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)**

NOTICE OF ADMINISTRATIVE DECISIONS

In their Motion for a Preliminary and Permanent Injunction, Plaintiffs stated that, on August 2, 2018, Plaintiff Henry Ford Health System ("Henry Ford") had appealed three administrative claims for reimbursement under the 340B Program to the Office of Medicare Hearings and Appeals ("OMHA"), and had requested review by an Administrative Law Judge ("ALJ"). ECF No. 2-1 at 14 (citing Ex I at 19–22; Ex. J at 20–23; Ex. K at 19–22). On October 30, 2018, the Deputy Chief ALJ issued orders dismissing two of Henry Ford's appeals. *See* Suppl. Ex. I at 23–31; Suppl. Ex. J at 24–32. The Henry Ford employee responsible for managing Henry Ford's administrative appeals under the 340B Program received these decisions on November 27, 2018, and Henry Ford appealed both of the dismissal orders to the Medicare Appeals Council on November 29, 2018. *See* Suppl. Ex. I at 32–36; Suppl. Ex. J at 33–37. The Henry Ford employee has not received the third appeal.

These decisions cast additional doubt on Defendants' argument that Plaintiffs' case should be dismissed for failure to exhaust administrative remedies, *see* ECF No. 15 at 26–27, ECF No. 20 at 10 n.6, and they lend additional support to Plaintiffs' response that further

exhaustion of Plaintiffs' administrative appeals is utterly futile. *See* ECF No. 2-1 at 16–20; ECF No. 16 at 12–14; ECF No. 19 at 1–2. In the dismissal orders, which are identical in their parts, the ALJ concludes that *administrative relief at every appeal level was foreclosed by Department of Health and Human Services ("HHS") regulations*. *See* Suppl. Ex. I at 35 (stating that the challenged reimbursement decision at issue "is not . . . subject to the Medicare claims appeal process," and thus "the appellant did not have the right to a redetermination, a reconsideration, or an ALJ hearing"); Suppl. Ex. J at 36 (same).

Specifically, the ALJ concluded that under the HHS regulations creating certain exceptions to "initial determinations," the reimbursement decisions under the 340B Program that Plaintiffs are challenging are not "initial determinations," and thus cannot be administratively appealed. Suppl. Ex. I at 35 (citing 42 C.F.R. § 405.926(c) and stating that "an issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS has sole responsibility" is not an "initial determination"); Suppl. Ex. J. at 36 (same). Previously, Defendants had consistently refused to adjudicate Plaintiffs' administrative appeals on the grounds that all administrative and judicial review is precluded by statute. *See, e.g.*, Suppl. Ex. L at 3; Suppl. Ex. N at 3; Suppl. Ex. P at 4. They even refused Plaintiff Henry Ford's request for expedited judicial review, even though expedited judicial review was plainly appropriate here since the only issue to be resolved is the legality of HHS's regulations reducing the reimbursement for 340B drugs, which no administrative body has the authority to resolve. ECF No. 19-1.

Plaintiffs have argued for the past year that they should not be required to exhaust the Medicare administrative appeals process because they challenge a regulation of general applicability that no individual adjudicator within HHS has authority to ignore. *See, e.g.*, ECF

No. 16 at 12–14; *Am. Hosp. Ass'n v. Hargan*, Case 1:17-cv-2447 (RC), Pls.' Reply Br. in Supp. of Mot. for Preliminary Injunction, ECF No. 20 at 16. In response, HHS has repeatedly argued that even this type of challenge must be pursued through the administrative appeals process. *See, e.g.*, ECF No. 15 at 26–27. It is ironic, to put it mildly, that an ALJ has now ruled that an HHS regulation forecloses this precise feature of Plaintiffs' challenge.

Regardless of whether the ALJ is correct in its interpretation of HHS's regulations, it is by now clear beyond cavil that Plaintiffs' administrative appeals are futile. Nevertheless, since this issue is still pending before the Court, Henry Ford dutifully has appealed the two ALJ dismissal decisions to the next level, the Medicare Appeals Council. *See* Suppl. Ex. I at 32–36; Suppl. Ex. J at 33–37. But there can be no doubt that those appeals will be dismissed or denied—whether based on the ALJ's reasoning, because of HHS's position that administrative and judicial review is precluded by statute, or because the Medicare Appeals Council, like every other adjudicator within HHS, has no authority to depart from HHS regulations and rule in Plaintiffs' favor on the merits of their challenge. *See* 42 C.F.R. § 405.1063(a).

Plaintiffs urge the Court to rule that further exhaustion would be entirely futile (*see Tataranowicz v. Sullivan*, 959 F.2d 268, 274–75 (D.C. Cir. 1992); *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110–12 (D.D.C. 2015), and to grant Plaintiffs' motion for a preliminary and permanent injunction.

Dated: December 3, 2018

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz (DC Bar No. 218990)
Ezra B. Marcus (DC Bar No. 252685)
ZUCKERMAN SPAEDER LLP
1800 M Street, NW, Suite 1000
Washington, DC 20036
Tel: 202-778-1800
Fax: 202-822-8136
wschultz@zuckerman.com
emarcus@zuckerman.com
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that, on December 3, 2018, 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

Supplemented Exhibit I

This is an electronic claim. The paper image below was generated for reference purposes only using paper form 308420-HFHB CEV PAPER UB04.

Note: This information is only for viewing. It cannot be used instead of a claim.

UB-04 Claim Image

Account: 725127902-[redacted]

Page: 1 of 1

1 HENRY FORD HOSPITAL
2799 WEST GRAND BLVD
DETROIT MI 48202
8009865840

2 HENRY FORD HOSPITAL
PO BOX 670884
DETROIT MI 48267

3a Pat Cntl # HB72512790200
3b Med Rec # [redacted]
4 Bill Type 0131
5 Fed Tax No. 381357020
6 Stmt. From 010318 Stmt. To 010318
7

8 Patient Name a
b [redacted]
9 Patient Address a [redacted]
b [redacted]
c [redacted] d [redacted] e

10 Birthdate	11 Sex	12 Admission Date	13 Hour	14 Type	15 Src	16 DHr	17 Stat	18	19	20	21	22	23	24	25	26	27	28	29 Acdt State	30
[redacted]	[redacted]			3	2		01	09												

31 Occurrence Code	Date	32 Occurrence Code	Date	33 Occurrence Code	Date	34 Occurrence Code	Date	35 Occurrence Span Code	From	Through	36 Occurrence Span Code	From	Through	37
18	050106	A1	[redacted]	B1	[redacted]									

38 MEDICARE
PO BOX 2201

DETROIT, MI 48231-2201

39 Value Codes Code Amount | 40 Value Codes Code Amount | 41 Value Codes Code Amount

42 Rev. Cd	43 Description	44 HCPCS/Rates	45 Serv. Date	46 Serv. Units	47 Total Charges	48 Non-Covered Charges	49
0258	PHARMACY - IV SOLUTIONS		010318	1	1475	000	
0260	IV THERAPY - GENERAL CLA	96375PO	010318	2	13000	000	
0335	RADIOLOGY - THERAPEUTIC	96413PO	010318	1	55000	000	
0335	RADIOLOGY - THERAPEUTIC	96415PO	010318	4	96000	000	
0636	N400641037621ML.5	J1200PO	010318	1	623	000	
0636	N400009004725UN.8	J2930PO	010318	1	2236	000	
0636	N450242005306ML100	J9310POJG	010318	10	2414300	000	
0001	PAGE 1 OF 1	CREATION DATE	010918	TOTALS	2582634	000	

50 Payor	51 Health Plan ID	52 Rel. Info.	53 Asg. Ben.	54 Prior Pymts.	55 Est. Amt. Due	56 NPI 1134144801
MEDICARE	2001003	Y	Y	000	2582634	57 Other
BLUE CROSS BLUE SHIELD	10001007	Y	Y	000	000	Prv ID

58 Insured Name	59 P. Rel	60 Insured's Unique ID	61 Group Name	62 Ins. Grp. Num
[redacted]	18	[redacted]		[redacted]
[redacted]	18	[redacted]		

63 Treatment Auth. Codes | 64 Document Control Number | 65 Employer Name

66 Dx 0 | 67 M0579 Z5112 | 68

69 Admit Dx | 70 Pat Reason Dx M0579 | 71 PPS Code | 72 ECI | 73

74 Prin. Procedure Code Date | a. Other Procedure Code Date | b. Other Procedure Code Date | 75
c. Other Procedure Code Date | d. Other Procedure Code Date | e. Other Procedure Code Date

76 Attending NPI 1609830397 Qual
Last RUBIN First BERNARD
77 Operating NPI Qual
Last First
78 Other NPI Qual
Last First
79 Other NPI Qual
Last First

80 Remarks

81 CC a B3 282N00000X
b
c
d

WPS GHA - MAC J8 MI PART A
PO BOX 8799
PART A J8
MADISON, WI 537088799

MEDICARE
REMITTANCE
ADVICE

PAYER BUSINESS CONTACT INFORMATION:
EDI DEPARTMENT
EDIMEDICAREA@WPSIC.COM
(866)234-7331

PAYER TECHNICAL CONTACT INFORMATION:
EDI DEPARTMENT
EDIMEDICAREA@WPSIC.COM
(866)234-7331

HENRY FORD HEALTH SYSTEM
PO BOX 670884
DETROIT, MI 482670884

NPI #: 1134144801
DATE: 01/25/2018
PAGE #: 1

CHECK/EFT #: EFT1130670

REND-PROV	SERV-DATE	POS	PD-PROC/MODS	PD-NOS	BILLED	ALLOWED	DEDUCT	COINS	PROV-PD
RARC				SUB-NOS	SUB-PROC	GRP/CARC	CARC-AMT	ADJ-QTY	BS
NAME: [redacted]			HIC: [redacted]	ACNT:HB72512790200		ICN:21800900583604 ASG:N		MOA:MA01	MA18
1134144801	0103	010318		1.000	14.75	14.75	0.00	0.00	0.00
						CO-97	14.75		04
1134144801	0103	010318	96375PO	2.000	130.00	130.00	0.00	14.16	55.51
						CO-45	59.20		
						CO-253	1.13		
1134144801	0103	010318	96413PO	1.000	550.00	550.00	183.00	20.30	79.56
						CO-45	265.52		
						CO-253	1.62		
1134144801	0103	010318	96415PO	4.000	960.00	960.00	0.00	44.51	174.49
						CO-45	737.44		
						CO-253	3.56		
1134144801	0103	010318	J1200PO	1.000	6.23	6.23	0.00	0.00	0.00
1134144801	0103	010318	J2930PO	1.000	22.36	CO-97	6.23		04
						22.36	0.00	0.00	0.00
1134144801	0103	010318	J9310POJG	10.000	24143.00	CO-97	22.36		04
						6418.12	0.00	1283.62	5031.81
						CO-45	17724.88		
						CO-253	102.69		
PT RESP	1545.59	CARC	18939.38	CLAIM TOTALS	25826.34	8101.46	183.00	1362.59	5341.37
ADJ TO TOTALS: PREV PD				INTEREST	0.00	LATE FILING CHARGE	0.00	NET	5341.37

CLAIM INFORMATION FORWARDED TO: BCBS OF MICHIGAN
000000027
OTHER CLAIM REL IDENTIFICATION: (EA) 55810719

WPS GHA - MAC J8 MI PART A
NPI #: 1134244801
CHECK/EFT #:EFT1130670

HENRY FORD HEALTH SYSTEM
01/25/2018

PAGE #2

MEDICARE
REMITTANCE
ADVICE

GLOSSARY:

253	Sequestration - reduction in federal payment
45	Charge exceeds fee schedule/maximum allowable or contracted/legislated fee arrangement. (Use only with Group Codes PR or CO depending upon liability)
4 (BS)	Benefit for Billed Service Not Separately Payable
97	The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
CO	Contractural Obligations
MA01	Alert: If you do not agree with what we approved for these services, you may appeal our decision. To make sure that we are fair to you, we require another individual that did not process your initial claim to conduct the appeal. However, in order to be eligible for an appeal, you must write to us within 120 days of the date you received this notice, unless you have a good reason for being late.
MA18	Alert: The claim information is also being forwarded to the patient's supplemental insurer. Send any questions regarding supplemental benefits to them.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

1251279102

MEDICARE REDETERMINATION REQUEST FORM — 1ST LEVEL OF APPEAL

1. Beneficiary's name: [redacted]

2. Medicare number: [redacted]

3. Item or service you wish to appeal: J9310

4. Date the service or item was received: 01/03/18

5. Date of the initial determination notice (please include a copy of the notice with this request):
(If you received your initial determination notice more than 120 days ago, include your reason for the late filing.)
01/25/18

5a. Name of the Medicare contractor that made the determination (not required):

5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
(for providers and suppliers only)

6. I do not agree with the determination decision on my claim because:
The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg, 52,356. Numerous comments to the proposed rule (see pp. 52,499-502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $7,344.77.

