UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, *et al.*, *Defendants.*	**Civil Action No. 18-2084 (RC)**

PLAINTIFFS' SUPPLEMENTAL BRIEF ON REMEDIES

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INTRODUCTION

Plaintiffs brought this action challenging the Department of Health and Human Services' (HHS's) unlawful reduction of Medicare payments to public and non-profit hospitals for separately payable, outpatient drugs purchased under section 340B of the Public Health Services Act (hereinafter 340B drugs). In November 2017, HHS issued a regulation that cut Medicare payments for these drugs by nearly 30% beginning on January 1, 2018. Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017) (2018 OPPS Rule). On December 27, 2018 this Court granted Plaintiffs' motion for permanent injunction on the grounds that the Secretary exceeded his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) in setting the 340B drug reimbursement rates in the 2018 OPPS Rule, and ordered the parties to provide supplemental briefing on the appropriate remedy. As described below, there is a straightforward method by which HHS can make whole the Hospital Plaintiffs and member hospitals of Association Plaintiffs that received the reimbursement reductions that resulted from the 2018 OPPS Rule. Plaintiffs' proposal is easy to implement, will not have disruptive consequences for the Medicare program, does not require a new rulemaking for 2018, and is comparable to actions that other courts and HHS have taken in the past to correct previous erroneous payments to Medicare providers. [1]

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[1] HHS has issued a regulation that includes the unlawful methodology for reimbursement for 340B outpatient drugs for 2019. Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818 (Nov. 21, 2018) (2019 OPPS Rule). Once Plaintiffs have presented a claim for a drug covered by that rule, Plaintiffs will amend the complaint and argue that Defendants should reimburse the Hospital Plaintiffs and member hospitals of Association Plaintiffs for claims that have been reduced pursuant to the 2019 OPPS Rule in accordance with the methodology adopted by the Court to remedy underpayments for 2018 claims and process all future 2019 claims in accordance with this Court's December 28, 2018 opinion.

ARGUMENT

From 2013 until 2017, 340B drugs were reimbursed based on the statutory rate of ASP plus 6 percent. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II); 42 U.S.C. § 1395w-3a; 77 Fed. Reg. 68,210, 68,386 (Nov. 15, 2012); 80 Fed. Reg. 70,298, 70,439 (Nov. 13, 2015); 82 Fed. Reg. 33,558, 33,634 (July 20, 2017). In 2018, HHS cut the reimbursement rate by using a methodology based on ASP minus 22.5 percent. 2018 OPPS Rule, 82 Fed. Reg. at 52,362. Although HHS argued that it had the authority to make the 2018 cut as an "adjust[ment]" under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), this Court found that HHS illegally breached the statutory scheme established by Congress for determining reimbursement rates for 340B drugs. Having found that the cuts made in 2018 were illegal, this Court should now order HHS to make the affected hospital providers whole.

I. Payments to Hospitals to Compensate for Underpayments Due to HHS's Illegal Action Can Be Made in a Manner that Is Straightforward and Easy to Administer.

This Court should order HHS to recalculate the payments due to 340B hospitals for 2018 claims to ensure that those hospitals receive payment based on the statutory rate of ASP plus 6 percent provided by the 2017 OPPS rule. 81 Fed. Reg. 79,562, 79,718 (Nov. 14, 2016). Hospitals that have already received payment for 340B claims using the 2018 methodology should receive a supplemental payment for those claims in an amount that equals the difference between the amount they received and the amount they are entitled to (based on the ASP plus 6% methodology) under this Court's order, plus interest.[2] While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case.[3]

[2] *See Shands Jacksonville Med. Ctr. v. Azar,* 2018 U.S. Dist. LEXIS 217391, at *69-70 (D.D.C. Dec. 28, 2018) (the Secretary did not contest that the hospital plaintiffs were entitled to interest).

[3] Hospitals are required to collect a 20% copay from patients and also to factor in a reduction of approximately 2% pursuant to the sequester rules, which required certain payment reductions. *See* 2 U.S.C. § 901a(6)(A) (capping

Hospitals that have not received payment for 340B claims should receive the full amount to which they are entitled (the amount they would have received under the 2017 OPPS rule).

