[ORAL ARGUMENT NOT YET SCHEDULED]

Nos. 19-5048, 19-5198

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, Secretary of Health & Human Services, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

JOINT APPENDIX

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APPEAL,CLOSED,TYPE-C

U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:18-cv-02084-RC
Internal Use Only

AMERICAN HOSPITAL ASSOCIATION et al
Assigned to: Judge Rudolph Contreras
Case: 1:17-cv-02447-RC
Case in other court: USCA, 19-05048
Cause: 42:405 Review of HHS Decision (SSID)

Date Filed: 09/05/2018
Date Terminated: 07/12/2019
Jury Demand: None
Nature of Suit: 151 Contract: Recovery Medicare
Jurisdiction: U.S. Government Defendant

Plaintiff

AMERICAN HOSPITAL ASSOCIATION

represented by **Margaret M. Dotzel**
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Plaintiff

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Plaintiff

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Plaintiff

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Plaintiff

HENRY FORD HEALTH SYSTEM

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Ezra B. Marcus
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Plaintiff

FLETCHER HOSPITAL, INC.
doing business as
PARK RIDGE HEALTH

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Ezra B. Marcus
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William Barnett Schultz
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V.

Defendant

ALEX M. AZAR II
in his official capacity as the Secretary of Health and Human Services

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Defendant

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

represented by **Justin Michael Sandberg**
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

FEDERATION OF AMERICAN HOSPITALS

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Date Filed	#	Page	Docket Text
09/05/2018	1		COMPLAINT against ALEX M. AZAR II, DEPARTMENT OF HEALTH

			AND HUMAN SERVICES (Filing fee $ 400 receipt number 0090–5672969) filed by FLETCHER HOSPITAL, INC., EASTERN MAINE HEALTHCARE SYSTEMS, AMERICAN HOSPITAL ASSOCIATION, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, HENRY FORD HEALTH SYSTEM. (Attachments: # 1 Summons Alex M. Azar II, # 2 Summons U.S. Department of Health and Human Services, # 3 Civil Cover Sheet)(Schultz, William) (Entered: 09/05/2018)
09/05/2018	2		MOTION for Preliminary Injunction *and Permanent Injunction* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM (Attachments: # 1 Memorandum in Support, # 2 Exhibit Index, # 3 Exhibit A, # 4 Exhibit B–1, # 5 Exhibit B–2, # 6 Exhibit C, # 7 Exhibit D, # 8 Exhibit E, # 9 Exhibit F, # 10 Exhibit G, # 11 Exhibit H, # 12 Exhibit I, # 13 Exhibit J, # 14 Exhibit K, # 15 Exhibit L, # 16 Exhibit M, # 17 Exhibit N, # 18 Exhibit O, # 19 Exhibit P, # 20 Exhibit Q, # 21 Exhibit R, # 22 Exhibit S, # 23 Exhibit T, # 24 Exhibit U, # 25 Exhibit V, # 26 Exhibit W, # 27 Exhibit X, # 28 Text of Proposed Order)(Schultz, William). Added MOTION for Permanent Injunction on 9/12/2018 (znmw). (Entered: 09/05/2018)
09/05/2018	3		NOTICE OF RELATED CASE by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM. Case related to Case No. 17–cv–2447. (Schultz, William) (Entered: 09/05/2018)
09/05/2018	4		LCvR 7.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by AMERICAN HOSPITAL ASSOCIATION (Schultz, William) (Entered: 09/05/2018)
09/05/2018	5		LCvR 7.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by ASSOCIATION OF AMERICAN MEDICAL COLLEGES (Schultz, William) (Entered: 09/05/2018)
09/05/2018	6		LCvR 7.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by AMERICA'S ESSENTIAL HOSPITALS (Schultz, William) (Entered: 09/05/2018)
09/05/2018	7		LCvR 7.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by EASTERN MAINE HEALTHCARE SYSTEMS (Schultz, William) (Entered: 09/05/2018)
09/05/2018	8		LCvR 7.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by HENRY FORD HEALTH SYSTEM (Schultz, William) (Entered: 09/05/2018)
09/05/2018	9		LCvR 7.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by FLETCHER HOSPITAL, INC. (Schultz, William) (Entered: 09/05/2018)
09/05/2018			Case Assigned to Judge Rudolph Contreras. (zmd) (Entered: 09/06/2018)

09/06/2018	10		SUMMONS (2) Issued Electronically as to ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Summons 2nd) (zmd) (Entered: 09/06/2018)
09/06/2018	11		NOTICE of Appearance by Ezra Marcus on behalf of All Plaintiffs (Marcus, Ezra) (Entered: 09/06/2018)
09/10/2018	12		NOTICE of Appearance by Justin Michael Sandberg on behalf of All Defendants (Sandberg, Justin) (Entered: 09/10/2018)
09/13/2018	13		RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to Federal Defendants; ALEX M. AZAR II & DEPARTMENT OF HEALTH AND HUMAN SERVICES. Date of Service 9/12/2018. (Schultz, William) Modified on 9/24/2018 to correct party served (jf). (Entered: 09/13/2018)
09/14/2018	14		MOTION to Dismiss by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Exhibit, # 2 Exhibit, # 3 Text of Proposed Order)(Sandberg, Justin) (Entered: 09/14/2018)
09/14/2018	15		RESPONSE re 2 MOTION for Preliminary Injunction *and Permanent Injunction* MOTION for Permanent Injunction filed by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Exhibit, # 2 Exhibit)(Sandberg, Justin) (Entered: 09/14/2018)
09/26/2018	16		RESPONSE re 14 MOTION to Dismiss *and Reply in Support of 2 Motion for Preliminary and Permanent Injunction* filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM. (Attachments: # 1 Supplemented Exhibit L, # 2 Supplemented Exhibit N, # 3 Supplemented Exhibit P, # 4 Supplemented Exhibit R, # 5 Exhibit Y)(Marcus, Ezra) (Entered: 09/26/2018)
09/26/2018	18		REPLY to opposition to motion re 2 MOTION for Preliminary Injunction *and Permanent Injunction* MOTION for Permanent Injunction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM. (See Docket Entry 16 to view document) (tth) (Entered: 10/01/2018)
09/28/2018	17		Unopposed MOTION for Extension of Time to File Response/Reply as to 14 MOTION to Dismiss by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Text of Proposed Order)(Sandberg, Justin) (Entered: 09/28/2018)
09/28/2018			MINUTE ORDER granting 17 Defendants' Unopposed Motion for Extension of Time: It is hereby ORDERED that Defendants may file a reply brief in support of their motion to dismiss on or before October 10, 2018. SO ORDERED. Signed by Judge Rudolph Contreras on September 28, 2018. (lcrc3) (Entered: 09/28/2018)
10/09/2018	19		NOTICE *of Administrative Decision* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, EASTERN MAINE HEALTHCARE

			SYSTEMS, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM (Attachments: # 1 EAJR Ruling)(Marcus, Ezra) (Entered: 10/09/2018)
10/10/2018	20		REPLY to opposition to motion re 14 MOTION to Dismiss filed by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 10/10/2018)
10/19/2018	21		NOTICE *of Party Name Change* by EASTERN MAINE HEALTHCARE SYSTEMS (Marcus, Ezra) (Entered: 10/19/2018)
11/06/2018	22		NOTICE of Change of Address by Justin Michael Sandberg (Sandberg, Justin) (Entered: 11/06/2018)
12/03/2018	23		NOTICE *of Administrative Decisions* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Supplemented Exhibit I, # 2 Supplemented Exhibit J)(Marcus, Ezra) (Entered: 12/03/2018)
12/27/2018	24		ORDER denying 14 Defendants' Motion to Dismiss; granting 2 Plaintiffs' Motion for a Permanent Injunction; and denying as moot 2 Plaintiffs' Motion for a Preliminary Injunction. See document for details. Signed by Judge Rudolph Contreras on December 27, 2018. (lcrc3) (Entered: 12/27/2018)
12/27/2018	25		MEMORANDUM OPINION denying 14 Defendants' Motion to Dismiss; granting 2 Plaintiffs' Motion for a Permanent Injunction; and denying as moot 2 Plaintiffs' Motion for a Preliminary Injunction. See document for details. Signed by Judge Rudolph Contreras on December 27, 2018. (lcrc3) (Entered: 12/27/2018)
01/06/2019	26		MOTION to Stay *Due to Lapse in Appropriations* by ALEX M. AZAR II, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Text of Proposed Order)(Sandberg, Justin) (Entered: 01/06/2019)
01/07/2019	27		RESPONSE re 26 MOTION to Stay *Due to Lapse in Appropriations* filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Text of Proposed Order)(Marcus, Ezra) (Entered: 01/07/2019)
01/09/2019	28		NOTICE OF SUPPLEMENTAL AUTHORITY by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 USCA Order)(Marcus, Ezra) (Entered: 01/09/2019)
01/23/2019	29		Unopposed MOTION for Extension of Time to File *Brief on Remedy* by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Text of Proposed Order)(Sandberg, Justin) (Entered: 01/23/2019)
01/24/2019			MINUTE ORDER granting 29 Defendants' Unopposed Motion for Extension of Time. It is hereby ORDERED that the parties shall file their supplemental briefs

			regarding the appropriate remedy on or before January 31, 2019. SO ORDERED. Signed by Judge Rudolph Contreras on January 24, 2019. (lcrc3) (Entered: 01/24/2019)
01/31/2019	30		NOTICE of Appearance by Margaret M. Dotzel on behalf of All Plaintiffs (Dotzel, Margaret) (Entered: 01/31/2019)
01/31/2019	31		MEMORANDUM by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # 1 Declaration)(Sandberg, Justin) (Entered: 01/31/2019)
01/31/2019	32		MEMORANDUM by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Attachments: # 1 Exhibit A)(Marcus, Ezra) (Entered: 01/31/2019)
01/31/2019			MINUTE ORDER denying as moot 26 Defendants' Motion to Stay, given the restoration of appropriations to the Department of Justice. SO ORDERED. Signed by Judge Rudolph Contreras on January 31, 2019. (lcrc3) (Entered: 01/31/2019)
02/07/2019	33		Unopposed MOTION for Leave to File *Amicus Curiae Brief* by FEDERATION OF AMERICAN HOSPITALS (Attachments: # 1 Exhibit A – Amicus Brief, # 2 Text of Proposed Order)(Carroll, Kelly) (Entered: 02/07/2019)
02/07/2019	34		Unopposed MOTION for Leave to File *Supplemental Complaint* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Text of Proposed Order)(Marcus, Ezra) (Entered: 02/07/2019)
02/08/2019			MINUTE ORDER granting 33 Unopposed Motion for Leave to File Amicus Curiae Brief. It is hereby ORDERED that the Amicus Curiae brief attached to the motion (ECF No. 33-1) is DEEMED FILED. SO ORDERED. Signed by Judge Rudolph Contreras on February 8, 2019. (lcrc3) (Entered: 02/08/2019)
02/08/2019			MINUTE ORDER granting 34 Plaintiffs' Unopposed Motion for Leave to File Supplemental Complaint. It is hereby ORDERED that Exhibit C to Plaintiffs' motion (ECF No. 34-3) is deemed filed and served as the operative pleading in this case. SO ORDERED. Signed by Judge Rudolph Contreras on February 8, 2019. (lcrc3) (Entered: 02/08/2019)
02/08/2019	38		AMICUS BRIEF by FEDERATION OF AMERICAN HOSPITALS. (znmw) (Entered: 02/20/2019)
02/08/2019	39		SUPPLEMENTAL COMPLAINT against ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES filed by FLETCHER HOSPITAL, INC., AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AMERICAN HOSPITAL ASSOCIATION, NORTHERN LIGHT HEALTH, HENRY FORD HEALTH SYSTEM.(znmw) (Entered: 02/20/2019)
02/11/2019	35		

			MOTION for Permanent Injunction by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Text of Proposed Order)(Schultz, William) (Entered: 02/11/2019)
02/14/2019	36		RESPONSE *Regarding Appropriate Remedy* filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 02/14/2019)
02/14/2019	37		SUPPLEMENTAL MEMORANDUM to re 24 Order on Motion for Preliminary Injunction,, Order on Motion for Permanent Injunction,, Order on Motion to Dismiss, filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Dotzel, Margaret) (Entered: 02/14/2019)
02/21/2019	40		MOTION for Leave to File *Amicus Curiae Brief of the Federation of American Hospitals in Response to Defendants Opposition Brief on Remedy* by FEDERATION OF AMERICAN HOSPITALS (Attachments: # 1 Exhibit A – FAH Response Brief, # 2 Text of Proposed Order)(Carroll, Kelly) (Entered: 02/21/2019)
02/22/2019	41		NOTICE OF APPEAL TO DC CIRCUIT COURT by UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II. Fee Status: No Fee Paid. Parties have been notified. (Sandberg, Justin) (Entered: 02/22/2019)
02/22/2019	42		Partial MOTION to Dismiss , Partial MOTION to Dismiss for Lack of Jurisdiction by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Text of Proposed Order)(Sandberg, Justin) (Entered: 02/22/2019)
02/22/2019	43		Memorandum in opposition to re 35 MOTION for Permanent Injunction filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 02/22/2019)
02/25/2019	44		Transmission of the Notice of Appeal, Order Appealed (Memorandum Opinion), and Docket Sheet to US Court of Appeals. The Court of Appeals docketing fee was not paid because the appeal was filed by the government re 41 Notice of Appeal to DC Circuit Court. (tth) (Entered: 02/25/2019)
02/26/2019	45		REPLY to opposition to motion re 35 MOTION for Permanent Injunction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Marcus, Ezra) (Entered: 02/26/2019)
02/26/2019	46		Memorandum in opposition to re 42 Partial MOTION to Dismiss Partial MOTION to Dismiss for Lack of Jurisdiction filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT

			HEALTH. (Marcus, Ezra) (Entered: 02/26/2019)
02/28/2019			USCA Case Number 19-5048 for 41 Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (zrdj) (Entered: 02/28/2019)
03/15/2019	47		NOTICE Of Motion to Stay Appeal by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Exhibit Motion to Hold Appeal in Abeyance)(Schultz, William) (Entered: 03/15/2019)
03/27/2019	48		ORDER of USCA as to 41 Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ; USCA Case Number 19-5048. (zrdj) (Entered: 04/01/2019)
05/06/2019	49		ORDER granting in part and denying in part 35 motion for permanent injunction; granting 40 motion for leave to file; denying 42 motion to dismiss: See document for details. Signed by Judge Rudolph Contreras on 5/6/19. (lcrc1) (Entered: 05/06/2019)
05/06/2019	50		MEMORANDUM OPINION granting in part and denying in part 35 motion for permanent injunction; granting 40 motion for leave to file; denying 42 motion to dismiss: See document for details. Signed by Judge Rudolph Contreras on 5/6/19. (lcrc1) (Entered: 05/06/2019)
05/10/2019	51		MOTION for a Firm Date by which Defendants Must Propose a Remedy , MOTION to Expedite *Response Deadline* by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH (Attachments: # 1 Text of Proposed Order, # 2 Text of Proposed Order)(Marcus, Ezra) (Entered: 05/10/2019)
05/22/2019			Set/Reset Deadlines: Status Report due by 8/5/2019 (tj) (Entered: 05/22/2019)
05/23/2019	52		Unopposed MOTION for Extension of Time to File Response/Reply *to Motion to Submit Proposed Remedy* by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Text of Proposed Order)(Sandberg, Justin) (Entered: 05/23/2019)
05/24/2019			MINUTE ORDER granting 52 Defendants' Unopposed Motion for Extension of Time. It is hereby ORDERED that Defendants shall respond to 51 Plaintiffs' Motion for a Firm Date By Which Defendants Must Propose a Remedy for Violations of the Medicare Act on or before May 31, 2019. SO ORDERED. Signed by Judge Rudolph Contreras on May 24, 2019. (lcrc3) (Entered: 05/24/2019)
05/24/2019			Set/Reset Deadlines: Defendants response to 51 Plaintiffs' Motion for a Firm Date By Which Defendants Must Propose a Remedy for Violations of the Medicare Act due by 5/31/2019 (hs) (Entered: 05/24/2019)
05/31/2019	53		RESPONSE re 51 MOTION for a Firm Date by which Defendants Must Propose a Remedy MOTION to Expedite *Response Deadline* filed by ALEX