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. § 1395l(t)(14)(A)(iii)(II), the authority to pay for this drug, 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 is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

8. ☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the redetermination.
☒ I do not have evidence to submit.

9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative

10. Name, address, and telephone number of person appealing: Shannon Weier, 5600 New King Dr Suite 250
Troy, MI 48098, 248-641-4084

11. Signature of person appealing:

12. Date signed:

PRIVACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare and Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about these disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at http://www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

Form CMS-20027 (12/10)

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

WPS | GOVERNMENT HEALTH ADMINISTRATORS

March 06, 2018

Henry Ford Health System
PO BOX 670884
DETROIT, MI 48267

Medicare Number of Beneficiary:
[redacted]
725127902

Beneficiary Contact Information

1-800-MEDICARE
or
1-800-633-4227

Provider Contact Information

If you have questions, write or call:

WPS Government Health Administrators - J8
Medicare Appeals PO Box 8604
Madison, WI 53708-8604
(866) 234-7331

Re: Appeal # 1-7298171151
MEDICARE APPEAL DECISION

Dear Henry Ford Health System,

This letter is to inform you of the decision on your Medicare appeal. An appeal is a new and independent review of a claim. On February 13, 2018, we received a redetermination request for outpatient hospital / asc services provided by Henry Ford Health System. WPS Government Health Administrators - J8 was contracted by Medicare to review your appeal.

The redetermination decision is unfavorable because the services in question have already been paid by the Medicare Administrative Contractor (MAC) on January 25, 2018. We have evaluated the information submitted, and there does not appear to be any errors impacting the payment amount, which is the maximum payment amount allowed by Medicare for this service. As a result, we are issuing an unfavorable decision on your request for redetermination for claims referenced in Attachment A.

If you disagree that the claim in question was previously processed for payment, and/or you otherwise disagree with this decision, you may appeal to a Qualified Independent Contractor (QIC). You must file your appeal, in writing, within 180 days of receipt of this letter.

MAXIMUS Federal Services Inc.
Medicare Part A West
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

Sincerely,

Travis Parvin
WPS Government Health Administrators - J8
A Medicare Contractor

cc [redacted]

1251271902

MEDICARE RECONSIDERATION REQUEST FORM — 2ND LEVEL OF APPEAL

1. Beneficiary's name: [redacted]

2. Medicare number: [redacted]

3. Item or service you wish to appeal: J9310

4. Date the service or item was received: 01/03/18

5. Date of the redetermination notice (please include a copy of the notice with this request):
(If you received your redetermination notice more than 180 days ago, include your reason for the late filing.)
3/6/18

5a. Name of the Medicare contractor that made the redetermination (not required if copy of notice attached):

5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
(for providers and suppliers only)

6. I do not agree with the redetermination decision on my claim because:
The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg. 52,356. Numerous comments to the proposed rule (see pp. 52,499-502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $7,344.77.

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. § 1395l(t)(14)(A)(iii)(II), the authority to pay for this drug, 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 is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

8. ☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the reconsideration.
☒ I do not have evidence to submit.

9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative

10. Name, address, and telephone number of person appealing: Shannon Weier, 5600 New King Dr Suite 250 Troy, MI 48098, 248-641-4084

11. Signature of person appealing: Shannon Weier

12. Date signed: 3-27-18

PRIVACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare and Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about these disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at http://www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

Form CMS-20033 (12/10)

MAXIMUS
Federal Services

If you have any questions regarding this case, write or call:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave
Suite #706
Pittsford, NY 14534-1302

Provider inquiries:

Visit www.q2a.com
or
Call 1-585-348-3201

Beneficiary inquiries:

Call 1-800-MEDICARE
or
1-800-633-4227

Who We Are

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review this file and make an independent decision.

QIC Part A West Fax Cover Sheet

DATE: 07/10/2018 Tue

TO: ATTN:shannon

Agency:

Fax Number: 2486414072

RE: 1-7446923443

Comments:

Total Pages: 6

If you experience any problems with receiving this transmission, please contact me as soon as possible.

MAXIMUS Inc at 585-348-3400

Thank you.

Medicare Part A West QIC
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

HENRY FORD HEALTH SYSTEM
5600 NEW KING STREET SUITE 250
TROY, MI 48098

The enclosed letter is about your appeal.

[A]

MAXIMUS Federal Services
Medicare Part A West QIC
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

P. SIMON
17000 HARBOR HILL DR
CLINTON TWP, MI 48035-2358

The enclosed letter is about your appeal.

1-7446923443

CMS

Medicare Appeal Number: 1-7446923443

725127902

MAXIMUS Federal Services

If you have questions, write or call:

MAXIMUS
Federal Services
QIC Part A West
3750 Monroe Ave.
Suite 706
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.g2a.com
Or
Call: 585-348-3020

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

HENRY FORD HEALTH SYSTEM
5600 NEW KING STREET SUITE 250
TROY, MI 48098

June 1, 2018

RE: Beneficiary: [redacted]
HIC #: [redacted]
Appellant: Henry Ford Health System

Dear Henry Ford Health System:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for drug services provided to [redacted] the beneficiary, on January 3, 2018.

The appeal decision is favorable. Our decision is that your claim is covered by Medicare. Please see below regarding further appeal rights. More information on the decision is provided below. You are not required to take any action.

The Medicare contractor that initially received your claim is responsible for processing this favorable determination in accordance with standard Medicare payment methodologies. Any outstanding debts, prior coverage, and prior reimbursement will be taken into account when processing this decision.

A copy of this letter was sent to the beneficiary or his/her estate.

MAXIMUS Federal Services (MAXIMUS) was contracted by Medicare to review your appeal.

Appeal Details at Issue

Number	Provider	DOS
[redacted]	Henry Ford Health System	January 3, 2018

Summary of the Facts

Henry Ford Health System, the provider, billed for rituximab injection (J9310) provided to the beneficiary on January 3, 2018. At initial determination, Wisconsin Physician Services, the Medicare Administrative Contractor with jurisdiction, denied payment for the services. At redetermination Wisconsin Physician Services denied payment for services again. MAXIMUS received a request for reconsideration on April 7, 2018.

Decision

We have determined that Medicare will cover the claim for the drug services provided to the beneficiary on January 3, 2018. We have also determined that you are not responsible for payment for the drug services at issue.

Explanation of the Decision

The issue is whether the drug services provided to the beneficiary on January 3, 2018 met Medicare criteria for coverage.

Medicare will pay for services that are reasonable and medically necessary for the diagnosis or treatment of a condition, illness or injury in the beneficiary (Social Security Act, Section 1862 (a)(1)(A)). When an appellant requests a reconsideration, all documentation to support the services being appealed must be included with the request for reconsideration. The provider is responsible for providing sufficient documentation to support that payment is due and the services were medically necessary and provided as billed (42 Code of Federal Regulations (CFR), Section 424.5(a)(6)).

Medicare may cover a drug or biological if it is safe and effective and otherwise reasonable and necessary. In addition, reimbursement policies may be defined as outlined in specific National and Local Coverage Determinations (NCDs/LCDs) in the jurisdictions where they apply (Medicare Benefit Policy Manual, Chapter 15, Section 50.4.1).

In this case, Wisconsin Physician Services determined that the services failed to meet Medicare criteria for coverage. When requesting this appeal, the appellant argued that the services met Medicare coverage criteria.

The qualified independent contractor performed an independent review and determined that the services at issue met Medicare coverage criteria. This appeal concerns reimbursement of

charges for rituximab injection (J9310) billed for the dates of service of January 3, 2018. Clinical indications and coding requirements that qualify J9310 for Medicare coverage eligibility are outlined in Medicare approved compendia. The documentation supports that the provider was underpaid and was not reimbursed at 95% of the AWP for rituximab billed for date of service of January 3, 2018. Therefore, the provider should be reimbursed at 95% of the AWP for J9310 for January 3, 2018.

Additional Information

Medicare requires that all evidence be presented before the reconsideration is issued. On further appeal, an ALJ will not consider any new evidence unless you show good cause for not presenting the evidence to the Qualified Independent Contractor (QIC). This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary. (42 CFR, Section 405.966).

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see 'Other Important Information' on the page titled "Important Information About Your Appeal Rights."

Who is Responsible for the Bill?

You meet Medicare coverage criteria for drug services. Medicare is responsible for the bill.

If you need more information or have any questions, please call the phone number on the front of this letter.

Sincerely,

Jennifer Frantz
Project Director

cc:

[redacted]

WISCONSIN PHYSICIAN SERVICES (via facsimile or electronic communication)

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may appeal the decision to an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). You or your representative may present your case to the ALJ at a hearing.

As of 1/1/ 2018, you must have $160 in dispute to appeal to an ALJ. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided by a QIC; (2) all of the claims are listed on your request for hearing; (3) your request for hearing is filed within 60 days of receipt of all of the QIC reconsiderations being appealed; and (4) you explain why you believe the claims involve similar or related services.

You can find more information about your right to an ALJ hearing at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ hearing within **60 days** of receiving this letter. If your request for hearing is being filed late, you must explain why your request is being filed late. After you file an appeal, you may check your appeal's status via the OMHA website at www.hhs.gov/omha (click on Appeal Status Lookup).

When preparing your request for hearing, please use **Form OMHA-100**, available at: www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for hearing must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's reconsideration; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

You must send a copy of your request for hearing to the other parties who received a copy of this decision (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your hearing request to the QIC that issued this decision or to the Medicare Administrative Contractor that issued the redetermination.

Mail your hearing request to (tracked mail is suggested):

HHS OMHA Central Operations
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

OMHA processes Medicare **Beneficiary** appeals on a priority basis. If you are a Beneficiary or you represent a Beneficiary, mail your hearing request to:

HHS OMHA Central Operations
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

If you are a Beneficiary or represent a Beneficiary, you can also call the OMHA Beneficiary help line at 1-844-419-3358 for assistance. This is a toll free call. For more information on the OMHA Beneficiary prioritization program, including limitations for Beneficiaries represented by a provider/supplier, or a shared representative, visit the OMHA website at www.hhs.gov/omha or call the Beneficiary help line.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign and date a statement naming that person to act for you and send it with your request for hearing. Call 1-800-MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Help With Your Appeal

You can have a friend or someone else help you with your appeal. If you have any questions about payment denials or appeals, you can also contact your State Health Insurance Assistance Program (SHIP). For information on contacting your local SHIP, call 1-800-MEDICARE (1-800-633-4227).

Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this decision, please write to us and attach a copy of this letter, at:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave., Suite 706
Pittsford, NY 14534-1302

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

If you need large print or assistance, call 1-800-633-4227

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Reopening Medicare Appeal Number: 1-7446923443R1

72512790 2

MAXIMUS Federal Services

If you have questions, write or call:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave.
Suite 706
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.q2a.com
Or
Call: (585) 348-3020

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

June 25, 2018

HENRY FORD HEALTH SYSTEM
ATTN: MEDICARE APPEALS DEPT
5600 NEW KING ST, SUITE 250
TROY, MI 48098

Re: **Reconsideration decision review**

Beneficiary:	[redacted]
HIC #:	XXX-XX-[redacted]
Appellant:	Henry Ford Health System
Dates of Service:	January 3, 2018 to January 3, 2018

Dear Medicare Appeals Dept:

Please be advised that we have reviewed the above-captioned reconsideration decision. As a result of our review, we conclude that good cause exists to reopen your appeal. Therefore, we will process your request for reconsideration under the new Medicare Appeal Number noted above. You will receive this new reconsideration decision through the mail.