This calculation can be done on a hospital-by-hospital basis rather than on a claim-by-claim basis. CMS can use its own database, the National Claims History, to determine the total dollar amount that each of the approximately 1,000 340B hospitals received as reimbursement for its 2018 340B drug claims.[4] This can be done by restricting CMS's data to 340B hospitals subject to the 2018 rate reduction (for which CMS can easily compile a list), further restricting it to separately payable drugs for which payment was made by the Medicare Program, and then limiting it to the drugs that were paid using the ASP minus 22.5 percent methodology. Once the total amount that each hospital was paid under the 2018 rate is calculated, that amount can be multiplied by a single factor—which will be uniform across hospitals—to determine how much

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sequestration reduction for Medicare programs at 2%). Under the 2017 OPPS payment rate, the claimed amount would be calculated as follows:

- (ASP+6%) – Patient Copay [(ASP+6%)(0.2)] – Sequestration Deduction [((ASP+6%) – Patient Copay)(0.02)].

Thus, a drug with an ASP of $100 would have a claimed amount of $83.10:

- ($100(1.06)) – ($106(0.2)) – (($106-$21.2)(0.02)) = $83.10.

By contrast, under the now overturned 2018 OPPS payment rate, the claimed amount would be calculated as follows:

- (ASP–22.5%) – Patient Copay [(ASP–22.5%)(0.2)] – Sequestration Deduction [((ASP–22.5%) – Patient Copay)(0.02)].

Thus, a drug with an ASP of $100 would have a claimed amount of $60.76:

- ($100 (0.775)) – ($77.50(0.2)) – ($77.50-$15.5) (0.02) = $60.76.

Because the same copay and sequestration percentage reductions would apply each year, however, accounting for these reductions would not affect the multiplier relationship between the amount a hospital should have received (using the 2017 OPPS methodology) and the amount the hospital actually received—specifically, the amount using the 2017 OPPS methodology is approximately 1.368 times the 2018 payment. In the example above, a hospital that has received a 2018 payment of $60.76 would calculate the amount owed by first multiplying $60.76 times 1.368, to derive the amount due under 2017 OPPS methodology, or $83.10, and then subtract the payment received ($60.76), to get $22.36.

[4] Using the HRSA covered entity database (at https://340bopais.hrsa.gov/coveredentitysearch), CMS determined that there are 1,338 OPPS hospitals in the 340B program. Of these, 320 were exempt from the reduced payments -- 270 rural sole community hospitals, 47 children's hospitals, and 3 exempt cancer hospitals. 82 Fed. Reg. at 52,622. Thus, approximately 1,000 hospitals received reimbursement for 340B drugs at the reduced rate during 2018.

the hospital should have been paid and thus how much the reimbursement to the hospital was reduced as a result of the 2018 OPPS Rule. The Court should order that each hospital be compensated according to the amount that its reimbursements were reduced plus interest.

II. There Is Ample Authority to Provide Reimbursement in This Case.

A. Courts and HHS Have Provided Comparable Remedies in Equally and More Complicated Cases.

There are several recent examples of cases in which HHS has paid hospitals to compensate for past underpayments. In *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011), the court invalidated portions of a regulation on the grounds that HHS had incorrectly implemented a statutory provision regarding how certain wage indices should be calculated. The error was carried forward each year, and as a result it had progressively reduced Medicare payments for inpatient services at affected hospitals. *Id.* at 214-216. The court remanded to CMS to explain why it had not undone all of its prior errors, and if it could not provide an explanation beyond its desire for finality, the court ordered CMS to recalculate the payments due to hospitals under a formula that removed all of the prior, progressive errors. *Id.* at 216. CMS ultimately corrected the errors for the future and settled past claims where hospitals had been underpaid by paying the hospitals corrected amounts going back several years. *See e.g.,* Rich Daly, *CMS may owe $3 billion; Payments to settle lawsuits in Medicare pay deals*, MODERN HEALTHCARE, APR. 14, 2012, https://www.modernhealthcare.com/article/20120414/MAGAZINE/304149931. Thousands of hospitals were affected. For example, more than 3,000 hospitals sought recovery in just five of the lawsuits brought by a single law firm.[5]