			M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 05/31/2019)
06/03/2019	54		MOTION for Entry of Final Judgment , MOTION for Reconsideration *of May 6, 2019 Order*, MOTION to Expedite *Briefing* by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (Attachments: # 1 Text of Proposed Order)(Sandberg, Justin) (Entered: 06/03/2019)
06/04/2019			MINUTE ORDER: Upon consideration of 54 Defendants' Motion for Reconsideration, Entry of Final Judgment, and Expedited Briefing, it is hereby ORDERED that the motion for expedited consideration is GRANTED. It is FURTHER ORDERED that Plaintiffs shall file their response brief to Defendants' motion by no later than June 11, 2019. SO ORDERED. Signed by Judge Rudolph Contreras on June 4, 2019. (lcrc3) (Entered: 06/04/2019)
06/04/2019	55		REPLY to opposition to motion re 51 MOTION for a Firm Date by which Defendants Must Propose a Remedy MOTION to Expedite *Response Deadline* filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Marcus, Ezra) (Entered: 06/04/2019)
06/07/2019	56		RESPONSE re 54 MOTION for Entry of Final Judgment MOTION for Reconsideration *of May 6, 2019 Order* MOTION to Expedite *Briefing* filed by AMERICA'S ESSENTIAL HOSPITALS, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FLETCHER HOSPITAL, INC., HENRY FORD HEALTH SYSTEM, NORTHERN LIGHT HEALTH. (Marcus, Ezra) (Entered: 06/07/2019)
06/10/2019	57		REPLY to opposition to motion re 54 MOTION for Entry of Final Judgment MOTION for Reconsideration *of May 6, 2019 Order* MOTION to Expedite *Briefing* filed by ALEX M. AZAR II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Sandberg, Justin) (Entered: 06/10/2019)
07/09/2019			MINUTE ORDER: It is hereby ORDERED that the parties shall appear for a status conference on July 10, 2019, at 10:30 AM in Courtroom 14 before Judge Rudolph Contreras. SO ORDERED. Signed by Judge Rudolph Contreras on July 9, 2019. (lcrc3) (Entered: 07/09/2019)
07/09/2019			Set/Reset Hearings: Status Conference set for 7/10/2019 at 10:30 AM in Courtroom 14 before Judge Rudolph Contreras. (tj) (Entered: 07/09/2019)
07/10/2019			Minute Entry for proceedings held before Judge Rudolph Contreras: Status Conference held on 7/10/2019. Parties inform the court of the status of this action. (Court Reporter: Patricia Kaneshiro Miller.) (tj) (Entered: 07/10/2019)
07/10/2019	58	14	ORDER granting 54 Defendants' Motion for Entry of Final Judgment and denying as moot 51 Plaintiffs' Motion for a Firm Date. See document for details. Signed by Judge Rudolph Contreras on July 10, 2019. (lcrc3) Modified on 7/10/2019 (lcrc3,). Modified on 7/10/2019 (lcrc3). (Entered: 07/10/2019)
07/10/2019	59	15	MEMORANDUM OPINION granting 54 Defendants' Motion for Entry of Final Judgment and denying as moot 51 Plaintiffs' Motion for a Firm Date. See

			document for details. Signed by Judge Rudolph Contreras on July 10, 2019. (lcrc3) (Entered: 07/10/2019)
07/11/2019	60	12	NOTICE OF APPEAL TO DC CIRCUIT COURT by UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II. Fee Status: No Fee Paid. Parties have been notified. (Sandberg, Justin) (Entered: 07/11/2019)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001,

THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K Street, NW, Suite 100
Washington, DC 20001,

AMERICA'S ESSENTIAL HOSPITALS,
401 Ninth Street, NW, Suite 900
Washington, DC 20004,

EASTERN MAINE HEALTHCARE SYSTEMS,
43 Whiting Hill Road
Brewer, ME 04412,

HENRY FORD HEALTH SYSTEM,
1 Ford Place
Detroit, MI 48202, and

FLETCHER HOSPITAL, INC., d/b/a PARK RIDGE HEALTH,
100 Hospital Drive
Hendersonville, NC 28792,

Plaintiffs,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case No. _____

COMPLAINT

The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc. d/b/a Park Ridge Health bring this action against Defendants Department of Health and Human Services ("HHS") and Alex M. Azar II, in his official capacity as the Secretary of HHS, and allege the following:

NATURE OF ACTION

1. Plaintiffs bring this action under the Social Security Act and the Administrative Procedure Act ("APA") to challenge certain provisions of a final rule issued on November 1, 2017, by the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS. *See* 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017). The rule concerns the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Year 2018. The portions of the rule being challenged in this case reduced by nearly 30% Medicare reimbursements to certain public and not-for-profit hospitals and clinics for prescription drugs purchased by those institutions on a discounted basis under section 340B of the Public Health Service Act (the "340B Program"). These challenged portions of the rule will hereafter be referred to as the "340B Provisions of the OPPS Rule" or "the OPPS Rule." The 340B Provisions of the OPPS Rule took effect on January 1, 2018.

2. Congress enacted the 340B Program in 1992 and through that Program lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. By lowering hospitals' purchase costs for patient drugs, Congress enabled these hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R.

REP. No. 102–384(II), at 12 (1992). *See also* 82 Fed. Reg. at 52,493 & n.18 (quoting House report and noting that "[t]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients"). The 340B Provisions of the new OPPS Rule specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The new OPPS Rule eliminates nearly all of the differential between national Medicare reimbursement rates and the discounted purchase costs mandated for 340B hospitals, costing those hospitals an estimated (by CMS) $1.6 billion, in violation of both the Secretary's statutory authority under the Social Security Act to reimburse hospitals for outpatient drugs and the purpose and design of the Public Health Service Act provisions establishing the 340B program.

3. Plaintiffs American Hospital Association, Association of American Medical Colleges, and America's Essential Hospitals (the "Association Plaintiffs") are hospital associations whose members, including Plaintiffs Eastern Maine Healthcare Systems, Park Ridge Health, and Henry Ford Health System (the "Hospital Plaintiffs"), have used the 340B Program to provide critical healthcare services to their communities, including to underserved patient populations in those communities. Those hospitals and their poor and underserved patient populations have suffered, and will continue to suffer, harm from the negation of the cost-reimbursement differential through the 340B Provisions of the OPPS Rule. Plaintiffs are entitled to declaratory and injunctive relief, including a preliminary injunction setting aside the 340B Provisions of the OPPS Rule pending resolution of this action.

PARTIES

4. Plaintiff American Hospital Association ("AHA") is a national not-for-profit organization headquartered in Washington, D.C. AHA represents and serves nearly 5,000

hospitals, health care systems, and networks, plus 43,000 individual members (largely hospital professional staff). AHA's mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to their communities and committed to health improvement. AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It also ensures that members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters.

5. Many of AHA's member hospitals participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for the vulnerable populations they serve. These AHA members have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rule and will continue to be significantly harmed if the OPPS Rule remains in effect.

6. Plaintiff Association of American Medical Colleges ("AAMC") is a national not-for-profit association headquartered in Washington, D.C. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its membership consists of all 151 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

7. Many of AAMC's member teaching hospitals participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for their communities, including vulnerable populations in those communities. These AAMC members have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rule and will continue to be significantly harmed if the OPPS Rule remains in effect.

8. Plaintiff America's Essential Hospitals ("AEH") is a national not-for-profit association headquartered in Washington, D.C. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Since 1981, AEH has initiated, advanced, and preserved programs and policies that help these hospitals ensure access to care. Its 325 hospital members are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

9. Almost all of AEH's member hospitals participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for the communities they serve, including vulnerable populations within those communities. These AEH members have been significantly harmed by the elimination of this differential from Medicare payments in the OPPS Rule and will continue to be significantly harmed if the OPPS Rule remains in effect.

10. Plaintiff Eastern Maine Healthcare Systems ("EMHS") is an integrated health care system headquartered in Brewer, Maine, near Bangor, Maine, and is a member of the Plaintiff AHA. EMHS provides services throughout virtually the entire State of Maine – including both the urban populations in south and central Maine and the rural populations

residing in Maine's economically challenged northern and eastern regions. EMHS-affiliated entities employ over 700 physicians providing access to care for the 93% of Maine's population living in EMHS service areas.

11. Maine has the oldest population of any state and the largest percentage of Medicare eligible citizens in the nation. A large percentage of EMHS's services is provided to elderly and disadvantaged populations.

12. The 340B Provisions of the OPPS Rule severely threaten EMHS's ability to provide critical healthcare programs to its communities, including the underserved populations in those communities, by depriving it of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

13. Plaintiff Henry Ford Health System ("Henry Ford") is a not-for-profit integrated health care delivery system headquartered in Detroit, Michigan. Henry Ford serves the metropolitan Detroit and Jackson areas of Michigan. The system has 30,000 employees, 26 medical centers, six acute care hospitals with a total of 2,405 inpatient beds, including its flagship hospital—Henry Ford Hospital ("HFH")—a large academic safety net hospital located within the city of Detroit, and Henry Ford Allegiance, ("HF Allegiance") located in the city of Jackson. HFH is a member of Plaintiffs AHA, AAMC, and AEH. HF Allegiance is a member of Plaintiff AHA.

14. Located in Detroit's Midtown, HFH has served the Detroit community—which has the highest rate of concentrated poverty among the top 25 metro areas in the United States—for over 100 years. HFH is an 877-bed tertiary care hospital, education and research center, which provides comprehensive and advanced inpatient and outpatient care. HFH is also a Level 1 trauma center and one of the largest U.S. teaching hospitals.

15. Located in Jackson, HF Allegiance is a 475-bed healthcare organization that has served as the sole health system for the south central Michigan community since 1918. With more than 400 physicians, HF Allegiance's network of 40 facilities complements traditional acute care with mission-based services to address the health needs of its economically-challenged, underserved community. Jackson has a median income of $28,000 and a 36% poverty rate.

16. By depriving Henry Ford of millions of dollars previously generated by the differential between Medicare reimbursements and 340B discounts, the 340B Provisions of the OPPS Rule severely threaten the ability of Henry Ford, including HFH and HF Allegiance, to provide critical healthcare programs to their communities, including the underserved populations in those communities.

17. Plaintiff Park Ridge Health ("Park Ridge") is a not-for-profit health care system headquartered in Hendersonville, North Carolina, south of Asheville, North Carolina, and is a member of the Plaintiff AHA. Park Ridge employs 119 doctors, nurses and other healthcare professionals who practice at 30 locations across Henderson, Buncombe, and Haywood Counties. Park Ridge is part of Adventist Health System ("AHS"), a network of approximately 45 Seventh-day Adventist-affiliated hospitals, as well as skilled nursing facilities, physician offices, home health agencies, hospice providers, and urgent care facilities in nine states.

18. The communities Park Ridge serves contain a large percentage of elderly and retired persons, including a large number of Medicare beneficiaries. In fiscal year 2016, Medicare was responsible for approximately 52% of Park Ridge's gross revenues. The 340B Provisions of the OPPS Rule severely threaten Park Ridge's ability to provide critical healthcare programs to its communities, including the underserved populations in those communities, by

depriving it of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

19. Defendant HHS is a cabinet-level department of the United States government headquartered at 200 Independence Avenue, SW, Washington, D.C. 20201. CMS, which issued the 340B Provisions of the OPPS Rule, is an agency within HHS.

20. Defendant Alex M. Azar II ("the Secretary") is the Secretary of Health and Human Services") and maintains offices at 200 Independence Avenue, SW, Washington, D.C. 20201. In that capacity, he is responsible for the conduct and policies of HHS, including the conduct and policies of CMS. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

21. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Administrative Procedure Act, 5 U.S.C. § 701–06.

22. This Court has subject matter jurisdiction over this action under 42 U.S.C. § 405 and 28 U.S.C. § 1331.

23. This judicial district is an appropriate venue pursuant to 28 U.S.C. § 1391(e), 42 U.S.C. § 405(g), and 42 U.S.C. § 1395ff(b)(2)(C)(iii).

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

24. Congress established the 340B Program in 1992 as part of the Public Health Service Act. The 340B Program provides certain hospitals serving a disproportionate share of low-income individuals and federally-funded clinics (called "covered entities" in the statute) with outpatient prescription drug discounts comparable to those that Congress had made

available to state Medicaid agencies in 1990. Under the 340B Program, private prescription drug manufacturers, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs, are required to offer covered entities discounts calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1). As the Health Resources & Services Administration ("HRSA"), the agency within HHS responsible for administering the 340B Program, has recognized, the purpose of the Program is to enable eligible public and not-for-profit hospitals and other covered institutions to use their scarce resources to reach more patients, and to provide more comprehensive services.

25. Since the 340B Program was first implemented, covered entities have retained all savings generated through the program and have used those savings to provide additional critical healthcare services for their communities, including underserved populations within those communities – for example, by increasing service locations, developing patient education programs, and providing translation and transportation services.

26. Recognizing the value of the 340B Program, Congress has increased the categories of eligible "covered entities." In 1992, when Congress first created the Program, "covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income populations. *See* 42 U.S.C. §§ 256b(a)(4)(A)-(E), (G), (L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O).

27. Each of the Hospital Plaintiffs and many other members of the Association Plaintiffs are "covered entities" under the 340B Program and are paid under the OPPS system.

B. Medicare OPPS Reimbursement

28. In 1997, Congress acted to control Medicare expenditures for outpatient services and directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient departments, for example rehabilitation services. *See* 42 U.S.C. § 1395*l*. CMS updates the OPPS payment rates annually.

29. Beginning in 2004, Congress required CMS to set reimbursement rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled into the price of an outpatient service. These drugs include outpatient drugs covered under the 340B program.

30. A provision of the statute provides CMS with two choices in setting Medicare reimbursement rates for separately payable drugs in 2006 and subsequent years. Under Subclause I of that statutory provision, CMS must set rates based on the acquisition costs of these drugs, if specified statistically sound survey data on acquisition cost are available for each drug. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Under Subclause II, if the specified acquisition cost data are not available, CMS is required to reimburse based on average sales price ("ASP")—a defined quantity under a different statutory provision—plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

31. In 2012, after concluding that it could not obtain the acquisition cost required in order to reimburse under Subclause I based on acquisition cost, CMS adopted the reimbursement method under Subclause II - the statutory default rate of ASP plus 6% - for all separately payable drugs. CMS applied this statutory default rate without further adjustments for each subsequent year, until January 1, 2018.

C. CMS's Proposed and Final Rule to Reduce Payment Rate for 340B Drugs

32. On July 13, 2017, CMS issued its proposed rule on OPPS and Ambulatory Surgical Center payment systems for the Calendar Year 2018. In addition to updating the OPPS with 2018 rates, CMS proposed to change how Medicare pays certain hospitals for separately payable drugs purchased under the 340B Program. 82 Fed. Reg. 33,558, 33,634 (July 20, 2017). Specifically, CMS proposed lowering the government payment rate for such drugs from the previous (statutory default) rate of ASP plus 6% to ASP minus 22.5% - a reduction in the reimbursement rate of 28.5 %. *Id.* at 33,634.

33. CMS admitted that its reason for proposing this reduction was that a lower reimbursement rate would better reflect the acquisition cost of the drugs. According to CMS, the new rate would better recognize "the significantly lower acquisition costs of such drugs incurred by a 340B hospital," *id.*, and "better represent[] the average acquisition cost for these drugs and biologicals," *id.* at 33634. On November 1, 2017, CMS issued the final version of the 340B Provisions of the OPPS rule, adopting the proposed rate of ASP minus 22.5% for drugs purchased under the 340B Program. 82 Fed. Reg. 52,356, 52,362.

34. This new reimbursement rate nearly eliminated the benefit of the 340B program for certain covered entities for Medicare/340B drugs by eliminating the difference between the purchase price paid *by* hospitals for those drugs and Medicare payments *to* hospitals for those drugs.

35. In reducing the payment rate for certain 340B drugs by nearly 30%, CMS purported to rely on its authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which allows the Secretary to "calculate" and "adjust" the statutory default rate of ASP plus 6%. *E.g.*, 82 Fed. Reg. at 52,499 (noting that "calculate and adjust" authority gives the Secretary "broad

discretion" to adjust payments for drugs). The 340B Provisions of the OPPS Rule exceed the Secretary's authority because the reduction set forth in the Rule is expressly based on the estimated acquisition costs of 340B drugs, *i.e.*, a variation of the cost-based methodology set forth under Subclause I of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). *E.g.*, 82 Fed. Reg. at 52,501. Because CMS, by its own admission, cannot now and has never been able to reliably collect the statistically significant cost data for each drug required under the statute to invoke Subclause I, it improperly sought to use *aggregate* acquisition costs as estimated by the Medicare Payment Advisory Commission ("MedPAC") as a proxy for that data in issuing the OPPS Rule – even though payment under Subclause II expressly must be based on average sales price, *not* acquisition costs. In doing so, the Secretary impermissibly invoked his authority under Subclause II to circumvent the requirements under Subclause I.

36. The Secretary's authority under Subclause II of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), to "calculate" and "adjust" the ASP-plus-6% formula, does not allow CMS to reduce the statutory rate by nearly 30%, depriving affected hospitals of drug-price savings totaling an estimated $1.6 billion (CMS's estimate). Rather, this authority only permits the Secretary to calculate the ASP as set forth in the statute and to fine-tune the default rate.

