surgical Centers bills to be 85% of charge (previously no fee schedule). Utah Code 34A-3-108(11).

## (In)sights

A new trend that we are seeing in the implant marketplace is based on an old concept: **repackaging**. Repackaging medications has been in the workers' compensation marketplace for several years. Repackaging companies package and sell medications at a rate that is multiple times higher than the underlying medications' retail price. Similar to this, we are now seeing distributing companies repackage different parts of an implantable construct under a different name. We have seen the invoices for these newly named constructs at 10+ times the cost of the individual items. Since we have an extensive database and decades of product knowledge from the device side of the industry, we are able to reprice these constructs at their true cost and not at the inflated pricing.



## Did you Know?

► In 2009, there were 5,039 outpatient surgery centers throughout the nation. This number grew to 5,446 in 2014 and is increasing every year.

► According to a study conducted by HealthCare Blue Book, the Ambulatory Surgery Center Association (ASCA) and HealthSmart, a leading provider of third-party administrative services for self-funded employers:

- **“A review of commercial medical-claims data found that U.S. healthcare costs are reduced by more than \$38 billion per year due to the availability of ambulatory surgery centers (ASCs) as an appropriate setting for outpatient procedures.”**
- **“This cost reduction is driven by the fact that, in general, ASC prices are significantly lower than hospital outpatient department (HOPD) prices for the same procedure in all markets, regardless of payer.”**

► A study published in Health Affairs analyzed data from the National Survey of Ambulatory Surgery and discovered that procedures performed in the ASC setting are performed in a more efficient manner. Procedures performed in the ASC take 25% less time than those performed in a hospital setting.

**Source: Health Affairs**

## Technology Highlight

**NuVasive** is an innovative medical technology company focused on developing minimally disruptive, procedurally-integrated solutions for the spine. NuVasive's commitment to the development of MIS technology has helped surgeons and patients achieve better outcomes, fewer infection rates and shift more spine procedures to the ASC setting.

In addition, NuVasive developed **The Better Way Back program**, which connects prospective patients who are suffering from chronic back, leg and neck pain with patient ambassadors who similarly had to consider, or go the route of, spine surgery. NuVasive engages the patients through the physicians who introduce them to the program. The patient is provided information on surgical and non-surgical options by over 2,000 ambassadors nationwide.

NuVasive recently hosted the **NuVasive Spine Summit** bringing together top spine surgeons as well as hospital administrators to discuss various topics including value-based care and data gathering. One of the key topics was delivering quality of care and improved outcomes in the midst of a changing healthcare environment.

Keynote speaker Elizabeth Teisberg, Professor at the Dell Medical School at the University of Texas at Austin and author of *Redefining Health Care*, stated that “Quality is better health for individual people.” Although the message may seem simple, the measurement and execution can be difficult. How do you determine what constitutes quality? Teisberg stated that physicians often measure pain scores, fusion rates, etc. to measure quality and success. However, if the patients are not able to return to function, is the procedure still a success?

The message during the discussion was that the culture needs to change for physicians and healthcare providers to share their data outcomes and become more transparent. Through this collaboration, all can benefit from new technology, procedures and approaches. And the organizations that continue to learn from their own experience, as well as those of others, will deliver better outcomes.

**For more information on the NuVasive Spine Summit, please go to [www.nuvasive.com](http://www.nuvasive.com).**







## Encompass Physician Spotlight

### THE CORE INSTITUTE

At the CORE Institute, all patient activities, evaluations, and procedures are conducted with the philosophy of “Keep Life In Motion.” Their goal always is focused on how to improve the long-term care of the patient and ensure their patients stay in motion for years to come. This philosophy promotes patient and physician dialogue to better understand the patient’s goals and determine the best treatment plan.

Dr. Sean Bak, an orthopedic surgeon at CORE, states that “Not every patient ultimately will see a quality of life improvement from surgery or a positive impact on their long-term health. We don’t just simply look at number of surgeries or technical success. We are more interested in quality of care, efficiency and patient experience.”

Surgical Spotlight  
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## FDA News and Recalls

► **FDA gives clearance for a lateral body fusion device.** 4WEB Medical received 510K clearance from the FDA for its lateral interbody fusion device. The product will be marketed under the trade name ‘Lateral Spine Truss System’.  
**Source: 3D Printing Industry**

► **A recall has been initiated by Medtronic involving some lots of its neurovascular products,** namely the Alligator retrieval device, the Pipeline embolization device, the X-Celerator hydrophilic guidewire and the stylet containing UltraFlow and Marathon flow directed micro catheters. The recall was issued over concerns about the risk of blood clots, which can happen if the polytetrafluoroethylene coating separates from parts of the devices and enters the bloodstream. **Source: The Wall Street Journal**

► **CMS Approves Transitional Pass-Through Payment for Outpatient Use of Neuro’s Senza® Spinal Cord Stimulation System.** The Centers for Medicare & Medicaid Services (CMS) has approved a transitional pass-through payment for High Frequency Stimulation under the Medicare hospital outpatient prospective payment system effective January 1, 2016. This pass-through payment for HF10™ therapy will be in addition to the established reimbursement for spinal cord stimulation devices. CMS determined the Senza SCS System delivering HF10 therapy met the criteria for a new device category based on the published randomized control trial (RCT) evidence submitted. The Healthcare Common Procedure Coding System (HCPCS) code for this new device category is C1822.

## Company News

► ForeSight and Encompass continue to work toward maintaining and increasing security standards. We have passed our SOC2 – Type 1 audit. We are also going to begin a SOC2 – Type 2 audit, as well as a HITRUST Assessment.

► ForeSight is proud to add leading Physician Groups to the Encompass Specialty Surgical Management Program. Some of these groups include:

- CORE (Phoenix, AZ)
- Signature Medical Group (St. Louis/KC, MO)
- Midwest Orthopaedics at Rush (Chicago, IL)
- Orlando Orthopedic Center (Orlando, FL)
- Sarasota Orthopedic Associates (Sarasota, FL)
- Kansas City Orthopedic Institute (Kansas City, MO)
- Colorado Orthopedic Consultants (Denver, CO)