Sincerely,

Jennifer Frantz
Project Director

JF/dpf

V2.0

Appeal #:	1-7446923443 Find
Received:	04/07/2018
Deadline:	
Decision:	06/01/2018
New Appeal #	1-7446923443R1
Status:	QIC Reopened

The case has been reopened; refer to the New Appeal No. for further information.

Appeal #:	1-7446923443R1 Find
Received:	06/13/2018
Deadline:	10/11/2018
Decision:	
New Appeal #	
Status:	QIC Review

The QIC has received the request for reconsideration and has not yet made a decision; the deadline indicates the day by which the QIC must mail a decision letter.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare Appeal Number: 1-7446923443

72512902

MAXIMUS Federal Services

If you have questions, write or call:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave.
Suite 706
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.q2a.com
Or
Call: (585) 348-3020

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

IMPORTANT INFORMATION REGARDING YOUR APPEAL

July 11, 2018

HENRY FORD HEALTH SYSTEM
ATTN: MEDICARE APPEALS DEPT
5600 NEW KING ST, SUITE 250
TROY, MI 48098

Re:	Beneficiary:	[redacted]
	HIC #:	XXX-XX-[redacted]
	Appellant:	Henry Ford Health System
	Dates of Service:	January 3, 2018 to January 3, 2018

Dear Medicare Appeals Dept:

On June 25, 2018, MAXIMUS Federal Services (MAXIMUS) sent you an acknowledgement letter advising that the above-captioned reconsideration decision was being reopened and a new decision would be mailed to you under Medicare Appeal Number 1-7446923443R1.

Please disregard the correspondence that you received relative to Medicare Appeal 1-7446923443R1. MAXIMUS will not be issuing a new reconsideration decision at this time. Please note that Medicare Appeal # 1-7446923443R1 has been deleted from our system.

Sincerely,

Jennifer Frantz
Project Director

JF/jr

V2.0

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

REQUEST FOR ADMINISTRATIVE LAW JUDGE (ALJ) HEARING OR REVIEW OF DISMISSAL

Section 1: Which Medicare Part are you appealing (if known)? (*Check one*)

☐ Part A ☒ Part B ☐ Part C (*Medicare Advantage*) or Medicare Cost Plan ☐ Part D (*Prescription Drug Plan*)

Section 2: Which party are you, or which party are you representing? (*Check one*)

☐ The Medicare beneficiary or enrollee, or a successor (such as an estate), who received or requested the items or services being appealed, or is appealing a Medicare Secondary Payer issue.

☒ The provider or supplier that furnished the items or services to the Medicare beneficiary or enrollee, a Medicaid State agency, or an applicable plan appealing a Medicare Secondary Payer issue.

☐ Other. *Please explain*:

Section 3: What is your (the appealing party's) information? (*Representative information in next section*)

Name (*First, Middle Initial, Last*)	Firm or Organization (*if applicable*)		
Shannon Weier	Henry Ford Health System		
Address where appeals correspondence should be sent	**City**	**State**	**ZIP Code**
5600 New King Dr., Suite 250	Troy	MI	28098
Telephone Number	**Fax Number**	**E-Mail**	
(248) 641-4084		sweier2@hfhs.org	

Section 4: What is the representative's information? (*Skip if you do not have a representative*)

Name	Firm or Organization (*if applicable*)		
Mailing Address	**City**	**State**	**ZIP Code**
Telephone Number	**Fax Number**	**E-Mail**	

Did you file an appointment of representation (form CMS-1696) or other documents authorizing your representation at a prior level of appeal?

☐ No. *Please file the document(s) with this request.*
☐ Yes

Section 5: What is being appealed? *Submit a separate request for each Reconsideration or Dismissal that you wish to appeal. If the appeal involves multiple beneficiaries or enrollees, use the multiple claim attachment (OMHA-100A).*

Name of entity that issued the Reconsideration or Dismissal (*or attach a copy of the Reconsideration or Dismissal*)	Reconsideration (Medicare Appeal or Case) Number (*or attach a copy of the Reconsideration or Dismissal*)		
MAXIMUS FEDERAL SERVICES	1-7446923443 + 1-7446923443R1		
Beneficiary or Enrollee Name	**Health Insurance Claim Number**		
[redacted]	218009005836 04 M1A		
Beneficiary or Enrollee Mailing Address	**City**	**State**	**ZIP Code**
[redacted]	[redacted]	[redacted]	[redacted]
What item(s) or service(s) are you appealing? (*N/A if appealing a Dismissal*)	**Date(s) of service being appealed** (*if applicable*)		
J9310	1-03-18		
Supplier or Provider Name (*N/A for Part D appeals*)	**Supplier or Provider Telephone Number** (*N/A for Part D appeals*)		
HENRY FORD HOSPITAL	800-986-5840		
Supplier or Provider Mailing Address (*N/A for Part D appeals*)	**City**	**State**	**ZIP Code**
2799 WEST GRAND BLVD	DETROIT	MI	48202

Section 6: For appeals of prescription drugs ONLY (*Skip for all other appeals*)

Part D Prescription Drug Plan Name	What drug(s) are you appealing?

Are you requesting an expedited hearing?
(*An expedited hearing is only available if your appeal is not solely related to payment (for example, you do not have the drug) and applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function*)

☐ No. ☐ Yes. *On a separate sheet, please explain or have your prescriber explain why applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function.*

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed? (*Attach a continuation sheet if necessary*)

See attached continuation sheet.

Section 8: Are you submitting evidence with this request, or do you plan to submit evidence?

- [x] I am not planning to submit evidence at this time. (*Skip to Section 9, below*)
- [ ] I am submitting evidence with this request.
- [ ] I plan to submit evidence. Indicate what you plan to submit and when you plan to submit it:

Was the evidence already submitted for the matter that you are appealing?

- [ ] No. *Part A and Part B appeals only. If you are a provider or supplier, or a provider or supplier that is representing a beneficiary, you must include a statement explaining why the evidence is being submitted for the first time and was not submitted previously.*
- [ ] Yes.

Section 9: Is there other information about your appeal that we should know?

Are you aggregating claims to meet the amount in controversy requirement? (*If yes, attach your aggregation request. See 42 C.F.R. § 405.1006(e) and (f), and 423.1970(c) for request requirements.*)	[x] No	[ ] Yes
Are you waiving the oral hearing before an ALJ and requesting a decision based on the record? (*If yes, attach a completed form OMHA-104 or other explanation. N/A if requesting review of a dismissal.*)	[ ] No	[x] Yes
Does the request involve claims that were part of a statistical sample? (*If yes, please explain the status of any appeals for claims in the sample that are not included in this request.*)	[x] No	[ ] Yes

Section 10: Certification of copies sent to other parties (*Part A and Part B appeals only*)

If another party to the claim or issue that you are appealing was sent a copy of the Reconsideration or Dismissal, you must send a copy of your request for an ALJ hearing or review of dismissal to that party.

Indicate the party (or their representative) to whom and address where you are sending a copy of the request, and when the copy will be sent *(attach a continuation sheet if there are multiple parties)*.

Name of Recipient		
Mailing Address		
City	State	ZIP Code
Date of Mailing		

- [x] Check here if no other parties were sent a copy of the Reconsideration or Dismissal.

Section 11: Filing instructions

Your appealed claim must meet the current amount in controversy requirement to file an appeal. See the Reconsideration or Dismissal or visit www.hhs.gov/omha for information on the current amount in controversy. Send this request form to the entity in the appeal instructions that came with your reconsideration (for example, requests for hearing following a Part C reconsideration are generally sent to the entity that conducted the reconsideration). If instructed to send to OMHA, use the addresses below.

Beneficiaries and enrollees, send your request to:	**For expedited Part D appeals, send your request to:**	**All other appellants, send your request to:**
OMHA Centralized Docketing Attn: Beneficiary Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing Attn: Expedited Part D Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316

We must receive this request within 60 calendar days after you received the Reconsideration or Dismissal that you are appealing. We will assume that you received the Reconsideration or Dismissal 5 calendar days after the date of the Reconsideration or Dismissal, unless you provide evidence to the contrary. *If you are filing this request late, attach a completed form OMHA-103 or other explanation for the late filing.*

PRIVACY ACT STATEMENT

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed?

(continuation sheet)

The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg. 52,356. Numerous comments to the proposed rule (see pp. 52,499–502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $7,344.77.

The new rate violates 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for the drug, 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 is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

Maximus Federal Services ("Maximus"), a Qualified Independent Contractor, initially issued a favorable reconsideration decision in this appeal (Appeal # 1-7446923443). Maximus was subsequently instructed by the Centers for Medicare and Medicaid Services ("CMS") to reopen and dismiss the appeal on the grounds that, in CMS's view, there are no administrative appeal rights for reimbursement disputes related to the 340B Program. In light of that instruction, Maximus reopened the appeal (Appeal # 1-7446923443R1) and issued the enclosed letter, dated July 11, 2018, stating that the reopened appeal "ha[d] been deleted from [its] system" and that it "w[ould] not be issuing a new reconsideration decision at this time." The July 11, 2018 letter constitutes a dismissal of Henry Ford's appeal.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

WAIVER OF RIGHT TO AN ADMINISTRATIVE LAW JUDGE (ALJ) HEARING

Instructions: If you are an appellant or other party to a hearing before an Administrative Law Judge (ALJ) with the Office of Medicare Hearings and Appeals (OMHA), you may waive your right to the oral hearing and request that a decision be made based on the record. When you waive your right to a hearing, either an ALJ or an attorney adjudicator may decide your appeal.

If you are the appellant and want your appeal to be decided without a hearing, complete this form and include it with your request for an ALJ hearing (form OMHA-100) or, if you have already filed your request for an ALJ hearing, send this form to the assigned OMHA adjudicator (visit www.hhs.gov/omha and use the appeal status lookup tool to find your assigned adjudicator). Any other party that wants the appeal to be decided without a hearing may complete this form and send it to the assigned OMHA adjudicator. If an adjudicator has not yet been assigned, send this form to OMHA Central Operations, Attention: Waiver Mail Stop (visit www.hhs.gov/omha or call the number at the bottom of this form for the full mailing address).

If all of the parties to the appealed matter who would be sent a notice of hearing do not also waive the ALJ hearing (for example, a provider or supplier that was held financially responsible for the denied items or services), or the assigned ALJ or attorney adjudicator believes a hearing is necessary to decide the appeal, a hearing may be held by an ALJ, and the ALJ will issue the decision or other dispositive order in the appeal.

Section 1: What is the OMHA appeal number or the reconsideration (Medicare appeal or case) number?

OMHA Appeal Number *(if known)*	Reconsideration Number (*if OMHA appeal number not known*)
	Reconsideration Appeal #: 1-7446923443 & # 1-7446923443R1

Section 2: What is the information for the party waiving the hearing? (*Representative information in next section*)

Name *(First, Middle initial, Last)*	Firm or Organization (*if applicable*)	Telephone Number
Shannon Weier	Henry Ford Health System	(248) 641-4084

Section 3: What is the representative's information? (*Skip if you do not have a representative*)

Name	Firm or Organization (*if applicable*)	Telephone Number

Section 4: Explain why you wish to waive your right to an ALJ hearing and have the appeal decided based on the record:

There are no factual disputes in this appeal, which challenges provisions of the 2018 hospital OPPS rule regarding payments under the 340B program. Furthermore, an ALJ would not have authority to invalidate these provisions of the regulation, and thus could not issue a favorable decision in this appeal. 42 C.F.R. § 405.1063(a). Concurrently with this request for ALJ review, Henry Ford is requesting that the Departmental Appeals Board certify this appeal for expedited judicial review pursuant to 42 C.F.R. § 405.990.

Section 5: Acknowledge the following by signing and dating this form:

I understand that I may have a right to a hearing before an ALJ. I understand that having an ALJ hearing would provide me with the opportunity to present oral testimony and to present and/or question witnesses. I understand that this opportunity to be seen and heard could be helpful to the ALJ in making a decision.

I understand that my waiver of an ALJ hearing does not affect the right of other parties to an ALJ hearing.

I understand that even if all parties waive their right to an ALJ hearing, if the ALJ determines that a hearing is necessary to obtain testimony from a non-party, the ALJ may still hold a hearing to obtain that testimony. If a hearing is held, the ALJ will offer the parties the opportunity to appear at the hearing (which may be in person, by telephone or by video-teleconference), but may hold the hearing even if none of the parties decide to appear. I understand that if a hearing is held and I do not attend the hearing, I still have the right to submit written evidence.

