At the end of November, the United States Supreme Court took a rare step and heard oral arguments involving a 340B Drug Pricing Program matter in American Hospital Association v. Becerra. During oral arguments, the Supreme Court justices questioned whether CMS had acted
within its authority to implement sweeping Medicare reimbursement cuts for certain separately reimbursable 340B drugs back in 2018 that continue today. With potentially billions of dollars in reimbursement on the line, this case is going to be a big one that Covered Entities (CEs) should be watching closely. If the Supreme Court sides with American Hospital Association (AHA), CEs stand to benefit tremendously.

Along with potentially billions of dollars, the stakes are high because as Justice Breyer pointed out, the decision will have “implications well beyond this case.” The case invokes an older legal doctrine, Chevron, which gives agencies, such as CMS, the authority to make decisions when statutes are not clear. If the Supreme Court decides to apply Chevron and rule in favor of HHS, CMS could conceivably gain more power to maintain the reimbursement cuts and have paved the way for even more 340B reimbursement cuts in the future. On the other hand, the Supreme Court could decide to rule in favor of 340B hospitals and reverse the 340B reimbursement cuts. If that happens, CEs will have to determine if further individual action will be needed to pursue prior 340B underpayments, or if CMS will increase payments on a go-forward basis as a remedy.

Although the Supreme Court has until the end of its term in June to issue its opinion on the case, we anticipate a decision will be published no later than early spring at this time.

What Covered Entities Can Do Next

1. Take Advantage of Opportunities to Provide Feedback to CMS on 2020 Actual Acquisition Cost (AAC) Survey Results

CEs should be wary of what CMS will do with the 2020 AAC survey results if the Supreme Court rules in favor AHA. As the attorney for HHS pointed out during oral arguments: 340B hospitals won’t “want the result of the survey because the survey is going to lead to lower rates for them, lower rates even than they have now under HHS’s guidelines.” Given this insight to survey results, CEs must push back on CMS when given the opportunity to ensure that lower reimbursement rates are not implemented. CEs can provide feedback by submitting comment on CMS’s use of existing AAC survey data or the use of a new survey 340B. As HHS highlighted, very few hospitals responded, so CEs should continue to seek counsel regarding resisting the survey on numerous grounds.

2. Expect CMS to Push Back on Issuing a New Survey

Justice Kagan repeatedly stated during oral arguments, if CMS has AAC survey data, they can do one thing (i.e., use the AAC data to set new payment rates), but if they do not have survey data, then they can do another thing (i.e., pay at ASP+6%). HHS pushed back on this notion and also followed up with stating it has the survey data based on the 2020 340B Drug Acquisition Cost Survey it issued to 340B hospitals. However, AHA argued that the 2020 340B Drug Acquisition Cost Survey issued by CMS is not a valid statistical representation of 340B hospitals and thus, the results should not be considered to influence reimbursement rates. Rather, a survey issued to all hospitals is the appropriate survey representation.

If HHS loses the case and the Supreme Court says that CMS must follow the procedures outlined in
the statute, then the question becomes whether the 2020 survey of 340B hospitals was representative enough to use the results. If the survey is deemed insufficient, or if CMS opts to reissue a survey to avoid additional judicial scrutiny, hospitals should carefully consider all options and plan to consider submitting comments to CMS.

3. Plan to Appeal

If AHA prevails and the Supreme Court strikes down the reimbursement cuts, CEs can begin to develop a strategy to seek underpayments. CEs can also analyze financial impact of 2018-current Medicare reimbursement reductions regarding separately payable 340B drugs to calculate aggregate underpayment. CEs should start assessing avenues to appeal for additional reimbursement dating back to 2018. If the Supreme Court agrees with AHA and rules that CMS did not have the authority to implement the reimbursement cuts in 2018, it’s possible that CEs will be entitled to additional reimbursement that has been withheld. CEs can analyze financial impact of 2018-current Medicare reimbursement reductions regarding separately payable 340B drugs to calculate aggregate underpayment.

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