Recent SCOTUS Decisions Impacting Healthcare

August 3, 2022

The Supreme Court issued a number of groundbreaking decisions impacting healthcare companies and their stakeholders in its 2021–2022 term. With Justice Amy Coney Barrett replacing Ruth Bader Ginsberg (resulting in a 6-3 conservative majority), the Supreme Court not only held in *Dobbs v. Jackson* that there is no longer a Constitutional right to abortion (overruling nearly 50 years of precedent) but also issued a number of decisions impacting vaccine mandates, Medicare, Medicaid, administrative agency deference, and a host of other critical issues confronting the healthcare ecosystem.

We summarize below some of the most important Supreme Court decisions impacting the healthcare industry in the 2021–2022 term. Despite the swearing in of Ketanji Brown Jackson on June 30, 2022, replacing Justice Breyer, we do not anticipate any major changes in the functioning or trajectory of the Supreme Court and anticipate an eventful 2022–2023 term.

***Whole Woman's Health v. Jackson* (12/10/2021)**. Abortion providers sought pre-enforcement review of the Texas Heartbeat Act, which bans abortions after six weeks of pregnancy and allows for enforcement via private civil actions against anyone who performs an abortion or assists someone in gaining access to one. The Supreme Court held 5-4 that providers challenging the constitutionality of the statute could not bring suit against judges, clerks, or the state Attorney General to prevent them from enforcing the law. The Court reasoned that while *Ex parte Young*, 209 U.S. 123, established a narrow exception allowing an action to prevent state officials from enforcing state laws that are contrary to federal law, federal courts are nevertheless not normally permitted to issue injunctions against state court judges or clerks. In addition, the petitioners could not sue the Attorney General, because the Attorney General does not have enforcement authority under the statute. The Court did, however, in an 8-1 decision with Justice Thomas as the lone dissenter, allow a portion of the case to proceed against the Texas Medical Board and licensing authorities, because licensing officials "may or must take enforcement actions" against abortion providers if such providers violate the Texas statute.

Takeaway: Without ruling on abortion itself, the Supreme Court effectively made challenges to certain types of abortion laws and any other potentially unconstitutional state laws harder to bring—ruling that the "chilling effect" of such a law merely being on the books is an insufficient basis to bring a suit before the statute is actually enforced. This ruling likely will make it more difficult for parties to bring suits in federal court challenging the constitutionality of certain types of state laws at an early stage.

***Biden v. Missouri* (01/13/2022)**. After the Secretary of Health and Human Services ("HHS") imposed the COVID vaccine requirement on all healthcare facilities participating in the Medicare and Medicaid programs, groups of states led by Louisiana and Missouri challenged the rule, leading to preliminary injunctions against its enforcement. The Supreme Court held 5-4 that HHS was authorized to issue the vaccine mandates because it was similar to other safety requirements that HHS was authorized to impose on participants in federal healthcare programs.

Takeaway: This opinion affirms the Supreme Court's deference to regulations that are within the traditional scope of the agency's regulatory authority. However, the dissenting Justices' position—that if Congress wanted to give HHS power to impose vaccine mandates it should have specifically authorized it to do so—may have foreshadowed *West Virginia v. EPA* (below) and the Court's eventual application of the major questions doctrine.

***NFIB v. OSHA* (01/13/2022)**. On the same day it upheld the HHS vaccine requirement, the Supreme Court struck down a vaccine mandate enacted by the Secretary of Labor and the Occupational Safety and Health Administration ("OSHA") in what was effectively a 6-3 decision.[1] The mandate would have required approximately 84 million workers to receive COVID vaccines (or obtain a weekly COVID test and wear a mask at work). The Supreme Court held that while OSHA is empowered to set workplace safety standards, the vaccine mandate is a broad public health measure and therefore not within OSHA's jurisdiction. The Court explained that COVID is not specifically an occupational hazard since it poses a universal risk regardless of where people gather and the mandate was not specifically tailored toward workplace environments with elevated COVID risks.

Takeaway: This opinion reflects the Supreme Court's increasing skepticism of regulations it perceives as outside of the scope of an agency's jurisdiction/traditional sphere of influence. The Supreme Court was willing to uphold CMS's vaccine mandate

[1] The decision was a *per curiam* opinion, meaning it does not identify the author and was issued in the name of the court as a whole rather than signed by individual justices. Here, Justice Gorsuch wrote a concurring statement joined by Justices Alito and Thomas, while Justices Breyer, Sotomayor, and Kagan wrote a joint dissent.

in the context of traditional regulatory oversight over healthcare providers but was unwilling to affirm OSHA's mandate as it was (in the Supreme Court's view) overstepping its role by issuing a regulation that was not tailored to workplace safety.

