LEGAL UPDATES

U.S. Supreme Court Hears Oral Arguments in Two Hospital Cases This Week

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This is a big legal week for hospitals and health systems as the U.S. Supreme Court heard not one, but TWO different oral arguments related to federal government payments to hospitals and health systems. In both cases, the Supreme Court will hear complaints from hospital advocates about the way that the Department of Health and Human Services (HHS), through the Centers for Medicare and Medicaid Institutes (CMS), interpreted a federal regulation setting reimbursement rates.

In the first case, *Becerra v. Empire Health Foundation*, health systems argue that HHS is incorrectly interpreting a formula used in the Medicare disproportionate share hospital (DSH) program which reimburses hospitals for services provided to low-income patients. In the second case, *American Hospital Association v. Becerra*, some hospitals take issue with cuts in reimbursement for drugs distributed through outpatient departments.

In addition to the hospital payment impact, both cases may provide the Supreme Court with an opportunity to reconsider how much deference federal courts should give to federal agencies when they interpret statutes. The Chevron doctrine, first established in *Chevron U.S.A. Inc. v. Natural Resources Defense Council* a 1984 Supreme Court decision, provides a process for federal agencies to follow when the intent of a statute may not be clear. Generally, under *Chevron*, federal courts will give great deference to an agency's interpretation. Some Supreme Court justices have been critical of the *Chevron* doctrine and this week's hospital cases may provide an opportunity for the Supreme Court to revise the standard.

While the *Chevron* issue may have national impact, the substantive outcomes of these cases will provide guidance and direction for a broad range of health care providers and the federal agencies that administer federal health care programs such as Medicare and Medicaid.

More information and background about each case follows:

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DSH Case – Becerra v. Empire Health Foundation

1. In this case, hospitals and health systems are challenging DSH payment calculations established by HHS in a 2005 rule.

2. The Hospitals won at the Appeals Court level and the case was argued before Supreme Court on Monday, November 29, 2021.

3. The formula is used to provide additional compensation to hospitals under a program called "disproportionate share hospitals," or "DSH." DSH hospitals serve a high percentage of low-income patients.

4. Generally speaking, the DSH program is intended to provide increased benefits for hospitals that serve a high percentage of low-income Medicare recipients and Medicaid recipients.

5. In determining if a hospital has a high percentage of low-income Medicare and Medicaid recipients, HHS uses two formulas (one for each program) and both formulas use "patient days" in the calculation.

6. The Medicaid formula divides the number of "patient days" for patients "who (for such days) were eligible for" Medicaid by the total number of patient days.

7. The Medicare formula is slightly more complicated because, unlike Medicaid, which is only available for low-income patients, Medicare eligibility is based on objective criteria that does not include the patient's income status. Not all Medicare beneficiaries would be considered low-income. To determine which Medicare patients are also low-income, the statutory formula only includes in the numerator those patients who are "entitled to benefits under Medicare and are also "entitled to SSI benefits." SSI refers to the Supplemental Security Income (SSI) program which provides benefits to low-income people.

8. The confusion related to the 2005 rule arises in how HHS interprets the two key phrases used in the statute to establish the formula for eligible benefits: "entitled to" and "eligible for."

9. Prior to 2005, HHS interpreted those terms to mean different things. The term "eligible for" included anyone who met the eligibility standards for the program even if they did not actually use the program benefits to pay for the hospital services and "entitled to" only included those who were eligible for the benefit and had the hospital services paid for by the program.

10. In 2005, HHS changed its interpretation of "entitled to" to now include anyone eligible for the program, whether or not the program paid for their services. This resulted in both terms having the same meaning under the 2005 rule.

11. HHS argues that its 2005 interpretations is consistent with other Medicare and Medicaid laws and that the original statute is ambiguous, so the interpretation is reasonable.

12. Opponents of the 2005 rule argue that attaching the same meaning to two different terms used in a statute is inconsistent with basic rules of statutory construction.

