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Buckle Up: Wild Ride Awaits Health, Life Sci Policy In 2022

By **Jeff Overley and Adam Lidgett**

Law360 (January 3, 2022, 12:03 PM EST) -- Health care and life sciences lawyers are bracing for a fast and furious 2022 as important legislation rolls out and revs up across the health insurance, health care, drug and device industries, fueling activity in a dizzying number of legal practices. Here, Law360 surveys the road ahead in five key policy areas this year.

'Extraordinarily Bumpy' Debut For Health Care Billing Law

Attorneys are forecasting a turbulent takeoff in early 2022 for the No Surprises Act, which aims to shield patients from eye-popping invoices they didn't see coming. Those invoices often arise after surgeries that utilize out-of-network anesthesiologists or health emergencies that necessitate out-of-network ambulance rides.

The NSA — which **became law one year ago** and saw key provisions take effect on New Year's Day — shields patients from many types of out-of-network charges. With patients out of the payment picture, health care providers and health care payors will be left to figure out reimbursement among themselves. The NSA has devised an arbitration process for intractable disputes, which are expected to arise frequently.

One reason that experts expect a discombobulated debut is that regulators haven't fully fleshed out guidance on the law's nuts and bolts.

"We are poised for an extraordinarily bumpy rollout for the No Surprises Act, given the magnitude of operational changes both health insurers and providers need to make in a short period of time," Manatt Phelps & Phillips LLP partner Michael S. Kolber, who advises payors, told Law360.

Complicating matters further, the NSA joins **a patchwork of state laws on surprise billing**; there can be different compliance obligations under different laws depending on a patient's specific type of health insurance plan, health care provider or health care service.

"It's going to be really confusing," Morgan Lewis & Bockius LLP partner Susan Feigin Harris, who advises providers, said in an interview. "I would assume that most [doctors and hospitals] are going to try to figure out the easiest way to ensure that they're compliant across the board."

> In an effort to preserve access to care, we're suing the administration over its misguided implementation of the No Surprises Act. The September Rule would degrade the patient protections against unanticipated medical bills it aimed to establish. https://t.co/qWFEiWxVlR
>
> — AMA (@AmerMedicalAssn) Dec. 10, 2021

And in yet another wrinkle, at least three lawsuits in D.C. and Texas federal courts are challenging the NSA's regulatory framework as skewed in favor of insurers. Those cases will directly affect how

the arbitration process works, and they could indirectly affect how much leverage payors and providers have when hammering out contractual rates.

Manatt Phelps partner Harvey L. Rochman, who advises providers, told Law360 that the litigation raises significant issues "regarding how out-of-network rates will be set where the parties cannot agree, which is fundamental to the balance of power between payors and providers in contract negotiations."