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[5] *See Franciscan Health Sys., v. Sebelius,* Civ. No. 1:11-cv-00961-RCL (D.D.C. May 24, 2011); *Alexian Bros. Med. Ctr. v. Sebelius,* Civ. Action No, 1:11-cv-00711-RCL (D.D.C. Apr. 12, 2011); *Alamance Reg'l Med. Ctr., Inc.*

In a more recent case in this district, the court ordered HHS to adjust a cancer hospital's OPPS payments for a past calendar year. *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar,* 324 F. Supp. 3d 1 (D.D.C. 2018), *appeal filed* Sept. 19, 2018 (No. 18-5277). A provision of the Affordable Care Act, 42 U.S.C. § 1395*l*(t)(18), had directed HHS to institute adjustments for cancer hospitals for services furnished beginning in 2011, but HHS had not made this adjustment until 2012. In finding that decision unlawful, the court stated that to comply with a Congressionally-mandated effective date, HHS could make retroactive adjustments, possibly even without corresponding changes elsewhere, without running afoul of the budget-neutrality requirement. 324 F. Supp. 3d at 15-16. As the court pointed out, budget neutrality had not previously been an obstacle when HHS had made retroactive adjustments. *Id.* at 15. The court further found that concerns about judicial "meddling," or that requiring retroactive payments would "wreak havoc" in a fundamentally prospective payment system, are no reason to ignore congressional mandates in the OPPS statute (although there was no indication in the opinion that the court had concluded that such payments would actually "wreak havoc" with the Medicare payment system). *Id.* at 16. Likewise the *Moffitt* court found that concerns about requiring retroactive payments are no reason to withhold a remedy for violations of the Medicare statute. *Id.*

Another recent case in this district, *Shands Jacksonville Medical Center v. Burwell,* 139 F. Supp. 3d 240 (D.D.C. 2015), illustrates that HHS is perfectly capable of making retrospective rate adjustments to remedy legal errors when a court orders it to do so. The *Shands* court identified some of the same concerns that this Court expressed regarding the potential for disruption by making retroactive changes to the OPPS system. 139 F. Supp. 3d at 269-70. In that

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v. Sebelius, Civ. Action No. 1:11-cv-00698-RCL (D.D.C. Apr. 8, 2011); *Albany Med. Ctr. Hosp. v. Sebelius,* Civ. Action No. 1:11-cv-00712-RCL (D.D.C. Apr. 12, 2011); *Accord Med. Mgmt., LP v. Sebelius,* Civ. Action No. 1:11-cv-00645-RCL (D.D.C. Mar. 30, 2011).

case, plaintiffs challenged Medicare's across-the-board 0.2 percent reduction in compensation for hospital inpatient services. *Id.* at 243-44. In its first opinion, the court found that HHS had violated the Administrative Procedures Act by adopting the 0.2 percent cut without providing the opportunity for meaningful comment. *Id.* at 265. The court remanded the case to HHS to give the Secretary the opportunity to remedy that error. *Id.* at 270-71.

HHS subsequently abandoned the 0.2 percent cut and chose to compensate hospitals that had been affected by its unsupported 0.2 percent across-the-board cut for three years by adopting a one-time, prospective increase of 0.6 percent. *Shands Jacksonville Med. Ctr. v. Azar,* 2018 U.S. Dist. LEXIS 217391, at *66-67 (citing Hospital Inpatient Prospective Payment Systems, 81 Fed. Reg. 56,762 (Aug. 22, 2016)). In its proposal regulation implementing this fix, HHS explained that although the Department "generally do[es] not believe it is appropriate in a prospective system [like Medicare] to retrospectively adjust rates even where . . . a prospective change in policy is warranted," it was proposing "this action in the specific context . . . in which [it was] ordered by a Federal Court to further explain the basis of an adjustment [it had] imposed for past years." 81 Fed. Reg. 24,946, 25,138 (Apr. 27, 2016). Although several plaintiffs raised issues about whether the one-time increase made them whole and continued to seek vacatur, the court agreed with the HHS approach. *Shands,* 2018 U.S. Dist. LEXIS 217391, at *96. The same rationale (a court order) would be the basis for retrospectively adjusting the rates for 2018 340B drug claims.

In the present case, HHS did not just make a computational error (as in *Cape Cod*), delay a statutorily mandated payment (as in *H. Lee Moffitt Cancer Center*), or apply an unsupported across-the-board cut (as in *Shands*); instead, HHS illegally altered the statutory scheme established by Congress for determining reimbursement rates for 340B drugs. This Court should,

as the courts in *Cape Cod*, *H. Lee Moffitt Cancer Center,* and *Shands* did, take steps to ensure that HHS corrects its error and order HHS to recalculate the payments due to 340B hospitals for 2018 claims for reimbursement for 340B drugs.[6]

B. <u>HHS Has Acknowledged that Reimbursement Is Appropriate and That a Method for Reimbursement Exists</u>

In its opposition to Plaintiffs' preliminary injunction motion in the case Plaintiffs filed in 2017, HHS acknowledged that the Hospital Plaintiffs and member hospitals of Association Plaintiffs are entitled to reimbursement if plaintiffs prevailed on the merits. HHS stated:

> Plaintiffs' alleged economic loss here would be recoverable if the Court were to enter a final judgment in their favor (assuming that the Court would have jurisdiction to do so). Indeed, if Plaintiffs hypothetically were to prevail and obtain an order directing Defendants to reinstate the ASP+6% OPPS payment rate for 340B drugs, they could seek payment for their Medicare claims under the higher ASP+6% rate in a variety of ways, depending on the processing status of the claim. *See, e.g.*, 42 C.F.R. § 405.942(a); 42 C.F.R. § 405.980(a)(1).

Am. Hosp. Ass'n v. Hargan, No. 17-2447, ECF. No. 18 at 49 (D.D.C.). The regulations cited by HHS provide that claims can be reopened for a year without a showing of good cause, demonstrating that there is an administrative process that hospitals could use to obtain all the payments to which they are entitled. This process is extremely cumbersome and would be burdensome on HHS, the Hospital Plaintiffs and the members of the Association Plaintiffs.

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[6] As this Court noted, "[t]he typical remedy for an agency rule promulgated contrary to law is to vacate the rule." ECF No. 25 at 33, citing *Humane Soc'y of the U.S. v. Zinke*, 865 F.3d 585, 614 (D.D.C. 2017); *St. Lawrence Seaway Pilots Ass'n, Inc. v. U.S. Coast Guard*, 85 F. Supp. 3d 197, 208 (D.D.C. 2015) (internal citations omitted). This Court stated that in determining whether to provide this remedy (as well as the Plaintiffs' request that hospitals be made whole), the Court must consider ""'the seriousness of the . . . deficiencies' of the [agency's] action" and 'the disruptive consequences of vacatur.'" ECF No. 25 at 34, citing *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 197 (D.C. Cir. 2009) (quoting *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1048-49 (D.C. Cir. 2002)). HHS's regulation here was not just seriously deficient: it was illegal. Moreover, the remedy plaintiffs are proposing would not disrupt the Medicare program and is consistent with remedies HHS has adopted in remedying past violations of law.

As an example, Northern Light Health, one of the plaintiff hospitals, has 15,331 340B drug claims from 2018 for which it is entitled to payment. It has not appealed most of these claims because it was instructed by its Medicare Administrative Contractor that, with respect to payments under the 2018 rule, "the amount paid is final," and "an appeal will not be considered when submitted to dispute" such a payment. *See* Ex. A, Aff. of Margaret Stavitz. Since there does not appear to be a provision allowing bundling of claims at the early stages of the CMS appellate process, it would be an extraordinary waste of CMS and hospital resources to require separate appeals in order for hospitals to receive the reimbursement to which they are entitled.[7]

The fact that, as defendants acknowledge, individual hospitals could use these administrative processes to obtain relief bolsters the argument that this Court has authority to order the relief Plaintiffs are requesting. As Plaintiffs have proposed, this relief may be provided without imposing a substantial burden on either Plaintiffs or HHS and without wreaking the kind of havoc on the system that this Court seeks to avoid.

III. Budget Neutrality Is Not an Issue.

Budget neutrality is not a barrier to the relief sought here. First, there is a serious question as to whether even HHS's *initial* change to reimbursement for 340B drugs was subject to budget neutrality. HHS made that change pursuant to 42 U.S.C. § 1395*l*(t)(14) rather than 42 U.S.C. § 1395*l*(t)(9), and only the latter provision references budget neutrality. Tellingly, during oral argument in the D.C. Circuit in the prior iteration of this case, government counsel expressed uncertainty as to whether the 340B provisions of the 2018 OPPS Rule were required to be budget neutral. Specifically, she admitted that: "I'm not sure that [the government] would say

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[7] This problem is exacerbated by the substantial back up that already exists in CMS at the level of the administrative law judge for administrative appeals of Medicare reimbursement claims. *See, e.g.*, *American Hosp. Ass'n v. Azar*, No 14-851 (JEB), 2018 WL 5723141 (D.D.C. Nov. 1, 2018) (mandamus order directing HHS to reduce the appeals backlog with the goal of eliminating it by 2022).

that all adjustments need to be budget neutral under [(t)]14." Oral Arg. Tr. 34:6-7, *Am. Hosp. Ass'n v. Azar,* No. 18-5004, Docket No.1770299.

In any event, expenditures need not be budget neutral when they fix a prior, improper underpayment. In fact, CMS has a policy that allows for retroactive correction of the wage index without any budget neutrality adjustment when the error was due to something CMS did and not something a hospital could have known about and sought to have corrected on its own. *See* 42 CFR § 412.64(k). Moreover, not all changes in expenditures under the OPPS system must be budget neutral—only "adjust[ments]" under Paragraphs (2)(D), (2)(E), and (9). *See* 42 U.S.C. § *1395l*(t)(2)(D), (2)(E), (9)(B). For example, budget neutrality does not apply to changes in enrollment or utilization or with respect to drugs when the average sales price increases. It only applies to the specific adjustments identified in Paragraphs (2) and (9), and it surely does not apply when a hospital wins an administrative appeal and receives a higher reimbursement on one of its claims.

Likewise, repaying hospitals for the illegal rate cut at issue in this case would not constitute an "adjust[ment]" under one of the paragraphs that implicate budget neutrality. HHS did not make an "adjustment" pursuant to Paragraph (9), but instead illegally "rework[ed] the statutory scheme – by applying a different methodology than the provision requires." ECF No. 25 at 28-29. Thus, HHS has no authority to impose budget neutrality on these payments back to hospitals.

In *H. Lee Moffitt Cancer Center and Research Institute Hospital,* the court determined that HHS could make retroactive adjustments, possibly even without corresponding changes elsewhere, without running afoul of the budget-neutrality requirement. There the court pointed out that "HHS [previously] made a 'retroactive payment adjustment' under § (t)(2)(E) for certain

services rendered by rural hospitals in 2006." 324 F. Supp. 3d at 15-16 (citing 71 Fed. Reg. 67,960, 68,101 (Nov. 24, 2006)). The court also noted that "HHS did not suggest any conflict between that retroactive adjustment and budget neutrality." *Id.* at 15. Finally, the court found that "if HHS can correct its own administrative error by means of a retroactive adjustment, surely it can comply with a congressionally-mandated effective date by means of a retroactive adjustment." *Id.* at 16. Likewise, in the present case, HHS should be able to make retroactive payments pursuant to a court order (to remedy its illegal behavior) without running afoul of any budget neutrality requirement if one exists.

