Court

How the Supreme Court transformed healthcare in 2022

With four seismic 2022 decisions, the Supreme Court of the United States (SCOTUS or the Court) has underscored the critical role federal law and national regulations play in healthcare. As with any heavily regulated industry, healthcare depends on predictable policy. These 2022 decisions create uncertainty, creating challenges for healthcare providers both in planning for the future and operating in the present due to concerns that SCOTUS will aggressively challenge executive agency regulations and control which services and public health strategies are legal. Healthcare providers must anticipate change while operating in a highly competitive environment.

A core cause of uncertainty inheres in the gap between laws and the detailed regulations that drive the marketplace. Congress passes legislation that provides conceptual directives without details as to how to implement them. It then passes them on to the President. If signed into law, Executive Branch agencies/departments then prepare rules for implementation. In healthcare, the Centers for Medicare & Medicaid Services (CMS) and others act in that role. Staff frame regulations, draft rules, solicit public comment, and release final rules. In these multiple steps, an agency inevitably engages in interpretation, which may or may not match either the legislative intent or language. That gap can become the basis of legal challenges.

Said cases then involve the court system. SCOTUS accepts only 100 to 150 cases annually, chosen based on significance or disagreements among lower courts. Decisions then potentially drive the redirection of policy implementation, change in laws, or the need to send a case back to an agency to revise its regulations. Changes may be retrospective or prospective, thus creating further uncertainty for providers, who must

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Costs

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plan far into the future for certain strategies. An actively interventional Court represents a shift in power away from executive agencies, which have historically enjoyed substantial leeway in regulatory design.

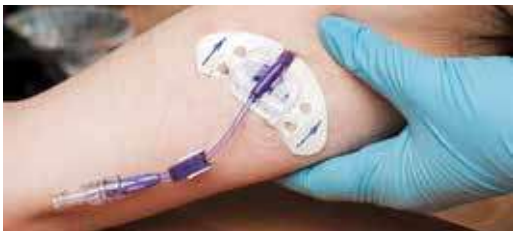
Weights on the Underserved

Furthermore, the impact of these decisions weighs especially heavily on underserved communities and those at a socioeconomic disadvantage: These communities rely disproportionately on government programs to fund their healthcare. For context, federal and state governments directly pay for more than 50% of the total cost of care delivery, which involves hospitals and other facilities, physicians and other providers, post-acute care, and medications. Policy changes and legal challenges affect providers to the underserved because they are most often directly under government control.

Examples include critical access to hospitals, safety net providers, Federally Qualified Health Centers (FQHCs), and community clinics. Providers must anticipate change while maximizing the financial leverage of government-supported programs. These financially marginal providers depend most often on government funding for their existence (see "The Scope of 2022 Court Decisions").

Case Summaries

Underscoring the U.S. government's critical role in regulating and funding healthcare access, these cases indicate an activist approach by SCOTUS. Both broad public health and narrow bureaucratic issues can arise. Legality of services and public health policies may face major changes. Given the extent of public sector involvement in care delivery to underserved communities, the Court has the potential for an especially powerful impact on providers. The following four cases address these topics.



1 American Hospital Association v. Becerra

The Court overruled CMS' change in methodology for the allocation of the 340B Drug Pricing Program. This provision supports nonprofit hospitals' ability to purchase high-cost pharmaceuticals such as chemotherapeutics by drug manufacturers providing significant discounts, which are especially critical for safety-net hospitals.

For context, 340B provided "about $4 billion [in funding] per year in 2007–09, [rising] to $38 billion in 2020," or almost 7% of the U.S. pharmaceutical market.[1] Furthermore, Justice Kavanaugh wrote that it "may be that the reimbursement payments were intended to offset the considerable costs of providing healthcare to the uninsured and underinsured in low-income and rural communities."[2,8]

In 2018, the Department of Health and Human Services (HHS) reduced reimbursement rates for hospitals serving large, underinsured populations by $1.6 billion.[2] These financially weak hospitals were impeded in delivering high-cost drugs. This is a critical concern considering that minorities and those living in poverty are at high risk for chronic diseases such as cancer. This unanimous court decision denies HHS the ability to arbitrarily change how hospitals implement 340B. Instead, if HHS intends to make price adjustments, those adjustments must be based on hospital and drug valuation criteria set forth in the 2003 Act. Broadly, this case reinforces that the government drives healthcare funding, especially for underserved populations.

2 West Virginia v. EPA

The Court ruled that a methodology the Environmental Protection Agency (EPA) created to cap emissions under the Clean Power Plan (CPP) exceeded the scope of its congressionally delegated authority by pushing utilities to make systemwide moves from coal power generation to cleaner forms of electricity production such as wind and solar energy. Under the "major questions doctrine," the Court indicated its likelihood to apply this strict standard to agency action by requiring explicit congressional authorization for action rather than the wide latitude agencies have historically received. Chief Justice Roberts, writing for the majority, found that the EPA did not have the expertise to properly consider the impact on additional national policies. Therefore, the intention of Congress would not have been to grant them this power. This decision could potentially apply to healthcare through CMS' regulation of the industry, even in areas long established.

This decision creates uncertainty regarding regulations/policy implementation. Restricting EPA's ability to address climate change speaks to the Court's view of agency-driven interpretation of laws for implementation. CMS' future development of rules/regulations might face strict scrutiny by the Court and, thus, a high risk of *ex post facto* change. Broadly, given the vague definition of "extraordinary" or "major questions" doctrine, the Court opens questions for action by federal agencies. In health policy, narrowing broad language and, thus, flexibility in rulemaking will tighten scrutiny and affect providers.[1]

For example, eligibility rules for the Children's Health Insurance Program (CHIP) and Medicaid face challenges. CMS' current proposal is to simplify the process to access and maintain access to low-income programs benefiting millions of people, especially minorities. Approximately 15 million people risk losing coverage once the public health emergency ends. An additional 6.8 million people would have continued eligibility if not for governmental roadblocks. The precedent set by *West Virginia v. EPA* is that if a party chose to sue and held up the proposal, millions of people could find themselves without coverage whether they were eligible or not. The retroactive implications could be disastrous if millions suddenly found that past coverage was in error or should have been provided. This would affect families across the country.

The Scope of 2022 SCOTUS Decisions

The four Court decisions fall into two primary categories:

- **Those that impact how detailed regulations apply in implementing existing laws and their resulting payments to providers**
- **The range of services legally allowed and the government's power to implement public health policies**

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3 *Dobbs v. Jackson Women's Health Organization*

The Court overturned *Roe v. Wade* (1973) and *Planned Parenthood of Southeastern Pa. v. Casey* (1992) allowed states to prohibit all abortion services. This decision raises a host of questions for healthcare providers (hospitals and physicians) and insurers nationally and, more challengingly, on a state-by-state basis. Areas of potential litigation and liability/criminality concern the current nationwide right to treatment, use of life-saving drugs that may harm a fetus, legality of providing advice or assistance in seeking abortions, and interstate regulations of travel and commerce.[6]

The range of uncertainty created by *Dobbs v. Jackson Women's Health (Dobbs)* is unique among recent SCOTUS decisions. Treatments that could be challenged threaten the national power of the Emergency Medical Treatment and Active Labor Act of 1986 (EMTALA), which establishes standards for emergency treatment of patients receiving Medicare payments. Pre-*Dobbs*, the requirement of care included saving the life of a pregnant woman rather than the fetus. That may change, and doctors now must weigh legal risk in making emergency treatment decisions.

Analogously, selected treatments for early-stage breast cancer pose material risk to a fetus; however, these oncolytics represent effective cancer treatments. Again, doctors and hospitals potentially face legal risk in treating pregnant women with cancer. Even providing advice on referrals for abortion services could create legal peril for providers. For example, a 10-year-old victim of rape was forced to travel to Indiana to obtain an abortion because the procedure was illegal in her home state of Ohio.[5] Some sources even speculate that OB/GYNs may choose not to practice in states with stringent anti-abortion laws.[3,7]

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4 *Biden v. Missouri*

The Court upheld the right of CMS to regulate Medicare and Medicaid providers in areas clearly related to their delivery of healthcare services. In this case, the question addressed COVID regulations. Specifically, the Court affirmed CMS' mandate that "in order to receive Medicare and Medicaid funding, participating facilities must ensure that their staff... are vaccinated against COVID-19." Had this 5–4 decision gone against CMS, a core lever of national policy during the pandemic could have been blocked, changing policies across the nation.[4]

The Supreme Court as composed June 30, 2022, to present. Front row, left to right: Associate Justice Sonia Sotomayor, Associate Justice Clarence Thomas, Chief Justice John G. Roberts, Jr., Associate Justice Samuel A. Alito, Jr., and Associate Justice Elena Kagan. Back row, left to right: Associate Justice Amy Coney Barrett, Associate Justice Neil M. Gorsuch, Associate Justice Brett M. Kavanaugh, and Associate Justice Ketanji Brown Jackson.

Implications

The current Court expresses willingness to insert itself into regulatory processes and override agency implementation of congressionally passed laws and precedents that define what services agencies can legally provide and what public health policies they can implement. Such Court intervention creates great uncertainty versus the status quo and historical patterns of how CMS and others operate. Providers face long-term uncertainty regarding consistency in the application of laws and regulations over multiple years. This is a serious challenge given long timelines for facility and program development on the delivery side and policy planning and court action on the governmental side. Given these decisions, providers of healthcare services should:

- Keep up to date on impending new and changing regulations, their associated comment periods, final rulings, court challenges, and potential implications. State regulations might also present challenges.
- Maximize compliance with current rules but also develop contingency plans for potential major changes.
- Consider clinical implications of certain decisions, such as *Dobbs,* which could be interpreted so that treatments for cancer could be denied during pregnancy.
- Engage with national organizations/advocates when new issues arise that warrant challenges in the political or legal realms.
- Support efforts by safety net organizations to expand the services they are not currently offering to the public and enhance those they do provide.

Furthermore, providers and insurers operating in multiple states must prepare for differing state-by-state regulations. The array of problems that arise from differing state regulations include operating efficiency, legal exposure for hospitals and doctors who cross state lines, and consistency of care.

These 2022 SCOTUS decisions make it imperative for providers to engage with public policy and Court decisions. A wide range of government programs and policies support care to the underserved and how they operate. Examples include the 1,400-plus FQHCs that provide primary care, behavioral health, and dental coverage for 30 million medically underserved; the American Rescue Plan Act of 2021; the Health Workforce Strategic Plan; and wide-ranging single-issue programs.

These legal cases bring to light the way government and nonprofit healthcare providers overlap in providing underserved communities' access to needed medical care. The decisions underscore the importance for providers to examine the needs of the populations they serve and what federal or state programs could support care delivery, especially to poorly insured populations. Providers must maximize their range and operational effectiveness. GPJ

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