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A boost for new technologies

U.S. Food and Drug Administration Commissioner Scott Gottlieb, M.D., announced steps to work with private payers to shorten the time between the FDA's decision to grant marketing clearance to a new device, and the time that public and private payers decide whether and how they will provide coverage.

Gottlieb announced that CareFirst BlueCross BlueShield and United Health Group have joined the FDA's list of private payers already available to participate in medical device manufacturer pre-submission meetings. Six other payer/health technology assessment organizations already participate in the program (called the Private Payor Program), including BlueCross BlueShield Association, Duke Evidence Synthesis Group, ECRI Institute, Humana, Kaiser Permanente, and the National Institute for Health and Care Excellence (NICE).

"By facilitating communications between device makers and payors, the FDA hopes to shorten the time between FDA approval and coverage decisions," wrote Gottlieb in a blog post. "This can be particularly beneficial for manufacturers creating new and innovative devices who also need to secure coverage of their devices by payors."

Worth the risk?

The FDA issued draft guidance to update the current framework on acceptable levels of uncertainty in regulatory decision-making for medical devices, reported the Regulatory Affairs Professionals Society. The draft guidance is intended to further clarify the approach used by agency staff when making benefit-risk determinations for certain device submissions. The draft guidance acknowledges the need for "considering the applicable patient population's willingness to accept more uncertainty in a device's benefits and risks, particularly when there are no acceptable alternatives available" in order to "appropriately address uncertainty in benefit-risk determinations supporting certain FDA premarket decisions."

Provider consolidation: Thumbs down?

In highly concentrated markets, hospitals' acquisitions of physician practices lead to a 12 percent increase in marketplace premiums, a 9 percent increase in outpatient specialist prices, and a 5 percent increase in primary care prices, according to a study in September *Health Affairs*. The percentage of physicians in practices owned by a hospital increased from about 25 percent in 2010 to more than 40 percent in 2016.

Progress slows in fight against cardiovascular disease

Despite decades-long improvement, rates of myocardial infarction, stroke, and other cardiovascular disease (CVD) events have plateaued and are increasing among certain groups, including adults aged 35 to 64 years, according to the Centers for Disease Control and Prevention and the Centers for Medicare & Medicaid Services.

The events that the CDC/CMS Million Hearts program seeks to prevent include emergency department visits, hospitalizations, and deaths due to myocardial infarction, stroke, heart failure, and related conditions. In 2016 alone, these events accounted for an estimated 2.2 million hospitalizations (850.9 per 100 000 population) and 415 480 deaths (157.4 per 100 000); the burden was greatest in the Southeast and Midwest.

Without intervention and if the 2016 event rates remain constant through 2021, an estimated 16.3 million potentially preventable events (3.3 million/year) are projected to occur, including 2.2 million emergency department visits, 2.2 million deaths, and 11.8 million hospitalizations resulting in projected estimated costs of $170 billion. Approximately one-third of these events are projected to occur among adults aged 35 to 64 years.