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June 14, 2018

Mark Langer, Clerk of Court
U.S. Court of Appeals for the District of Columbia Circuit
335 Constitution Avenue, NW
Washington, DC 20001

Re: *American Hospital Ass'n v. Alex M. Azar II*, No. 18-5004 (argued
May 4, 2018 before Circuit Judges Srinivasan, Millett and Katsas)

Dear Mr. Langer:

Pursuant to Fed. R. App. P. 28(j), Appellants provide two recent notices issued by Medicare Administrative Contractors (MACs). The notices confirm that the rulemaking process was Appellants' only administrative opportunity to present their challenge to the rule at issue in this case and that Appellants will not be afforded any administrative remedy to exhaust.

In their reply brief (ADD1-ADD2), appellants reproduced a pleading filed by the government in another case, advising the district court that section 340B hospitals are not entitled to file administrative appeals to contest drug reimbursement determinations made under the new 340B reimbursement rule and that administrative appeals, if attempted, will be promptly dismissed.

After argument, two MACs, which manage provider claims on behalf of the Center for Medicare and Medicaid Services (CMS) in 23 states, including the first level of appeal, confirmed the government's no-appeal position. MAC Noridian stated that it had received "a substantial volume" of appeals and gave notice that "drugs purchased through the 340B Program do not have appeal rights; requests for an appeal will be dismissed." See Exhibit A. MAC National Government Services stated that "an appeal will **not** be considered when submitted to dispute CMS' 340B national payment policy." See Exhibit B (emphasis in original).

Sincerely,

/s/ Michael R. Smith

Michael R. Smith

cc: All Counsel (via CM/ECF)

EXHIBIT A: MAC NORIDIAN



Jurisdiction F - Part A

Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming

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340B Drug Reimbursement Claims Have No Appeal Rights

The Noridian Redetermination Department has received a substantial volume of requests appealing the reimbursement of drugs purchased through the 340B Program. Drugs purchased through the 340B Program do not have appeal rights; requests for an appeal will be dismissed.

View calculator details and calculate the reimbursement using the new [340B Drug Program Reimbursement Calculator](#).

Last Updated Jun 06, 2018

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EXHIBIT B:
MAC NATIONAL GOVERNMENT
SERVICES

Medicare Reimbursement For 340B-Acquired Drugs

Beginning January 1, 2018, separately payable Part B drugs (assigned status indicator “K”), other than vaccines (assigned status indicator “L” or “M”) and drugs on pass-through payment status (assigned status indicator “G”), that are acquired through the 340B Program or through the 340B prime vendor program will be paid at the ASP minus 22.5 percent when billed by a hospital paid under the Outpatient Prospective Payment System (OPPS) that is not excepted from the payment adjustment.

Hospital types that are excepted from the 340B payment policy in CY 2018 include rural sole community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals. Critical Access Hospitals and Maryland waiver hospitals are not paid under the OPPS and therefore are not impacted by this policy.

Medicare will continue to pay separately payable drugs that were not purchased with a 340B discount at ASP+6 percent.

Applicable Modifiers

Hospitals paid under the OPPS that are not excepted from the 340B drug payment policy for CY 2018, are required to report modifier “JG” on the same claim line as the drug HCPCS code to identify a 340B-acquired drug.

Providers who are excepted from the 340B payment adjustment in CY 2018, are required to report informational modifier “TB” for 340B-acquired drugs, and will continue to be paid ASP+6 percent.

Modifiers for 340B-Acquired Drugs 2-Digit HCPCS Modifier	Short Descriptor	Long Descriptor	Effective Date
JG	340B acquired drug	Drug or biological acquired with 340B drug pricing program discount	01/01/2018
TB	Tracking 340B acquired drug	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	01/01/2018

For additional information refer to the CMS document “Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS) Frequently Asked Questions” at

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf>

Appeals

Providers and beneficiaries have the right to appeal claim determinations made by National Government Services. The purpose of the appeals process is to ensure the correct adjudication of claims. Appeals activities conducted by National Government Services are governed by CMS.

If the drug was not reimbursed by Medicare and the provider believes that the drug should have been covered, the provider should consider filing an appeal. However, when a service is reimbursed in accordance with Medicare’s National payment policy for 340B-acquired drugs, the amount paid is final. The method of

Resources

- Change Request 10385, January 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version 19.0
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3940CP.pdf>
- Change Request 10417, January 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3941CP.pdf>
- CMS "Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS) Frequently Asked Questions"
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf>