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The Rulings That Quickly Made 2022 Huge For Health Law

By **Jeff Overley**

Law360 (July 21, 2022, 11:20 PM EDT) -- A spree of remarkable rulings has already made 2022 a jaw-dropping year for health care and pharmaceutical law, where the U.S. Supreme Court reshaped abortion rights, opioid crisis prosecutions, Medicare's rulemaking powers and vital sources of hospital income. At the midyear mark, Law360 recaps the rulings and analyzes their implications.

Abortion Rights Suddenly Changing at 'Incredible Pace'

In one of the most consequential and controversial rulings in Supreme Court history, right-leaning justices on June 24 overturned another of the high court's most consequential and controversial rulings — Roe v. Wade — and thereby eliminated the half-century-old constitutional right to abortion.

Within weeks of the 5-4 decision in Dobbs v. Jackson Women's Health Organization, highly restrictive abortion laws took effect in roughly a dozen states, and enforcement of similar statutes is anticipated soon in roughly a dozen more. In some states, the availability of abortion care has been changing by the day amid a flurry of court rulings.

"The status of the right to abortion is being defined by legislatures, statutes and court proceedings unfolding across the country at an incredible pace," Lesley C. Reynolds, a member of Reed Smith LLP's reproductive health working group, told Law360.

In addition to affecting patient access, the fluctuating legal landscape is complicating the everyday delivery of health care services. Doctors and pharmacists have reported concerns about legal exposure in connection with procedures and pills that could, at least in theory, facilitate an unlawful abortion.

"Providers have struggled to keep up with the rapidly changing state laws and to understand how those laws — often drafted by non-clinicians — are to be applied to the care being provided to patients," Jennifer Nelson Carney, an Epstein Becker Green lawyer, told Law360.

Additional complexity surrounds the intersection of state and federal views on permissible reasons for ending pregnancies. As one example, the Biden administration on July 11 floated guidance contending that doctors must perform abortions in certain emergency circumstances regardless of state bans. Three days later, the Texas attorney general sued, accusing the administration of using the Emergency Medical Treatment and Labor Act "to transform every emergency room in the country into a walk-in abortion clinic."

Gregory N. Etzel, a Texas-based partner at Morgan Lewis & Bockius LLP, told Law360 that it remains to be seen whether the administration will pursue formal rulemaking to buttress the legal foundation of its guidance. The extent to which EMTALA preempts state restrictions "will ultimately be sorted out by the courts," Etzel added.

For now, the clash is one more illustration of the compliance thicket that medical professionals must traverse in the post-Roe world. As Etzel put it, the guidance adds "another legal consideration that must be calculated by hospitals and physicians who are caught in the middle of what may be a complicated preemption fight."

Trio of Rulings Reverberates Across Hospital Finances

Three rulings this year carry multibillion-dollar implications for different sources of hospital industry income, although the precise effects will vary by hospital and be determined by upcoming regulatory actions.

The most straightforward ruling, ironically, involved Medicare Act text that various Supreme Court justices called "indecipherable" and "baffling" and "a lot to digest." In a 5-4 decision, the high court upheld the federal government's calculation of "disproportionate share hospital" payments for hospitals with sizable shares of low-income patients. For most of those hospitals, the outcome will mean less money.

In a second ruling, the Supreme Court rejected a $1.6 billion annual cut to hospital reimbursement that began in 2018 in the so-called 340B program, which guarantees drug discounts for hospitals in lower-income areas. Regulators on July 15 acknowledged the ruling and committed to eliminating the payment cut, but also said they were "still evaluating how to apply the Supreme Court's recent decision to prior calendar years."

"The outstanding question of remedy really is the billion-dollar question," Reed Smith partner James F. Segroves said in an interview.

It's worth noting that the outcome is not a universal boon for hospital pocketbooks. That's because the savings from reduced 340B reimbursement was redistributed throughout the entire hospital industry; with that reduction having been deemed unlawful, there won't be any savings to sprinkle around the industry.

In a third ruling, a Texas federal judge in February dismantled a key component of a high-stakes arbitration system created by the No Surprises Act, which shields patients from "surprise medical bills" for services unexpectedly performed by out-of-network providers.

Crowell & Moring LLP counsel Rochelle-Leigh Rosenberg noted that the system of independent dispute resolution "is one of the centerpieces of the No Surprises Act." Rosenberg observed that the process covers "hotly litigated categories of out-of-network reimbursement disputes, such as claims for emergency care and out-of-network anesthesia services at in-network hospitals, in more than half of all U.S. states" without comparable billing protections for patients.

In a recent court filing, the U.S. Department of Justice confirmed that a forthcoming final rule "will address the substantive issues that were the subject of the district court's decision" invalidating the arbitration framework.

"Depending on what the final rule says, it could cause yet another shake-up for payers and providers," Reed Smith partner Alexandra M. Lucas told Law360.

A key question is whether regulators will again tell arbitrators to presume that insurers' median reimbursement rates reflect appropriate payment, or if they'll instead introduce a new metric aimed at fostering fair and balanced dispute resolution.