***Gallardo v. Marstiller* (06/06/2022)**. This 7-2 opinion addressed a state's authority to recover certain expenditures made by its Medicaid program. The petitioner, a Medicaid beneficiary, suffered catastrophic injuries after being hit by a car and eventually recovered $800,000 in a court-approved settlement. The state of Florida sought to recover from the settlement the cost of future Medicaid expenditures on this beneficiary's behalf (who remained in a persistent vegetative state) under the Florida's Medicaid Third-Party Liability Act. The Supreme Court ruled in favor of Florida, holding that, while the Medicaid Act prohibits states from recovering medical payments from a beneficiary's property, that provision does not apply to state laws that are authorized pursuant to, and in compliance with, the Medicaid Act.

Takeaway: This decision is unlikely to have a significant impact on private industry, but may encourage states to authorize their Medicaid programs to act in a similar manner as Florida in this case.

***AHA v. Becerra* (06/15/2022)**. By way of background, HHS's reimbursement rates for Medicare Part B drugs provided by hospitals for outpatient care are subject to judicial review, and HHS cannot vary the reimbursement rates only for low-income/rural hospitals (known as Section 340B hospitals) absent a survey of hospitals' costs in acquiring the drugs. The Medicare statute provides two options that HHS can follow to set reimbursement rates for certain outpatient drugs provided to Medicare patients by hospitals. If HHS conducts a survey of hospitals' acquisition costs for each covered outpatient drug, then the agency may set reimbursement rates based on the hospitals' average acquisition cost per drug. This option allows for the rates to vary by hospital groups. Alternatively, HHS must set reimbursement rates based on the average price of the drug charged by manufacturers as calculated and adjusted by the Secretary of HHS. This option does not authorize HHS to vary reimbursement rates for different groups.

For 2018 and 2019, HHS did not conduct a survey, yet it established separate reimbursement rates for 340B hospitals. The American Hospital Association challenged the reimbursement rates, and, in response, HHS claimed that judicial review of the reimbursement rates is precluded and that HHS had authority to "adjust" the rates under the second option described above. In a unanimous decision, the Supreme Court rejected HHS's reasoning and found that judicial review was not precluded. As a result, because HHS did not conduct the requisite survey, its decision to vary reimbursement rates only for 340B hospitals was deemed unlawful.

Takeaway: This case is most notable for what it does not do. Some industry groups and conservative legal organizations had urged the court to use this case as an opportunity to undermine the *Chevron* Doctrine, which requires courts to grant deference to federal agency statutory interpretation—but even though the Supreme Court refused to defer to the agency in this case, it ignored *Chevron* deference issues entirely.

Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita, Inc. **(06/21/22)**. The Supreme Court held 7-2 that the Marietta Memorial Hospital Employee Health Benefit Plan does not violate the Medicare Secondary Payer Act, which prohibits health plans from differentiating in benefits between individuals with and without end-stage renal disease. The Marietta Memorial Hospital Employee Health Benefit Plan has three tiers of reimbursement, and dialysis providers like DaVita fall within the lowest tier of reimbursement. As such, dialysis services are subject to relatively limited reimbursement rates. DaVita argued that the Plan's limited coverage for dialysis violated the Medicare Secondary Payer statute. The Court determined that the Plan did not differentiate in the benefits it provides for individuals with and without end-stage renal disease, because the Plan's terms applied uniformly to all Plan participants.

Takeaway: This opinion is favorable for insurers, because the Supreme Court interpreted the Medicare Secondary Payor Act in a manner that provides them greater flexibility in crafting benefit plans.

Dobbs v. Jackson Women's Health Organization **(06/24/2022)**. In a momentous and controversial decision, the Supreme Court held 5-4 that the Constitution does not confer a right to abortion—overruling *Roe v. Wade* and *Planned Parenthood v. Casey*.[2] The Court reasoned that the Constitution does not expressly mention a right to abortion, and the question at issue was whether that right is implied by the language of the Constitution. The Court's substantive due process analysis examined whether the right is "deeply rooted in our history and tradition" and essential to our nation's "scheme of ordered liberty." After reviewing historical evidence of the criminalization of abortion, among other things, the Court concluded that a right to abortion is not deeply rooted in the nation's history and traditions and thus cannot be recognized as a component of the liberty protected in the Due Process Clause. The minority issued a forceful dissent, arguing—among other things—that principles of stare decisis and the liberty interests protected by the Fourteenth Amendment required the court to uphold *Roe* and *Casey*.