I understand that my waiver may be denied if it is determined that my attendance is necessary to decide the appeal.

If I change my mind and decide that I would like a hearing before an ALJ, I understand I must submit a withdrawal of this waiver (see form OMHA-114) before a notice of decision or other dispositive order is issued by an ALJ or attorney adjudicator. If I withdraw my waiver of hearing, I understand that any applicable time frame to decide the appeal may be extended in order to schedule and hold the hearing. I also understand that if a hearing has already been conducted, the ALJ may decide not to conduct another one.

Party or Representative Signature	Date
Shannon Weier	8-2-18

Privacy Act Statement

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
786-792-3778 (ALJ Haring Team)
305-536-4382 (Fax)
866-231-3087 (Toll Free)

Date: 10/30/2018

7251279O2

HENRY FORD HEALTH SYSTEM
5600 NEW KING STREET.
SUITE 250
TROY, MI 48098

NOTICE OF DISMISSAL

Appellant: HENRY FORD HEALTH SYSTEM
OMHA Appeal Number: 1-7881597354

Enclosed is an order dismissing the request for hearing in the above case. As explained below, the dismissal is binding unless it is vacated by the Medicare Appeals Council, or by the OMHA adjudicator who issued the dismissal.

What if I disagree with the dismissal?

If you disagree with the dismissal, you may file an appeal with the Medicare Appeals Council. Other parties may appeal the dismissal as well. In addition, the Medicare Appeals Council may decide to review the dismissal on its own motion.

You also have the right to request that the adjudicator who issued the dismissal vacate the dismissal by sending a letter explaining why you believe the dismissal should be vacated, along with a copy of the dismissal, to the adjudicator's attention at the OMHA field office address listed at the top of this notice. If good and sufficient cause is established, the adjudicator may vacate the dismissal within 6 months of the date of this notice. The adjudicator may decide not to vacate the dismissal, and the adjudicator's decision whether to vacate the dismissal is not subject to further review. IMPORTANT NOTE: Filing a request with the adjudicator to vacate the dismissal does not extend the 60-day period described below for filing an appeal of the dismissal with the Medicare Appeals Council.

If you are not already represented, you may appoint an attorney or other person to represent you.

If no party appeals the dismissal, the Medicare Appeals Council does not review the dismissal, and the adjudicator does not vacate the dismissal, the reconsideration is binding on all parties.

How much time do I have to file an appeal?

If you choose to file an appeal with the Medicare Appeals Council, the Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the dismissal. Your appeal must be in writing, except that a request for expedited review of a Part D dismissal may be made orally as described below. Your appeal must identify the parts of the dismissal that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the dismissal.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's dismissal (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed dismissal to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227**.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed dismissal. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator dismissal order;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D dismissal may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of dismissal. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may deny review of the dismissal or vacate the dismissal and remand the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll-free), if you have questions about filing an appeal.

cc:

MAXIMUS
QIC Part A West Appeals–ALJ
3750 Monroe Ave, Suite 706
Pittsford, NY 14534

Enclosures:

OMHA-173, Order of Dismissal
DAB-101, Request for Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, VA

Appeal of:	**Henry Ford Health System**	OMHA Appeal No.:	**1-7881597354**
Beneficiary:	[redacted]	Medicare Part:	**Part B**
Medicare No.:	[redacted]	Before:	**Brian J. Haring** **Deputy Chief Administrative Law Judge**

ORDER OF DISMISSAL

This case is before me on a request for hearing filed by the appellant on August 3, 2018. Along with the request for hearing, the appellant submitted a signed Waiver of Right to an Administrative Law Judge (ALJ) Hearing (OMHA-104) form dated August 2, 2018.

Pursuant to 42 C.F.R. section 405.1052(a)(2), an ALJ dismisses a request for hearing when the person or entity requesting the hearing has no right to it under section 405.1002. The regulations at 42 C.F.R. section 405.926 describe actions that are not initial determinations subject to the Medicare claim appeals process in 42 C.F.R. part 405, subpart I. Included in the list of actions that are not initial determinations is:

> Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

42 C.F.R. § 405.926(c).

In the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period, the Centers for Medicare & Medicaid Services (CMS) adopted the statutory default policy to pay for separately payable Part B drugs and biologicals, including drugs purchased under the 340B Drug Pricing Program (340B Program), at the average sales price (ASP) plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Social Security Act (the Act). 77 Fed. Reg. 68210, 68386 (Nov. 15, 2012).

The U.S. Government Accountability Office previously estimated that discounts under the 340B Program ranged from 20 to 50 percent. U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs*

Improvement 2 (2011). In a May 2015 Report to Congress, the Medicare Payment Advisory Commission conservatively estimated that, on average, hospitals (excluding critical access hospitals) in the 340B Program receive a minimum discount of 22.5 percent of the ASP for drugs paid under the OPPS. Medicare Payment Advisory Comm'n, *Overview of the 340B Drug Pricing Program* 27–28 (2015).

Section 1833(t)(14)(A)(iii)(II) of the Act states that, if hospital acquisition costs data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as calculated and adjusted by the Secretary as necessary. In the OPPS/ASC final rule with comment period for CY 2018, CMS used this authority to adjust the payment rate for separately payable drugs and biologicals acquired under the 340B Program (other than drugs on pass-through payment status and vaccines) from ASP *plus* 6 percent to ASP *minus* 22.5 percent, effective January 1, 2018. (The reduction is not applicable to rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals in CY 2018). 82 Fed. Reg. 59216, 59353–71 (Dec. 14, 2017). CMS stated that this adjustment would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. *Id.* at 59222.

In this case, the appellant provided a rituximab injection (J9310) to the beneficiary on January 3, 2018. The appellant received payment for the claim at issue from the Medicare Administrative Contractor (MAC) on January 25, 2018. (Ex. 1, pp. 29–35). The appellant requested a redetermination of the claim on the basis that: "the payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule." (Ex. 1, p. 59). The appellant asserted that the rate adjustment exceeded the Secretary's statutory authority, and that the drug should be reimbursed at the 2017 rate of ASP plus 6 percent. (Ex. 1, p. 59).

On March 5, 2018, the MAC issued a redetermination informing the appellant that the decision was unfavorable because the claim had already been paid. (Ex. 1, pp. 46–50). The appellant then requested reconsideration. On June 1, 2018, the Qualified Independent Contractor (QIC) issued a favorable reconsideration decision, finding that Medicare would cover the claim for J9310. (Ex. 1, pp. 12–19). The QIC decision indicated that the provider had been underpaid and had not been reimbursed at 95 percent of the average wholesale price (AWP) for 2018 for J9310. (Ex. 1, p. 14). The QIC found that the appellant should be reimbursed at 95 percent of the AWP for 2018 for J9310. (Ex. 1, p. 14). Following the reconsideration decision, the QIC notified the appellant that the reconsideration would be reopened, but later retracted the reopening. (Ex. 1, pp. 4, 6).

On August 3, 2018, the Office of Medicare Hearings and Appeals (OMHA) received the appellant's request for hearing. (Ex. 1, pp. 1–3, 5). In its request for hearing, the appellant again challenged the amount of payment it had received for J9310. (Ex. 1, p. 5). The appellant's request involves an issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS has sole responsibility. As provided in 42 C.F.R. section 405.926(c), this is not an initial determination subject to the Medicare claims appeal process. Because there was no initial determination in this case, the appellant did not have the right to a redetermination, a reconsideration, or an ALJ hearing. 42 C.F.R. §§ 405.940, 405.960, 405.1002. In accordance with 42 C.F.R. section 405.1052(a)(2), the appellant's request for hearing shall be dismissed because there is no right to hearing in this appeal.

Therefore, the request for hearing is hereby dismissed.

SO ORDERED

Dated: OCT 30 2018

Brian J. Haring
Deputy Chief Administrative Law Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)
SHANNON WEIER

2. ALJ APPEAL NUMBER (on the decision or dismissal)
1-7881597354

3. BENEFICIARY*
[redacted]

4. HEALTH INSURANCE CLAIM NUMBER (HICN)*
[redacted]

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER
HENRY FORD HEALTH SYSTEM

6. SPECIFIC ITEM(S) OR SERVICE(S)
J9310

7. Medicare claim type: ☐ Part A ☑ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☑ No If No, Specific Dates of Service: 01-03-18

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☑ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☑ dismissal order [check one] dated 10-30-18. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

PLEASE SEE ATTACHED CONTINUATION SHEET

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE 11-29-18			DATE		
APPELLANT'S SIGNATURE (the party requesting review) Shannon Weier			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME SHANNON WEIER			PRINT NAME		
ADDRESS 5600 NEW KING DR SUITE 250			ADDRESS		
CITY, STATE, ZIP CODE TROY MI 48098			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER 248-641-4084	FAX NUMBER 248-641-4072	E-MAIL SWEIERD@HFHS.ORG	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

Form DAB-101 – Continuation Sheet

The Deputy Chief Administrative Law Judge dismissed Henry Ford Health System's appeal challenging the reimbursement amount that it received for certain drugs purchased under the 340B Drug Pricing Program. Henry Ford Health System disagrees with this ruling because, unless it is reversed, Henry Ford Health System will not receive the reimbursement amount required by law.

The payment received for drugs purchased under the 340B Program reflects the reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided in the 2018 Outpatient Prospective Payment System Rule. 82 Fed. Reg. 52,356 (Nov. 13, 2017). Numerous comments to the proposed rule (*see* pp. 52,499–502) correctly explained that this rate exceeds the Secretary's authority. As the comments explained, the new rate violates applicable law because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%) under 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for outpatient drugs provided under Part B; (2) is based on acquisition costs, when reliable data on acquisition costs are concededly unavailable, in violation of 42 U.S.C. § 1359*l*(t)(14)(A)(iii); and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B Program, in violation of 42 U.S.C § 256b.

The reimbursement rate should reflect the 2017 rate of ASP plus 6%, as required by law. The payment should be $7,344.77.

6656758.3

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, VA

Appeal of:	**Henry Ford Health System**	OMHA Appeal No.:	**1-7881597354**
Beneficiary:	[redacted]	Medicare Part:	**Part B**
Medicare No.:	[redacted]	Before:	**Brian J. Haring** **Deputy Chief Administrative Law Judge**

ORDER OF DISMISSAL

This case is before me on a request for hearing filed by the appellant on August 3, 2018. Along with the request for hearing, the appellant submitted a signed Waiver of Right to an Administrative Law Judge (ALJ) Hearing (OMHA-104) form dated August 2, 2018.

Pursuant to 42 C.F.R. section 405.1052(a)(2), an ALJ dismisses a request for hearing when the person or entity requesting the hearing has no right to it under section 405.1002. The regulations at 42 C.F.R. section 405.926 describe actions that are not initial determinations subject to the Medicare claim appeals process in 42 C.F.R. part 405, subpart I. Included in the list of actions that are not initial determinations is:

> Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

42 C.F.R. § 405.926(c).

In the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period, the Centers for Medicare & Medicaid Services (CMS) adopted the statutory default policy to pay for separately payable Part B drugs and biologicals, including drugs purchased under the 340B Drug Pricing Program (340B Program), at the average sales price (ASP) plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Social Security Act (the Act). 77 Fed. Reg. 68210, 68386 (Nov. 15, 2012).

The U.S. Government Accountability Office previously estimated that discounts under the 340B Program ranged from 20 to 50 percent. U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs*

Improvement 2 (2011). In a May 2015 Report to Congress, the Medicare Payment Advisory Commission conservatively estimated that, on average, hospitals (excluding critical access hospitals) in the 340B Program receive a minimum discount of 22.5 percent of the ASP for drugs paid under the OPPS. Medicare Payment Advisory Comm'n, *Overview of the 340B Drug Pricing Program* 27–28 (2015).

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Therefore, the request for hearing is hereby dismissed.

SO ORDERED

Dated: OCT 30 2018

Brian J. Haring
Deputy Chief Administrative Law Judge

Supplemented Exhibit J

This is an electronic claim. The paper image below was generated for reference purposes only using paper form 308420-HFHB CEV PAPER UB04.

Note: This information is only for viewing. It cannot be used instead of a claim.