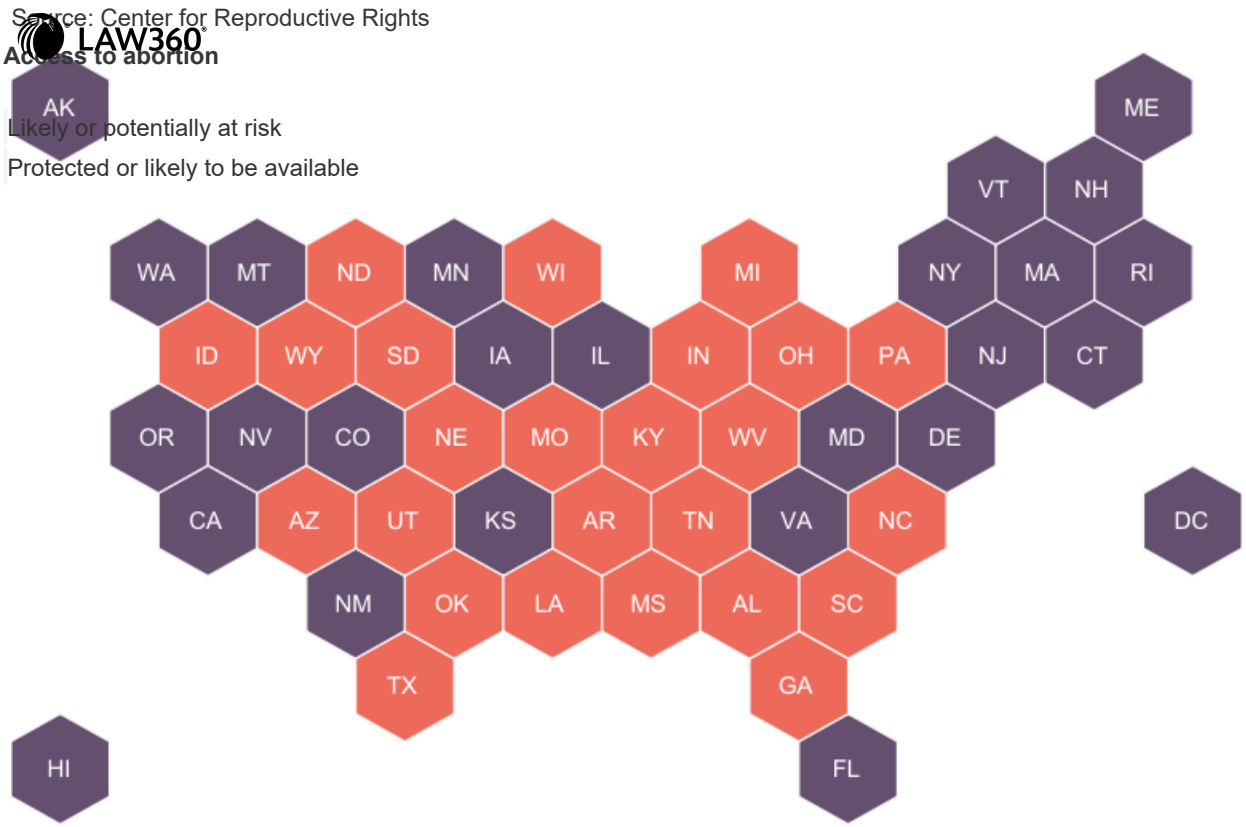
"How that issue is resolved will have a significant impact going forward," Rochman said.

Flurry Of Abortion Bans If Roe V. Wade Falls

The U.S. Supreme Court by late June is expected to rule on a Mississippi law banning most abortions after 15 weeks of pregnancy — nearly two months before a fetus can survive outside the womb, and therefore earlier than permitted under the high court's landmark 1973 decision in Roe v. Wade.

At oral arguments in December, high court conservatives **signaled openness** to nullifying Roe and giving states wide discretion to outlaw abortion. That outcome would fulfill a decadeslong goal of many right-leaning lawyers and activists, and it would likely unleash an avalanche of abortion policy debates in statehouses across the country.

"If Roe were overturned or fundamentally weakened, 21 states have laws or constitutional amendments already in place that would make them certain to attempt to ban abortion as quickly as possible," the Guttmacher Institute, a research group that supports abortion rights, wrote in an analysis shortly before December's arguments.



But the opposite dynamic could play out in left-leaning states, either before or after the Supreme Court's ruling, if policymakers react by expanding support for abortion services.

"State lawmakers can — and must — shore up abortion access in their own states," the institute wrote in a separate analysis in November.

Democrats Eye 'Sweeping' Legislation On Drug Prices

President Joe Biden ran for the White House in 2020 with **aggressive drug-pricing pledges** accompanied by charges that "prescription drug corporations are profiteering off of the pocketbooks of sick individuals." His best chance at delivering on the lofty promises and tough talk has appeared to be the Build Back Better Act.

> Prescription drug corporations are profiteering off of the pocketbooks of sick individuals — it's wrong.
>
> It's time to stand up to this abuse of power – and I'm ready to take on the battle as president. Read my plan: https://t.co/ysfLJKi5xY
>
> — Joe Biden (@JoeBiden) Nov. 26, 2019

The BBB, a massive social spending bill, has "several pretty sweeping drug pricing provisions," Ropes & Gray LLP attorney Margaux Hall, who focuses on drug pricing, told Law360.

Broadly speaking, the BBB would empower Medicare to negotiate prices for a relatively small number of the priciest prescription drugs, require rebates when drug prices rise faster than inflation and cap out-of-pocket costs for many Americans purchasing insulin. The White House has used those ideas as a cudgel against Sen. Joe Manchin, D-W.Va., who has balked at the BBB's price tag and whose support is needed to pass the legislation.

