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US Regulatory Roundup, October 2019: Expanded Medicare Coverage, Guidance Docs, 'Regulatory Legos,' And More

by Shawn M. Schmitt

News that the US House advanced three bills calling for Medicare coverage for hearing, dental and vision exams and procedures – and that the Senate is considering a similar measure – was of most interest to our online readers last month. Meanwhile, an array of guidance document news from the FDA and the International Medical Device Regulators Forum (IMDRF) also piqued reader interest, as did news that the head of the FDA's device center floated the idea of developing so-called regulatory building blocks, or "regulatory Legos." Here are October's 10 most popular US regulation and policy stories from *Medtech Insight*.

News that the US House advanced three bills calling for Medicare coverage for hearing, dental and vision exams and procedures – and that the Senate is considering a similar measure – was of most interest to *Medtech Insight*'s online readers in October.

Last month's No. 1 story explains that the three bills – H.R. 4665 (Medicare Vision Act of 2019), H.R. 4650 (Medicare Dental Act of 2019) and H.R. 4618 (Medicare Hearing Act of 2019) – will now move to the House floor for consideration.

The Vision Act would cover 80% of an ophthalmology exam and $100 of the costs of eyeglasses or contact lenses every two years, while the Dental Act would cover 10% of the costs of tooth extractions, bridges, crowns and dental implants starting in 2022, once every six months – and 10% additional each year after, up to a limit of 50% of the price of those items in 2026. Further, the Hearing Act would cover a hearing exam and costs of hearing aids when prescribed by a qualified physician or audiologist once every five years, beginning in 2022.

Democrats have introduced a similar – yet more generous – bill in the Senate. S. 1423 – the Medicare and Medicaid Dental, Vision and Hearing Benefit Act of 2019 – would offer dental and hearing care to Medicare recipients at increasing amounts of 10% of the costs of care each year, starting in 2020 and for eight years after.

Meanwhile, an array of guidance document news from the Food and Drug Administration and the International Medical Device Regulators Forum (IMDRF) also piqued reader interest in October. *Our No. 2 story* on an FDA final guidance tells how the agency updated its recommendations around the guidewire clearance process for the first time in almost a quarter-century to reflect growing evidence linking some guidewire coatings to a range of adverse events.

And the IMDRF proposed an overarching device cybersecurity guidance that aims to set best practice principals for not only the medtech industry, but also other key stakeholders, such as health-care providers and hospital systems. *Our No. 5 story* on the topic noted that the IMDRF's document is heavily influenced by US and Canadian regulators, which have had the most experience in developing such guidances for their own jurisdictions.

Our *No. 7* story from last month offers expert insight into an executive order from President Trump aimed in part at the transparency around government agency guidance docs (yet lacks true teeth to make significant changes), while our *No. 8* story shares a list from the FDA of guidances it will prioritize in 2020.

In other FDA news: As the agency gears up for user-fee negotiations with the medtech industry beginning next year, the head of the Center for Devices and Radiological Health (CDRH) has floated the idea of developing so-called regulatory building blocks. Jeff Shuren says the FDA and industry must rethink the regulatory process because industry is moving at a rapid pace, with more complex science and technologies coming to the forefront. That means industry is moving a lot faster than the current regulatory framework that was put in place decades ago.

"Do we want to have regulatory frameworks in which every few years we're running back to Congress to make changes because that is a multiyear process?" Shuren asks in *October's No. 4 story*. "Should we really have cookie-cutter pathways? Or should we have building blocks, something we call 'regulatory Legos,' where we have enough tools to put it together to best meet those new technologies that are going to come both today and in the future, so we don't have to keep going back to Congress to make changes?"

Product recalls was also a hot topic last month. In particular, our in-depth feature on a new app called SoomSafety – which allows users to scan medical device barcodes to get up-to-date information about the products, including whether they're subject to an ongoing recall – was the *No. 6 story*.

Other articles of interest last month: an *agreement between Becton Dickinson & Co. and the state of Georgia* allows the company to continue sterilizing medical devices with ethylene oxide (EtO) at its Covington, GA, plant (and possibly averting a serious device shortage across the US); the FDA is prioritizing *research into ways metals in implanted devices* may impact human health, via two new papers and a planned November panel meeting; and *the latest on the agency's harmonization* of its Quality System Regulation with international standard ISO 13485:2016.

The 10 most popular US regulation and policy stories in October are listed in the table below.

Rank	Title
1	*US House Panel Approves Medicare Hearing, Dental And Vision Coverage; Senate Bill Introduced*
2	*New Guidewire 510(k) Guidance From FDA Advises On Coating Tests*
3	*QSR/ISO 13485 Harmonization Update: FDA Enforcement Discretion Likely When New Rule Stands Up; Draft Reg Coming By Year's End*
4	*US FDA Toying With Idea Of 'Regulatory Legos' In MDUFA V*
5	*US, Canada Setting Trend For Global Cybersecurity Guidance*
6	*'SoomSafety': How A Real-Life Recall Scare Led A Father To Develop A Free App That Gives Detailed Device Safety Info*
7	*Where's The Beef? Trump Executive Order On Agency Transparency A Nothingburger For FDA, Lacks Teeth To Tackle True Guidance Doc Issues, Expert Says*
8	*There's A Lot On FDA's 2020 Guidance Priorities Lists – But The Software Pre-Cert Program Isn't One Of Them*
9	*BD, State Of Georgia Agree To Allow EtO Sterilization Plant To Keep Operating, Averting Potential Device Shortage*
10	*FDA Raises Questions On Metal Implant Safety*