UB-04 Claim Image

Account: 724979871 [redacted]

Page: 1 of 1

1 HENRY FORD HOSPITAL 2799 WEST GRAND BLVD DETROIT MI 48202 8009865840	2 HENRY FORD HOSPITAL PO BOX 670884 DETROIT MI 48267	3a Pat Cntl # HB72497987100 3b Med Rec # [redacted]	4 Bill Type 0131
		5 Fed Tax No. 381357020	6 Stmt. From 010418
			Stmt. To 010418
8 Patient Name a [redacted] b	9 Patient Address a [redacted] b [redacted]	c [redacted] d [redacted]	e

10 Birthdate	11 Sex	Admission 12 Date	13 Hour	14 Type	15 Src	16 DHr	17 Stat	Condition Codes 18	19	20	21	22	23	24	25	26	27	28	29 Acdt State	30
[redacted]		3	2			01	09													

31 Occurrence Code	Date	32 Occurrence Code	Date	33 Occurrence Code	Date	34 Occurrence Code	Date	35 Occurrence Span Code	From	Through	36 Occurrence Span Code	From	Through	37
18	090712	A1	[redacted]	B1	[redacted]									

38 MEDICARE PO BOX 2201 DETROIT, MI 48231-2201	39 Value Codes Code	Amount	40 Value Codes Code	Amount	41 Value Codes Code	Amount

42 Rev. Cd	43 Description	44 HCPCS/Rates	45 Serv. Date	46 Serv. Units	47 Total Charges	48 Non-Covered Charges	49
0258	PHARMACY - IV SOLUTIONS		010418	2	2800	000	
0260	IV THERAPY - GENERAL CLA	96375PO	010418	2	13000	000	
0335	RADIOLOGY - THERAPEUTIC	96413PO	010418	1	55000	000	
0335	RADIOLOGY - THERAPEUTIC	96415PO	010418	1	24000	000	
0636	N400641037625ML.5	J1200PO	010418	1	623	000	
0636	N400009001103UN1	J1720PO	010418	1	3314	000	
0636	N454396080101ML1	J2507POJG	010418	8	4200500	000	
0001	PAGE 1 OF 1		CREATION DATE 011018		TOTALS 4299237	000	

50 Payor	51 Health Plan ID	52 Rel. Info.	53 Asg. Ben.	54 Prior Pymts.	55 Est. Amt. Due	56 NPI	1134144801
MEDICARE	2001003	Y	Y	000	4299237	57 Other Prv ID	
AARP	0000005	Y	Y	000	000		

58 Insured Name	59 P. Rel	60 Insured's Unique ID	61 Group Name	62 Ins. Grp. Num
[redacted]	18	[redacted]		
[redacted]	18	[redacted]	AARP	

63 Treatment Auth. Codes	64 Document Control Number	65 Employer Name

66 Dx 0 | 67 M1A9XX | 68

69 Admit Dx	70 Pat Reason Dx	M1A9XX	71 PPS Code	72 ECI	73

74 Prin. Procedure Code	Date	a. Other Procedure Code	Date	b. Other Procedure Code	Date	75
c. Other Procedure Code	Date	d. Other Procedure Code	Date	e. Other Procedure Code	Date	

76 Attending	NPI 1174691612	Qual	
Last DOYLE		First THOMAS	
77 Operating	NPI	Qual	
Last		First	
78 Other	NPI	Qual	
Last		First	
79 Other	NPI	Qual	
Last		First	

80 Remarks	81 CC a	B3	282N00000X
	b		
	c		
	d		

WPS GHA - MAC J8 MI PART A
PO BOX 8799
PART A J8
MADISON, WI 537088799

MEDICARE
REMITTANCE
ADVICE

PAYER BUSINESS CONTACT INFORMATION:
EDI DEPARTMENT
EDIMEDICAREA@WPSIC.COM
(866)234-7331

PAYER TECHNICAL CONTACT INFORMATION:
EDI DEPARTMENT
EDIMEDICAREA@WPSIC.COM
(866)234-7331

HENRY FORD HEALTH SYSTEM
PO BOX 670884
DETROIT, MI 482670884

NPI #: 1134144801
DATE: 01/30/2018
PAGE #: 1

CHECK/EFT #: EFT1131757

REND-PROV	SERV-DATE	POS	PD-PROC/MODS	PD-NOS	BILLED	ALLOWED	DEDUCT	COINS	PROV-PD
RARC				SUB-NOS	SUB-PROC	GRP/CARC	CARC-AMT	ADJ-QTY	BS
NAME: [redacted]			HIC: [redacted]	ACNT:HB72497987100		ICN:21801000637704 ASG:N		MOA:MA01	
1134144801	0104	010418		2.000	28.00	28.00	0.00	0.00	0.00
						CO-97	28.00		04
1134144801	0104	010418	96375PO	2.000	130.00	130.00	0.00	14.16	55.51
						CO-45	59.20		
						CO-253	1.13		
1134144801	0104	010418	96413PO	1.000	550.00	550.00	100.84	36.73	143.97
						CO-45	265.52		
						CO-253	2.94		
1134144801	0104	010418	96415PO	1.000	240.00	240.00	0.00	11.13	43.62
						CO-45	184.36		
						CO-253	0.89		
1134144801	0104	010418	J1200PO	1.000	6.23	6.23	0.00	0.00	0.00
						CO-97	6.23		04
1134144801	0104	010418	J1720PO	1.000	33.14	33.14	0.00	0.00	0.00
						CO-97	33.14		04
1134144801	0104	010418	J2507POJG	8.000	42005.00	12051.86	0.00	1303.27	10533.62
						CO-45	29953.14		
						CO-253	214.97		

PT RESP 1466.13 CARC 30749.52 CLAIM TOTALS 42992.37 13039.23 100.84 1365.29 10776.72
ADJ TO TOTALS: PREV PD INTEREST 0.00 LATE FILING CHARGE 0.00 NET 10776.72
OTHER CLAIM REL IDENTIFICATION: (EA) 63159854

GLOSSARY:

253	Sequestration - reduction in federal payment
45	Charge exceeds fee schedule/maximum allowable or contracted/legislated fee arrangement. (Use only with Group Codes PR or CO depending upon liability)
4 (BS)	Benefit for Billed Service Not Separately Payable
97	The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
CO	Contractural Obligations
MA01	Alert: If you do not agree with what we approved for these services, you may appeal our decision. To make sure that we are fair to you, we require another individual that did not process your initial claim to conduct the appeal. However, in order to be eligible for an appeal, you must write to us within 120 days of the date you received this notice, unless you have a good reason for being late.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

72497987

MEDICARE REDETERMINATION REQUEST FORM — 1ST LEVEL OF APPEAL

1. Beneficiary's name: [redacted]

2. Medicare number: [redacted]

3. Item or service you wish to appeal: J2507

4. Date the service or item was received: 01/04/18

5. Date of the initial determination notice (please include a copy of the notice with this request):
(If you received your initial determination notice more than 120 days ago, include your reason for the late filing.)
01/30/18

5a. Name of the Medicare contractor that made the determination (not required):

5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
(for providers and suppliers only)

6. I do not agree with the determination decision on my claim because:
The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg, 52,356. Numerous comments to the proposed rule (see pp. 52,499-502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $14,876.96.

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. § 1395l(t)(14)(A)(iii)(II), the authority to pay for this drug, 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 is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

8. ☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the redetermination.
☒ I do not have evidence to submit.

9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative

10. Name, address, and telephone number of person appealing: Shannon Weier, 5600 New King Dr, Suite 250
Troy, MI 48098, 248-641-4084

11. Signature of person appealing:

12. Date signed:

PRIVACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare and Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about these disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at http://www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

Form CMS-20027 (12/10)

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

WPS | GOVERNMENT HEALTH ADMINISTRATORS

March 06, 2018

Henry Ford Health System
PO BOX 670884
DETROIT, MI 48267

Medicare Number of Beneficiary:
[redacted]
724979871

Beneficiary Contact Information

1-800-MEDICARE
or
1-800-633-4227

Provider Contact Information

If you have questions, write or call:

WPS Government Health Administrators - J8
Medicare Appeals PO Box 8604
Madison, WI 53708-8604
(866) 234-7331

Re: Appeal # 1-7303803951
MEDICARE APPEAL DECISION

Dear Henry Ford Health System,

This letter is to inform you of the decision on your Medicare appeal. An appeal is a new and independent review of a claim. On February 19, 2018, we received a redetermination request for drugs services provided by Henry Ford Health System. WPS Government Health Administrators - J8 was contracted by Medicare to review your appeal.

The redetermination decision is unfavorable because the services in question have already been paid by the Medicare Administrative Contractor (MAC) on January 30, 2018. We have evaluated the information submitted, and there does not appear to be any errors impacting the payment amount, which is the maximum payment amount allowed by Medicare for this service. As a result, we are issuing an unfavorable decision on your request for redetermination for claims referenced in Attachment A.

If you disagree that the claim in question was previously processed for payment, and/or you otherwise disagree with this decision, you may appeal to a Qualified Independent Contractor (QIC). You must file your appeal, in writing, within 180 days of receipt of this letter.

MAXIMUS Federal Services Inc.
Medicare Part A West
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

Sincerely,

Travis Parvin
Redetermination Representative
WPS Government Health Administrators - J8
A Medicare Contractor

cc: [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

7249798711

MEDICARE RECONSIDERATION REQUEST FORM — 2ND LEVEL OF APPEAL

1. Beneficiary's name: [redacted]
2. Medicare number: [redacted]
3. Item or service you wish to appeal: J2507
4. Date the service or item was received: 01/04/18
5. Date of the redetermination notice (please include a copy of the notice with this request):
   (If you received your redetermination notice more than 180 days ago, include your reason for the late filing.)
   3/6/18

   5a. Name of the Medicare contractor that made the redetermination (not required if copy of notice attached):

   5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
   (for providers and suppliers only)
6. I do not agree with the redetermination decision on my claim because:
   The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg. 52,356. Numerous comments to the proposed rule (see pp. 52,499-502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $14,876.96.
7. Additional information Medicare should consider:
   The new rate violates 42 U.S.C. § 1395l(t)(14)(A)(iii)(II), the authority to pay for this drug, 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 is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.
8. ☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the reconsideration.
   ☒ I do not have evidence to submit.
9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative
10. Name, address, and telephone number of person appealing: Shannon Weier, 5600 New King Dr Suite 250 Troy, MI 48098, 248-641-4084
11. Signature of person appealing: Shannon Weier
12. Date signed: 04/10/18

PRIVACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare and Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about these disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at http://www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

Form CMS-20033 (12/10)

MAXIMUS
Federal Services

If you have any questions regarding this case, write or call:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave
Suite #706
Pittsford, NY 14534-1302

Provider inquiries:

Visit www.q2a.com
or
Call 1-585-348-3201

Beneficiary inquiries:

Call 1-800-MEDICARE
or
1-800-633-4227

Who We Are

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review this file and make an independent decision.

QIC Part A West Fax Cover Sheet

DATE: 07/10/2018 Tue

TO: ATTN:Shannon

Agency:

Fax Number: 2486414072

RE: 1-7456775570

Comments:

Total Pages: 6

If you experience any problems with receiving this transmission, please contact me as soon as possible.

MAXIMUS Inc at 585-348-3400

Thank you.

Medicare Part A West QIC
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

HENRY FORD HEALTH SYSTEM
5600 NEW KING DR, SUITE 250
TROY, MI 48098

The enclosed letter is about your appeal.

[A]

MAXIMUS Federal Services
Medicare Part A West QIC
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

M. AULT
2028 DECKER RD
WALLED LAKE, MI 48390-2526

The enclosed letter is about your appeal.

1-7456775570

CMS

Medicare Appeal Number: 1-7456775570

7249979871

HENRY FORD HEALTH SYSTEM
5600 NEW KING DR, SUITE 250
TROY, MI 48098

MAXIMUS Federal Services

If you have questions, write or call:

MAXIMUS
Federal Services
QIC Part A West
3750 Monroe Ave.
Suite 706
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.q2a.com
Or
Call: 585-348-3020

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

June 1, 2018

RE: Beneficiary: [redacted]
HIC #: [redacted]
Appellant: Henry Ford Health System

Dear Henry Ford Health System:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for drug services provided to [redacted], the beneficiary, on January 4, 2018.

