

November 21, 2019

**ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M**

SUBJECT: 340B Medicare Reimbursement Cuts

In calendar year (CY) 2018, the Centers for Medicare & Medicaid Services (CMS) began reimbursing covered outpatient drugs and biologicals acquired through the 340B drug pricing program at average sales price (ASP) minus 22.5% when billed by a hospital paid under the outpatient prospective payment system (OPPS).¹ CMS continued this payment policy in CY 2019, and finalized in the CY 2020 OPPS rule the decision to continue this payment policy and extend it to non-excepted off-campus provider-based departments.

The American Hospital Association (AHA) challenged the CY 2018 reimbursement cuts (*American Hospital Association et al. v. Azar et al.*), bringing a lawsuit on behalf of all hospitals and health system affected by this payment policy. On May 6, 2019, the U.S. District Court for the District of Columbia ruled that the Secretary exceeded his statutory authority by implementing 340B reimbursement cuts in both CY 2018 and CY 2019. CMS disagreed with the district court's decision and filed an appeal on July 10, 2019.

While we await the outcome of CMS' appeal, IHA is working to ensure that any final decision will be appropriately applied to all 340B providers across Illinois. AHA advised that there is no need for 340B providers who are not specifically named as plaintiffs in their lawsuit to file a separate appeal challenging 340B Medicare reimbursement cuts. However, it suggests that 340B providers preserve their right to an administrative appeal by notifying their Medicare Administrative Contractor (MAC) of **their intent to appeal** each current and future claim involving 340B drugs reimbursed at ASP minus 22.5% or any other level below the statutorily prescribed rate from Jan. 1, 2018 through final adjudication and 340B payment litigation.

We are including the following template letter for you to customize and send to your MAC regarding your right to appeal. If you have not already sent similar documentation to your MAC, we suggest doing so at your earliest opportunity.

Please note that this letter is written to reflect hospitals working with National Government Services (NGS). You may need to modify the letter if you work with a different MAC, and we have highlighted the sentences that require alteration in such cases.

¹ This reimbursement cut does not apply to rural sole community hospitals, children's hospitals or prospective payment system-exempt cancer hospitals.

Template Letter

Dear **National Government Services [Change to reflect your MAC]**:

Since January 1, 2018, our hospital has been receiving payments for 340B drugs that reflect the new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 Medicare outpatient prospective payment system (OPPS) final rule. *See* 82 Fed. Reg. 52,356 (Nov. 13, 2017). As explained in numerous comments to the proposed rule, *see id.* at 52,499–502, and in a lawsuit filed by the American Hospital Association and others, *see American Hospital Association v. Azar*, Case No. 1:17-cv-2447-RC (D.D.C. filed Nov. 13, 2017), Case No. 18-5004 (D.C. Cir. filed Jan. 10, 2018), the purported establishment of this improper rate exceeds the Secretary’s authority.

The reimbursement rate for 340B drugs should reflect the ASP plus 6% 2017 rate, as required by law. The new rate violates 42 U.S.C. § 1395l(t)(14)(A)(iii)(II), the authority to pay for 340B and other covered outpatient drugs, because it: (1) is not an “adjustment” to the statutory default rate (ASP+6%); (2) is based on acquisition cost, when reliable data on acquisition cost concededly are unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

National Government Services [Change to reflect your MAC] has made clear via a 2018 notice that an appeal will not be considered when submitted to dispute CMS’ 340B national payment policy. While we are not seeking separate individual redeterminations of payments for 340B drugs, we understand this action taken at your direction will not prejudice our right to seek full payment for 340B drugs (at the 2017 rate of ASP plus 6%) if the court rules in the pending case that the reduction in the 2018 OPPS rule was unlawful.

We understand your notice and this response to preserve our right to appeal. To the extent you disagree, we believe this notification constitutes sufficient notice that our hospital, in its capacity as a provider-party, is requesting to appeal each current and future claim processed by **National Government Services [Change to reflect your MAC]** and involving 340B drugs, as defined under section 340B of the Public Health Services Act, furnished by our hospital on behalf of a Medicare beneficiary since January 1, 2018 through final adjudication of the aforementioned 340B payment litigation and reimbursed at ASP minus 22.5% or any other level that falls below the statutorily prescribed rate.

To the extent required, we also believe that the Secretary’s intransigence in failing to correct his unlawful payment reductions and your notice that you will refuse to process our appeal requests, constitutes good cause to support an extension of the timeframe to appeal until such time as the litigation surrounding the 340B drug payment reductions is finally adjudicated.