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'American Hospital Association v. Becerra': The Economics of Healthcare

Recent SCOTUS decision has far-reaching implications for acute care providers who provide services to uninsured, underinsured, and rural communities.

By Kerry Cahill

COVID-19, inflation, politics, and an impending recession: it is indisputable that the last two years have had an indelible effect on the healthcare industry. Acute care providers, in particular, have faced a plethora of economic challenges, including increasing costs for drugs and medical devices. However, on June 15, 2022, in *American Hospital Association v. Becerra, Secretary of Health and Human Services*, 142 S.Ct. 1896 (2022), the American Hospital Association (AHA) secured a win for 340B hospitals—often referred to as safety net hospitals—by successfully challenging the Department of Health and Human Services' (DHHS) calculation of reimbursement rates. As a result, the *Becerra* court affirmed that DHHS was not statutorily authorized to vary reimbursement rates for different hospital groups; DHHS's power to increase or decrease the price is distinct from its power to set different rates for different groups of hospitals. *Id.* As a result, the *Becerra* decision has far-reaching implications for acute care providers who provide services to uninsured, underinsured, and rural communities.

Legislative Backdrop

In order to appreciate the impact of *Becerra*, it is imperative to have a general understanding of the evolution of the regulatory landscape for healthcare providers. During the nineteenth century, acute care was generally provided in the homes of the wealthy or through benevolent institutions, including voluntary, religious, and public or governmental institutions. Generally, the Wilson-Gorman Tariff Act of 1894 applied to these early acute care providers, which provided that charitable organizations should enjoy tax-exempt status, provided they operate for charitable purposes.

At the beginning of the twentieth century, significant advancements in technology and the creation of health insurance spurred the development of the community hospital. Better patient outcomes were the product of x-rays, laboratories, and aseptic surgery—which were only available in hospital facilities. In 1917, the Revenue Act established an individual income tax deduction for contributions made to tax-exempt charitable organizations, which helped spur donations to

these early hospitals. Additionally, following World War II, there was a surge of public demand for community hospitals, particularly to accommodate veterans and provide obstetrical services. As a result, in 1946, Congress enacted the Hill-Burton Act, first enacted as Title VI of the Public Health Service Act of 1944, 42 U.S.C.A. s 291 et seq., which made federal funds available for hospital construction in underserved areas.

On July 30, 1965, President Lyndon B. Johnson signed the Social Security Amendments of 1965 into law, creating the Medicare and Medicaid programs. PL 89-97 (1965). These programs were intended to provide money for the care of the aged and poor in an effort to reduce barriers of access to healthcare. In 1986, Congress enacted the Emergency Medical

Treatment & Labor Act (EMTALA), 42 U.S.C.A. §1395dd(d), to ensure public access to emergency services regardless of ability to pay. In 2010, Congress enacted the Patient Protection and Affordable Care Act (the ACA), 42 U.S.C. 18001 et seq. The ACA, in part, created a mandate for tax-exempt hospitals to conduct a community health needs assessment (CHNA) every three years. I.R.C. §501(r)(3)(A)(2010). This assessment requires "input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health." I.R.C. §501(r)(3)(B)(i)(2010). Further, the hospitals must then adopt an implementation strategy to meet the community health needs identified in the assessment. I.R.C. §501(r)(3)(B)(ii)(2010).

Hospital Participation in the 340B Program

By 1990, hospitals were facing unprecedented economic challenges—including a duty to treat uninsured and underinsured patients while facing skyrocketing pharmaceutical costs. As a result, Congress enacted the Medicaid Drug Rebate Program (MDRP), which helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. The MDRP requires a pharmaceutical manufacturer to enter into a contract, called a National Drug Rebate Agreement (NDRA) with the Secretary of the Department of Health and Human Services (HHS), in exchange for state Medicaid coverage of most of the manufacturer's drugs.

In 1992, Congress enacted Section 340B of the Public Health Service Act, under Section 602 of the Veteran's Health Care Act, to combat a dramatic rise in drug costs. See 42 U.S.C. §256b. In addition to the NDRA, Section 340B requires pharmaceutical manufacturers to enter into a pricing agreement (a "PPA") with the HHS Secretary for the 340B Drug Pricing Program in order for their drugs to be covered by Medicaid and Medicare Part B. *Id.* Under a PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, or "covered entities." 42 U.S.C. §256b(a)(4). Covered entities include but are not limited to federally qualified health centers, entities receiving Section 256a grants, subsection (d) hospitals, children's hospitals excluded from the Medicare prospective payment system, critical access hospitals, rural referral centers, and sole community hospitals. *Id.*

The same year, the Veterans Health Care Act of 1992 (VHCA), P.L. 102-585, 38 U.S.C. §101 et seq., was implemented. The VHCA requires manufacturers to have a master agreement with the Secretary of Veterans' Affairs for the Federal Supply Schedule as a condition for receiving payment. 38 U.S.C. §8126.