37. The 340B Provisions of the OPPS Rule also exceed the Secretary's authority because they undermine the 340B Program by depriving eligible hospitals of a critical portion of the resources Congress intended to provide those hospitals through 340B discounts. Elimination of these resources has and will continue to put public and not-for-profit covered entities into even more precarious financial situations, curtailing their ability to provide essential healthcare services and programs to their communities, including underserved populations within those

communities. This is inconsistent with the intent of the 340B program, which was designed to help covered entities stretch scarce federal resources to reach more patients. CMS's efforts in the 340B Provisions of the OPPS Rule to "align" (82 Fed. Reg. at 52,495) the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congress' intent to create a differential between reimbursements and purchase prices and thereby to generate resources for covered entities to use in their communities.

38. The new payment rate set forth in the 340B Provisions of the OPPS Rule has substantially impacted the day-to-day operations of many covered entities, including the Hospital Plaintiffs and other members of the Association Plaintiffs. These entities rely on the 340B savings, and the price differential Congress created through that program, to provide vital health services to their communities, including vulnerable and underserved populations within those communities. Elimination of the differential in connection with Medicare payments for 340B drugs will threaten many of these critical programs, and thus the poor and underserved populations who depend on 340B hospitals, in direct contravention of the purpose and design of the 340B program.

39. On July 25, 2018, HHS issued a notice of proposed rulemaking for the 2019 OPPS Rule. With minor modifications, the Proposed 2019 OPPS Rule would "continue the 340B Program policies that were implemented in [calendar year] 2018"—*i.e.* the policy of "pay[ing] for separately payable Medicare Part B drugs . . . that are acquired through the 340B Program at ASP minus 22.5 percent." CMS, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 37,046, 37,125–26 (July 31, 2018).

ADMINISTRATIVE REVIEW OF PLAINTIFFS' CLAIMS FOR PAYMENT

40. After a health-care provider performs Medicare-eligible services, it submits a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). The MAC makes an initial determination whether to pay the claim, and if so, how much to pay. 42 C.F.R. § 405.920. If the MAC denies a claim for payment in whole or in part, the Social Security Act provides a four-level administrative appeal process. First, the provider may present its claim again to the MAC for "redetermination." 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Second, the provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960. Third, the provider may seek *de novo* review by an administrative law judge in the Office of Medicare Hearings and Appeals. 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. §405.1000–58. If, however, an appeal turns on a question of law or regulation and does not present any material disputes of fact, then after or simultaneous with requesting third-level review by an administrative law judge, a provider may ask the Departmental Appeals Board to certify the appeal for expedited access to judicial review. 42 U.S.C. § 1395ff(b)(1)(A), (b)(2); 42 C.F.R. § 405.990. Fourth, the provider may seek *de novo* review by the Medicare Appeals Council, which is a part of the HHS Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 1100.

41. If HHS's final decision after this process is unfavorable, a provider may seek judicial review. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 1136.

A. Henry Ford Health System

42. On January 9, 2018, Henry Ford presented a claim for payment to WPS Government Health Administrators ("WPS"), a MAC, for separately payable drugs subject to the 340B Program. On January 25, 2018, WPS issued an initial determination advising Henry Ford

that the claim would be labeled 21800900583604MIA (hereinafter "Claim '604") and that $5,031.81 would be remitted to Henry Ford on that claim.

43. On January 10, 2018, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21801000637704MIA (hereinafter "Claim '704") and that $10,533.62 would be remitted to Henry Ford on that claim.

44. On January 10, 2018, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21801000640004MIA (hereinafter "Claim '004") and that $3,734.85 would be remitted to Henry Ford on that claim.

45. Consistent with the payment reduction in the 340B Provisions of the OPPS Rule, WPS's payments on Claims '604, '704, and '004 were approximately 30% less than what it had paid Henry Ford on identical claims in 2017. On February 8, 2018, Henry Ford submitted redetermination requests to WPS for each of the three claims in which it demanded full reimbursement in the amount of $7,344.77 on Claim '604, $14,876.96 on Claim '704, and $5,451.99 on Claim '004. On each of the three redetermination request forms, Henry Ford contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(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.

46. On March 6, 2018, WPS issued unfavorable decisions on each of Henry Ford's three redetermination requests, correctly explaining in each of the three redetermination letters

that the amount it had already paid was "the maximum payment allowed by Medicare" for the service at issue.

47. On March 27, 2018 (Claims '604 and '004) and April 10, 2018 (Claim '704), Henry Ford submitted reconsideration requests regarding its three claims to Maximus Federal Services ("Maximus"), a QIC. In each of its three reconsideration requests, Henry Ford raised the same argument that it had raised in its redetermination requests to WPS.

48. Maximus initially issued favorable reconsideration decisions on each of Henry Ford's three claims on May 22, 2018 (Claim '004) and June 1, 2018 (Claims '604 and '704), stating that Henry Ford "was underpaid" on each claim. However, after CMS recouped the payments on Claims '704 and '004, it reprocessed those claims and reissued payments for exactly the same lower amounts that it had issued previously in conformity with the new OPPS Rule. CMS never reprocessed Claim '604. Henry Ford later learned that each of the three appeals had been reopened at the direction of CMS, which had determined that there are no administrative appeal rights for claims related to the 340B Program. Henry Ford subsequently received letters regarding each of its three reconsideration requests from Maximus, all dated July 11, 2018, in which Maximus stated that each of the three reopened appeals "ha[d] been deleted from our system" and that "MAXIMUS will not be issuing a new reconsideration decision at this time." These letters constituted dismissals of each of Henry Ford's three appeals. To date, Henry Ford has not been paid any amount of money on any of its three claims other than the deficient initial remittances made pursuant to the new OPPS Rule.

49. On August 2, 2018, Henry Ford submitted requests to the Office of Medicare Hearings and Appeals for review by an Administrative Law Judge ("ALJ") of Maximus's decisions on each of Henry Ford's three reconsideration requests. In each of its three ALJ

hearing requests, Henry Ford raised the same argument that it had raised in its redetermination requests to WPS and in its reconsideration requests to Maximus.

50. On August 10, 2018, Henry Ford submitted a request to the Departmental Appeals Board for expedited access to judicial review pursuant to 42 C.F.R. § 405.990 on its three appeals. The request explained that there are no material facts in dispute and that Henry Ford's challenge to the remittances on its three claims turns on purely legal disputes about the whether the 2018 changes to the 340B Program exceeded Secretary's statutory authority to adjust reimbursement rates and whether administrative and judicial review of such challenges is available.

51. In light of these events, Henry Ford has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

B. Eastern Maine Healthcare Systems

52. On January 23, 2018, EMHS presented a claim for payment to National Government Services ("NGS"), a MAC, for separately payable drugs subject to the 340B Program. On February 6, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21802300601207MEA (hereinafter "Claim '207"), and that a total of $4,826.63 would be remitted to EMHS on that claim.

53. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700697107MEA

(hereinafter "Claim '107"), and that a total of $4,826.63 would be remitted to EMHS on that claim.

54. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700743607MEA (hereinafter "Claim '607") and that a total of $4,598.67 would be remitted to EMHS on that claim.

55. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700741907MEA (hereinafter "Claim '907") and that a total of $3,338.66 would be remitted to EMHS on that claim.

56. On February 6, 2018, EMHS presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 21, 2018, NGS issued an initial determination advising EMHS that the claim would be labeled 21803700775907MEA (hereinafter "Claim '5907") and that a total of $3,083.06 would be remitted to EMHS on that claim.

57. Consistent with the payment reduction in the 340B Provisions of the OPPS Rule, NGS's payments on Claims '207, '107, '607, '907, and '5907 were approximately 30% less than what it had paid EMHS on identical claims in 2017. On March 19, 2018, EMHS submitted redetermination requests to NGS for each of the five claims in which it demanded full reimbursement in the amount of $7,045.30 on Claim '207, $7,045.30 on Claim '107, $6,712.57 on Claim '607, $4,873.33 on Claim '907, and $4,500.23 on Claim '5907. On each of the five

redetermination request forms, EMHS contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(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.

58. On May 30, 2018 (Claim '607), May 31, 2018 (Claims '207 and '107), and June 1, 2018 (Claims '907 and '5907), NGS issued letters dismissing EMHS's five redetermination requests on the grounds that "[42 U.S.C. § 1395w-4(i)(1)] prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) and 42 U.S.C. § 1395*l*(t)(12)(A), (C), (E))."

59. On July 17, 2018 EMHS submitted reconsideration requests regarding its five claims to C2C Solutions, Inc., a QIC. In each of its five reconsideration requests, EMHS raised the same argument that it had raised in its redetermination requests to NGS.

60. In light of these events, EMHS has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

C. Park Ridge Health

61. On February 5, 2018, Park Ridge presented a claim for payment to First Coast Service Options, Inc. ("First Coast"), a MAC, for separately payable drugs subject to the 340B Program. On February 20, 2018, First Coast issued an initial determination advising Park Ridge that the claim would be labeled 21803603179407FLA (hereinafter "Claim '407"), and that a total of $3,685.12 would be remitted to Park Ridge on the claim.

62. On February 7, 2018, Park Ridge presented a claim for payment to First Coast for separately payable drugs subject to the 340B Program. On February 22, 2018, First Coast issued an initial determination advising Park Ridge that the claim would be labeled 21803900902607FLA (hereinafter "Claim '2607"), and that a total of $3,685.12 would be remitted to Park Ridge on the claim.

63. Consistent with the payment reduction in the 340B Provisions of the OPPS Rule, First Coast's payments on Claims '407 and '2607 were approximately 30% less than what it had paid Park Ridge on identical claims in 2017. On May 11, 2018, Park Ridge submitted redetermination requests to First Coast for both claims in which it demanded full reimbursement in the amount of $5,342.66 on Claim '407 and $5,342.66 on Claim '2607. On both of its redetermination request forms, Park Ridge contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(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.

64. On June 1, 2018, First Coast issued letters dismissing Park Ridge's redetermination requests on the grounds that "administrative review is not available for this issue."

65. On July 23, 2018, Park Ridge submitted reconsideration requests regarding both of its two claims to C2C Solutions, Inc., a QIC. In both of its reconsideration requests, Park Ridge raised the same argument that it had raised in its redetermination requests to First Coast.

66. In light of these events, Park Ridge has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator

within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

COUNT 1

OPPS RULE – VIOLATION OF THE SOCIAL SECURITY ACT

67. Plaintiffs incorporate by reference the foregoing paragraphs.

68. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

69. The nearly 30% reduction in payment for 340B drugs under the OPPS Rule is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 2

HENRY FORD CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

70. Plaintiffs incorporate by reference paragraphs 1 through 51.

71. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

72. The remittances to Henry Ford for Claims '604, '704, and '004 reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 3

EMHS CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

73. Plaintiffs incorporate by reference paragraphs 1 through 41 and 52 through 60.

74. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

75. The remittances to EMHS for Claims '207, '107, '607, '907, and '5907 reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 4

PARK RIDGE CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

76. Plaintiffs incorporate by reference paragraphs 1 through 41 and 61 through 66.

77. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

78. The remittances to Park Ridge for Claims '407 and '2607 reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in its favor and against Defendants:

A. Declaring that the 340B Provisions of the OPPS Rule are an unlawful exercise of Defendants' authority, in violation of the Social Security Act and section 340B of the Public Health Service Act;

B. Directing Defendants to strike the changes in the payment methodology for section 340B drugs from the OPPS Rule and directing Defendants to use the methodology used in calendar year 2017 for all future 340B Program payments in 2018;

C. Directing Defendants to: reimburse Henry Ford $2,312.96 in connection with Claim '604, $4,343.34 in connection with claim '704, and $1,717.14 in connection with claim '004; reimburse EMHS $2,218.67 in connection with Claim '207, $2,218.67 in connection with Claim '107, $2,113.90 in connection with Claim '607, $1,534.67 in connection with Claim '907, and $1,417.17 in connection with Claim '5907; and reimburse Park Ridge $1,657.54 in connection with Claim '407 and $1,657.54 in connection with Claim '2607, plus prejudgment interest;

D. Directing Defendants to reimburse all Hospital Plaintiffs and all Organizational Plaintiffs' provider members for the difference between amounts already paid in 2018 for 340B drugs pursuant to the OPPS Rule and what would have been paid for those same drugs under the methodology used in calendar year 2017.

E. Directing Defendants to conform the payment methodology that they use for 340B drugs in 2019 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition costs to calculate prices unless Defendants have complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I); and

F. Granting such other relief to which Plaintiffs may be entitled at law or in equity.

Dated: September 5, 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
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wschultz@zuckerman.com
emarcus@zuckerman.com

Attorneys for Plaintiffs

AO 440 (Rev. 06/12, DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Eastern Maine Healthcare Services, Henry Ford Health System, Fletcher Hospital, Inc. *Plaintiff(s)* v. Alex M. Azar II, and the U.S. Department of Health & Human Services *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Alex M. Azar II
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

William B. Schultz
Zuckerman Spaeder LLP
1800 M Street, NW Suite 1000
Washington, DC 20036

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12, DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Eastern Maine Healthcare Services, Henry Ford Health System, Fletcher Hospital, Inc. *Plaintiff(s)* v. Alex M. Azar II, and the U.S. Department of Health & Human Services *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Alex M. Azar II
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

William B. Schultz
Zuckerman Spaeder LLP
1800 M Street, NW Suite 1000
Washington, DC 20036

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

CIVIL COVER SHEET

JS-44 (Rev. 6/17 DC)

I. (a) PLAINTIFFS

The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Henry Ford Health System, Eastern Maine Healtcare Systems, Fletcher Hospital, Inc. d/b/a Park

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF D.C.
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

Alex M. Azar II and the U.S. Department of Health and Human Servicse

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT D.C.
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

William B. Schultz, Ezra B. Marcus
Zuckerman Spaeder LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
(202) 778-1800

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY!

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A.** *Antitrust*

- ☐ 410 Antitrust

○ **B.** *Personal Injury/ Malpractice*

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ **C.** *Administrative Agency Review*

- ☒ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

◉ **D.** *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E.** *General Civil (Other)* OR ○ **F.** *Pro Se General Civil*

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ I. *FOIA/Privacy Act* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

○ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

Challenge, under 42 U.S.C. § 405(g), to Medicare determinations by CMS that violate the Social Security Act.

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☒ NO ☐ If yes, please complete related case form

DATE: Sept. 5, 2018 **SIGNATURE OF ATTORNEY OF RECORD** /s/ William B. Schultz

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

Exhibit V

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

AFFIDAVIT OF TONY FILER
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Tony Filer, state as follows under the pains and penalties of perjury.

I am the Senior Vice President & Chief Financial Officer for Eastern Maine Healthcare Systems ("EMHS"), a Plaintiff in this action. I have been employed by EMHS for one and a half years. The information set forth in this affidavit is based upon my personal knowledge.

EMHS and the Population It Serves

1. EMHS is an integrated health care system that provides services throughout virtually the entire State of Maine – including both the urban populations in south and central Maine and the rural populations residing in Maine's economically challenged northern and eastern regions.

2. Among the health delivery services/programs EMHS offers are: trauma level acute care services, general medical and critical access hospitals, a free-standing acute

psychiatric hospital, primary care and specialty physician practices, long-term care, home health care, hospice, ground and air emergency transport services.

3. EMHS-affiliated entities employ over 700 physicians providing access to care for the 93 percent of Maine's population living in EMHS service areas.

4. Access to specialist care for two-thirds of Maine's rural geography is provided overwhelmingly by physicians on the active medical staff of two Bangor based hospitals (Eastern Maine Medical Center and Acadia Hospital) in the EMHS system.

5. EMHS is a member of the American Hospital Association, another of the Plaintiffs in this case.

6. Maine's population is the oldest per capita in the country, with Medicare beneficiaries forming 23 percent - the largest percentage in America – of the State's population. Maine's citizens suffer a high incidence of chronic disease, and many are dually-eligible for Medicare and Medicaid.

7. During the period FY2013-FY2017, approximately 44-47% of the services provided by EMHS were paid for by Medicare. During this same period, EMHS operations generated average annual operating income of approximately $4 million, or operating margins averaging considerably less than 1% per year.

8. EMHS member organizations include general medical hospitals that qualify as "covered entities," as defined in 42 U.S.C. § 256b(a)(4)(l) for purposes of the 340B drug program created by Congress in 1992 ("the 340B Program"), servicing an aging community with a large proportion of Medicare beneficiaries.

9. EMHS submitted comments to the Center for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services ("HHS") opposing the regulation at

issue in this case, the 340B Provisions of the OPPS Rule, which CMS issued on November 1, 2017.

The Impact of the 340B Provisions of the OPPS Rule on EMHS PPS Hospitals

10. The 340B Provisions of the OPPS Rule have reduced Medicare outpatient payments to prospective payment hospitals for drugs purchased by those hospitals under the 340B discounted drug program ("340B Program").

11. Prior to 2018, the CMS payment rate for these drugs was Average Sales Price ("ASP") plus 6%. The OPPS Rule reduce this payment rate by almost 30%, to ASP minus 22.5%.

