



# The healthcare headlines you probably missed this week

By Stephanie Zaremba | May 18, 2017

**H**ealthcare news? Anyone? Given the turmoil in Washington these days, a little run-of-the-mill regulatory news feels like a relief. And while Affordable Care Act repeal efforts are back behind closed doors for now, we've still seen some significant healthcare policy developments in recent weeks. Here are six of them.

## Two-thirds of doctors — as expected — can skip MIPS

The Centers for Medicare and Medicaid Services is starting to notify clinicians that don't need to participate in MIPS. Those that bill less than \$30,000 a year to Medicare Part B, care for fewer than 100 enrollees, or participate in an alternative payment model are exempt from participating.

More than 800,000 clinicians — about two-thirds — will get to skip MIPS compliance this year, which is what most observers had predicted. Of course, not everyone is off the hook. About 400,000 clinicians will be subject to a 4 percent penalty if they aren't successful under MIPS this year. Clinicians can check if they are exempt using this CMS tool.

## Gottlieb confirmed as FDA Commissioner

Scott Gottlieb, M.D., a former Food and Drug Administration and CMS official in the George W. Bush administration, was confirmed by the Senate last week on a 57-42 vote for the top job at the FDA. He'll lead the \$5 billion agency that regulates drugs, devices, tobacco, cosmetics, and food.

While Gottlieb is a more traditional pick than some of the other names that had been floated for the job, there is no doubt that he will push the FDA to modernize and use new authority under the 21st Century Cures Act to speed and streamline drug and device approvals.

## Sanofi makes a bold pledge on drug prices

A handful of pharmaceutical companies have already made pledges to cap drug price increases, but Sanofi's announcement last week was the most aggressive yet. The French drug company, whose best-known drug might be the anticoagulant medication Lovenox, pledged to not raise prices above the medical inflation rate without justification.

Medical inflation is usually around 5 percent, while Sanofi competitors agreed to target a 10 percent cap. Sanofi will also disclose annual aggregate gross and net price increases for all of its products.

## HHS to increase efficiency

Health and Human Services Secretary Tom Price recently told his staff that he wants the department to be far more efficient. He warned of potentially difficult decisions, though was careful to say this was not merely a workforce downsizing exercise. And he challenged his staff to find ways for the department to better fulfill its mission.

Clinicians and patients know well the frustration of dealing with government inefficiencies, so this announcement gives some hope that perhaps some of the most maddening processes could see improvement over the next few years.

## Appellate court also says no to Cigna-Anthem merger

The U.S. Court of Appeals for the District of Columbia refused to overturn the lower court decision, affirming that Anthem's \$54 billion bid to acquire Cigna would harm competition. The two companies are also suing each other for various breach of contract claims as a result of the failed merger.

Aetna and Humana also walked away from their merger deal when a U.S. judge ruled that it would substantially diminish competition in the insurance industry. All four companies asserted that the mergers were necessary to deliver affordable insurance to American consumers, so these court decisions will certainly impact the continued upheaval in some of the ACA individual marketplaces.

## FDA user fee legislation continues to move through the Senate

The FDA's user fee reauthorization bill, which addresses the medical device and generic drug user fee agreements that expire at the end of September, passed out of the Senate Committee on Health, Education, Labor, and Pensions last week.

Senate leadership is committed to keeping this bill relatively clean – meaning it won't have a lot of extraneous provisions tacked on – though two amendments were added in committee.

The first provision would require the FDA to review generic drug applications more quickly if sufficient alternatives are not already on the market. The second would allow sicker patients to participate in clinical trials. The bill next heads to the Senate floor where it is not expected to face much opposition.

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