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) was implemented. 42 U.S.C. §1395 et seq. Under the MPDIMA, HHS was obligated to annually set reimbursement rates for certain outpatient prescription drugs provided by hospitals through utilization of two formulas. 42 U.S.C. §1395l(t)(14). Under the first formula, DHHS must conduct a survey of hospitals' acquisition costs for each covered outpatient drug ("Formula 1"). 42 U.S.C. §1395l(t)(14)(A)(iii)(I). Thereafter, DHHS can set reimbursement rates based on the hospitals' average acquisition cost for each drug, and the Secretary may vary the reimbursement rates by hospital group. *Id.* Under the second formula, if hospital acquisition cost data are not available, DHHS must set reimbursement rates based on the average price charged by manufacturers for the drug as calculated and adjusted by the Secretary ("Formula 2"). 42 U.S.C. §1395l(t)(14)(A)(iii)(II).

DHHS Reimbursement Calculation

In *Becerra*, the AHA contested DHHS's calculation of the 2018 and 2019 outpatient drug reimbursement rates for Section 340B hospitals under the Medicare statute. *Becerra*, 142 S.Ct. 1896 (2022).

From the time Section 340B took effect in 2006 through 2018, DHHS utilized Formula 2, setting the reimbursement rates at about 106% of each covered drug's average sales price and using the same reimbursement rate for all hospitals. *Id.* However, in its final rules for 2018 and 2019, DHHS established two separate reimbursement rates: a reimbursement rate for non-340B hospitals which remained at the historical rate of approximately 106% of the average sales price for each drug, and a rate for 340B hospitals equal to 77.5% of the

average sales price for each drug. *Id*.; *See also* 82 Fed. Reg. 52496, 52499. DHHS alleged that its reimbursement rates resulted in what it perceived as overpayments to hospitals serving low-income or rural populations, as drug manufacturers were already obligated to discount drugs to 340B hospitals in accordance with 42 U.S.C. §256(a)(1). *Id*. As a result, DHHS perceived 340B hospitals as generating significant profits when providing prescription drugs to Medicare patients. *Id*. DHHS alleged this saved Medicare (and deprived hospitals) of approximately $1.6 billion annually, which would be re-allocated for other Medicare services. *Id*.; *See also* 82 Fed. Reg. 52509-52510.

In response to the loss of approximately $3.2 billion, the AHA, on behalf of the 340B hospitals, challenged DHHS, contending that it was Congress' specific intention that the reimbursements help offset the considerable costs of providing healthcare to uninsured and underinsured individuals in low-income and rural communities—further fulfilling the obligations of EMTALA and the ACA in rendering critical and necessary care to the most vulnerable patient population. *Id*.

Ultimately, the *Becerra* court found DHHS deviated from the two formulas Congress set to calculate the reimbursement rates. The *Becerra* court reasoned, in the absence of a survey as required under Formula 1, DHHS must set uniform reimbursement rates for all hospitals for each covered drug, and the rates must be equal to the average price for that drug for that year in accordance with Formula 2. Noting DHHS's discretion to adjust the price up or down, the *Becerra* court found that DHHS could not vary the reimbursement rates by hospital group. *Id.* Ultimately, the *Becerra* court remanded the matter for proceedings consistent with its opinion—which could potentially result in the reimbursement of $3.2 billion to 340B hospitals.

Agency Discretion, Chevron Deference, and Judicial Review

During oral argument, the Supreme Court spent a substantial amount of time questioning the parties about *Chevron* deference. Derived from *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), the Supreme Court established a principle of administrative law which compels federal courts to defer to a federal agency's interpretation of an ambiguous or unclear statute that Congress delegated to the agency to administer. Specifically, the *Chevron* court held that "when a challenge to an agency construction of a statutory provision, fairly conceptualized, centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail." *Id*. at 866.

Yet, after significant briefing and extensive discourse at oral argument regarding Chevron deference, the *Becerra* court found that the formulary statute was not ambiguous or unclear—DHHS did not conduct a survey of hospitals' acquisition costs in accordance with Formula 1 and acted unlawfully by reducing the reimbursement rates for 340B hospitals in accordance with Formula 2. The court's decision directly contradicts the prior decision of the Court of Appeals, which found the payment statute to be ambiguous and afforded *Chevron* deference to DHHS's interpretation of the statute and calculation of payments. Accordingly, while many proponents of Chevron deference are fearful this could mean the end of affording judicial deference to administrative decisions, it also establishes a precedent for governmental accountability in administering social service programming.

Commonality Among Division

Despite the past century of progress, there are still many opportunities to promote optimal health outcomes and remove barriers to care—particularly for the most vulnerable populations. For 340B hospitals, the question remains as to whether and how they can be reimbursed. Moreover, the *Becerra* case presents an opportunity to reevaluate the ways we compensate 340B hospitals, and partner with them to provide acute care to the most vulnerable community populations.

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