12. EMHS estimates that the payment reduction set forth in the 340B Provisions of the OPPS Rule has resulted in a reduction in CMS payments associated with this program to EMHS of approximately $5.4 million per year. Taking into account any redistributions to EMHS under these provisions, EMHS estimates that its net loss under the 340B Provisions of the OPPS Rule will be approximately $3.6 million year.

13. Participation in the 340B program and the margin between hospitals' drug acquisition costs and Medicare payment rates that this program creates have helped EMHS provide health care programs to its communities, including underserved and uninsured populations within those communities, that would otherwise be financially unsustainable. For FY 17 EMHS member organizations provided traditional charity care totaling $26,658,000.

14. The 340B Provisions of the OPPS Rule at issue in this case would threaten many EMHS programs by depriving EMHS of the resources that help these programs to exist. Savings achieved through the purchase of eligible 340B discount drugs are foundational in supporting the services provided by EMHS member hospitals. Eroding those savings with a Medicare B

payment reduction for certain drugs will erode hospital margins and diminish our capacity to provide essential services to all patients in need irrespective of their ability to pay for the care delivered.

15. While many factors will have to be considered in determining how to address the $3.6 million in lost savings annually from the 340B Provisions of the OPPS Rule, the critical EMHS functions that would likely be impacted by those provisions, to at least some degree, include: implementation of identified statewide Community Health Needs Assessment ("CHNA") priorities and critical capital improvements.

16. EMHS' members are required by federal law to conduct a CHNA assessment and adopt an appropriate implementation strategy. Information from the statewide CHNA, completed in 2016, documents a number of priorities for community health investments needed to improve the health status of Maine citizens. EMHS member organizations, including the 340B participating hospitals, invest in many priority areas of health improvement statewide. Identification of priorities for investment is balanced with available financial resources.

17. One of EMHS' 340B participating hospitals, Eastern Maine Medical Center, identified addressing cardiovascular disease as a priority in its CHNA. Another EMHS 340B participating hospital, Inland Hospital, identified health literacy as a priority in its CHNA. Addressing cardiovascular disease and improving health literacy are two specific areas of need that require increased resources and strategies, and the 340B payment reduction further negatively impacts EMHS' ability to meet these needs.

18. Critical capital improvements are another area that the 340B payment reductions have already impacted and will continue to impact as long as they are in effect. Because of the 340B payment reductions, EMHS has reprioritized scarce capital dollars to reflect the shortfall in

available funds while balancing equipment needs with the financial health of the organization. EMHS 340B participating hospitals, including Eastern Maine Medical Center, The Aroostook Medical Center, and Inland Hospital, have had to postpone or cancel millions of dollars in critical capital improvement projects this fiscal year. Those projects, if they could be funded, would improve patient care in the hospitals' operating rooms, diagnostic departments and emergency services, among others. For instance, Inland Hospital has postponed the purchase of gastrointestinal ("GI") equipment to replace an aging set of scopes and software that would greatly enhance its ability to diagnose and treat GI conditions. The ability of EMHS to fund this and other projects, now or in the near future, is seriously impaired by the 340B payment reductions. If the 340B payment reductions are allowed to continue, EMHS will have a growing, cumulative backlog of critical capital needs that will likely result in harm not only to EMHS but also to the patients who rely on its services.

19. The 340B Provisions of the OPPS Rule have had and will continue to have a significant impact more generally on EMHS's overall service capabilities, affecting its budgeted operations, bond covenants, and other systems and arrangements that allow it to offer essential health care to Maine's communities, including the uninsured and underserved in those communities.

Signed under penalty of perjury this 24th day of August, 2018.

Tony Filer
Senior Vice President
& Chief Financial Officer
Eastern Maine Healthcare Systems

Exhibit W

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, 800 Tenth Street, NW, Suite 400 Washington, DC 20001, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, 200 Independence Avenue, SW Washington, DC 20201, *et al.*, *Defendants.*	**Case No.** _____

AFFIDAVIT OF ROBIN DAMSCHRODER
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Robin Damschroder, state as follows under the pains and penalties of perjury.

1. I am Robin Damschroder of Henry Ford Health System ("HFHS"), a Plaintiff in this action.

2. I currently serve as the Chief Financial Officer of HFHS. I hold a Masters in Health Services Administration.

3. The information set forth in this affidavit is based upon my personal knowledge.

HFHS and the Population It Serves

4. Founded in 1915 by auto pioneer Henry Ford, HFHS is a non-profit integrated health care delivery system headquartered in Detroit, Michigan. HFHS serves the metropolitan Detroit and Jackson areas of Michigan. The system has 30,000 employees, 26 medical centers, six acute care hospitals with a total of 2,405 inpatient beds, including Henry Ford Hospital ("HFH"), which is our flagship hospital and is a large academic safety net hospital located within the city of Detroit, and Henry Ford Allegiance ("HF Allegiance"), located in the city of Jackson.

5. HFH and HF Allegiance have a long and distinguished history of serving as safety-net hospitals for vulnerable people living in their communities. There are no public hospitals in Detroit or Jackson, so the few private hospitals in these cities share the burden of charity care and other forms of uncompensated care in the city as well as in the surrounding communities.

6. Located in Detroit's Midtown, HFH has served the Detroit community—which has the highest rate of concentrated poverty among the top 25 metro areas in the United States—for over 100 years and serves 22% of the Medicaid population in the region HFH is an 877-bed tertiary care hospital, education and research center, which provides comprehensive and advanced inpatient and outpatient care. HFH is also a Level 1 trauma center and one of the largest U.S. teaching hospitals.

7. Located in Jackson, HF Allegiance is a 475-bed healthcare organization that has served as the sole health system for the south central Michigan community since 1918. With more than 400 physicians, HF Allegiance's network of 40 facilities complements traditional acute care with mission-based services to address the health needs of its economically-challenged, underserved community. Jackson has a median income of $28K and a 36% poverty rate. It serves 19% of the Medicaid population in the region.

8. Both HFH and HF Allegiance are members of the American Hospital Association, another Plaintiff in this case.

9. HFH is also a member of the Association of American Medical Colleges and American Essential Hospitals, also Plaintiffs in this case.

10. The communities served by HFH and HF Allegiance also include a significant number of Medicare beneficiaries. In fiscal year 2016, Medicare was responsible for approximately 47% of HFH and 48% of HF Allegiance's gross revenues.

11. Both HFH and HF Allegiance are "covered entities," as defined in 42 U.S.C. § 256b(a)(4)(L), for purposes of the 340B drug program created by Congress in 1992 ("the 340B Program"), servicing a large percentage of indigent patients.

The Impact of the 340B Provisions of the OPPS Rule on HFHS, HFH, and HF Allegiance

12. The 340B Provisions of the OPPS Rule, issued by the Centers for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services, which went into effect on January 1, 2018, have reduced Medicare payments to hospitals for drugs purchased by those hospitals under the 340B discounted drug program ("340B Program").

13. Prior to 2018, the CMS payment rate for these drugs was Average Sales Price ("ASP") plus 6%. The OPPS Rule reduced this payment rate to ASP minus 22.5%.

14. The almost 30% payment reduction set forth in the 340B Provisions of the OPPS Rule has resulted in a severe reduction in drug payments to HFH and HF Allegiance. That loss totals approximately $9 million through the end of June 2018. Approximately $4.5 million of that loss was due to reduction in Medicare fee-for-service payments and approximately $4.5 million was due to reduction in payments from Medicare Advantage plans (privately administered plans which tie payments for pharmaceuticals to payments under the OPPS). If the 340B Provisions remain in effect, HFHS expects that these losses will double by the end of 2018. These cuts have been partially offset by the budget neutrality provisions of the OPPS Rule, but by the end of 2018, HFH and HF Alliance are forecast to suffer net outpatient cuts of $6 million and $2.5 million, respectively.

15. Participation in the 340B program and the margin between hospitals' drug acquisition costs and Medicare payment rates that this program creates have helped HFH and HF Allegiance provide uncompensated health care programs to its communities, including the

underserved and indigent populations within those communities, that would otherwise be financially unsustainable.

16. The forms of uncompensated care that HFH and HF Allegiance are able to provide because of 340B Program discounts include: providing free and reduced cost medications to the underserved across HFHS; staffing the Community Health and Social Services ("CHASS") Clinic, which provides free primary care services to about 1,300 uninsured and underinsured Detroit residents every month in Southwest Detroit, with HFHS physicians; operating school-based and community health programs in 11 child and adolescent health centers and two mobile medical units, which provide primary care services in Detroit, Warren, and Mount Clemens; and embedding pharmacists in primary care and specialty clinics in Detroit to optimize treatment of chronic diseases and expand patient access through face-to-face appointments. Collectively, these programs further the goal of preventing the need for "charity care" in the form of expensive treatments for uninsured patients.

17. HFHS provided over $443 million in uncompensated care in 2017 across its system. The total uncompensated care includes charity care, bad debt and Medicare and Medicaid underpayments. Only a small fraction of the uncompensated care we provide is counted as charity care, but we need the 340B program savings to help cover all forms of uncompensated care that we provide.

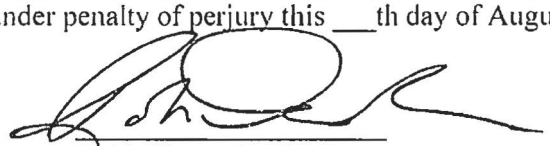
18. In short, without the 340B program, HFHS would not be able to provide the breadth of uncompensated care or other services that it currently provides across its system to vulnerable and low-income individuals.

19. The 340B Provisions of the OPPS Rule at issue in this case are threatening HFHS programs (including the programs described above in paragraph 16) by depriving HFHS of the

resources that allow these programs to exist, eroding its margin and diminishing its capacity to provide essential services.

20. If the 340B Program cuts in the OPPS Rule continue, HFHS will be forced to evaluate – and likely limit or curtail, some of the more costly programs designed to serve our most vulnerable community members.

Signed under penalty of perjury this ___th day of August, 2018.



Robin Damschroder
Chief Financial Officer
Henry Ford Health System

Exhibit X

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

AFFIDAVIT OF WENDI BARBER
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Wendi Barber, state as follows under the pains and penalties of perjury.

1. I am the Vice President of Finance and Chief Financial Officer ("CFO") of Fletcher Hospital, Inc. d/b/a Park Ridge Health ("Park Ridge"), a Plaintiff in this action.

2. I have been Vice President of Finance and CFO at Park Ridge for four (4) years. Before joining Park Ridge, I was the CFO at Castle Medical Center on the island of O'ahu in Hawaii for three (3) years – which like Park Ridge participated in the 340B drug program at issue in this case. I hold both a bachelor's degree and master's degree in business administration.

3. The information set forth in this affidavit is based upon my personal knowledge.

Park Ridge and the Population It Serves

4. Park Ridge is a not-for-profit health care system headquartered in Hendersonville, North Carolina, about 15 miles south of Asheville, North Carolina. Park Ridge employs more than 125 providers who practice at 34 locations across Henderson, Buncombe, and Haywood Counties. Our combined network of 250 medical providers serves the

communities of Hendersonville, Mills River, Fletcher, Clyde, Arden, Weaverville and Asheville, North Carolina, and includes 30 primary care providers and over 89 specialists and hospital-based providers representing over 20 specialties.

5. Park Ridge has served these communities for over 100 years, including when, in 1916, it employed the very first registered nurses in North Carolina.

6. Park Ridge is part of Adventist Health System ("AHS"), a network of approximately 48 Seventh-day Adventist-affiliated hospitals, as well as skilled nursing facilities, physician offices, home health agencies, hospice providers, urgent care facilities, and other providers in nine states. Park Ridge is the only Adventist-affiliated hospital in North Carolina.

7. Park Ridge is also a member of the American Hospital Association ("AHA"), another of the Plaintiffs in this case.

8. Park Ridge is licensed as a 103-bed hospital, with significant capacity to care for behavioral patients. It also has several outpatient clinics.

9. The communities Park Ridge serves contain a large percentage of elderly and retired persons, including a large number of Medicare beneficiaries. In fiscal year 2017, Medicare was responsible for approximately 52% of Park Ridge's gross revenues. Approximately two thirds of Park Ridge's behavioral and psychological health services are devoted to geriatric patients.

10. Park Ridge was able to provide nearly $25 million in uncompensated care in 2017.

11. Park Ridge is a "covered entity," as defined in 42 U.S.C. § 256b(4)(A), for purposes of the 340B drug program created by Congress in 1992 ("the 340B Program"), by

virtue of its qualification as a "disproportionate share" hospital that treats a large percentage of indigent patients.

The Impact of the 340B Provisions of the OPPS Rule on Park Ridge

12. The 340B Provisions of the OPPS Rule, which were issued by the Centers for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services ("HHS") on November 1, 2017 and went into effect on January 1, 2018, have reduced Medicare payments to hospitals for drugs purchased under the 340B discounted drug program ("340B Program").

13. The previous CMS payment rate for these drugs was Average Sales Price ("ASP") plus 6%. The OPPS Rule reduced this payment rate by 28.5 percentage points, from ASP plus 6% to ASP minus 22.5%.

14. Based on 2016 annualized volume, Park Ridge has estimated that the payment reduction set forth in the 340B Provisions of the OPPS Rule will result in a loss to Park Ridge of over $3.7 million per year. Taking into account the budget-neutrality provisions of the OPPS Rule, Park Ridge has estimated that its net losses under the 340B Provisions of the OPPS Rule will be approximately $3.3 million per year.

15. Participation in the 340B program and the margin between hospitals' drug acquisition costs and Medicare payment rates that this program creates have helped Park Ridge provide, on its own and in partnership with other not-for-profit community-based services, health care programs to its communities, including the underserved populations within those communities, that would otherwise be financially unsustainable.

16. Because of the 340B program, Park Ridge has been able to increase its margin to, among other things, (1) help support increased access to behavioral health and psychiatric

services, which serve a large geriatric population and a disproportionate share of indigent patients in the community, including by beginning much-needed renovations within the inpatient unit, (2) establish four infusion centers for the comprehensive treatment of cancer and other diseases (centers which provide services to a disproportionately large Medicare population, even as compared to the large Medicare population Park Ridge otherwise serves), (3) expand its obstetrics and gynecology ("OBGYN") capabilities (which also serve a disproportionate share of indigent patients in the community), and (4) partner with various community not-for-profits to address other healthcare and social needs within Western North Carolina, such as obesity, prescription drug abuse, child advocacy, affordable housing, community health and wellness, and economic development.

17. In short, the savings from the 340B program provide Park Ridge with increased resources that, in turn, enable it to provide services that it otherwise could not make available, allowing low-income individuals to receive services that they would not otherwise be able to afford.

18. The 340B Provisions of the OPPS Rule at issue in this case threaten various Park Ridge programs and community-based-partnerships that further serve the indigent as a result of the 340B program savings, by depriving Park Ridge of the resources that allow these programs to exist. For example, the nearly-30% payment reduction set forth in those provisions is threatening the continued health, and potentially the existence, of Park Ridge's geriatric behavioral health services and four infusion centers, which as noted above serve a disproportionately large percentage of Medicare beneficiaries. Park Ridge has planned to purchase a second CT scanner to ensure appropriate and timely clinical care for stroke patients, but it has been forced to delay these plans because of the 340B Program cuts. Park Ridge is also

being forced to delay replacement of aging imaging equipment, including X-Ray rooms that are now past their useful life. The nearly 30% payment reduction in the OPPS Rule is threatening Park Ridge's geriatric psychiatric program, its planned expansion of primary care services, and its ongoing ability to support its local Federally Qualified Health Center, pregnancy centers in underserved communities, non-acute behavioral health needs, and child-advocacy programs in partnership with the county.

19. If the 340B Provisions of the OPPS Rule and the new payment rate are allowed to remain in effect, Park Ridge will be forced to evaluate and likely curtail at least some of the important programs through which it provides uncompensated care to the communities it serves.

Signed under penalty of perjury this 4 th day of September, 2018.

Wendi Barber

Wendi Barber
Vice President of Finance and
Chief Financial Officer
Park Ridge Health

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,		
Plaintiffs,	Civil Action No.:	18-2084 (RC)
v.	Re Document Nos.:	2, 14
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,		
Defendants.		

ORDER

DENYING DEFENDANTS' MOTION TO DISMISS; GRANTING PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**, the Secretary's Motion to Dismiss (ECF No. 14) is **DENIED**, and Plaintiffs' Motion for a Permanent Injunction (ECF No. 2) is **GRANTED**. It is **HEREBY ORDERED** that:

1. The parties shall provide supplemental briefing on the appropriate remedy, limited to no more than 25 pages per brief, within 30 days of this Order's issuance; and
2. The parties shall respond to those briefs, limited to no more than 15 pages per response, within 14 days after the supplemental briefs are filed.

SO ORDERED.

Dated: December 27, 2018

RUDOLPH CONTRERAS
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,		
Plaintiffs,	Civil Action No.:	18-2084 (RC)
v.	Re Document Nos.:	2, 14
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,		
Defendants.		

