Michigan Outpatient Cardiovascular Association

October Edition

Blue Cross Blue Shield to pay $2.8B to settle class action provider antitrust case

The proposed class action settlement is the largest antitrust payout to ever be awarded in healthcare, according to a Monday statement from law firm Whatley Kallas, which represented the plaintiffs.

At the center of the case is the Blue plans' use of "exclusive service areas" and its reimbursement policies under the BlueCard program.

The BCBSA had a policy that prohibited Blues plans from selling policies to hospitals outside their service areas, according to the suit. Often, the result was hospitals only had one Blues plan available within their state, constraining plan options and allowing the insurer to drive up prices.

When providers cared for patients covered by another Blues plan, they were forced to submit claims through the BlueCard program, which providers used for administrative tasks related to claims, prior authorization requests and other things. Providers said the system was "non-transparent" and came with "additional costs, inefficiencies, and frustration," according to the memorandum.

The settlement lifts the BSBCA's rule that allocated one Blues plan to each service area, opening the door for hospitals and providers to negotiate new contracts.

Of the proposed $2.8 billion settlement, providers and healthcare workers will pocket approximately $2 billion. Providers will take approximately 92% of the funds while workers will take 8%. The plaintiffs' attorneys are set to receive up to $700 million, and an additional $100 million will be reserved to notify providers about the settlement and enforce the deal's terms.

Providers and healthcare workers who qualify for payouts under the settlement include those who had Blues plan patients between July 2008 and October 2024.

Blue Cross will also spend "hundreds of millions" to create system-wide improvements for providers and "transform" the BlueCard program, according to the settlement. The association is tasked with building an information platform that facilitates member benefits, including verifying eligibility for services and providing timely claims status updates. Blue Cross Blue Shield to pay $2.8B to settle class action provider antitrust case | Healthcare Dive

First US cases performed with Vertex PE system in SPIRARE II pivotal study

The Vertex system is designed to treat acute pulmonary embolism (PE) in an endovascular procedure offering an "unprecedented level of control and precision", according to the company.
The first US case was performed at Staten Island University Hospital, Northwell Health (New York, USA) by Mitchell Weinberg and Vincent Gallo

"The unique manoeuvrability of the large-bore Vertex endoportal device enabled us to easily navigate across multiple bends through the right heart and into the pulmonary arteries. Once in the pulmonary arteries, the technology allowed us to stabilise the endoportal device, creating a secure base for us to safely advance the aspiration catheter deep within the pulmonary vasculature and capture hard-to-reach thrombi. With Endoportal Control, we achieved an excellent procedural result with remarkable speed and ease, especially given that it was our first time using this technology," said Weinberg.

"Navigating the pulmonary arteries can be challenging and often requires a complex trial-and-error approach involving multiple guidewires and ancillary devices in order to safely reach the target vessels. Using Endoportal Control with the Vertex system, we eliminated many of these extra steps and device exchanges, resulting in a much simpler procedure that allowed us to focus less on gaining vessel access and more on treating the patient. Our team is very excited to study this technology further, and I would like to thank Brandon Dilluvio on our team for his support in facilitating this first US procedure," said Gallo. First US cases

Medtronic receives US FDA approval of Affera mapping and ablation system and Sphere-9 catheter

Medtronic has announced US Food and Drug Administration (FDA) approval of the Affera mapping and ablation system with Sphere-9 Catheter, an all-in-one, high-density (HD) mapping and pulsed field (PF) and radiofrequency (RF) ablation catheter for treatment of persistent atrial fibrillation (AF) and for RF ablation of cavotricuspid isthmus (CTI) dependent atrial flutter.
With this approval, Medtronic says it is the first and only company with two PFA technologies available for patients with AF. The PulseSelect system, which was FDA approved in December 2023, offering a single-shot solution for pulmonary vein isolation (PVI) while the Affera Sphere-9 catheter enables physician treatment flexibility with its wide area focal design and 9mm lattice tip that can used with an 8.5Fr sheath.

"The significance of this innovative technology should be underscored; Affera is a game changer for treatment of AF and atrial flutter," said Vivek Reddy (Mount Sinai Health System, New York, USA). "The Affera system provides physicians with one safe, effective and efficient solution to this common and increasing problem in heart disease that needs optimized solutions for patients. With a short learning curve for experienced physicians, the possibilities are boundless for the treatment of AF."

The Sphere-9 catheter offers physicians the option of both PF and RF energy delivery, integrated with the Affera mapping and ablation system. The Sphere-9 catheter enhances workflow efficiency for physicians while providing excellent safety and efficacy outcomes. Medtronic receives US FDA approval of Affera mapping and ablation system

Corewell faces 3rd-largest union organization threat in U.S. in last 5 years

When Spectrum Health merged with Beaumont Health to create Corewell Health in 2022, the West Michigan company stepped into a hornet's nest.
Hospital worker morale had been swamped by then-leader John Fox under cost-cutting and restructuring measures. Several high-profile physicians left as Fox sought to "right-size" the operations and find a buyer. And the Michigan Nurses Association had been trying to organize nurses at Beaumont Royal Oak since at least 2019.

By the time Corewell was formed, the relationship between administrators, clinicians and staff was broken and, apparently, has not improved.

Now Corewell faces the third-largest union organizing effort in the nation since at least 2019, behind the organizing of 40,000 workers at Disney World in 2021 and the organizing of 15,500 workers at AT&T Mobility in Ohio, according to an analysis of data from the National Labor Relations Board.

Beaumont nurses claim diminishing working conditions before and since Corewell was formed out of the merger, while the Grand Rapids- and Southfield-based health system is contending with rising costs and large payroll from the legacy Beaumont operations.

The result of the vote by 9,168 nurses across eight former Beaumont hospitals next month could trigger one of the nation's most powerful union takeovers of health care and create a further ripple across the sector in the state.

The International Brotherhood of Teamsters began a quiet campaign at Corewell East, which is the group of former Beaumont hospitals in Southeast Michigan, roughly 11 months ago, said Kevin Moore, president of Teamsters Joint Council 43. Corewell Health faces 3rd-largest union threat in last 5 years | Crain's Detroit Business

TCT 2024: Adjustable valve replacement system wins Shark Tank innovation prize

Symbiosis, the developer of an adjustable transcatheter mitral valve replacement (TMVR) system—Valsync—has been chosen as the recipient of the Shark Tank innovation prize at the 2024 Transcatheter Cardiovascular Therapeutics (TCT) conference (27–30 October, Washington, DC, USA).

The Valysnc system comprises two highly compliant balloons, made of a flexible deformable material that can expand to fit the surrounding valve anatomy. The system is designed to be delivered transeptally, with an atrial balloon expanded and lowered onto supra-annular plane of the mitral valve. Afterwards a second balloon is secured in the ventricle, held in place by a series of barbs or arms.

The conformable design makes the device adaptable to unique valve shapes, Symbiosis says, and the balloons can be inflated or deflated based on real-time echo Doppler feedback to optimize the sealing effect and ensure proper alignment.

Symbiosis founder and CEO Shira Burg, a qualified veterinary doctor, with a PhD in cardiac electrophysiology, presented the Valsync system at TCT.

Presently Symbiosis is launching a chronic animal study using the device, and upon success anticipates a first-in-human trial to commence around late 2026. Though the valve is being tested in mitral applications, it could also be used to treat tricuspid valve disease.

Symbiosis has recently been bolstered by the addition of Stanton Rowe, the former chief scientific officer at Edwards Lifesciences, who was instrumental in the commercialization of the first transcatheter aortic valve implantation (TAVI) systems, to its advisory board.

Other finalists in the 2024 Shark Tank competition included AMX Technologies, which was named as the runner up for its clip removal procedure for the removal of failed transcatheter edge-to-edge repair (TEER). Paul Sorajja (Minneapolis Heart Institute, Minneapolis, USA) TCT 2024: Adjustable valve replacement system wins Shark Tank innovation prize

Gentuity HF-OCT imaging system receives FDA clearance

Gentuity has announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance for its Gentuity HF-OCT imaging system, featuring the Vis-Rx Micro-imaging catheter.

According to Gentuity, the imaging system is designed for use both before and after percutaneous coronary intervention (PCI), making it the only intravascular imaging platform specifically indicated for the assessment of the coronary vessel pre and post intervention.

Gentuity has developed and commercialised the Vis-Rx Micro-imaging catheter—a 1.8Fr catheter that the company describes as the world's smallest imaging platform. The low crossing profile of the Vis-Rx Micro-imaging catheter makes it capable of performing essential pre-PCI imaging, reducing the need for pre-dilation, streamlining the procedural workflow, and enhancing intervention accuracy by allowing clinicians to assess coronary arteries in their native state.

"We are excited to receive this FDA clearance, which marks a major milestone for the Gentuity HF-OCT imaging system," said Desmond Adler, president of Gentuity. "The ability to image pre-PCI where it is most needed—without predilation—offers clinicians unparalleled opportunities to optimise treatment plans and obtain previously unavailable insights throughout the entire procedure. Combined with our AI-guided analysis tools, best-in-class scan range for left main and bifurcation assessment, and seamless device setup, the Gentuity HF-OCT imaging system is truly an indispensable tool for advancing patient care."
Gentuity HF-OCT imaging system receives FDA clearance - Cardiovascular News

FYI:

- **October is Sudden Cardiac Arrest Awareness Month. Sudden Cardiac Arrest Awareness Month, observed each October, focuses on spreading knowledge about sudden cardiac arrest (SCA) — a medical emergency where the heart suddenly and unexpectedly stops beating.**
  October is Sudden Cardiac Awareness Month - HSI