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A CLOSER LOOK AT MEDICINE MAY | 2017

eNSIGHTS

Far-reaching impact of state waivers

The American Health Care Act passed by House Republicans would allow states to seek waivers to permit insurers and employers wide latitude in what kind of health insurance policies they offer and how much they could charge consumers.

As **NPR** explains, states could apply for waivers that would allow insurance companies to eliminate required coverage – called essential health benefits under the Affordable Care Act – including maternity care, mental health, and prescription drugs. Waivers would also allow insurers to charge higher premiums to people who have pre-existing health conditions and let their coverage lapse.

"The waivers could also impact people with employer-based insurance, because insurers could offer policies that have annual and lifetime benefit limits, which are banned under the Affordable Care Act, and some companies may choose those policies for their workers to lower premiums," **NPR** reports.

Although technically states interested in making a change would have to apply for waivers, analysts note the requirements are so light that essentially any state that wanted a waiver would receive one. Some observers fear that because the Republican proposal cuts federal subsidies, limits Medicaid, and restructures tax credits, it is likely to make health coverage unaffordable for millions of consumers.

"With the skimpier subsidies, states are going to be under enormous pressure to apply for these waivers," says Sabrina Corlette, a research professor at Georgetown University. "When confronted with insurer exits and big price hikes, many states with the best of intentions may feel they have little choice but to get a waiver," she commented to **Kaiser Health News**.

Insurance marketplace realities may have the final say as currently even in Democrat-friendly states many counties have only one insurer.

The GOP healthcare bill

House Republicans passed a bill in early May that, among other changes, would slash funding for Medicaid, allow insurers to charge older customers even higher premiums than under current law, and give states the option to seek a waiver that would permit insurers to sell scaled-back health coverage as they could before reform measures passed by Democrats.

Supporters say it would reshape healthcare through market forces and at the state level rather than through intervention by the federal government. Republicans also point out their proposal includes subsidies and tax credits to ease the burden on consumers. Besides, they argue, the healthcare system is unraveling as insurers are abandoning marketplaces or asking for such steep premium hikes as to make healthcare unaffordable.

The House measure will almost certainly be modified in the Senate, and the Senate version must then pass muster with House Republicans, who are likely to balk at major changes. No Democrat in the House voted for the legislation and indications are Senate Democrats too would be delighted to see Republicans fighting each other.

For hospitals, the most troublesome part of the House version is the revolutionary changes it proposes for Medicaid. The bill would end Medicaid as an open-ended entitlement and put it on a budget. Instead of paying a certain percentage of each enrollee's costs, the federal government would cap its contribution by giving states a specific sum of money for each beneficiary. Alternatively, states could take the money as a block grant with fewer federal requirements, thus freeing themselves to impose tougher eligibility controls.

The Congressional Budget Office estimated the effect would be to reduce federal spending on Medicaid by $880 billion, or nearly 25%, over 10 years. The American Hospital Association says the proposal will jeopardize health coverage for millions of Americans.

Representative Nancy Pelosi of California, the Democratic leader, warned moderate Republicans who supported the measure: "You have every provision of this bill tattooed on your forehead. You will glow in the dark on this one." Democrats have been openly gleeful as they anticipate voters will punish Republicans in next year's elections.

If so, it would be another odd turn in the political cycle because voters have consistently said they do not approve of Obamacare. Even though the Affordable Care Act of 2010 enacted protections for those with preexisting conditions and reduced the number of uninsured by 20 million, the American people never warmed up to the legislation and in fact punished the Democrats in the 2010 midterm elections.

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A view from afar

Risks in approved drugs

Nearly one out of every three drugs approved by the FDA has a new safety issue detected in the years after approval, says a Yale-led study published in the **Journal of the American Medical Association**.

While most of the safety concerns are not serious enough to require withdrawal of a drug from the market, the finding highlights the need for ongoing surveillance of new drugs in the post-market period, the researchers said.

As **Yale News** reports, to assess new drugs for safety and effectiveness, the FDA relies on premarket drug testing and clinical trials. Most of the trials involve fewer than 1,000 patients studied over a period of six months or less, making it difficult to detect safety issues that might be identified once more patients use the drug over a longer time period.

To identify factors that might enhance patient safety and regulatory surveillance efforts, the Yale-led team analyzed data on new drugs approved between 2001 and 2010, with follow-up through 2017. Researchers found that 32% of new drugs were flagged for a safety issue after approval, and the FDA acted promptly to warn physicians and consumers.

The fact that the FDA is issuing safety communications means it is doing a good job of following newly approved drugs and evaluating their safety in the post-market period, the researchers noted. But, they added, at a time when the FDA is under pressure to accelerate drug approvals the study provides key information to policymakers.

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On the horizon

Another blockbuster drug?

A rigorous two-year study, said to cost $1 billion, found the cholesterol-lowering drug Repatha significantly reduces the chance that a high-risk patient would have a heart attack or stroke.

The results were published in March in the **New England Journal of Medicine** and presented at the annual meeting of the American College of Cardiology. Researchers conducted a randomized, double-blind, placebo-controlled trial involving 27,564 patients with atherosclerotic cardiovascular disease and LDL cholesterol levels of 70 mg per deciliter or higher who were receiving statin therapy.