MEMORANDUM OPINION

DENYING DEFENDANTS' MOTION TO DISMISS; GRANTING PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I. INTRODUCTION

This action concerns whether the Department of Health and Human Services ("HHS") acted lawfully when it reduced Medicare payments worth billions of dollars to private institutions, to correct what it views as a fundamental misalignment of Medicare programs. Plaintiffs, a group of hospital associations and non-profit hospitals,[1] contend that HHS exceeded its statutory authority when it cut Medicare reimbursement rates for certain outpatient

[1] The hospital association Plaintiffs ("Association Plaintiffs") are the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH"). Compl. ¶¶ 4–9. The non-profit hospital Plaintiffs ("Hospital Plaintiffs") are the Henry Ford Health System ("Henry Ford"), Northern Light Health ("Northern Light")—formerly Eastern Maine Healthcare Systems—and Fletcher Hospital, Inc., doing business as Park Ridge Health ("Park Ridge"). Compl. ¶¶ 10–18; Notice of Party Name Change at 1, ECF No. 21 (stating that Eastern Maine Healthcare Systems has changed its name to Northern Light Health).

pharmaceutical drugs by nearly 30%. Defendants, HHS and its Secretary, contend that the rate adjustment was statutorily authorized and necessary to close the gap between the discounted rates at which Plaintiffs obtain the drugs at issue—through Medicare's "340B Program"—and the higher rates at which Plaintiffs were previously reimbursed for those drugs under a different Medicare framework.

Presently before this Court are Plaintiffs' motion for a preliminary or permanent injunction and Defendants' motion to dismiss. Among other relief, Plaintiffs ask the Court to vacate the Secretary's rate reduction, require the Secretary to apply previous reimbursement rates for the remainder of this year, and require the Secretary to pay Plaintiffs the difference between the reimbursements they have received this year under the new rates and the reimbursements they would have received under the previous rates. Defendants contest the Court's ability to hear the case, arguing that Congress has shielded the Secretary's action from judicial review, that the Secretary's boundless discretion precludes review, and that Plaintiffs' failure to exhaust their administrative remedies is fatal. Defendants also argue that the Secretary's action was well within his statutory authority.

For the reasons stated below, the Court concludes that it has jurisdiction to provide relief in this case and that Plaintiffs are entitled to such relief. While in certain circumstances the Secretary could implement the rate reduction at issue here, he did not have statutory authority to do so under the circumstances presented. Moreover, because the parties have fully and vigorously debated the merits of Plaintiffs' claims, which turn on questions of law, not fact, the Court concludes that further merits briefing would be redundant and inefficient. However, while Plaintiffs are entitled to *some* relief, the potentially drastic impact of this Court's decision on Medicare's complex administration gives the Court pause. Accordingly, the Court grants

Plaintiffs' motion for a permanent injunction and orders supplemental briefing on the question of a proper remedy.

II. BACKGROUND AND PROCEDURAL HISTORY

A. Medicare

Medicare is a federal health insurance program for the elderly and disabled, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395–1395*lll*. Medicare Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. HHS's Outpatient Prospective Payment System ("OPPS"), which directly reimburses hospitals for providing outpatient services and pharmaceutical drugs to Medicare beneficiaries, is a component of Medicare Part B. *See id.* at 1395*l*(t). OPPS requires "payments for outpatient hospital care to be made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Under this system, HHS—through the Centers for Medicare and Medicaid Services ("CMS")—sets annual OPPS reimbursement rates prospectively, before a given year, rather than retroactively based on covered hospitals' actual costs during that year.[2]

B. The 340B Program

In 1992, Congress established what is now commonly referred to as the "340B Program." Veterans Health Care Act of 1992, Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. The 340B Program allows participating hospitals and other health care providers ("covered entities") to purchase certain "covered outpatient drugs" from manufacturers at or below the drugs'

[2] CMS is a component of HHS and is overseen by the Secretary. *See* HHS Organizational Chart, HHS (Nov. 14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.

"maximum" or "ceiling" prices, which are dictated by a statutory formula and are typically significantly discounted from those drugs' average manufacturer prices. *See* 42 U.S.C. § 256b(a)(1)–(2).[3] Put more simply, this Program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011). It is intended to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,493 & 52,493 n.18 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419).[4] Importantly, and as discussed in greater detail below, the 340B Program allows covered entities to purchase certain drugs at steeply discounted rates, and then seek reimbursement for those purchases under Medicare Part B at the rates established by OPPS.

C. Medicare Reimbursement Rates for 340B Drugs

The statutory provision governing OPPS, codified at 42 U.S.C. § 1395*l*(t), imposes the framework by which HHS must set prospective Medicare reimbursement rates. Among other requirements under that provision, HHS must determine how much it will pay for "specified covered outpatient drugs" ("SCODs") provided by hospitals to Medicare beneficiaries. 42 U.S.C. § 1395*l*(t)(14)(A). SCODS are a subset of "separately payable drugs," which are not bundled with other Medicare Part B outpatient services and are therefore reimbursed on a drug-

[3] The manufacturers must offer these discounts as a condition of their participation in the Medicaid program. *Id.* § 256b(a)(3).

[4] While the regulations setting 340B drug reimbursement rates, including the 2018 OPPS Rule, are technically issued by CMS, *see* 82 Fed. Reg. at 52,356, for simplicity's sake the Court will refer to them as HHS regulations.

by-drug basis. *See id.* § 1395*l*(t)(14)(B). And as noted, the 340B Program covers certain separately payable drugs, some of which are SCODs and some of which are not. 82 Fed. Reg. at 52,496; Defs.' Mot. to Dismiss ("Defs.' Mot.") at 5, ECF No. 14.

Congress has authorized two potential methodologies for setting SCOD rates.[5] First, if HHS has certain "hospital acquisition cost survey data," it must set the reimbursement rate for each SCOD according to "the *average acquisition cost* for the drug for that year . . . as determined by the Secretary taking into account" the survey data. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). Second, if the survey data is not available, each SCOD's reimbursement rate must be set equal to "the *average price* for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales price ("ASP") of the drug plus 6%.[6] *Id.* § 1395w-3a(b)(1)(A)–(B); *see also* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center

[5] While not all separately payable drugs qualify as SCODs, to which the payment methodologies of § 1395*l*(t)(14)(A) apply, "[HHS] applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS." Defs.' Mot. at 6 n.1 (citing 77 Fed. Reg. at 68,383); *see also* 82 Fed. Reg. at 52,509 (stating that the rate reduction will apply to "separately payable Part B drugs . . . that are acquired through the 340B Program"). Thus, the methodology at issue here applies to all 340B drugs, not just SCODS covered by the 340B Program. This "is a policy choice rather than a statutory requirement." Defs.' Mot. at 6 n.1 (quoting 77 Fed. Reg. at 68,383). Because neither party raises the question of whether the Secretary's statutory authority to alter reimbursement rates for SCODs also governs the Secretary's "policy choice" to apply the same rates to non-SCOD, separately payable drugs, the Court will not address that question here.

[6] Both parties seem to agree that § 1395w-3a sets a default payment rate of 106% of a given drug's volume-weighted average sales price, and that this rate is the presumptive reimbursement rate under § 1395*l*(t)(14)(A)(iii)(II). *See* Defs.' Mot. at 6; Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. ("Pls.' Mem.") at 3–4, ECF No. 2-1; 82 Fed. Reg. at 52,501 (acknowledging ASP plus 6% as the "statutory benchmark").

Payment Systems and Quality Reporting Programs ("2012 OPPS Rule"), 77 Fed. Reg. 68,210, 68,387 (Nov. 15, 2012) (codified at 42 C.F.R. pt. 419) (adopting a reimbursement rate of ASP plus 6% for covered drugs in light of the "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost" and the concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost . . . .").

D. The 340B-Medicare Payment Gap

As explained above, hospitals participating in the 340B Program purchase 340B drugs at steeply discounted rates, and when those hospitals prescribe the 340B drugs to Medicare beneficiaries they are reimbursed by HHS at OPPS rates. Before 2018, the relevant OPPS rate for 340B drugs was ASP plus 6%. *See, e.g.*, 77 Fed. Reg. at 68,387. This rate resulted in a significant gap between what hospitals paid for 340B drugs and what they received in Medicare reimbursements for those drugs, because the 340B Program allowed participating hospitals to buy the drugs at a far lower rate than ASP plus 6%. *See* 82 Fed. Reg. at 52,495 (citing an Office of Inspector General report finding that this margin "allowed covered entities to retain approximately $1.3 billion in 2013"). Plaintiffs allege that the revenues derived from this payment gap have "helped [Plaintiffs] provide critical services to their communities, including underserved populations in those communities." Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. ("Pls.' Mem.") at 31 (citing Aff. of Tony Filer ("Northern Light Aff.") ¶ 13, Pls.' Mot. Prelim. & Permanent Inj. ("Pls.' Mot.") Ex. V, ECF No. 2-25; Aff. of Robin Damschroder ("Henry Ford Aff.") ¶¶ 15–18, Pls.' Mot. Ex. W, ECF No. 2-26; Aff. of Wendi Barber ("Park Ridge Aff.") ¶¶ 15–17, Pls.' Mot. Ex. X, ECF No. 2-27), ECF No. 2-1. They further allege that the narrowing of this gap "threatens these critical services" because Plaintiffs may be unable to

fund the services with lower reimbursement amounts. *Id.* (citing Northern Light Aff. ¶¶ 14–19; Henry Ford Aff. ¶¶ 19–20; Park Ridge Aff. ¶¶ 18–19).

E. The 2018 OPPS Rule

In mid-2017, HHS proposed reducing the Medicare reimbursement rates for SCODs and other separately payable drugs acquired through the 340B Program from ASP plus 6% to ASP minus 22.5%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,634 (Jul. 20, 2017) (codified at 42 C.F.R. pt. 419). HHS provided a detailed explanation of why it believed this rate reduction was necessary. First, HHS noted that several recent studies have confirmed the large "profit" margin created by the difference between the price that hospitals pay to acquire 340B drugs and the price at which Medicare reimburses those drugs. *See id.* at 33,632–33. Second, HHS stated that because of this "profit" margin, HHS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs." *Id.* at 33,633. It cited, as an example of this phenomenon, a 2015 Government Accountability Office Report finding that Medicare Part B drug spending was substantially higher at 340B hospitals than at non-340B hospitals. *Id.* at 33,632–33. The data indicated that "on average, beneficiaries at 340B . . . hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis." *Id.* at 33,633. Third, HHS expressed concern "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs," rather than the lower 340B rate paid by the covered hospitals. *Id.*

Thus, HHS concluded that lowering the Medicare reimbursement rates for 340B Program drugs would "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs[,] while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals to stretch scarce resources while continuing to provide access to care." *Id.* HHS, however, did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug." *Id.* at 33,634. For that reason, HHS estimated 340B hospitals' drug acquisition costs based on those hospitals' average 340B discount. *See id.* Specifically, HHS proposed applying the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC")—22.5% of a covered drug's average sales price—to govern the 340B drug reimbursement rates. *See id.* HHS believed that MedPAC's estimate was appropriate and, in fact, conservative because the "actual average discount experienced by 340B hospitals is likely much higher than 22.5[%]." *Id.*

In addition to explaining its rationale and methodology for reducing the 340B reimbursement rates to ASP minus 22.5%, HHS stated its purported statutory basis for taking that action. Because HHS did not "have hospital acquisition cost data for 340B drugs," 82 Fed. Reg. at 33,634, it could not invoke its express authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, HHS invoked its authority under § 1395*l*(t)(14)(A)(iii)(II), "which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug . . . as calculated and adjusted by the Secretary as necessary." 82 Fed. Reg. at 33,634. HHS would thus "adjust the applicable payment rate as necessary" for separately payable drugs acquired under the 340B program, "to ASP minus 22.5[%]." *Id.* HHS stated that the adjustment was necessary

because ASP minus 22.5% "better represents the average acquisition cost for [340B] drugs and biologicals." *Id.*

Plaintiffs strongly opposed the proposed 2018 340B reimbursement rates, and they voiced their opposition in comments to the proposed rule. Plaintiffs argued primarily that HHS did not have the legal authority to change the 340B reimbursement rates in the manner proposed, and that reducing reimbursement rates by nearly 30% would severely impact covered entities' ability to provide critical healthcare programs to their communities, particularly to their underserved patients. *See generally* AHA Comments, Pls.' Mot. Ex. C, ECF No. 2-6; AAMC Comments, Pls.' Mot. Ex. D, ECF No. 2-7; AEH Comments, Pls.' Mot. Ex. E, ECF No. 2-8; Henry Ford Comments, Pls.' Mot. Ex. F, ECF No. 2-9; Northern Light Comments, Pls.' Mot. Ex. G, ECF No. 2-9.

Nevertheless, in November 2017, HHS adopted the proposed 340B reimbursement rate reduction. *See* 82 Fed. Reg. at 52,362. In issuing its final rule, HHS responded to Plaintiffs' arguments about its authority to change Medicare reimbursement rates for 340B drugs. *See id.* at 52,499. HHS argued that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion, including discretion to adjust Medicare payment rates according to whether or not certain drugs were acquired at a significant discount. *Id.* HHS also disagreed with commenters that the authority to "calculate and adjust" drug rates as necessary was limited to "minor changes"; it saw "no evidence in the statute to support that position." *Id.* at 52,500. Accordingly, HHS used its purported authority "to apply a downward adjustment that is necessary to better reflect acquisition costs of [340B] drugs." *Id.* The 340B reimbursement rates

dictated by this rule, and its ASP minus 22.5% methodology, became effective on January 1, 2018. *Id.* at 52,356.

F. Procedural History

In late 2017, Plaintiffs raised an Administrative Procedure Act ("APA") challenge to the 2018 OPPS Rule's 340B provisions. *See generally* Compl., *Am. Hosp. Ass'n v. Hargan ("AHA I")*, No. 17-2447, ECF No. 1 (D.D.C.). However, this Court dismissed the action because Plaintiffs failed "to present any concrete claim for reimbursement to the Secretary for a final decision[,]" which is "a fundamental jurisdictional impediment to judicial review under 42 U.S.C. § 405(g)." *AHA I*, 289 F. Supp. 3d 45, 55 (D.D.C. 2017).[7] Both parties agree that Plaintiffs have now presented reimbursement claims covered by the 2018 OPPS Rule, Defs.' Mot. at 15 n.6; Pls.' Mem. at 11–12, and Plaintiffs have re-filed suit asserting nearly identical challenges to the rule, *see generally* Compl., ECF No. 1.

Plaintiffs allege that the Secretary's reimbursement rate reduction for 340B drugs violates the APA and the Social Security Act because it is "arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act." Compl. ¶¶ 68–69 (citing 42 U.S.C. §§ 405(g), 1395ii, 1395*l*(t)(14)(A)(iii); 5 U.S.C. § 706(2)). In conjunction with filing their complaint, Plaintiffs have moved for either a preliminary injunction or a permanent injunction under Rule 65 of the Federal Rules of Civil Procedure. Pls.' Mot. at 1, ECF No. 2. Plaintiffs request that this Court direct the Secretary to:

> [S]trike the changes in the payment methodology for 340B drugs from the OPPS Rule and use the methodology used in calendar year 2017 for all future 340B Program payments in 2018; pay the Hospital Plaintiffs and all provider members of the Association Plaintiffs the difference between the payments for 340B drugs that they received under the 2018 OPPS Rule and the payments they would have

[7] This decision was recently affirmed by the D.C. Circuit. *See Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 828 (D.C. Cir. 2018).

> received under the 2017 OPPS Rule; and conform the payment methodology that they use for 340B drugs in calendar year 2019 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition cost to calculate payment rates unless Defendants have complied with 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).

Pls.' Mem. at 35. The government has opposed Plaintiffs' motion and filed a motion to dismiss the action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). *See generally* Defs.' Mot. The parties' motions are fully briefed and ripe for this Court's consideration.

III. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(1)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) "presents a threshold challenge to the Court's jurisdiction." *Curran v. Holder,* 626 F. Supp. 2d 30, 32 (D.D.C. 2009) (quoting *Agrocomplect, AD v. Republic of Iraq,* 524 F. Supp. 2d 16, 21 (D.D.C. 2007)). "It is to be presumed that a cause lies outside [the federal courts'] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182–83 (1936); *Turner v. Bank of N.A.*, 4 U.S. 8, 11 (1799)). In determining whether the plaintiff has met this burden, a court must accept "the allegations of the complaint as true," *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015), and "construe the complaint 'liberally,' granting the plaintiff 'the benefit of all inferences that can be derived from the facts alleged,'" *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004) (quoting *Kowal v. MCI Commc'ns. Corp.*, 16 F.3d 1271, 1276 (D.C. Cir.1994)). However, "the [p]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13–14 (D.D.C. 2001)

(internal quotation marks omitted) (citing 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1350).