UPDATE: On June 24, 2022, the Supreme Court issued a 5-4 decision in favor of the U.S. Government in ***Becerra v. Empire Health Foundation***. The majority concluded that the rule issued by HHS in 2005 was consistent with the federal statute when it included anyone who met the eligibility standards for the Medicare program in the Medicare formula even if the patient did not actually use Medicare to pay for the hospital services. The Supreme Court opinion in ***Becerra v. Empire Health Foundation*** is available here.

340B Case – American Hospital Association v. Becerra

1. This case centers on whether CMS may use the Outpatient Prospective Payment System to cut reimbursement to hospitals participating in the federal 340B program.

2. Under a 2018 payment rule, HHS changed the amount it reimburses 340B hospitals for the costs associated with the acquisition of drugs that the hospital distributes in outpatient departments (the most expensive of which are chemotherapy and other anti-cancer medications).

3. Since 2003, Medicare reimburses hospitals for outpatient drugs based on the drug's "average price" which is to be determined by HHS.

4. Average price has generally been defined as the "average sales price plus 6%."

5. The federal government has created and expanded the 340B Program which requires pharmaceutical manufacturers that participate in federal health care programs to provide discounts to certain hospitals and other health care providers that serve poor, disadvantaged, and rural communities.

6. While the discount is based on a formula established by the federal government, general estimates indicate that it results in discounts between 20-50% off the pharmaceutical manufacturers retail price. The 340B program does not require that health care providers that receive discounts do anything particular with the funds so many hospitals use it to subsidize general operations. The program essentially requires pharmaceutical manufacturers, who receive payments from the federal government, to use a portion of those payments to subsidize certain hospitals and health care providers.

7. The controversy in this case arose because HHS decided to recapture some of the mandated 340B discount by reducing reimbursement for outpatient drugs that were acquired by hospitals eligible for the 340B program. Notably, because HHS decided to make this change in a budget-neutral manner, the recaptured funds were redistributed to other health care providers. So, the controversy is not about overall funding for health care providers, but rather about a shift in funding from 340B providers to non-340B providers.

8. For 340B hospitals, CMS changed the definition of "Average price," in 2018 from average sales price plus 6% to average sales price minus 22.5%.

9. The question the Supreme Court will be answering is whether HHS correctly interpreted its authority under the 2003 law when it redefined "average price" as it did.

10. The 340B Hospital lost at the Appeals Court level and the case was argued before Supreme Court on November 30, 2021.

UPDATE: On June 15, 2022 a unanimous U.S. Supreme Court held that HHS exceeded its legal authority when it changed reimbursement rates for certain outpatient prescriptions drugs only for 340B hospitals and not all hospitals. The key point in the Supreme Court's reasoning was that while HHS may increase or decrease the "average price" estimate used for calculating reimbursement, it may not set different rates for different groups of hospitals unless such differential rate is based on a survey of hospital acquisition costs. The Supreme Court opinion is available here.

ADDITIONAL UPDATE: There have been several developments related to CMS payments to hospitals under the 340B Program. As noted above, the Supreme Court in June 2022 concluded that HHS exceeded its legal authority when it changed 340B reimbursement rates in 2018. Lower courts were then charged with determining a remedy for HHS's violation. In response, the District Court for the District of Columbia, in two separate rulings, first vacated the rate cut for all claims occurring after September 27, 2022 and then directed CMS to devise a remedy for the underpayments that occurred from 2018 through the date of the court's first ruling. The ruling related to the historical charges is consistent

with an announcement from CMS in its 2023 Final Outpatient Prospective Payment System (OPPS) Rule (see p. 71,973) in which the agency indicated it would devise a remedy as part of its next rulemaking cycle. All court documents from this case are available [here]:

Notably, neither of the Supreme Court decisions relied on, nor mentioned, the Chevron doctrine so that doctrine remains in effect for now.

For more information about these cases, or federal reimbursement for hospitals and health system in general, contact Ben Peltier.