"[Arbitration] rulings are binding, and there is no opportunity to appeal, so consistency and reliability of those rulings is critical," Lucas said.

CSA Opinion Upends Opioid Cases Nationwide

In a decision on June 27, the Supreme Court held in Ruan v. U.S. that the DOJ must prove beyond a reasonable doubt that doctors prosecuted under the Controlled Substances Act for improper prescribing knew they weren't legitimately practicing medicine.

Experts have said the ruling casts doubt on CSA cases across the country, and imprisoned doctors have already begun challenging their convictions. As one example, a recent filing at the Tenth Circuit argued that Wichita, Kansas, physician Steven R. Henson — who is serving a life sentence for illicit opioid prescribing — was convicted based on a "radically different" standard than the Supreme Court's decision requires.

"The jury instructions in Dr. Henson's case allowed for conviction if he was, essentially, knowingly sloppy, regardless of whether he believed the prescriptions themselves were authorized," the filing said. "Under Ruan, a conviction cannot be sustained under that theory."

The Ruan case is also being wielded in civil opioid litigation, including a DOJ case accusing Walmart Inc. pharmacies of exacerbating widespread narcotic abuse. In a recent status report, Walmart told a Delaware federal judge that "in light of Ruan, Walmart believes the United States should voluntarily dismiss" portions of its case. In the same report, the DOJ sought "an opportunity to amend its complaint for several purposes, including to add factual allegations that further demonstrate Walmart's liability."

In its opinion, the high court said that "a strong scienter requirement" helps to prevent the punishment of beneficial medical care that pushes the limits of lawful conduct. That observation might help with legal defenses in certain cases, Covington & Burling LLP partner Laura Flahive Wu, who has represented companies in opioid litigation, told Law360.

"The Ruan opinion placed significant value on the regulatory framework [that] authorizes prescribers to dispense controlled substances by prescription," Wu said. "The court's emphasis on the Controlled Substances [Act] regulations and the role of a party, specifically prescribers, within that framework, could be used to guard against liability for the downstream impacts of regulated conduct."

On a related front, 2022 has also produced a major opioid ruling in West Virginia federal court. There, drug distributors in early July notched a resounding victory in the form of a 184-page opinion shielding them from liability for opioid abuse in hard-hit Cabell County.

'Major Questions Doctrine' Clouds HHS Rulemaking

The first half of 2022 ended with a bang on June 30 when the Supreme Court — in a 6-3 decision along ideological lines — invoked the "major questions doctrine" in West Virginia v. U.S. Environmental Protection Agency. The invocation carried big implications for climate change, but even bigger implications for executive branch rulemaking, much of which emanates from the U.S. Department of Health and Human Services.

Although the high court had previously applied versions of the doctrine, it had not done so explicitly. As described by the majority in the EPA case, regulations with vast "economic and political significance" can qualify as "major questions," and agencies must identify "clear congressional authorization" for such regulations.

Given that HHS oversees more than $1.5 trillion in annual spending, focuses on life-or-death topics and publishes thousands of pages of regulations per year, its policymaking could be especially vulnerable. Lobbyists and litigators might increasingly argue that disfavored HHS regulations present "major questions" and exceed congressional authorization.

"I think you'll see major-questions-doctrine arguments made regularly going forward in various regulatory comments that are submitted," Reed Smith's Segroves said.

Epstein Becker Green member Stuart M. Gerson echoed that prediction, saying, "You would find me, as a litigator who represents all sorts of health care providers, attempting to do it in an appropriate case. ... West Virginia v. EPA offers something that litigators like myself are going to look at seriously."

Gerson cautioned, however, that corporate health lawyers should "temper any alacrity with a realistic judgment" of whether something is truly major. Segroves offered a similar take, telling Law360 that a consensus view of the doctrine won't emerge anytime soon.

"Ultimately, what is a major question, and what is not a major question, is often in the eye of the beholder," he said. "And I think that it will take years for this decision to play out."

Even for regulations lacking major effects, West Virginia v. EPA could prove important. That's because the decision interpreted a federal statute without utilizing so-called Chevron deference — the longstanding practice of judicial deference to reasonable agency interpretations of ambiguous statutes.

Conservatives in recent years have been gunning for Chevron deference, ostensibly because it empowers bureaucrats to effectively rewrite federal laws. To the extent that deference is diminished, experts expect courts to strike down more regulations, which Democratic administrations typically issue more frequently and aggressively.

As in the EPA case, Chevron deference is seemingly being diluted via neglect; the Supreme Court even avoided the Chevron framework when deciding two HHS cases this year — the ones involving 340B and disproportionate share hospital payments — even though deference was a central theme at oral arguments.

In an interview, Gerson predicted that "Chevron is not going to die," and that "agencies will get deference in [cases that] involve technical matters that courts are not competent to decide." But generally speaking, he added, judges "have read Chevron out of the game — they're just ignoring it."