Patients were randomly assigned to receive evolocumab (Repatha) or matching placebo as subcutaneous injections. The drug lowered LDL cholesterol levels to a median of 30 mg per deciliter; in one fourth of the patients LDL levels dropped to below 20 mg.

"There seemed to be no floor to the benefits of cholesterol lowering, at least down to the stunningly low levels achieved in the study. The lower the LDL, the lower the risk, with no leveling off of the linear relationship," reported the **New York Times**.

Dr. David Maron, director of preventive cardiology at Stanford, who was not involved in the study, told the newspaper the results were "incredibly important. The future looks brighter for patients with established coronary disease."

Analysts expect to see a boost in sales of Repatha, which costs about $14,500 per year. **Reuters** reports health insurers and pharmacy benefit managers have been rejecting about 75% of prescriptions written for the drug despite multiple appeals by physicians.

Drug manufacturer Amgen, which reported just $40 million in third-quarter sales in 2016, says Repatha would be well on its way to becoming a $1 billion seller if all prescriptions written had been filled. The company has announced it is taking steps to remove barriers to access, including offering a money back guarantee to patients who have a heart attack or stroke while taking the drug.

Amgen paid for the recently reported study, helped design it, collected the data, and helped write the paper. The data analysis was done independently by a team of academic researchers led by Dr. Marc Sabatine, chairman of a cardiovascular research group called TIMI at Brigham and Women's Hospital, a teaching hospital for Harvard Medical School.

Nevertheless, Dr. Rita Redberg, a cardiologist at the University of California, told the **New York Times** she wonders about the potential for bias given Amgen's broad role in the study. Some observers say another reason for tempering enthusiasm is that while Repatha lowered the risk of cardiovascular events like heart attacks and strokes, it did not reduce overall death rates from cardiovascular causes.

The **Times** cites Ronny Gal, an analyst for Bernstein, as estimating insurers would have to pay nearly $1 million to prevent one cardiovascular event in a patient.

In an essay for **NPR**, Dr. Harlan Krumholz, a Yale cardiologist and widely respected analyst, said improvements effected by Repatha were smaller than what was expected, given that it reduced LDL to around 30 mg/dl.

"Many people in the treatment group still had heart attacks or strokes. The findings were not a home run – but perhaps a solid double," he wrote.

Payment upfront

The news agency **Reuters** recently highlighted some hospitals who are asking for payment upfront because of mounting unpaid bills from insured patients, a group that had previously not raised red flags.

"The ACA extended insurance to 20 million Americans, which initially helped hospitals begin to shrink debt from uninsured patients who could not pay their medical bills. But more and more, people in Obamacare plans or in employer-based health plans are choosing insurance that features low monthly payments. The trade-off is high out of pocket costs when they need care," it adds.

Along with requiring payment before scheduled care, some hospitals are experimenting with offering no-interest loans through ClearBalance, AccessOne, and Commerce Bank, among others. The companies provide loans to patients irrespective of their credit history, and the loans can be extended far longer than the few months hospitals traditionally require before sending a bill to collections.

"People are more likely to pay a bank than a hospital. People are aware that banks will come after them" says Mark Huebner, director of health services financing at Commerce Bank, which offers its line of credit at more than 200 hospitals.

One of the first to test the new payment strategy was Novant Health, headquartered in North Carolina with 14 medical centers and numerous outpatient and physician facilities. It saw patient debt increase when more local employers started adopting high deductible plans, including one that made its executives pay $10,000 in out-of-pocket expenses.

"To remain financially stable, we had to do something. Patients needed longer to pay. They needed a variety of options," says April York, senior director of patient finance at Novant. She told **Reuters** her organization's patient default rate dropped to 12% from 32% after it started offering no-interest loans.

Nearly 45% of Americans polled by the Kaiser Family Foundation said they would have difficulty paying an unexpected $500 medical bill. **Reuters** notes the average deductible this year for the least expensive of the widely used Obamacare health plans is $6,000 for an individual – an 18% increase since 2014 – deductibles for family coverage are typically more than double the individual amount.

Wake Forest Baptist Medical Center in North Carolina is another group that is offering no-interest loans and longer repayment options to patients, some of whom have deductibles as high as $15,000.

CFO Chad Eckes told **Reuters** many patients are unaware of increases in their deductibles. "It's a challenging position. It's a discussion no one wants to be in, and none of us enjoy," he added.

Eyes open during surgery

More patients are choosing to stay awake during surgery in part to avoid the expense and risks of anesthesia, reports the **New York Times**, adding OR teams are still adjusting to this unexpected development.

"For a thousand years, we talked about the operating theater and in recent years the patient has joined the cast," says Dr. Mark Siegler, a medical ethicist at the University of Chicago and one of several authors of a recent study on surgeon-patient communication during awake procedures. The study was published in the **American Journal of Surgery**.

Senior author Dr. Alexander Langerman of Vanderbilt University Medical Center told **Reuters Health** "the surgeons that we interviewed told us that having an 'awake' patient changed the way they communicated with their team. None had formal training in surgeon-patient communication during awake procedures."