"Sen. Manchin will have to explain to … families paying $1,000 a month for insulin why they need to keep paying that, instead of $35 for that vital medicine," said Jen Psaki, the White House press secretary, on Dec. 19 when Manchin came out against BBB.

Psaki's invocation of insulin costs underscored that policymaking to cut drug prices tends to be popular. During a Dec. 20 interview with West Virginia's "Talkline" radio show, Manchin reiterated his support for negotiating drug prices, but derided the proposal to only negotiate prices for a small number of drugs, dubbing it "picking and choosing, playing games." So, even if the BBB doesn't pass, its pharmaceutical provisions could reemerge.

"[A] distinct possibility is that the legislation is not enacted in its current form, but certain provisions remain or else surface in other bills," Hall said.

Ropes & Gray attorney Thomas N. Bulleit made a similar point, telling Law360 that "everything is still up for grabs," and that "we're still editing the film, and we don't know what's going to end up on the cutting room floor."

In any event, the topic appears likely to continue fueling a Capitol Hill lobbying blitz in 2022. There has been, for example, intense opposition from trade groups Pharmaceutical Research and Manufacturers of America and the Biotechnology Innovation Organization. The groups are contending — as they have for many years — that strong limits on drug pricing will disrupt the development of vital new medications.

> Consequences of Congress' drug pricing plans will make a broken system worse and gut incentives for future R&D. Patients deserve commonsense, patient-centered, bipartisan solutions. Congress: fix the drug pricing legislation now. https://t.co/14FASq3ndn
>
> — PhRMA (@PhRMA) Dec. 15, 2021

Democrats have been contrasting the pharmaceutical industry's immense wealth with the financial challenges of consumers. In December, the Democratic staff of the House Oversight and Reform Committee published a lengthy report that **decried drug pricing practices** as "unsustainable, unjustified and unfair to patients and taxpayers."

Washington University School of Law professor Rachel Sachs, who studies drug pricing, told Law360 that if the BBB drug pricing provisions actually become law one way or another, they would help tens of millions of people, including millions of Medicare beneficiaries wrestling with out-of-pocket expenses.

"Even if it wouldn't solve every problem, it would be a significant improvement over existing issues," Sachs said.

She added that a central problem currently is the ability of pharmaceutical giants to jack up prices with near impunity, and she said that the BBB could "for the first time restrict their ability to do that."

"I would say it is a transformative change to the way we pay for prescription drugs in this country," Sachs said.

Bipartisan Action Looms For FDA, Pharma Patents

While the BBB has been a Democratic endeavor, other important changes involving drug prices are expected to get bipartisan attention. Some of those changes can be found at the legal intersection of antitrust, intellectual property and the U.S. Food and Drug Administration — specifically, several bills that the Senate Judiciary Committee **has unanimously advanced**.

> Affordable Prescriptions for Patients Act addresses evergreening & product hopping abuses that drug companies engage in to extend their monopolies over certain medications. I'm a cosponsor of this Cornyn/Blumenthal bill which passed the Judiciary Cmte by a unanimous voice vote
>
> — ChuckGrassley (@ChuckGrassley) July 29, 2021

Those bills would curtail tactics that brand-name drugmakers deploy to stifle generic competition. The tactics include asserting dozens of patents in the "patent dance" that governs litigation involving biologic drugs, and engaging in "product hopping" aimed at switching existing customers to reformulated versions of drugs that are losing patent protection, instead of lower-cost generics.

"They're bipartisan bills — very bipartisan," Hogan Lovells lobbyist Anna Weinstein told Law360, adding that she envisions "opposite spectrums of the political map coming together on these bills."

Additional bipartisan legislation in 2022 is all but guaranteed on the subject of "user fees" that prescription drug and medical device makers pay for FDA activities related to product approvals.

"We all know that the legislative activity comes to a real slowdown after Memorial Day in an election year," Weinstein said. "Despite that, I'm definitely expecting activity around the user-fee act reauthorization."

That confidence is widely shared because Congress reliably renews the user-fee legislation every five years with virtually unanimous support, and there's no sign it won't do so again before a September deadline.