In the aftermath of *Dobbs*, the abortion debate has shifted to the states, where litigation is ongoing in certain states regarding the viability of certain abortion-related statutes,

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[2] The ultimate question of whether or not to uphold the Mississippi law at issue was decided 6-4. Chief Justice Roberts filed an opinion concurring in the judgment, but declining to overturn *Roe* and *Casey*.

and state lawmakers are debating whether to enact laws that either expand or restrict the availability of abortions.

Takeaway: The full impact of this decision cannot be summed up and simplified: the consequences are broad and the legal issues myriad. We note that one of the first lines of conflict is likely to be federal preemption of state laws in connection with the administration of stabilizing emergency treatment. A wide range of additional issues are also implicated, including state travel restrictions, telemedicine, drug importation, and provider liability. Further, the potential ultimate impact of the decision on gay marriage, contraception, and a host of legal precedents concerning so-called "individual privacy" remains unclear as of this writing. Watch this space for further updates on the potential challenges healthcare organizations face in a post-*Roe* world and how to navigate them.

***Becerra v. Empire Health Foundation* (06/24/2022)**. The Supreme Court held 5-4 that HHS followed the correct procedures when it promulgated a rule changing the way it calculates Medicare Part A reimbursement rates for disproportionate share hospitals ("DSH")—which are qualifying hospitals that treat low-income patients. The HHS regulation reduced the proportion of patients considered low-income, resulting in decreased payments for most DSH hospitals. The Empire Health Foundation argued that the regulation was inconsistent with the calculation methods outlined in the Medicare statute. However, the Supreme Court found that the HHS regulation correctly construed the statutory language at issue and was therefore a valid rule.

Takeaway: An increasingly rare victory for administrative agencies, court confirmed the agency's interpretation of the statute. As in *AHA v. Becerra*, this decision is notable because it ignores entirely the *Chevron* Doctrine—which remains valid precedent at least for the time being.

***Xiulu Ruan v. U.S.* (06/27/2022)**. The Supreme Court unanimously held that a physician may be convicted of unlawful distribution of a controlled substance under 21 U.S.C. § 841(a)(1) only if the physician knowingly or intentionally prescribed a controlled substance without authorization. The Supreme Court emphasized that there is a strong presumption in criminal law that the government must prove *mens rea, i.e.*, that the defendant intended to violate the law. Proof of *mens rea* is critical to distinguishing between doctors engaging in socially-beneficial prescribing and unauthorized prescribing for improper purposes.

Takeaway: This Supreme Court opinion will likely make it more difficult for the government to bring prosecutions predicated on allegedly improper opioid prescribing due to the need to establish criminal intent. More generally, *Ruan* will make it more challenging for federal prosecutors to bypass the need to prove that the defendant purposely intended to violate the law. In addition, although *Ruan* is applicable only to

federal criminal statutes, the principles it outlines may be viewed as persuasive in state courts in analogous circumstances, which potentially may include both opioid prescribing and, in some states, medical practices that may run afoul of abortion prohibitions.

***West Virginia v. EPA* (06/30/2022)**. In this momentous decision, the Supreme Court held 6-3 that Congress had not granted the EPA the authority to promulgate emissions restrictions to combat climate change under the Clean Power Plan. The Court found that so-called “major questions” like the EPA’s authority to issue “generation-shifting” regulations to address climate change were reserved for Congress absent clear delegation of authority—which it concluded the EPA did not have. The minority issued a forceful dissent, arguing—among other things—that the Supreme Court was overriding legislative choice and abandoning principles of statutory interpretation by establishing a new and ambiguous “major questions” doctrine that permits courts to overturn agency regulations. As we will discuss in a forthcoming client alert, it seems likely that stakeholders in the healthcare and life sciences industry may invoke the “major questions” doctrine as a means of seeking to invalidate regulations issued by the Food and Drug Administration, HHS, or other regulators.

Takeaway: This decision may be a sign of a more activist Supreme Court willing to curtail major administrative agency decisions, unless authority has been expressly delegated to the agency by Congress. Based upon this decision, we expect significant future litigation challenging administrative agency action based upon application of the “major questions” doctrine.

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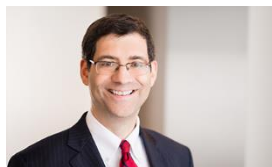

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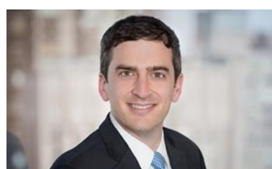

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