Finally, as discussed above, budget neutrality would play no role if individual hospitals used the administrative process to successfully obtain full payment on 340B claims that HHS had illegally withheld. Plaintiffs' proposal will yield precisely the same result, but in a far more administratively efficient manner.

CONCLUSION

For the reasons set forth herein, this Court should order HHS to recalculate the payments due to Hospital Plaintiffs and hospital members of Association Plaintiffs for 2018 340B drug claims to ensure that those hospitals receive payment based on the statutory rate of ASP plus 6 percent provided by the 2017 OPPS rule. Hospitals that have received payment for 340B claims using the 2018 methodology prior to the Court's order should receive payment for those claims in an amount that equals the difference between the amount they received and the amount to which they are entitled (based on the ASP plus 6% methodology) under this Court's order, plus interest. Hospitals that have not received payment prior to the Court's order for 2018 340B

claims should receive the full amount to which they are entitled (the amount they would have received under the 2017 OPPS rule).

Date: January 31, 2019

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that, on January 31, 2019, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ Ezra B. Marcus
Ezra B. Marcus

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, *et al.*, *Defendants.*	**Civil Action No. 18-2084 (RC)**

AFFADAVIT OF MARGARET STAVITZ
IN SUPPORT OF PLAINTIFFS' SUPPLEMENTAL BRIEF ON REMEDIES

I, Margaret Stavitz, state as follows under penalty of perjury:

1. I am the Vice President of Enterprise Revenue Cycle Northern Light Health (NorthernLight).

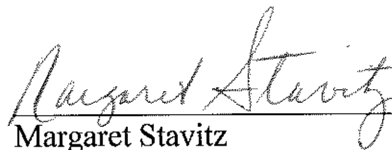
2. Along with others at Northern Light, I am responsible for filing Medicare reimbursement claims for outpatient drugs purchased under section 340B of the Public Health Services Act (340B drugs).

3. Northern Light filed 15,331 340B drug claims for 2018. For each 340B drug claim, it is my understanding that in accordance with the 2018 Outpatient Prospective Payment System Rule, Northern Light has been reimbursed average sales price minus 22.5%, rather than average sales price plus 6%, which had been the reimbursement rate in 2017 and in a number of prior years.

4. Along with others at Northern Light, I have responsibility for administratively appealing the 2018 340B drug claims that were subject to the reduced Medicare reimbursement for 340B drugs.

5. Northern Light's Medicare Administrative Contractor instructed Northern Light that "the amount paid is final" and an "appeal will not be considered when submitted to dispute" such a payment. See Exhibit 1. In addition, it is my understanding that no Department of Health and Human Services official or contractor will have the authority to grant Northern Light's appeals because the payment reduction is required by a regulation.

Signed under penalty of perjury this 29 day of January 2019



Margaret Stavitz
Vice President of Enterprise Revenue Cycle
Northern Light Health

NEWS AND ALERTS

INCREASE IN APPEAL REQUESTS THAT ARE DISMISSED RELATED TO 340B DRUGS

Beginning 1/1/2018, 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 OPPS that is not excepted from the payment adjustment.

Please note than 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 reimbursement is not an appropriate reason for an appeal and an appeal will not be considered when submitted to dispute CMS' 340B national payment policy.

For additional information on 340B drugs refer to the article titled, "340B-Acquired Drugs: Medicare Reimbursement and Appeals" located on our NGSMedicare.com News page.

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NEWS AND ALERTS

340B-ACQUIRED DRUGS: MEDICARE REIMBURSEMENT AND APPEALS

Beginning 1/1/2018, 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 OPPS that is not excepted from the payment adjustment. Hospital types that are excepted from the 340B payment policy in CY 2018 include rural 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	1/1/2018
TB	Tracking 340B acquired drug	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	1/1/2018

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

Appeals

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

If the drug was not reimbursed by Medicare and you believe the drug should have been covered, you 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 reimbursement is not an appropriate reason for an appeal and an appeal will not be considered when submitted to dispute CMS' 340B national payment policy.

Resources

NEWS AND ALERTS

- Change Request 10385, January 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version 19.0
- Change Request 10417, January 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)

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