The appeal decision is favorable. Our decision is that your claim is covered by Medicare. Please see below regarding further appeal rights. More information on the decision is provided below. You are not required to take any action.

The Medicare contractor that initially received your claim is responsible for processing this favorable determination in accordance with standard Medicare payment methodologies. Any outstanding debts, prior coverage, and prior reimbursement will be taken into account when processing this decision.

A copy of this letter was sent to the beneficiary or his/her estate.

MAXIMUS Federal Services (MAXIMUS) was contracted by Medicare to review your appeal.

Appeal Details at Issue

Number	Provider	DOS
[redacted]	Henry Ford Health System	January 4, 2018

Summary of the Facts

Henry Ford Health System, the provider, billed for injection, pegloticase (J2507) provided to the beneficiary on January 4, 2018. At initial determination, Wisconsin Physician Services, the Medicare Administrative Contractor with jurisdiction, denied payment for the services. At redetermination Wisconsin Physician Services denied payment for services again. MAXIMUS received a request for reconsideration on April 11, 2018.

Decision

We have determined that Medicare will cover the claim for the drug services provided to the beneficiary on January 4, 2018. We have also determined that you are not responsible for payment for the drug services at issue.

Explanation of the Decision

The issue is whether the drug services provided to the beneficiary on January 4, 2018 met Medicare criteria for coverage.

Medicare will pay for services that are reasonable and medically necessary for the diagnosis or treatment of a condition, illness or injury in the beneficiary (Social Security Act, Section 1862 (a)(1)(A)). When an appellant requests a reconsideration, all documentation to support the services being appealed must be included with the request for reconsideration. The provider is responsible for providing sufficient documentation to support that payment is due and the services were medically necessary and provided as billed (42 Code of Federal Regulations (CFR), Section 424.5(a)(6)).

Medicare may cover a drug or biological if it is safe and effective and otherwise reasonable and necessary. In addition, reimbursement policies may be defined as outlined in specific National and Local Coverage Determinations (NCDs/LCDs) in the jurisdictions where they apply (Medicare Benefit Policy Manual, Chapter 15, Section 50.4.1).

In this case, Wisconsin Physician Services determined that the services failed to meet Medicare criteria for coverage. When requesting this appeal, the appellant argued that the services met Medicare coverage criteria.

The qualified independent contractor performed an independent review and determined that the services at issue met Medicare coverage criteria. This appeal concerns reimbursement of charges for injection, pegloticase (J2507) billed for the date of service January 4, 2018.

The beneficiary with a history of chronic gout was treated with pegloticase. Clinical indications and coding requirements that qualify J2507for Medicare coverage eligibility are outlined in Medicare approved compendia.

The documentation supports that the provider was underpaid and was not reimbursed at the average wholesale price (AWP) for 2018 for J2507. Additional payment is allowable at the AWP of J2507for January 2018.

Additional Information

Medicare requires that all evidence be presented before the reconsideration is issued. On further appeal, an ALJ will not consider any new evidence unless you show good cause for not presenting the evidence to the Qualified Independent Contractor (QIC). This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary. (42 CFR, Section 405.966).

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see 'Other Important Information' on the page titled "Important Information About Your Appeal Rights."

Who is Responsible for the Bill?

You meet Medicare coverage criteria for drug services. Medicare is responsible for the bill.

If you need more information or have any questions, please call the phone number on the front of this letter.

Sincerely,

Jennifer Frantz
Project Director

cc:

WISCONSIN PHYSICIAN SERVICES (via facsimile or electronic communication)

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may appeal the decision to an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). You or your representative may present your case to the ALJ at a hearing.

As of 1/1/ 2018, you must have $160 in dispute to appeal to an ALJ. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided by a QIC; (2) all of the claims are listed on your request for hearing; (3) your request for hearing is filed within 60 days of receipt of all of the QIC reconsiderations being appealed; and (4) you explain why you believe the claims involve similar or related services.

You can find more information about your right to an ALJ hearing at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ hearing within **60 days** of receiving this letter. If your request for hearing is being filed late, you must explain why your request is being filed late. After you file an appeal, you may check your appeal's status via the OMHA website at www.hhs.gov/omha (click on Appeal Status Lookup).

When preparing your request for hearing, please use **Form OMHA-100**, available at: www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for hearing must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's reconsideration; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

You must send a copy of your request for hearing to the other parties who received a copy of this decision (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your hearing request to the QIC that issued this decision or to the Medicare Administrative Contractor that issued the redetermination.

Mail your hearing request to (tracked mail is suggested):

HHS OMHA Central Operations
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

OMHA processes Medicare **Beneficiary** appeals on a priority basis. If you are a Beneficiary or you represent a Beneficiary, mail your hearing request to:

HHS OMHA Central Operations
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

If you are a Beneficiary or represent a Beneficiary, you can also call the OMHA Beneficiary help line at 1-844-419-3358 for assistance. This is a toll free call. For more information on the OMHA Beneficiary prioritization program, including limitations for Beneficiaries represented by a provider/supplier, or a shared representative, visit the OMHA website at www.hhs.gov/omha or call the Beneficiary help line.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign and date a statement naming that person to act for you and send it with your request for hearing. Call 1-800-MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Help With Your Appeal

You can have a friend or someone else help you with your appeal. If you have any questions about payment denials or appeals, you can also contact your State Health Insurance Assistance Program (SHIP). For information on contacting your local SHIP, call 1-800-MEDICARE (1-800-633-4227).

Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this decision, please write to us and attach a copy of this letter, at:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave., Suite 706
Pittsford, NY 14534-1302

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

If you need large print or assistance, call 1-800-633-4227

WPS GHA - MAC J8 MI PART A
PO BOX 8799
PART A J8
MADISON, WI 537088799

MEDICARE
REMITTANCE
ADVICE

PAYER BUSINESS CONTACT INFORMATION:
EDI DEPARTMENT
EDIMEDICAREA@WPSIC.COM
(866)234-7331

PAYER TECHNICAL CONTACT INFORMATION:
EDI DEPARTMENT
EDIMEDICAREA@WPSIC.COM
(866)234-7331

HENRY FORD HEALTH SYSTEM
PO BOX 670884
DETROIT, MI 482670884

NPI #: 1134144801
DATE: 06/15/2018
PAGE #: 1

CHECK/EFT #: EFT1166481

REND-PROV	SERV-DATE	POS	PD-PROC/MODS	PD-NOS / SUB-NOS	BILLED / SUB-PROC	ALLOWED / GRP/CARC	DEDUCT / CARC-AMT	COINS / ADJ-QTY	PROV-PD / BS / RARC
NAME: [redacted]			MID: [redacted]	ACNT:HB72497987100		ICN:21815600090108 ASG:N		MOA:MA01	N793 N469
1134144801	0104	010418		2.000	28.00	28.00	0.00	0.00	0.00
						CO-97	28.00		04
1134144801	0104	010418	96375PO	2.000	130.00	130.00	0.00	14.16	55.51
						CO-45	59.20		
						CO-253	1.13		
1134144801	0104	010418	96413PO	1.000	550.00	550.00	100.84	36.73	143.97
						CO-45	265.52		
						CO-253	2.94		
1134144801	0104	010418	96415PO	1.000	240.00	240.00	0.00	11.13	43.62
						CO-45	184.36		
						CO-253	0.89		
1134144801	0104	010418	J1200PO	1.000	6.23	6.23	0.00	0.00	0.00
						CO-97	6.23		04
1134144801	0104	010418	J1720PO	1.000	33.14	33.14	0.00	0.00	0.00
						CO-97	33.14		04
1134144801	0104	010418	J2507POJG	8.000	42005.00	12051.86	0.00	1303.27	10533.62
						CO-45	29953.14		
						CO-253	214.97		

PT RESP 1466.13 CARC 30749.52 CLAIM TOTALS 42992.37 13039.23 100.84 1365.29 10776.72
ADJ TO TOTALS: PREV PD INTEREST 0.00 LATE FILING CHARGE 0.00 NET 10776.72
OTHER CLAIM REL IDENTIFICATION: (EA) 63159854

GLOSSARY:

253	Sequestration - reduction in federal payment
45	Charge exceeds fee schedule/maximum allowable or contracted/legislated fee arrangement. Usage: This adjustment amount cannot equal the total service or claim charge amount; and must not duplicate provider adjustment amounts (payments and contractual reductions) that have resulted from prior payer(s) adjudication. (Use only with Group Codes PR or CO depending upon liability)
4 (BS)	Benefit for Billed Service Not Separately Payable
97	The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
CO	Contractural Obligations
MA01	Alert: If you do not agree with what we approved for these services, you may appeal our decision. To make sure that we are fair to you, we require another individual that did not process your initial claim to conduct the appeal. However, in order to be eligible for an appeal, you must write to us within 120 days of the date you received this notice, unless you have a good reason for being late.
N469	Alert: Claim/Service(s) subject to appeal process, see section 935 of Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).
N793	Alert: CMS is changing from the Medicare Health Insurance Claim number (HICN) to the new Medicare Beneficiary Identifier (MBI). You can use either the HICN or MBI during the transition period. Visit www.cms.gov/newcard for important dates and information about this change.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Reopening Medicare Appeal Number: 1-7456775570R1

7249798711

MAXIMUS Federal Services

If you have questions, write or call:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave.
Suite 706
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.q2a.com
Or
Call: (585) 348-3020

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

June 25, 2018

HENRY FORD HEALTH SYSTEM
ATTN: MEDICARE APPEALS DEPT
5600 NEW KING ST, SUITE 250
TROY, MI 48098

Re: **Reconsideration decision review**

Beneficiary:	[redacted]
HIC #:	XXX-XX-[redacted]
Appellant:	Henry Ford Health System
Dates of Service:	January 4, 2018 to January 4, 2018

Dear Medicare Appeals Dept:

Please be advised that we have reviewed the above-captioned reconsideration decision. As a result of our review, we conclude that good cause exists to reopen your appeal. Therefore, we will process your request for reconsideration under the new Medicare Appeal Number noted above. You will receive this new reconsideration decision through the mail.

Sincerely,

Jennifer Frantz
Project Director

JF/dpf

V2.0

Appeal #:	1-7456775570 Find
Received:	04/11/2018
Deadline:	
Decision:	06/01/2018
New Appeal #	1-7456775570R1
Status:	QIC Reopened

The case has been reopened; refer to the New Appeal No. for further information.

Appeal #:	1-7456775570R1 Find
Received:	06/13/2018
Deadline:	10/11/2018
Decision:	
New Appeal #	
Status:	QIC Review

The QIC has received the request for reconsideration and has not yet made a decision; the deadline indicates the day by which the QIC must mail a decision letter.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare Appeal Number: 1-7456775570

724979871

MAXIMUS Federal Services

If you have questions, write or call:

MAXIMUS Federal Services
QIC Part A West
3750 Monroe Ave.
Suite 706
Pittsford, NY
14534-1302

Provider Inquiries

Visit: www.g2a.com
Or
Call: (585) 348-3020

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are MAXIMUS Federal Services. We are experts on appeals. Medicare hired us to review your file and make an independent decision.

IMPORTANT INFORMATION REGARDING YOUR APPEAL

July 11, 2018

HENRY FORD HEALTH SYSTEM
ATTN: MEDICARE APPEALS DEPT
5600 NEW KING ST, SUITE 250
TROY, MI 48098

Re:	Beneficiary:	[redacted]
	HIC #:	XXX-XX-[redacted]
	Appellant:	Henry Ford Health System
	Dates of Service:	January 4, 2018 to January 4, 2018

Dear Medicare Appeals Dept:

On June 25, 2018, MAXIMUS Federal Services (MAXIMUS) sent you an acknowledgement letter advising that the above-captioned reconsideration decision was being reopened and a new decision would be mailed to you under Medicare Appeal Number 1-7456775570R1.

Please disregard the correspondence that you received relative to Medicare Appeal 1-7456775570R1. MAXIMUS will not be issuing a new reconsideration decision at this time. Please note that Medicare Appeal # 1-7456775570R1 has been deleted from our system.

