



May 23, 2019

THE LATEST RULING IN THE 340B CASE: A LITTLE BACKGROUND AND WHERE WE ARE NOW

A brief summary of what has occurred since late 2018:

- On December 27, 2018, in response to a lawsuit filed by the AHA, AAMC, AEH, Henry Ford Health System, Northern Light Health, and Fletcher Hospital, Inc. Judge Contreras of the United States District Court for the District of Columbia ruled that CMS exceeded its authority when it issued the final FY 2018 Outpatient Prospective Payment (OPPS) rule and cut payments to 340B DSH hospitals from ASP + 6% to ASP-22.5%. Judge Contreras declined to rule on the legality of identical cuts for FY 2019 on the ground that the claims were premature. He also ordered the government and the plaintiffs to submit briefs on what the remedy should be. That briefing was completed on February 14, 2019.
- On May 6, 2019, the judge issued an opinion that reaffirmed his FY 2018 ruling, and found, as plaintiffs had requested, that the identical FY 2019 OPPS cuts were also unlawful. But instead of ordering a remedy, Judge Contreras directed HHS to “take the first crack” at doing so for both FY2018 and FY2019. He also directed the parties to submit a status report regarding HHS’s progress to develop a remedy by August 5.
- On May 10 the plaintiffs filed a motion asking the Court to require HHS to propose a remedy by June 28, 2019, noting, among other concerns, that if the remedy issue isn’t resolved promptly the government “may issue a 2020 OPPS rule reducing reimbursements for 340B drugs by nearly 30% in violation of the law, just as they did in 2018 and 2019.”

The status of the government’s appeal:

- In February 2019 the government filed a notice of appeal of the district court’s December 2018 decision. It is unclear whether Judge Contreras’s decision was appealable (since the case was still ongoing), and at the request of both parties the Court of Appeals for the D.C. Circuit subsequently issued an order holding that appeal in abeyance but directing the parties to notify the court “within 30 days of the district court’s resolution of proceedings concerning the appropriate remedy.”

While we are pleased that Judge Contreras concluded that both the 2018 and 2019 340B cuts were unlawful, the timing of the next phase of the litigation will hinge largely on how the government responds to the judge’s order:

- First, we have no timetable for when Judge Contreras will rule on our motion to require the government to propose a remedy by the end of June. The Government has indicated that it opposes the motion and has until May 24 to formally respond.
- Second, regardless of whether the deadline for proposing a remedy is in June or August, HHS will need to decide how to respond to the judge's order. There are many variations on the remedy it could propose or it could decline to propose one as it did in briefing the remedy earlier this year, although that would risk annoying the judge.
- Third, unless the remedy proposed by HHS effectively deals with the cuts, restoring funds to those affected, we will continue to press HHS and the courts for an effective remedy and to forestall further cuts in 2020. That could mean urging the District Court to order the remedies the plaintiff hospital associations and hospital systems proposed in January, and, if the court orders a less than satisfactory remedy, asking the Court of Appeals to take up the remedy issue. At this time, we do not know if the proposed FY2020 OPPS rule will again include the nearly 30% cuts that were in the FY 2018 and 2019 rules. In any circumstance, the plaintiffs will continue to press this case through the courts as quickly as the courts will allow, until the unlawfully withheld funds are restored and further cuts disallowed.