The Court must confirm its jurisdiction for each type of claim brought before it, including APA challenges. Indeed, while the "APA generally establishes a cause of action for those suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action," the "APA does not apply . . . to the extent that . . . statutes preclude judicial review." *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (internal quotation marks omitted) (quoting 5 U.S.C. § 701(a)(1); *Koretoff v. Vilsack*, 614 F.3d 532, 536 (D.C. Cir. 2010)). Similarly, courts lack jurisdiction over claims brought under the Social Security Act until the claimants have exhausted their administrative remedies and received final decisions from the Secretary regarding the issues underlying those claims. 42 U.S.C. § 405(g).

B. Federal Rule of Civil Procedure 12(b)(6)

The Federal Rules of Civil Procedure require that a complaint contain "a short and plain statement of the claim" to give the defendant fair notice of the claim and the grounds upon which it rests. Fed. R. Civ. P. 8(a)(2); *accord Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (per curiam). A motion to dismiss under Rule 12(b)(6) does not test a plaintiff's ultimate likelihood of success on the merits; rather, it tests whether a plaintiff has properly stated a claim. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *abrogated on other grounds by Harlow v. Fitzgerald*, 457 U.S. 800 (1982). A court considering such a motion presumes that the complaint's factual allegations are true and construes them liberally in the plaintiff's favor. *See, e.g.*, *United States v. Philip Morris, Inc.*, 116 F. Supp. 2d 131, 135 (D.D.C. 2000).

To survive a motion to dismiss, a complaint need not contain all elements of a prima facie case. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 511–14 (2002); *Bryant v. Pepco*, 730 F. Supp. 2d 25, 28–29 (D.D.C. 2010). However, the "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This means that a plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 at 555 (citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are therefore insufficient to withstand a motion to dismiss. *Iqbal*, 556 U.S. at 678. A court need not accept a plaintiff's legal conclusions as true, *see id.*, nor must a court presume the veracity of legal conclusions couched as factual allegations, *see Twombly*, 550 U.S. at 555.

C. Administrative Procedure Act

The APA governs the conduct of federal administrative agencies. *See* 5 U.S.C. §§ 101–913. It permits a court to "compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1), and to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A). It provides for judicial review of a "final agency action for which there is no other adequate remedy in a court[,]" *id.* § 704, except when "statutes preclude judicial review" or the "agency action is committed to agency discretion by law[,]" *id.* § 701(a).

IV. ANALYSIS

By and large, the Secretary's arguments for dismissal concern whether this Court has jurisdiction to hear Plaintiffs' allegations. First, the Secretary argues that Plaintiffs' failure to

exhaust their administrative remedies forecloses judicial review. Second, the Secretary argues that certain Medicare provisions preclude the Court's review. Third, the Secretary argues that the decision to reduce 340B drug reimbursement rates was "committed to agency discretion by law," and therefore outside the scope of APA review. Fourth, the Secretary argues that he had clear statutory authority to "adjust" 340B drug reimbursement rates. The Court addresses each argument in turn and concludes that the potential jurisdictional obstacles are not fatal here, and that the Secretary's action exceeded his authority to "adjust" rates. Accordingly, Plaintiffs are entitled to relief, to be determined after the Court considers the parties' supplemental briefing.

A. Plaintiffs Need Not Exhaust Their Administrative Remedies

The Secretary argues that the Court lacks jurisdiction because Plaintiffs failed to exhaust their administrative remedies prior to filing suit. In evaluating this argument, the Court must consider the mechanism by which Plaintiffs have brought this suit. Plaintiffs assert their claims under a specific Social Security Act provision, 42 U.S.C. § 405(g),[8] which is the proper provision by which to raise an APA challenge to a Medicare-related agency action. 42 U.S.C. §§ 405(h),[9] 1395ii; *Heckler v. Ringer*, 466 U.S. 602, 615 (1984); *Am. Hosp. Ass'n v. Azar ("AHA*

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[8] This provision states, in relevant part, that:

> Any individual, after any *final decision* of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States . . . .

42 U.S.C. § 405(g) (emphasis added).

[9] This provision states that:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency *except as herein provided*. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346

II"), 895 F.3d 822, 825 (D.C. Cir. 2018). And as noted, judicial review of a claim brought under § 405(g) is foreclosed until the claimants have exhausted their administrative remedies and received a final decision from the Secretary. 42 U.S.C. § 405(g); *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976); *AHA II*, 895 F.3d at 826. Although the concept of "exhaustion" exists under typical administrative law principles, the Supreme Court has explained that § 405(h)'s channeling mechanism imposes an even more exacting exhaustion requirement. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000) ("[T]he bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'. . . ."). Indeed, § 405(h) "demands the 'channeling' of virtually all legal attacks through the agency." *Id.* at 13.

Section 405(g)'s review channeling mechanism contains two elements. First, the provision contains a jurisdictional, non-waivable "requirement that a claim for benefits shall have been presented to the Secretary." *Eldridge*, 424 U.S. at 328. Second, the provision contains a non-jurisdictional "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id.* This requirement may be waived by the agency or a court. [10] *See*

> [federal defendant jurisdiction] of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h) (emphasis added). The Supreme Court has interpreted § 405(h) to require that Medicare claims be pursued through the special review system laid out in § 405(g), rather than through other judicial mechanisms that may otherwise be available. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8–15 (2000). 42 U.S.C. § 1395ii expressly applies § 405(h) to claims arising under the Medicare provisions of the Social Security Act, and the D.C. Circuit has reasoned that "expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception 'herein provided' in § 405(g)." *Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 825 (D.C. Cir. 2018) (citing *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1103 (11th Cir. 1998)).

[10] In arguing that Plaintiffs must fully exhaust their administrative remedies, the Secretary notes that the Social Security Act provides an "abbreviated review process" by which a claimant may request expedited judicial review. Defs.' Mot. at 27 (citing 42 U.S.C. § 1395ff(b)(2)(A); 42 C.F.R. § 405.990). However, the Secretary does not explain why that

id. at 330. Together, these requirements serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13. Because, as noted, both parties agree that Plaintiffs have satisfied § 405(g)'s presentment requirement, the Court must consider whether Plaintiffs may be excused from exhausting their administrative remedies.

"A court may waive the exhaustion requirements of § 405(g) when: (1) the issue raised is entirely collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; [or] (3) exhaustion would be futile." *Triad at Jeffersonville I, LLC v. Leavitt,* 563 F. Supp. 2d 1, 16 (D.D.C. 2008) (citing *Bowen v. City of New York*, 476 U.S. 467, 483–85 (1986)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In such situations, a "district court may, in its discretion, excuse exhaustion if 'the litigant's interests in immediate judicial review outweigh the government's interests in the efficiency or administrative autonomy that the exhaustion doctrine is designed to further.'" *Avocados Plus Inc. v. Veneman,* 370 F.3d 1243, 1247 (D.C. Cir. 2004) (quoting *McCarthy v. Madigan,* 503 U.S. 140, 146 (1992)).

Here, Plaintiffs rely solely on what they claim is the futility of exhausting their administrative remedies. "Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with [the] other factors . . . ." *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015); *see also Tataranowicz*, 959 F.2d at 274 (waiving the plaintiffs' §405(g) exhaustion requirement as futile, without recourse to other factors). That said, the ordinary standard for futility in administrative law cases is inapplicable

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provision would prevent a court from waiving 42 U.S.C. § 405(g)'s exhaustion requirement when appropriate, nor does the Secretary cite case law establishing that principle.

in Medicare cases. *See Weinberger v. Salfi*, 422 U.S. 749, 766 (1975) (stating that § 405(g) is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility"). Instead, the Court must consider whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. *Tataranowicz*, 959 F.2d at 275 (citing *Salfi*, 422 U.S. at 765).

Applying these principles, the futility of requiring Plaintiffs to exhaust their administrative remedies in this case is readily apparent. The Secretary does not argue that proceeding with Plaintiffs' lawsuit would somehow "interfere with the agency's efficient functioning."[11] Nor does the Secretary contend that this dispute must be resolved based on facts that would be more fully developed through the administrative process. Indeed, as the Secretary recognizes, Plaintiffs' claim "raises pure legal questions regarding the scope of the Secretary's statutory authority . . . ." Defs.' Mot. at 28 n.10. Finally, there is no reason to believe that the agency might overturn the regulation, should Plaintiffs be given additional opportunities to raise their arguments through the administrative process. In the notice and comment proceedings, HHS specifically considered and rejected the arguments that Plaintiffs now raise here. *See* 82 Fed. Reg. at 52,499–502 (asserting that the Secretary could reduce SCOD reimbursement rates pursuant to the Secretary's authority to "adjust" reimbursement rates under 42 U.S.C § 1395*l*(t)(14)(A)(iii)(II), and rejecting Plaintiffs' claims to the contrary). Moreover, HHS's

[11] In fact, Plaintiffs assert, and the Secretary does not contest, that clarity regarding the 340B reimbursement rates will *improve* the agency's efficiency by resolving a large portion of the agency's administrative appeal workload raising the same issues addressed by this opinion. *See* Pls.' Mem. Ex. T at 2 n.2.

proposed 2019 OPPS Rule continues to reimburse 340B drugs at ASP minus 22.5%, indicating HHS's commitment to its position here. Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("Proposed 2019 OPPS Rule"), 83 Fed. Reg. 37,046, 37,122 (July 31, 2018) (to be codified at 42 C.F.R. pt. 419).

In fact, as Plaintiffs point out and the Secretary does not dispute, because the 2018 OPPS Rule is final, it appears that no administrative review body would even have authority to alter or deviate from its requirements, due to the Rule's binding nature on HHS. Indeed, HHS regulations provide that "[a]ll laws *and regulations* pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council." 42 C.F.R. § 405.1063(a) (emphasis added); *see also* HHS Expedited Access to Judicial Review Ruling at 6, ECF No. 19-1 (stating that "neither the ALJ nor the [Medicare Appeals] Council has the authority to find the 2018 OPPS Rule invalid").

When faced with similar circumstances, the Supreme Court and other courts in this jurisdiction have waived the Social Security Act's exhaustion requirement.[12] *See Mathews v. Diaz*, 426 U.S. 67, 76–77 (1976) (treating, for jurisdictional purposes, the Secretary's "stipulat[ion] that no facts were in dispute, that the case was ripe for disposition by summary judgment, and that the only issue before the District Court was the constitutionality of the statute . . . as tantamount to a decision denying the application and as a waiver of the exhaustion requirements" because the "constitutional question [was] beyond the Secretary's competence");

[12] Because the Court concludes that Plaintiffs' exhaustion of their administrative remedies here would be futile, it need not consider Plaintiffs' argument that they *have* exhausted their administrative remedies with respect to certain claims for reimbursement. *See* Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 11–12, ECF No. 16.

Tataranowicz, 959 F.2d at 274 (excusing exhaustion requirement on futility grounds where "the Secretary g[ave] no reason to believe that the agency machinery might accede to plaintiffs' claims"); *Nat'l Ass'n for Home Care & Hospice*, 77 F. Supp. 3d at 112 (excusing exhaustion requirement on futility grounds because plaintiff's "statutory claim—that the Secretary exceeded her authority under the [Affordable Care Act] in promulgating [a rule]—[was] a purely legal challenge to the agency's established interpretation of the Medicare Act"); *Hall v. Sebelius*, 689 F. Supp. 2d 10, 23–24 (D.D.C. 2009) (stating that "exhaustion may be excused where 'an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law'" (quoting *DL v. District of Columbia*, 450 F. Supp. 2d 11, 17 (D.D.C. 2006)). The Court does the same here. Because Plaintiffs have presented claims for reimbursement to the Secretary under the 2018 OPPS Rule, and because Plaintiffs' exhaustion of their administrative remedies would be futile, the Court waives Plaintiffs' exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).

B. This Court Is Not Precluded From Evaluating Plaintiffs' *Ultra Vires* Claim

The Secretary also argues that the Court is precluded by certain Medicare provisions from hearing Plaintiffs' suit. Again, the precise mechanism by which Plaintiffs have brought this suit is key to the Court's analysis. Although, as discussed above, this Court has jurisdiction under § 405(g) to hear Plaintiffs' action, Plaintiffs ultimately seek relief not under § 405(g), but under the APA. *See* Compl. ¶¶ 68–69. And under the APA, litigants may seek review of agency action, "except to the extent that [a] statute[] preclude[s] judicial review." 5 U.S.C. § 701(a)(1).

"There is a 'strong presumption that Congress intends judicial review of administrative action.'" *Amgen*, 357 F.3d at 111 (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). This presumption weighs "particularly strong[ly]" in favor of "judicial review

of agency action taken in excess of delegated authority," as alleged here. *Id.* at 111–12 (citing *Leedom v. Kyne,* 358 U.S. 184, 190 (1958); *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1173 (D.C. Cir. 2003)). To overcome the presumption, there must be "'clear and convincing evidence' of a contrary legislative intent." *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967) (quoting *Rusk v. Cort*, 369 U.S. 367, 380 (1962)), *overruled on other grounds by Califano v. Sanders,* 430 U.S. 99, 107 (1977). This analysis requires that the Court look to the statute's "express language . . . the structure of the statutory schemes, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.,* 467 U.S. 340, 345 (1984).

The Secretary contends that three Medicare provisions preclude this Court's review of Plaintiffs' suit: 42 U.S.C. § 1395*l*(t)(12)(A), (t)(12)(C), and (t)(12)(E). Defs.' Mot. at 17. Subsection (t)(12)(A) states:

> There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of . . . the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, *other adjustments*, and methods described in paragraph (2)(F).

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). Subsection (t)(12)(C) states that "[t]here shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of . . . *periodic adjustments* made under paragraph [9]."[13] *Id.* § 1395*l*(t)(12)(C) (emphasis added). And subsection (t)(12)(E) states:

[13] Both parties agree that because of a scrivener's error, subsection (t)(12)(C) explicitly refers to "periodic adjustments made under paragraph [(t)](6)" but should refer to subsection (t)(9). *See* Defs.' Mot. at 6 n.2; Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 7 n.6, ECF No. 16. Subsection (t)(9) requires that "[t]he Secretary . . . review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph [(t)](2)." *Id.* § 1395(t)(9)(A).

> There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of . . . the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), *the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals*, and the application of any pro rata reduction under paragraph (6).

Id. § 1395*l*(t)(12)(E) (emphasis added).

It is uncontested that none of these subsections explicitly preclude judicial review of rate adjustments made under subsection (t)(14). *See* Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 3, ECF No. 16. And Plaintiffs argue that without this explicit reference, there is no "clear and convincing evidence" that subsection (t)(12) is intended to preclude judicial review of the subsection (t)(14) rate adjustment at issue here. *Id.* a 3–4. The Secretary, on the other hand, argues that the separately payable drugs addressed by subsection (t)(14) fall within the OPPS payment "classification system" established under subsection (t)(2). Defs.' Mot. at 19. Therefore, according to the Secretary, adjustments to those drugs' reimbursement rates are "adjustments" described in subsection (t)(2), made to the agency's "fee schedule amount associated with particular . . . drugs," review of which are precluded by subsections (t)(12)(A) and (t)(12)(E). *Id.* at 19–21; Reply Supp. Defs.' Mot. ("Defs.' Reply") at 4–5, ECF No. 20. The Secretary further argues that in finalizing the 2018 OPPS Rule, the Secretary explicitly invoked his subsection (t)(9) authority to periodically revise relative payment rates, review of which is precluded by subsection (t)(12)(C). Defs.' Mot. at 20 (citing 82 Fed. Reg. at 52,356); Defs.' Reply at 7–8.

The parties' preclusion arguments notwithstanding, because Plaintiffs claim that the Secretary acted in excess of his statutory authority—that he acted *ultra vires*—the Court need not resolve the parties' conflicting interpretations of subsection (t)(12). "[T]he case law in this

circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans*, 321 F.3d at 1173 (citing *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996)). Thus, "the APA's stricture barring judicial review 'to the extent that statutes preclude judicial review,' 'does not repeal the review of *ultra vires* actions' . . . ." *Id.* (quoting 5 U.S.C. § 701(a)(1); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988)). Put simply, if the Secretary's 340B drug reimbursement rate reduction was an "adjustment" under subsection (t)(14), review of that adjustment is arguably precluded by subsection (t)(12). But if the Secretary's action was not an "adjustment," the Court may review it. *See Amgen*, 357 F.3d at 112 (section 1395*l*(t)(12)(A) prevents "review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of 'other adjustments' extends no further than the Secretary's statutory authority to make them.").