Sincerely,

Jennifer Frantz
Project Director

JF/jr

V2.0

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

REQUEST FOR ADMINISTRATIVE LAW JUDGE (ALJ) HEARING OR REVIEW OF DISMISSAL

Section 1: Which Medicare Part are you appealing (if known)? (*Check one*)

☐ Part A ☒ Part B ☐ Part C (*Medicare Advantage*) or Medicare Cost Plan ☐ Part D (*Prescription Drug Plan*)

Section 2: Which party are you, or which party are you representing? (*Check one*)

☐ The Medicare beneficiary or enrollee, or a successor (such as an estate), who received or requested the items or services being appealed, or is appealing a Medicare Secondary Payer issue.

☒ The provider or supplier that furnished the items or services to the Medicare beneficiary or enrollee, a Medicaid State agency, or an applicable plan appealing a Medicare Secondary Payer issue.

☐ Other. *Please explain*:

Section 3: What is your (the appealing party's) information? (*Representative information in next section*)

Name (*First, Middle Initial, Last*)	Firm or Organization (*if applicable*)		
Shannon Weier	Henry Ford Health System		
Address where appeals correspondence should be sent	City	State	ZIP Code
5600 New King Dr., Suite 250	Troy	MI	28098
Telephone Number	Fax Number	E-Mail	
(248) 641-4084		sweier2@hfhs.org	

Section 4: What is the representative's information? (*Skip if you do not have a representative*)

Name	Firm or Organization (*if applicable*)		
Mailing Address	City	State	ZIP Code
Telephone Number	Fax Number	E-Mail	

Did you file an appointment of representation (form CMS-1696) or other documents authorizing your representation at a prior level of appeal?

☐ No. *Please file the document(s) with this request.*
☐ Yes

Section 5: What is being appealed? *Submit a separate request for each Reconsideration or Dismissal that you wish to appeal. If the appeal involves multiple beneficiaries or enrollees, use the multiple claim attachment (OMHA-100A).*

Name of entity that issued the Reconsideration or Dismissal (*or attach a copy of the Reconsideration or Dismissal*)	Reconsideration (Medicare Appeal or Case) Number (*or attach a copy of the Reconsideration or Dismissal*)		
MAXIMUS FEDERAL SERVICES	1-7456775570 + 1-7456775570R1		
Beneficiary or Enrollee Name	Health Insurance Claim Number		
[redacted]	21801000637704 M1A		
Beneficiary or Enrollee Mailing Address	City	State	ZIP Code
[redacted]	[redacted]	[redacted]	[redacted]
What item(s) or service(s) are you appealing? (*N/A if appealing a Dismissal*)		Date(s) of service being appealed (*if applicable*)	
J2507		1-04-18	
Supplier or Provider Name (*N/A for Part D appeals*)	Supplier or Provider Telephone Number (*N/A for Part D appeals*)		
HENRY FORD HOSPITAL	800-986-5840		
Supplier or Provider Mailing Address (*N/A for Part D appeals*)	City	State	ZIP Code
2799 WEST GRAND BLVD	DETROIT	MI	48202

Section 6: For appeals of prescription drugs ONLY (*Skip for all other appeals*)

Part D Prescription Drug Plan Name	What drug(s) are you appealing?

Are you requesting an expedited hearing?
(*An expedited hearing is only available if your appeal is not solely related to payment (for example, you do not have the drug) and applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function*)

☐ No. ☐ Yes. *On a separate sheet, please explain or have your prescriber explain why applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function.*

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed? (*Attach a continuation sheet if necessary*)

See attached continuation sheet.

Section 8: Are you submitting evidence with this request, or do you plan to submit evidence?

☒ I am not planning to submit evidence at this time. (*Skip to Section 9, below*)

☐ I am submitting evidence with this request.

☐ I plan to submit evidence. Indicate what you plan to submit and when you plan to submit it:

Was the evidence already submitted for the matter that you are appealing?

☐ No. *Part A and Part B appeals only. If you are a provider or supplier, or a provider or supplier that is representing a beneficiary, you must include a statement explaining why the evidence is being submitted for the first time and was not submitted previously.*

☐ Yes.

Section 9: Is there other information about your appeal that we should know?

Are you aggregating claims to meet the amount in controversy requirement? (*If yes, attach your aggregation request. See 42 C.F.R. § 405.1006(e) and (f), and 423.1970(c) for request requirements.*)	☒ No	☐ Yes
Are you waiving the oral hearing before an ALJ and requesting a decision based on the record? (*If yes, attach a completed form OMHA-104 or other explanation. N/A if requesting review of a dismissal.*)	☐ No	☒ Yes
Does the request involve claims that were part of a statistical sample? (*If yes, please explain the status of any appeals for claims in the sample that are not included in this request.*)	☒ No	☐ Yes

Section 10: Certification of copies sent to other parties (*Part A and Part B appeals only*)

If another party to the claim or issue that you are appealing was sent a copy of the Reconsideration or Dismissal, you must send a copy of your request for an ALJ hearing or review of dismissal to that party.

Indicate the party (or their representative) to whom and address where you are sending a copy of the request, and when the copy will be sent *(attach a continuation sheet if there are multiple parties)*.

Name of Recipient		
Mailing Address		
City	State	ZIP Code
Date of Mailing		

☒ Check here if no other parties were sent a copy of the Reconsideration or Dismissal.

Section 11: Filing instructions

Your appealed claim must meet the current amount in controversy requirement to file an appeal. See the Reconsideration or Dismissal or visit www.hhs.gov/omha for information on the current amount in controversy. Send this request form to the entity in the appeal instructions that came with your reconsideration (for example, requests for hearing following a Part C reconsideration are generally sent to the entity that conducted the reconsideration). If instructed to send to OMHA, use the addresses below.

Beneficiaries and enrollees, send your request to:	**For expedited Part D appeals, send your request to:**	**All other appellants, send your request to:**
OMHA Centralized Docketing Attn: Beneficiary Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing Attn: Expedited Part D Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316

We must receive this request within 60 calendar days after you received the Reconsideration or Dismissal that you are appealing. We will assume that you received the Reconsideration or Dismissal 5 calendar days after the date of the Reconsideration or Dismissal, unless you provide evidence to the contrary. *If you are filing this request late, attach a completed form OMHA-103 or other explanation for the late filing.*

PRIVACY ACT STATEMENT

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed?

(continuation sheet)

The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg. 52,356. Numerous comments to the proposed rule (see pp. 52,499–502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $14,876.96.

The new rate violates 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for the drug, 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 is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

Maximus Federal Services ("Maximus"), a Qualified Independent Contractor, initially issued a favorable reconsideration decision in this appeal (Appeal # 1-7456775570). Maximus was subsequently instructed by the Centers for Medicare and Medicaid Services ("CMS") to reopen and dismiss the appeal on the grounds that, in CMS's view, there are no administrative appeal rights for reimbursement disputes related to the 340B Program. In light of that instruction, Maximus reopened the appeal (Appeal # 1-7456775570R1) and then dismissed it.

6496491.1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

WAIVER OF RIGHT TO AN ADMINISTRATIVE LAW JUDGE (ALJ) HEARING

Instructions: If you are an appellant or other party to a hearing before an Administrative Law Judge (ALJ) with the Office of Medicare Hearings and Appeals (OMHA), you may waive your right to the oral hearing and request that a decision be made based on the record. When you waive your right to a hearing, either an ALJ or an attorney adjudicator may decide your appeal.

If you are the appellant and want your appeal to be decided without a hearing, complete this form and include it with your request for an ALJ hearing (form OMHA-100) or, if you have already filed your request for an ALJ hearing, send this form to the assigned OMHA adjudicator (visit www.hhs.gov/omha and use the appeal status lookup tool to find your assigned adjudicator). Any other party that wants the appeal to be decided without a hearing may complete this form and send it to the assigned OMHA adjudicator. If an adjudicator has not yet been assigned, send this form to OMHA Central Operations, Attention: Waiver Mail Stop (visit www.hhs.gov/omha or call the number at the bottom of this form for the full mailing address).

If all of the parties to the appealed matter who would be sent a notice of hearing do not also waive the ALJ hearing (for example, a provider or supplier that was held financially responsible for the denied items or services), or the assigned ALJ or attorney adjudicator believes a hearing is necessary to decide the appeal, a hearing may be held by an ALJ, and the ALJ will issue the decision or other dispositive order in the appeal.

Section 1: What is the OMHA appeal number or the reconsideration (Medicare appeal or case) number?

OMHA Appeal Number *(if known)*	Reconsideration Number (*if OMHA appeal number not known*)
	Reconsideration Appeal #: 1-7456775570 & # 1-7456775570R1

Section 2: What is the information for the party waiving the hearing? (*Representative information in next section*)

Name *(First, Middle initial, Last)*	Firm or Organization (*if applicable*)	Telephone Number
Shannon Weier	Henry Ford Health System	(248) 641-4084

Section 3: What is the representative's information? (*Skip if you do not have a representative*)

Name	Firm or Organization (*if applicable*)	Telephone Number

Section 4: Explain why you wish to waive your right to an ALJ hearing and have the appeal decided based on the record:

There are no factual disputes in this appeal, which challenges provisions of the 2018 hospital OPPS rule regarding payments under the 340B program. Furthermore, an ALJ would not have authority to invalidate these provisions of the regulation, and thus could not issue a favorable decision in this appeal. 42 C.F.R. § 405.1063(a). Concurrently with this request for ALJ review, Henry Ford is requesting that the Departmental Appeals Board certify this appeal for expedited judicial review pursuant to 42 C.F.R. § 405.990.

Section 5: Acknowledge the following by signing and dating this form:

I understand that I may have a right to a hearing before an ALJ. I understand that having an ALJ hearing would provide me with the opportunity to present oral testimony and to present and/or question witnesses. I understand that this opportunity to be seen and heard could be helpful to the ALJ in making a decision.

I understand that my waiver of an ALJ hearing does not affect the right of other parties to an ALJ hearing.

I understand that even if all parties waive their right to an ALJ hearing, if the ALJ determines that a hearing is necessary to obtain testimony from a non-party, the ALJ may still hold a hearing to obtain that testimony. If a hearing is held, the ALJ will offer the parties the opportunity to appear at the hearing (which may be in person, by telephone or by video-teleconference), but may hold the hearing even if none of the parties decide to appear. I understand that if a hearing is held and I do not attend the hearing, I still have the right to submit written evidence.

I understand that my waiver may be denied if it is determined that my attendance is necessary to decide the appeal.

If I change my mind and decide that I would like a hearing before an ALJ, I understand I must submit a withdrawal of this waiver (see form OMHA-114) before a notice of decision or other dispositive order is issued by an ALJ or attorney adjudicator. If I withdraw my waiver of hearing, I understand that any applicable time frame to decide the appeal may be extended in order to schedule and hold the hearing. I also understand that if a hearing has already been conducted, the ALJ may decide not to conduct another one.

Party or Representative Signature	Date
Shannon Weier	8-2-18

Privacy Act Statement

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
786-792-3778 (ALJ Haring Team)
305-536-4382 (Fax)
866-231-3087 (Toll Free)

Date: 10/30/2018

7249798711

HENRY FORD HEALTH SYSTEM
5600 NEW KING DR, SUITE 250
TROY, MI 48098

NOTICE OF DISMISSAL

Appellant: HENRY FORD HEALTH SYSTEM
OMHA Appeal Number: 1-7881563605

Enclosed is an order dismissing the request for hearing in the above case. As explained below, the dismissal is binding unless it is vacated by the Medicare Appeals Council, or by the OMHA adjudicator who issued the dismissal.

What if I disagree with the dismissal?

If you disagree with the dismissal, you may file an appeal with the Medicare Appeals Council. Other parties may appeal the dismissal as well. In addition, the Medicare Appeals Council may decide to review the dismissal on its own motion.

You also have the right to request that the adjudicator who issued the dismissal vacate the dismissal by sending a letter explaining why you believe the dismissal should be vacated, along with a copy of the dismissal, to the adjudicator's attention at the OMHA field office address listed at the top of this notice. If good and sufficient cause is established, the adjudicator may vacate the dismissal within 6 months of the date of this notice. The adjudicator may decide not to vacate the dismissal, and the adjudicator's decision whether to vacate the dismissal is not subject to further review. IMPORTANT NOTE: Filing a request with the adjudicator to vacate the dismissal does not extend the 60-day period described below for filing an appeal of the dismissal with the Medicare Appeals Council.

If you are not already represented, you may appoint an attorney or other person to represent you.

