

HEALTH LAW NEWS

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D.C. COURT DECIDES MEDICARE 340B PROGRAM PAYMENT REDUCTION LAWSUIT REMEDY: SPOILER ALERT - THE END IS NOT HERE

On May 6, 2019, the United States District Court in Washington, D.C. issued its opinion on the appropriate remedy to address the invalidated payment cuts set forth in the 2018 and 2019 Outpatient Prospective Payment System final rules ("2018 and 2019 OPPS Rules") for drugs purchased under the 340B drug discount program ("340B Program"). The ruling brings providers one step closer to a final resolution regarding the Medicare 340B Program payment reduction that we addressed previously in more detail here.

In his decision, Judge Rudolph Contreras reiterated his belief that the Centers for Medicare & Medicaid Services ("CMS") violated its statutory authority by implementing a payment reduction for drugs purchased under the 340B Program, from Average Sales Price ("ASP") plus 6% to ASP minus 22.5%. The Court ordered a remand of both the 2018 and 2019 OPPS Rules so that CMS may have "the first crack at crafting appropriate remedial measures." Remanding both the 2018 and 2019 OPPS Rules to implement a legally compliant payment reduction model or create a structure to remedy the payment cuts going forward. If the hospital associations and hospital plaintiffs ("Plaintiffs") disagree with the remedy CMS adopts, they would then have the option to seek review of the revised Rules under the Administrative Procedures Act.

Notably, the Court did not grant a permanent injunction to the payment reduction as the Plaintiffs sought, nor did it agree that vacating the 2018 and 2019 OPPS Rules was warranted because it would "wreak havoc" on the system by requiring recoupment of already paid amounts, among other consequences. In effect, the remand gives the initial responsibility of how to "unscramble the egg" over to CMS, but the Court expects that CMS will act expeditiously and the matter remains in the Court's jurisdiction. Judge Contreras set a deadline of **August 5, 2019** for the parties to submit a status report regarding progress as to remedies concerning both the 2018 and 2019 OPPS Rules.

The Court's ruling may not prompt an immediate reissuance of the 2018 and 2019 OPPS Rules because this decision may be appealed. CMS may try to persuade the appellate court regarding the merits of its position regarding the payment reductions, and the Plaintiffs may challenge this ruling as insufficient to address the underlying payment cuts. In the interim, participants in the 340B Program should continue taking steps to affirmatively preserving their appeal rights, including at minimum, maintaining an accurate accounting of the payment reduction's impact.

As we suggested in our previous **article** about this 340B Program litigation, a prospective resolution appears more likely given the complex nature of the payment reductions and the issue of remedies, which Judge Contreras previously called a "quagmire that may be impossible to navigate." We will continue to monitor developments in this area.

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