Accordingly, to determine whether Plaintiffs raise an *ultra vires* claim falling outside the scope of subsection (t)(12)'s preclusion provisions, the Court must consider that claim's merits. *See id.* at 113 ("[T]he determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review."); *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20–21 (D.D.C. 2014) ("[I]f Apligraf qualifies as a SCOD, this Court may hear the case under the *ultra vires* doctrine of review," but "if Apligraf does not qualify as a SCOD, 42 U.S.C. § 1395*l* (t)(12)(A) precludes this Court's review."); *cf. COMSAT Corp. v. FCC*, 114 F.3d 223, 226–27 (D.C. Cir. 1997) (in determining whether a statutory provision precluded judicial review of an agency action, noting that such a determination "merges consideration of the legality of the [agency]'s action with consideration of th[e] court's

jurisdiction in cases in which the challenge to the [agency]'s action raises the question of the [agency]'s authority to enact a particular amendment. Where, as here, we find that the [agency] has acted outside the scope of its statutory mandate, we also find that we have jurisdiction to review the [agency]'s action."). Because the Court concludes, as explained below, that the Secretary exceeded his authority under the Medicare provisions of the Social Security Act, the Court also necessarily concludes that subsection (t)(12) does not preclude judicial review of Plaintiffs' claims.

C. HHS's 340B Reimbursement Rate Reduction Was *Ultra Vires*

Having waded through the potential impediments to its jurisdiction, the Court may consider Plaintiffs' core allegation; that the Secretary acted *ultra vires* in "adjusting" the 340B drug reimbursement rates from ASP plus 6% to ASP minus 22.5%. "To challenge agency action on the ground that it is *ultra vires*, [a plaintiff] must show a 'patent violation of agency authority.'" *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016) (quoting *Indep. Cosmetic Mfrs. & Distribs., Inc. v. U.S. Dep't of Health, Educ. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978)). "A violation is 'patent' if it is '[o]bvious' or 'apparent.'" *Id.* (quoting Black's Law Dictionary (10th ed. 2014)). "Such ultra vires review is 'quite narrow.'" *H. Lee Moffitt Cancer Center & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)).

Plaintiffs' *ultra vires* argument here turns on the scope of the Secretary's discretion under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) to alter the statutory benchmark drug reimbursement rates. As noted, under that provision, a given drug's reimbursement rate "shall be equal . . . [to] the average price for the drug in the year established under . . . section 1395w-3a of this title . . . *as*

calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* (emphasis added). And the parties agree that § 1395w-3a sets a default payment rate of ASP plus 6%, which HHS implemented for several years preceding the 2018 OPPS Rule. Defs.' Mot. at 6; Pls.' Mem. at 3–4; 77 Fed. Reg. at 68,387.

Thus, the principle dispute among the parties is whether the Secretary acted within his authority to "calculate[] and adjust[]" the statutory benchmark rate of ASP plus 6% when he reduced that rate to ASP minus 22.5% based on his estimation of 340B hospitals' drug acquisition costs, rather than the drugs' average sales prices. 82 Fed. Reg. at 52,496. The Secretary argues that the authority to "adjust" reimbursement rates is essentially a plenary power to change rates according to any methodology, so long as the rates are expressed as a function of average drug prices. *See* Defs.' Mot. at 34. This argument relies on the premise that the statute's text does not impose any limits on the Secretary's authority to adjust rates. *See id.* at 31. This is plainly wrong.

In fact, the statute's plain text *does* limit the Secretary's "adjust[ment]" authority. The D.C. Circuit held as much under nearly identical circumstances in *Amgen*. In that case, the Circuit considered the Secretary's authority to adjust reimbursement rates under a different, but related, Medicare provision: 42 U.S.C. § 1395*l*(t)(2)(E). *Amgen*, 357 F.3d at 107. Like subsection (t)(14)(A)(iii)(II), subsection (t)(2)(E) authorizes the Secretary to make "adjustments" to certain hospital reimbursement rates "to ensure equitable payments" under the OPPS scheme. 42 U.S.C. § 1395*l*(t)(2)(E).[14] In addressing the *Amgen* plaintiff's claim that the Secretary

[14] This subsection states:

> the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph [(t)](5) and transitional pass-through payments under paragraph [(t)](6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals[.]

exceeded his adjustment authority under subsection (t)(2)(E), the Circuit observed that "[l]imitations on the Secretary's equitable adjustment authority *inhere in the text* of § (t)(2)(E)." *Amgen*, 357 F.3d at 117 (emphasis added). Indeed, because the statute "only authorizes 'adjustments,'" it could not be read to permit "total elimination or severe restructuring of the statutory scheme." *Id.* Though the relatively insignificant rate reduction at issue in *Amgen* was not *ultra vires*, the Circuit concluded that because "the term 'adjustments'" did not "encompass the power to make 'basic and fundamental changes in the [statutory] scheme' . . . a more substantial departure from the default amounts would, at some point . . . cease to be an 'adjustment[].'" *Id.* (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994)).

Amgen's logic applies equally here. First, "identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007). Thus, because Congress did not intend for the term "adjust" to confer unbridled authority in the context of subsection (t)(2)(E), there is good reason to believe that Congress did not intend to confer such authority in the context of subsection (t)(14)(A)(iii)(II). But more fundamentally, the structure of subsection (t)(14)(A)(iii)(II) necessitates this conclusion. That provision commands that SCOD reimbursement rates "shall" be set "equal" to a rate specified in certain other statutory provisions; here, each drug's average sales price plus 6%. 42 U.S.C. § 1395*l* (t)(14)(A)(iii)(II). This clear directive is qualified only by the Secretary's authority to "adjust" those rates. *Id.* Notably, the Medicare subsection at issue in *Amgen* followed this very same structure by articulating a clear requirement and then qualifying that requirement with the modest authority to adjust rates. Thus, like in *Amgen*, the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not

make "basic and fundamental changes" under the purported auspices of making mere "adjustments" to the rates statutorily imposed by that subsection.[15] *See Amgen*, 357 F.3d at 117; *cf. Railway Labor Execs.' Ass'n. v. Nat. Mediation Bd.*, 29 F.3d 655, 669 (D.C. Cir. 1994) (en banc) ("[I]t goes without saying that the bald assertion of power by [an] agency cannot legitimize it.").

Amgen also answers another critical question: whether an abuse of the Secretary's adjustment authority might form the basis of an *ultra vires* action. That is to say, whether a court could find, under some set of circumstances, that the Secretary has "patent[ly]" violated his authority to "adjust" payment rates. *Fla. Health Scis. Ctr.*, 830 F.3d at 522. *Amgen* suggests that such a finding is possible. The D.C. Circuit explained that, although the Secretary's equitable adjustment authority permitted "the adjustment of OPPS payments otherwise set by the Medicare Act," it did not "give the Secretary the absurdly broad power to make drastic adjustments, such as the elimination of the entire pass-through program, and term it an 'equitable adjustment,' thereby undermining the mandatory nature of the pass-through payment system *while evading judicial review*." *Amgen, Inc.*, 357 F.3d at 117 (emphasis added). Rather, if the Secretary makes "basic and fundamental changes in the scheme . . . the Secretary would, in that event, exceed his statutory authority [to make adjustments] under § (t)(2)(E) [and] *the preclusion on judicial*

[15] In addition to arguing that § 1395*l*(t)(14)(A)(iii)(II)'s plain text imposes no limitation on the Secretary's adjustment authority, the Secretary argues that had Congress wished to limit that authority, it would have done so explicitly, as it did in the same subsection with respect to 2004 and 2005 payment rates. Defs.' Mot. at 31 (citing 42 U.S.C. § 1395*l*(t)(14)(A)(i)–(ii)). This argument is essentially an all or nothing proposition; Congress either imposes rigid instructions or it grants unbridled authority. As discussed, the Court believes that Congress acted with more nuance here. In granting the Secretary authority to "adjust" the statutory benchmark rate, Congress provided leeway for the Secretary to alter and even reduce that benchmark, but not leeway to toss it aside entirely.

review in § (t)(12)(A) would not apply." *Id.* (emphasis added). In other words, judicial review would be permitted because the Secretary's purported "adjustment" would be, in fact, an *ultra vires* act (i.e. a patent violation of his authority).

The question for the Court, then, is whether the change at issue here—reducing the default 340B drug reimbursement rate of ASP plus 6% to ASP minus 22.5%—is so substantial as to be a patent violation of the Secretary's § (t)(14)(A)(iii)(II) adjustment authority. Although similar arguments have been raised in this jurisdiction, no court has held that the Secretary acted outside of his authority to make "adjustments" to any Medicare reimbursement rates. For example, in *Amgen*, the D.C. Circuit had "no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments'" because the rate adjustment at issue there involved "only the payment amount for a single drug, [which] does not work 'basic and fundamental changes in the scheme' Congress created in the Medicare Act . . . ." *Amgen, Inc.*, 357 F.3d at 117 (quoting *MCI*, 512 U.S. at 225). Likewise, in other cases, courts have found that payment reductions of 0.2% and 2.9% were not significant enough to warrant a finding that the Secretary exceeded his adjustment authority. *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 260 (D.D.C. 2015) (citing *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 700 (D.C. Cir. 2014)).

But the circumstances here are quite different than those previously presented in this jurisdiction. The Secretary's rate adjustment at issue here does not affect a single drug or even a handful of drugs, but rather potentially thousands of pharmaceutical products found in the 340B Program. *See* 82 Fed. Reg. at 52,494 (discussing the number of 340B "covered products" available to 340B covered entities). Moreover, the changes that the Secretary imposed are not modest. Indeed, by changing the formula from the statutory default of ASP plus 6% to ASP

minus 22.5%, the Secretary is imposing a nearly 30% reduction from the formula that Congress expressly set as the standard. When viewed together, the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to "adjust[]" SCOD rates under § (t)(14)(A)(iii)(II).

In attempting to justify this drastic departure from the statutorily mandated rates, the Secretary argues that because § (t)(14)(A)(iii) "itself identifies 'acquisition cost[s]' as a valid reference point for drug payments," the Secretary must necessarily have been within his authority to adjust 340B reimbursement rates to achieve that goal. *Id.* at 29, 33. It is true that § (t)(14)(A)(iii) authorizes the Secretary to set reimbursement rates at levels consistent with hospitals' acquisition costs for those drugs. 42 U.S.C. 1395*l* § (t)(14)(A)(iii)(I). But that authorization is found in subsection *(I)*, which requires the Secretary to consider certain hospital acquisition cost survey data. *Id.*

Here, the Secretary eschewed the use of subsection (I) because the required acquisition cost data was not available. 82 Fed. Reg. at 52,496. And the statutory scheme is clear that if the Secretary does not have that data, he must calculate reimbursement rates by reference to the drugs' *average sales prices*. 42 U.S.C. § (t)(14)(A)(iii)(II). While the Secretary is permitted to make "adjust[ments]" to those rates for whatever reasons he deems "necessary," adjustments are all he can make.[16] *Id.* He cannot fundamentally rework the statutory scheme—by applying a

[16] The Secretary argues that subsection (II) cannot mandate a reimbursement rate "based strictly on ASP" because that interpretation would render the Secretary's adjustment authority meaningless. Defs.' Mot. at 29. The Court's holding is not so rigid; it agrees that the Secretary has *some* authority to deviate from the statutory benchmark of ASP plus 6%. The Court merely holds that if an adjustment is sufficiently large and entirely de-coupled from the methodology imposed by subsection (II), it may exceed the Secretary's statutory authority and cease to be an "adjustment."

different methodology than the provision requires—to achieve under subsection (II) what he could not do under subsection (I) for lack of adequate data.[17] Indeed, the Secretary's admission that he sought to mimic the result of subsection (I)—by setting rates designed to approximate *acquisition costs*—under the authority of subsection (II)—which dictates that rates approximate *average sales prices*—only further supports the notion that the Secretary's purported adjustments were, in fact, fundamental changes in the statutory scheme.[18] *See* 82 Fed. Reg. at 52,500 (stating that the Secretary is "using [his] authority [under § (t)(14)(A)(iii)(II)] to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs"). Congress could very well have chosen to treat Medicare reimbursements for 340B drugs differently than reimbursements for other separately payable drugs, but it did not do so. To the extent the Secretary disagrees on policy grounds with Congress's decision, *see, e.g.*, 82 Fed. Reg. at 52,495 ("While we recognize the intent of the 340B program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs."), the Secretary may either collect the data necessary to set payment rates based on acquisition costs, or he may raise his disagreement with Congress, but he may not end-run Congress's clear mandate.

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[17] Because the Court concludes that the Secretary's rate reduction is unsupported by the statute's unambiguous text, the Court need not address whether the Secretary's statutory interpretation is entitled to deference under *Chevron, U.S.A., Inc. v, NRDC*, 467 U.S. 837, 842–43 (1984). *See* Defs.' Mot. at 28.

[18] The Secretary urges the Court to take into account the rate reduction's "context," and consider that it will allow Medicare beneficiaries to "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." Defs.' Mot. at 32 (quoting 82 Fed. Reg. at 52,495). The Court does not dispute the Secretary's policy reasons for seeking to reduce 340B reimbursement rates. But a noble goal does not excuse the Secretary's *ultra vires* action taken in pursuit of that goal.

For these reasons, the Court concludes that the Secretary acted *ultra vires*.[19] This conclusion carries two implications. First, the Court's conclusion means that 42 U.S.C. § 1395*l*(t)(12), which ordinarily proscribes judicial review of the Secretary's OPPS reimbursement rate determinations, presents no barrier in this case.[20] Therefore, the Secretary's Federal Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction must fail. Second, the Court's conclusion means that Plaintiffs have adequately alleged a claim for relief under the APA, thereby defeating the Secretary's Federal Rule 12(b)(6) motion to dismiss.

D. Disposition

Having resolved that this Court has jurisdiction over this matter and that, on the merits, the Secretary's action was *ultra vires*, the Court must now consider the proper way forward.

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[19] Accordingly, the Court declines to address Plaintiffs' alternative arguments that (1) the Secretary's adjustment authority is limited to the consideration of hospitals' overhead costs, Pls.' Mem. at 26–27; (2) the Secretary's action was *ultra vires* because it improperly treats certain providers differently than others, *id.* at 27–28; and (3) the Secretary's action was *ultra vires* because it undermines the purpose of the 340B program, *id.* at 28–30.

[20] The Secretary also argues that, even if §1395*l*(t)(12) does not preclude judicial review, any payment adjustment under § 1395(t)(14)(A)(iii)(II) is committed to agency discretion by law, and is therefore unreviewable by this Court. Defs.' Mot. at 25–26; *see also* 5 U.S.C. § 701(a)(2) (stating that an agency action may not be challenged under the APA if it "is committed to agency discretion by law"). Again, the provision at issue requires the Secretary to set SCOD payment rates at "the average price for the drug . . . *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph*." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). In raising his "agency discretion by law" argument, the Secretary focuses on the part of the statute that reads "as necessary for the purposes of this paragraph." Defs.' Mot. at 25–26. According to him, this language leaves the court without any "meaningful standard against which to judge the agency's exercise of discretion." *Id.* at 25 (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). But this argument can only carry force to the extent that one understands the Secretary's 340B rate reduction to be an "adjustment." That is, a court may not inquire into the "necessity" of an "adjustment" made by the Secretary, but that does not prevent the Court from inquiring into whether the Secretary's actions were, in fact, an "adjustment" or something more. Because, as described above, the Secretary's actions did not constitute an "adjustment" for purposes of the statute, the Secretary's argument presents no barrier to this Court's review. *See Amgen*, 357 F.3d at 117 (interpreting the statutory scheme to impose limitations on the Secretary's authority to "adjust" reimbursement rates).

Plaintiffs urge the Court to "[a]dvanc[e] a decision on the merits" under Federal Rule of Civil Procedure 65(a)(2). Pls.' Mem. at 34. Rule 65(a)(2) states that "[b]efore or after beginning [a] hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." Fed. R. Civ. P. 65(a)(2); *accord Teva Pharm. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 181 n.1 (D.D.C. 2005) ("This type of consolidation is a procedural tool designed to conserve the resources of the Court and the parties by avoiding duplicative efforts." (citing *NOW v. Operation Rescue,* 747 F. Supp. 760, 768 (D.D.C. 1990))), *vacated on other grounds by* 441 F.3d 1 (D.C. Cir. 2006). In determining whether a decision on the merits is appropriate, a court must consider whether, at this stage, "the record is sufficient for a determination on the merits under the summary judgment standard, or, where reliance on the record is unnecessary, under the motion to dismiss standard." *March for Life v. Burwell*, 128 F. Supp. 3d 116, 124 (D.D.C. 2015). Both parties contend that the record is sufficient for a determination on the merits here, and the Court agrees.

The Secretary has had every opportunity and incentive to argue the merits of Plaintiffs' claim, and he was aware that the Court may enter judgment on the merits at this stage. Indeed, the Secretary urged this Court to decide this case on the merits, asserting that "[b]ecause Plaintiffs' APA claims raise pure legal questions regarding the scope of the Secretary's statutory authority, the Court may reach the merits of those claims on a Rule 12(b)(6) motion."[21] Defs.'