If no party appeals the dismissal, the Medicare Appeals Council does not review the dismissal, and the adjudicator does not vacate the dismissal, the reconsideration is binding on all parties.

How much time do I have to file an appeal?

If you choose to file an appeal with the Medicare Appeals Council, the Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the dismissal. Your appeal must be in writing, except that a request for expedited review of a Part D dismissal may be made orally as described below. Your appeal must identify the parts of the dismissal that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the dismissal.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's dismissal (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed dismissal to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227**.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed dismissal. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator dismissal order;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D dismissal may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of dismissal. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may deny review of the dismissal or vacate the dismissal and remand the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll-free), if you have questions about filing an appeal.

cc:

[redacted]

MAXIMUS
QIC Part A West Appeals–ALJ
3750 Monroe Ave, Suite 706
Pittsford, NY 14534

Enclosures:

OMHA-173, Order of Dismissal
DAB-101, Request for Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____ . I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, VA

Appeal of:	**Henry Ford Health System**	OMHA Appeal No.:	**1-7881563605**
Beneficiary:	[redacted]	Medicare Part:	**Part B**
Medicare No.:	[redacted]	Before:	**Brian J. Haring** **Deputy Chief Administrative Law Judge**

ORDER OF DISMISSAL

This case is before me on a request for hearing filed by the appellant on August 3, 2018. Along with the request for hearing, the appellant submitted a signed Waiver of Right to an Administrative Law Judge (ALJ) Hearing (OMHA-104) form dated August 2, 2018.

Pursuant to 42 C.F.R. section 405.1052(a)(2), an ALJ dismisses a request for hearing when the person or entity requesting the hearing has no right to it under section 405.1002. The regulations at 42 C.F.R. section 405.926 describe actions that are not initial determinations subject to the Medicare claim appeals process in 42 C.F.R. part 405, subpart I. Included in the list of actions that are not initial determinations is:

> Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

42 C.F.R. § 405.926(c).

In the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period, the Centers for Medicare & Medicaid Services (CMS) adopted the statutory default policy to pay for separately payable Part B drugs and biologicals, including drugs purchased under the 340B Drug Pricing Program (340B Program), at the average sales price (ASP) plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Social Security Act (the Act). 77 Fed. Reg. 68210, 68386 (Nov. 15, 2012).

The U.S. Government Accountability Office previously estimated that discounts under the 340B Program ranged from 20 to 50 percent. U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs*

Improvement 2 (2011). In a May 2015 Report to Congress, the Medicare Payment Advisory Commission conservatively estimated that, on average, hospitals (excluding critical access hospitals) in the 340B Program receive a minimum discount of 22.5 percent of the ASP for drugs paid under the OPPS. Medicare Payment Advisory Comm'n, *Overview of the 340B Drug Pricing Program* 27–28 (2015).

Section 1833(t)(14)(A)(iii)(II) of the Act states that, if hospital acquisition costs data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as calculated and adjusted by the Secretary as necessary. In the OPPS/ASC final rule with comment period for CY 2018, CMS used this authority to adjust the payment rate for separately payable drugs and biologicals acquired under the 340B Program (other than drugs on pass-through payment status and vaccines) from ASP *plus* 6 percent to ASP *minus* 22.5 percent, effective January 1, 2018. (The reduction is not applicable to rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals in CY 2018). 82 Fed. Reg. 59216, 59353–71 (Dec. 14, 2017). CMS stated that this adjustment would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. *Id.* at 59222.

In this case, the appellant provided an injection, pegloticase (J2507) to the beneficiary on January 4, 2018. The appellant received payment for the claim at issue from the Medicare Administrative Contractor (MAC) on January 30, 2018. (Ex. 1, pp. 40–46). The appellant requested a redetermination of the claim on the basis that: "the payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule." (Ex. 1, p. 78). The appellant asserted that the rate adjustment exceeded the Secretary's statutory authority, and that the drug should be reimbursed at the 2017 rate of ASP plus 6 percent. (Ex. 1, p. 78).

On March 5, 2018, the MAC issued a redetermination informing the appellant that the decision was unfavorable because the claim had already been paid. (Ex. 1, pp. 53–57). The appellant then requested reconsideration. On June 1, 2018, the Qualified Independent Contractor (QIC) issued a favorable reconsideration decision, finding that Medicare would cover the claim for J2507. (Ex. 1, pp. 18–20). The QIC decision indicated that the provider had been underpaid and had not been reimbursed at the average wholesale price for 2018 for J2507, but did not specify the correct reimbursement amount. (Ex. 1, p. 20). Following the reconsideration decision, the QIC notified the appellant that the reconsideration would be reopened, but later retracted the reopening. (Ex. 1, pp. 27–28).

On August 3, 2018, the Office of Medicare Hearings and Appeals (OMHA) received the appellant's request for hearing. (Ex. 1, pp. 1–3, 11). In its request for hearing, the appellant again challenged the amount of payment it had received for J2507 claim. (Ex. 1, p. 11). The appellant's request involves an issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS has sole responsibility. As provided in 42 C.F.R. section 405.926(c), this is not an initial determination subject to the Medicare claims appeal process. Because there was no initial determination in this case, the appellant did not have the right to a redetermination, a reconsideration, or an ALJ hearing. 42 C.F.R. §§ 405.940, 405.960, 405.1002. In accordance with 42 C.F.R. section 405.1052(a)(2), the appellant's request for hearing shall be dismissed because there is no right to hearing in this appeal.

Therefore, the request for hearing is hereby dismissed.

SO ORDERED

Dated: OCT 30 2018

Brian J. Haring
Deputy Chief Administrative Law Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)
SHANNON WEIER

2. ALJ APPEAL NUMBER (on the decision or dismissal)
1-7881563605

3. BENEFICIARY*
[redacted]

4. HEALTH INSURANCE CLAIM NUMBER (HICN)*
[redacted]

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER
HENRY FORD HEALTH SYSTEM

6. SPECIFIC ITEM(S) OR SERVICE(S)
J2507

7. Medicare claim type: ☐ Part A ☑ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☑ No If No, Specific Dates of Service: 01-04-18

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☑ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☑ dismissal order [check one] dated 10-30-18. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

PLEASE SEE ATTACHED CONTINUATION SHEET

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
11-29-18					
APPELLANT'S SIGNATURE (the party requesting review) Shannon Weier			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
SHANNON WEIER					
ADDRESS			ADDRESS		
51000 NEW KING DR SUITE 250					
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TROY MI 48098					
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL
248-641-4084	248-641-4072	SWEIER2@HFHS.ORG			

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

Form DAB-101 – Continuation Sheet

The Deputy Chief Administrative Law Judge dismissed Henry Ford Health System's appeal challenging the reimbursement amount that it received for certain drugs purchased under the 340B Drug Pricing Program. Henry Ford Health System disagrees with this ruling because, unless it is reversed, Henry Ford Health System will not receive the reimbursement amount required by law.

The payment received for drugs purchased under the 340B Program reflects the reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided in the 2018 Outpatient Prospective Payment System Rule. 82 Fed. Reg. 52,356 (Nov. 13, 2017). Numerous comments to the proposed rule (*see* pp. 52,499–502) correctly explained that this rate exceeds the Secretary's authority. As the comments explained, the new rate violates applicable law because it: (1) is not an "adjustment" to the statutory default rate (ASP+6%) under 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for outpatient drugs provided under Part B; (2) is based on acquisition costs, when reliable data on acquisition costs are concededly unavailable, in violation of 42 U.S.C. § 1359*l*(t)(14)(A)(iii); and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B Program, in violation of 42 U.S.C § 256b.

The reimbursement rate should reflect the 2017 rate of ASP plus 6%, as required by law. The payment should be $14,876.96.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, VA

Appeal of:	**Henry Ford Health System**	OMHA Appeal No.:	**1-7881563605**
Beneficiary:	[redacted]	Medicare Part:	**Part B**
Medicare No.:	[redacted]	Before:	**Brian J. Haring** **Deputy Chief Administrative Law Judge**

ORDER OF DISMISSAL

This case is before me on a request for hearing filed by the appellant on August 3, 2018. Along with the request for hearing, the appellant submitted a signed Waiver of Right to an Administrative Law Judge (ALJ) Hearing (OMHA-104) form dated August 2, 2018.

Pursuant to 42 C.F.R. section 405.1052(a)(2), an ALJ dismisses a request for hearing when the person or entity requesting the hearing has no right to it under section 405.1002. The regulations at 42 C.F.R. section 405.926 describe actions that are not initial determinations subject to the Medicare claim appeals process in 42 C.F.R. part 405, subpart I. Included in the list of actions that are not initial determinations is:

> Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

42 C.F.R. § 405.926(c).

In the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period, the Centers for Medicare & Medicaid Services (CMS) adopted the statutory default policy to pay for separately payable Part B drugs and biologicals, including drugs purchased under the 340B Drug Pricing Program (340B Program), at the average sales price (ASP) plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Social Security Act (the Act). 77 Fed. Reg. 68210, 68386 (Nov. 15, 2012).

The U.S. Government Accountability Office previously estimated that discounts under the 340B Program ranged from 20 to 50 percent. U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs*

Improvement 2 (2011). In a May 2015 Report to Congress, the Medicare Payment Advisory Commission conservatively estimated that, on average, hospitals (excluding critical access hospitals) in the 340B Program receive a minimum discount of 22.5 percent of the ASP for drugs paid under the OPPS. Medicare Payment Advisory Comm'n, *Overview of the 340B Drug Pricing Program* 27–28 (2015).

Section 1833(t)(14)(A)(iii)(II) of the Act states that, if hospital acquisition costs data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as calculated and adjusted by the Secretary as necessary. In the OPPS/ASC final rule with comment period for CY 2018, CMS used this authority to adjust the payment rate for separately payable drugs and biologicals acquired under the 340B Program (other than drugs on pass-through payment status and vaccines) from ASP *plus* 6 percent to ASP *minus* 22.5 percent, effective January 1, 2018. (The reduction is not applicable to rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals in CY 2018). 82 Fed. Reg. 59216, 59353–71 (Dec. 14, 2017). CMS stated that this adjustment would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. *Id.* at 59222.

In this case, the appellant provided an injection, pegloticase (J2507) to the beneficiary on January 4, 2018. The appellant received payment for the claim at issue from the Medicare Administrative Contractor (MAC) on January 30, 2018. (Ex. 1, pp. 40–46). The appellant requested a redetermination of the claim on the basis that: "the payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule." (Ex. 1, p. 78). The appellant asserted that the rate adjustment exceeded the Secretary's statutory authority, and that the drug should be reimbursed at the 2017 rate of ASP plus 6 percent. (Ex. 1, p. 78).

On March 5, 2018, the MAC issued a redetermination informing the appellant that the decision was unfavorable because the claim had already been paid. (Ex. 1, pp. 53–57). The appellant then requested reconsideration. On June 1, 2018, the Qualified Independent Contractor (QIC) issued a favorable reconsideration decision, finding that Medicare would cover the claim for J2507. (Ex. 1, pp. 18–20). The QIC decision indicated that the provider had been underpaid and had not been reimbursed at the average wholesale price for 2018 for J2507, but did not specify the correct reimbursement amount. (Ex. 1, p. 20). Following the reconsideration decision, the QIC notified the appellant that the reconsideration would be reopened, but later retracted the reopening. (Ex. 1, pp. 27–28).

On August 3, 2018, the Office of Medicare Hearings and Appeals (OMHA) received the appellant's request for hearing. (Ex. 1, pp. 1–3, 11). In its request for hearing, the appellant again challenged the amount of payment it had received for J2507 claim. (Ex. 1, p. 11). The appellant's request involves an issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS has sole responsibility. As provided in 42 C.F.R. section 405.926(c), this is not an initial determination subject to the Medicare claims appeal process. Because there was no initial determination in this case, the appellant did not have the right to a redetermination, a reconsideration, or an ALJ hearing. 42 C.F.R. §§ 405.940, 405.960, 405.1002. In accordance with 42 C.F.R. section 405.1052(a)(2), the appellant's request for hearing shall be dismissed because there is no right to hearing in this appeal.

Therefore, the request for hearing is hereby dismissed.

SO ORDERED

Dated: OCT 30 2018

Brian J. Haring
Deputy Chief Administrative Law Judge