Surgeons learn to use code words and limit the use of residents in surgeries where patients are awake. The **Times** reports that as a heads-up to staff members, some hospitals now post warning signs on the O.R. door: PATIENT AWAKE.

"As anesthesia alternatives like regional nerve blocks and site injections become increasingly sophisticated, many more procedures are possible with the patient fully alert or moderately sedated. Orthopedics is the chief specialty for such procedures, but surgery in breast, colorectal, thoracic, vascular, otolaryngological, urological, ophthalmological, and cosmetic specialties is also moving in this direction," the newspaper adds.

"It's not for the faint of heart. They have to cut the capsule of the knee, which is quite thick. I could feel the vibration of the saw cutting through the leg bones...Then they hammer, and it sends a shock wave slamming into your knee. It doesn't hurt, but you feel the pressure. And you smell burning flesh."

Studies show that regional anesthesia has fewer complications than general anesthesia and is less expensive. Patients recover faster and with fewer side effects, which can reduce the need for postoperative opioids.

"Indeed, a few studies suggest that some patients feel less anxious about staying awake during surgery, despite possible gruesome sights, than they do about being sedated," according to the **Times**. Some patients are very anxious about general anesthesia, particularly right before an operation, afraid they will not be able to wake up afterward, it adds.

Dr. David Howes, an emergency physician in Chicago, has had two total knee replacements with only regional nerve blocks and described his experience as a patient awake during surgery. "It's not for the faint of heart. They have to cut the capsule of the knee, which is quite thick. I could feel the vibration of the saw cutting through the leg bones," he told the newspaper.

"Then they hammer, and it sends a shock wave slamming into your knee. It doesn't hurt, but you feel the pressure. And you smell burning flesh," he added.

Insurers signal mounting troubles

Insurers in several states with early rate filings for consumer marketplaces are asking for double-digit hikes which exceed 50% in some cases. Some insurers have indicated they might withdraw from the exchanges unless they have guarantees they will keep receiving federal subsidies that help low-income enrollees.

The **Wall Street Journal** reports CareFirst BlueCross BlueShield is proposing a 52% average increase in Maryland and a 35% average rise in Virginia, while major exchange player Anthem is seeking an average boost of 37.7% in Virginia.

Cigna is seeking an increase of nearly 45% in rates on its individual plans in Virginia and hikes of 37% in Maryland. Kaiser Permanente's proposed average increase would be 15% in Virginia and 18% in Maryland, the newspaper reported.

Modern Healthcare reports that in Connecticut, where there are just two insurers selling individual plans next year, rate increases range from 15% to 34%. "The severity of the requested rate hikes was a surprise to health insurance experts who assumed the large increases experienced in 2017 were a one-time correction by health insurers that initially priced their plans too low," the publication says.

It adds that a few studies showed the market was improving, and experts expected more modest rate increases in 2018 as insurers grew closer to making a profit or at least breaking even.

Chet Burrell, chief executive of CareFirst, told the **Wall Street Journal** the insurer needs large increases because of the Trump administration's expected lack of enforcement of the ACA's coverage mandate, as well as previous underpricing, and an increasingly sick and high-cost pool of enrollees.

"He warned that the company fears it is seeing the 'early stages' of a so-called insurance death spiral, which involve a cycle of increasing rates and declining enrollment," the newspaper added. Separately, Medica, a nonprofit insurer, announced it is considering withdrawing from Iowa's exchange next year, a move that would likely leave much of the state with no marketplace plans, after earlier-announced departures by other insurers. In another blow to the exchanges, Aetna says it will pull out of the Affordable Care Act exchanges in Delaware and Nebraska in 2018, confirming the insurer will exit all of the marketplaces where it currently sells plans.

In a statement Aetna said "our individual Commercial products lost nearly $700 million between 2014 and 2016, and are projected to lose more than $200 million in 2017 despite a significant reduction in membership. Those losses are the result of marketplace structural issues that have led to co-op failures and carrier exits, and subsequent risk pool deterioration."

Echoing a point often made by Republicans, Health and Human Services Secretary Tom Price said "Aetna's decision to completely withdraw from the ObamaCare exchanges adds to the mountain of evidence that ObamaCare has failed the American people. Repealing and replacing it with patient-centered solutions that stabilize the marketplace to bring down costs and increase choices is the only solution."

Modern Healthcare notes the big rate requests in Virginia, Maryland, and Connecticut offer a glimpse into what insurers may be planning in the rest of the country. "These states are showing consistently big premium increases, and it does point to the likelihood we'll see that in other states as well," Larry Levitt, senior vice president of the Kaiser Family Foundation, commented to the publication.

Healthcare observers say one big reason for the steep rate increases is the uncertainty over whether key Obamacare-era provisions will remain in play in 2018. Those provisions include the individual mandate penalty that encourages people to enroll in coverage and the subsidies that help low-income members afford the coverage.

But insurers have also said the pool of individual plan members is growing sicker because fewer healthy members are signing up for coverage. The rate increases announced to date have yet to be reviewed by state insurance regulators in the various states and could be adjusted upwards or downwards.