The legislation consists largely of FDA commitments to review products within set time frames and to entertain new ways of assessing approval applications. It doesn't generate the same buzz as Medicare negotiating drug prices, but there's nonetheless great significance for product safety and accessibility, especially if the legislation becomes a vehicle to pass other bills.

McDermott Will & Emery LLP partner Michael W. Ryan told Law360 that there's chatter about the Medical Device User Fee Amendments, or MDUFA, becoming a vehicle to clarify the FDA's power to oversee thousands of diagnostics. Those diagnostics include so-called laboratory developed tests that have exploded in popularity and **sparked years of debate** about appropriate oversight.

"You're starting to hear, slowly, a drumbeat of folks saying, 'This might move [in 2022] with MDUFA,'" Ryan said. "And that is sort of a logical vehicle for that to move."

The revamped diagnostic oversight is outlined in a bipartisan, bicameral bill commonly called the VALID Act. Its goal of strengthening confidence in test reliability isn't controversial, but there are serious sticking points, including when to exempt older tests from FDA approval and when to require approval for test modifications.

"There's a good amount of work that needs to be done if that's going to move and make everybody happy," Ryan said.

Attorneys have also **predicted since early 2020** that the user-fee legislation might reflect the experience the FDA has gained during the coronavirus pandemic. Earlier health crises, such as

HIV/AIDS, have prompted the agency to evolve, and there are signs that history will repeat in 2022. As one example, the FDA recently noted in user-fee commitment letters that it has "expanded its use of alternate tools" to inspect foreign manufacturing sites because of COVID-19.

"As FDA continues to gain experience and lessons learned from the use of these tools, FDA will communicate its thinking on the use of such methods beyond the pandemic," the agency said.

Similarly, Weinstein told Law360 that the user-fee debate will likely include "a lot of discussion" about whether clinical trials and drug approvals that were streamlined for COVID-19 reasons can also be streamlined on a wider and longer-term basis.

"We've seen in the pandemic that the government, when all resources are focused, can speed up the process of drug review safely," she said. "There's a lot of interest in trying to figure out what lessons you can learn and apply to non-COVID-related drugs."

One key voice in the user-fee debate will likely be former FDA Commissioner Dr. Robert Califf, who has been nominated to lead the agency again and is on track for Senate confirmation in early 2022.

False Claims Act Architect Eyes 'Materiality' Revamp

As with broadly popular policymaking on drug prices, Congress might not see election-year politics as an obstacle to legislative action that protects taxpayer dollars by revamping the False Claims Act. And as lawmakers enter 2022, they already have momentum to do just that.

That's especially relevant for health and life sciences lawyers because FCA recoveries tend to come from entities that bill Medicare, including hospital chains, drugmakers and medical device companies.

"Anytime there's a proposed legislative amendment to the FCA, everybody's antenna … should be up," Polsinelli PC shareholder Kevin M. Coffey, who advises providers, drugmakers and device companies on fraud issues, told Law360.

The FCA's modern architect — Sen. Chuck Grassley, R-Iowa — **is pushing** the False Claims Amendments Act in response to the U.S. Supreme Court's landmark FCA decision more than five years ago in Universal Health Services v. Escobar. That decision has helped defendants argue that alleged misconduct wasn't "material" because the government kept paying claims after learning of allegations — something that Escobar called "very strong evidence" of immateriality.

Grassley's bill would weaken that part of Escobar, revising the FCA so that continued government payment despite knowledge of misconduct "shall not be considered dispositive if other reasons exist" for the continued payment.

"It's going to be much, much easier for a plaintiff to overcome challenges based on materiality" if the bill becomes law, Coffey said.

The prospects for passage look realistic. That's partly because Grassley has been building support from Democrats, including Sen. Dick Durbin, D-Ill., chairman of the Senate Judiciary Committee, which in late 2021 advanced the bill to the full Senate. There's also very similar precedent: Roughly a decade ago, Congress **overwhelmingly approved** the Fraud Enforcement and Recovery Act, which also strengthened the FCA in response to a defense-friendly decision by the Supreme Court.

"The FERA amendments were a pretty significant change to the False Claims Act. … They were able to get those through notwithstanding concerns or objections from trade organizations or other stakeholders," said Polsinelli shareholder Asher D. Funk. "Fraud fighting is typically a pretty bipartisan construct."

--Editing by Michael Watanabe.