[21] Even if the parties had not been on notice of the Court's inclination to render a decision on the merits, summary judgment would likely still be appropriate under Federal Rule of Civil Procedure 56. *See* Fed. R. Civ. P. 56(f)(3) (stating that a court may "consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute."). It is generally understood that "'[a] district court may grant summary judgment without notice if' . . . the losing party has had a full and fair opportunity to present arguments and . . . the parties have no genuine dispute as to a material fact." *Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1332 (Fed. Cir. 2010) (quoting *United States v. Grayson*, 879 F.2d 620, 625 (9th Cir. 1989)); *accord Colbert v. Potter*, 471 F.3d 158, 168 (D.C.

Mot. at 28 n.10. This, of course, is true. Plaintiffs' Complaint "actually presents no [disputed] factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); *see also* Defs.' Mot. at 28 n.10 ("[I]t is unnecessary for the Court to consider the administrative record in evaluating Plaintiffs' claim, since the claims present pure questions of statutory interpretation."); Defs.' Reply at 3 n.2 ("Defendant's motion . . . does not depend upon the contents of any documents other than the final rule challenged by plaintiffs and other judicially noticeable materials."). Thus, "the sufficiency of the complaint is the question on the merits, and there is no real distinction in this context between the question presented on a 12(b)(6) motion and a motion for summary judgment." *Marshall Cty.*, 988 F.2d at 1226; *see also March for Life*, 128 F. Supp. 3d at 124 ("Where a plaintiff's complaint properly states a claim, summary judgment is the appropriate method by which to resolve the merits of a dispute regarding federal agency action 'because the . . . regulation's validity is a question of law.'" (quoting *Lederman v. United States,* 89 F. Supp. 2d 29, 33 (D.D.C. 2000), *on recons. in part*, 131 F. Supp. 2d 46 (D.D.C. 2001))).

Consequently, in their briefing, both parties argued at length about the Secretary's authority to implement the Medicare rate reduction at issue. Moreover, the Secretary did not oppose, or even address, Plaintiffs' request that the Court render a judgment on the merits. And the Secretary gave no reason to believe that he might present different or additional legal

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Cir. 2006) (stating that summary judgment, even if entered erroneously, constitutes harmless error "[w]hen a nonmoving party could not have produced any 'evidence sufficient to create a substantial question of fact material to the governing issues of the case'" (quoting *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003)). In this case, the Secretary vigorously argued the merits of Plaintiffs' claim and conceded that there can be no genuine dispute of any material fact, as the case involves a pure question of law.

arguments at some later stage in the litigation.[22] As discussed above, having considered the parties' arguments, the Court concludes that the Secretary exceeded his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) in setting the 340B drug reimbursement rates in the 2018 OPPS Rule. Because the Secretary had every opportunity and every reason to present his merits arguments, because he did present those arguments, and because there is no reason to believe that a more developed record in the future could lead to any other outcome than the one reached today, the Court will enter judgment in favor of Plaintiffs.[23]

E. Remedies

The typical remedy for an agency rule promulgated contrary to law is to vacate the rule. *See Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017) (citing *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002)); *St. Lawrence Seaway Pilots Ass'n, Inc. v. U.S. Coast Guard*, 85 F. Supp. 3d 197, 208 (D.D.C. 2015). As noted, Plaintiffs seek that relief and its logical consequences, including that the Court require HHS to

[22] This Court held oral argument in *AHA I*, which involved the same parties, the same procedural posture, and substantially similar claims raised by Plaintiffs against the Secretary. *See AHA I*, 289 F. Supp. 3d at 50; Min. Entry, Dec. 21, 2017, *AHA I*, No. 17-2447 (noting that the Court heard oral argument on that date); Pls.' Mem. at 2 (conceding that *AHA I* concerned a "substantively identical challenge"); Defs.' Mot. at 15 (same). During that argument the Court asked the Secretary's counsel whether there was any reason why the Court should not enter judgment at this stage in the proceedings, and counsel could identify none apart from his general desire for a "second bite at the apple." The Court sees no reason to grant the Secretary a "second bite" when there is no evidence that the second bite would be any different than the first. The Court also declines to hear oral argument on the parties' motions at this stage because it believes that oral argument would "be of no meaningful assistance in rendering a final decision[,]" in light of the *AHA I* oral argument and the clear, thorough briefing in *AHA I* and this case. *Owen-Williams v. BB&T Inv. Servs., Inc.*, 797 F. Supp. 2d 118, 126 (D.D.C. 2011); *see also* LCvR 7(f) (stating that the decision to conduct an oral argument "shall be within the discretion of the Court").

[23] Because the Court has consolidated Plaintiffs' preliminary injunction motion with a decision on the merits, the Court "need not decide the preliminary injunction." *Pharm. Research & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 34 (D.D.C. 2014).

apply the 2017 OPPS drug reimbursement methodology—ASP plus 6%—to 340B drug payments made for the remainder of 2018,[24] and pay the Hospital Plaintiffs, and all 340B Program participants who are members of the Association Plaintiffs, the difference between the 340B drug payments that they have received under the 2018 OPPS Rule and the higher payments that they would have received under the 2017 OPPS Rule.[25] Pls.' Mot. at 1–2. In other words, Plaintiffs seek retroactive Medicare Part B payments and a reallocation of those payments going forward. Plaintiffs' complaint also seeks declaratory relief. Compl. at 23. In determining whether to provide these remedies, the Court must consider "'the seriousness of the . . . deficiencies' of the [agency's] action" and "the disruptive consequences of vacatur." *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 197 (D.C. Cir. 2009) (first alteration in original) (quoting *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1048–49 (D.C. Cir. 2002)).

Here, vacatur and the other relief sought by Plaintiffs are likely to be highly disruptive. An important component of the Medicare Part B scheme is its budget neutrality requirement. *See* 42 U.S.C. § 1395*l*(t)(9)(B) (stating that OPPS payment "adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made"). And the Secretary claims that this requirement applies to the 340B drug

[24] Considering the timing of the Court's Order, this first remedy is likely to have little impact compared to the second remedy.

[25] Plaintiffs also ask this Court to enjoin the Secretary and HHS from incorporating the payment methodology challenged here into the HHS rule setting 2019 340B drug reimbursement rates. *See* Pls.' Mem. at 35; Compl. at 24. However, Plaintiffs' complaint does not explicitly challenge the 2019 rule, and Plaintiffs have once again failed to show that they have presented the Secretary with a concrete claim for reimbursement under the 2019 rule, as required by 42 U.S.C. § 405(g). *See Eldridge*, 424 U.S. at 328. This Court is thus foreclosed from reviewing the 2019 rule, and it declines to impose injunctive relief concerning that rule. *AHA II*, 895 F.3d at 828.

reimbursements at issue here. Defs.' Mot. at 5, 14; *see also* 82 Fed. Reg. at 52,623 ("[W]e are implementing this payment reduction in a budget neutral manner within the OPPS").

Under the budget neutrality requirement, reducing 2018 340B reimbursement rates allowed the Secretary to increase reimbursements for other drugs and services covered under Medicare Part B; increasing 340B reimbursement rates would likewise require the Secretary to reduce reimbursements elsewhere in the program. For instance, in finalizing the 2018 OPPS Rule, the Secretary stated that "the reduced payments for separately payable drugs purchased through the 340B Program w[ould] increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount." 82 Fed. Reg. at 52,623. The Secretary could thus "increase OPPS payment rates for non-drug items and services by approximately 3.2[%]." *Id.* The retroactive OPPS payments that Plaintiffs seek here would presumably require similar offsets elsewhere; a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018.

The D.C. Circuit and other circuits have recognized the "havoc that piecemeal review of OPPS payments could bring about" in light of the budget neutrality requirement. *Amgen*, 357 F.3d at 112 (citing *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002) (noting the "disruptive" impact of requiring Medicare Part B payment adjustments); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386–87 (9th Cir. 1996)); *see also Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012) ("Judicial determinations forcing the Secretary to retroactively alter payment rates for various covered services—e.g., payment rates that are adjusted annually and are required to remain budget neutral—would likely wreak havoc on the already complex administration of Medicare Part B's outpatient prospective payment system." (citation omitted)). In the interest of

avoiding that havoc, and because neither party thoroughly addressed the question of remedies in their briefs,[26] the Court will order supplemental briefing on this issue.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**, the Secretary's Motion to Dismiss (ECF No. 14) is **DENIED**, and Plaintiffs' Motion for a Permanent Injunction (ECF No. 2) is **GRANTED**, insofar as Plaintiffs are entitled to equitable relief. Fashioning that relief, however, requires supplemental briefing from the parties addressing the relief's proper scope and implementation. Consequently, it is **HEREBY ORDERED** that:

1. The parties shall provide supplemental briefing on the appropriate remedy, limited to no more than 25 pages per brief, within 30 days of this Memorandum Opinion's issuance; and
2. The parties shall respond to those briefs, limited to no more than 15 pages per response, within 14 days after the supplemental briefs are filed.

An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: December 27, 2018

RUDOLPH CONTRERAS
United States District Judge

[26] The Secretary argues that the potential disruption caused by judicial intervention motivated Congress to preclude judicial review of OPPS payment adjustments. Defs.' Mot. at 40–41. The Secretary does not, however, address how that disruption may be mitigated in the event of a decision for Plaintiffs. And Plaintiffs make the conclusory argument that the disruption would be offset by gains resulting from the lawful implementation of Medicare Part B. Pls.' Opp'n at 10–11. While a noble sentiment, this does not bring the Court any closer to understanding how to provide Plaintiffs with relief without wreaking havoc on the system.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

DECLARATION OF ELIZABETH RICHTER

I, Elizabeth Richter, declare as follows:

1. I am the Deputy Center Director of the Center for Medicare within the Centers for Medicare & Medicaid Services ("CMS"). CMS is the federal agency within the United States Department of Health and Human Services ("HHS") responsible for administering the Medicare and Medicaid programs. The Center for Medicare is responsible for, among other things, developing the policies for, and managing the operations of, the fee-for-service portion of the Medicare program, including Medicare Part B payments. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me by CMS staff and contractors in the course of my official duties.

2. I am familiar with the subject matter of the above-captioned lawsuit. More specifically, I am aware that the district court in this case has concluded that the defendants – the U.S. Department of Health and Human Services and its Secretary – acted in an *ultra vires* manner by reducing the payment rate for drugs purchased through the 340B Program in the 2018

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Outpatient Prospective Payment System ("OPPS") Final Rule. I further understand that the court instructed the parties to file "supplemental briefing on the appropriate remedy."

3. The Medicare OPPS typically processes more than 100 million outpatient hospital claims every calendar year. For the 2018 OPPS calendar year, the agency expects to process more than 110 million such claims.

4. These OPPS claims relate to items and services provided by approximately 3,900 facilities for outpatient items and services covered under the OPPS. These items and services are provided to millions of different Medicare beneficiaries, who, by statute, are required to pay cost-sharing for such items and services, which is usually 20% of the total Medicare payment rate.

5. To provide some additional context for this payment system, in the 2018 OPPS calendar year Final Rule CMS estimated that OPPS expenditures would exceed $55 billion in Medicare Part B payments by the federal government and almost $14 billion in Medicare beneficiary cost-sharing payments, for a total of more than $69 billion in Medicare payments for the more-than 100 million claims submitted.

6. Medicare OPPS claims are paid every year according to OPPS payment rates that are established in advance of the upcoming calendar year. Developing this payment system, which is done on an annual basis, is a complicated process that begins several months before the release of the proposed rule, which typically occurs around July of each year. The process culminates in a final rule, usually released on or around November 1 to allow for the 60-day period required under the Congressional Review Act before the new payment rates take effect on January 1. The complex and interconnected nature of the many calculations necessary to develop the OPPS payment rates are described in greater detail on the CMS website. This 40-page "claims

accounting" document sets forth an accounting of the claims CMS used to calculate average costs for OPPS services, which were ultimately used to establish final payment rates for the 2018 OPPS. *See* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Claims-Accounting.pdf

7. In the calendar year 2018 OPPS Rule, CMS provided that as a result of the policy change with respect to drugs acquired under the 340B program, the agency estimated a payment reduction of $1.6 billion in separately paid OPPS drug payments. As required by statute, this reduction was offset in a budget neutral manner, and, as a result, CMS adjusted payments for *all non-drug* OPPS services by an equal amount (that is, CMS raised rates for non-drug items and services by $1.6 billion). A potential remedy that would address reversing this policy would be to reprocess *all* claims for items and services furnished by all providers paid under the OPPS (including those that are not party to this case), but that potential remedy requires an arduous, disruptive and time-consuming process of recalculating all OPPS rates for 2018 (because of the budget neutral aspect of the policy change), as well as a significant update of the claims processing system that would then apply newly calculated OPPS payment rates to all previously submitted 2018 claims. We estimate that it would cost between $25 million and $30 million in additional administrative expenses.

8. Moreover, this potential remedy could have a significant impact on the cost-sharing obligations of Medicare beneficiaries. If CMS is required to undertake the process of recalculating and reapplying new 2018 OPPS payment rates, that retroactive change in payment amount could significantly alter a Medicare beneficiary's cost-sharing amount, which is generally 20% of the allowed Medicare payment rate. For example, if Medicare previously paid

$3,300 for a drug in 2018, but as a result of a judicial decision it is determined that the Medicare-allowable payment amount should have been $5,300 for that drug, the cost-sharing amount borne by the Medicare beneficiary would increase by $400. Notably, this problem arises is in the context of a system that processes more than 100 million claims each calendar year. CMS is very concerned about the potential for confusion and anxiety among Medicare beneficiaries if CMS were to recalculate Medicare payments and change beneficiary financial obligations for calendar year 2018 because beneficiaries could be responsible for different cost-sharing amounts, which could be higher or lower than their original cost-sharing obligations, depending on the mix of items and services they received – i.e., if a beneficiary only received a 340B-acquired drug his cost-sharing would increase, and if he only received a non-drug OPPS service his cost sharing would decrease. The total amount of beneficiary cost-sharing impacted by reprocessing all such claims was estimated at $320 million in the 2018 OPPS final rule.

9. In addition, CMS utilizes Medicare contractors to process OPPS claims, and to reprocess all 2018 OPPS claims would take a substantial amount of time to effectuate. Based on the number of providers and claims involved for the 2018 OPPS calendar year, and the statutory requirement to continue to timely process real-time claims for the current period, among other things, we estimate this process would take at least a year. To date, CMS does not yet have all final-action claims submitted by providers for calendar year 2018, but based on claims received so far, we estimate if this potential remedy is mandated, that over 110 million claims would have to be reprocessed for 2018 OPPS claims, and that this would result in an additional administrative cost of paying Medicare contractors an additional $25-$30 million as referenced above. Moreover, based on current workload and agency estimates, for the vast majority of Medicare contractors (who process Medicare claims on behalf of CMS), it will take at least one

ER

year to complete all the adjustments for all the claims once new OPPS payment rates are calculated, developed, and loaded into Medicare claims-processing software. Medicare contractors have existing workloads to process claims, and they still are responsible for processing newly submitted claims for services furnished in 2019 in a timely manner. The timely processing of 2019 claims as they are submitted is important to ensure that providers receive payment from Medicare and can continue to provide services to beneficiaries, but it is also important because, by statute, the government would owe an additional amount of interest on such claims unless it continues to process them. Put simply, there is a limit to the number a claims a particular Medicare contractor can process in a day, and the year-long time estimate above is based on current workload and the additional claims that contractors might be able to process in addition to their normal workload.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: January 31, 2019

Baltimore, Maryland

Elizabeth Richter

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001,

THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K Street, NW, Suite 100
Washington, DC 20001,

AMERICA'S ESSENTIAL HOSPITALS,
401 Ninth Street, NW, Suite 900
Washington, DC 20004,

NORTHERN LIGHT HEALTH,
43 Whiting Hill Road
Brewer, ME 04412,

HENRY FORD HEALTH SYSTEM,
1 Ford Place
Detroit, MI 48202, and

FLETCHER HOSPITAL, INC., d/b/a PARK RIDGE HEALTH,
100 Hospital Drive
Hendersonville, NC 28792,

Plaintiffs,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Civil Action No. 18-2084 (RC)

SUPPLEMENTAL COMPLAINT

The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Northern Light Health, Henry Ford Health System, and Fletcher Hospital, Inc. d/b/a Park Ridge Health bring this action against Defendants Department of Health and Human Services ("HHS") and Alex M. Azar II, in his official capacity as the Secretary of HHS, and allege the following:

NATURE OF ACTION

1. Plaintiffs bring this action under the Social Security Act and the Administrative Procedure Act ("APA") to challenge certain provisions of a final rule issued on November 1, 2017, by the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS. *See* 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017). The rule concerns the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for Calendar Year 2018. The portions of the rule being challenged in this case reduced by nearly 30% Medicare reimbursements to certain public and not-for-profit hospitals and clinics for prescription drugs purchased by those institutions on a discounted basis under section 340B of the Public Health Service Act (the "340B Program"). These challenged portions of the rule will hereafter be referred to as the "340B Provisions of the 2018 OPPS Rule" or "the 2018 OPPS Rule." The 340B Provisions of the 2018 OPPS Rule took effect on January 1, 2018.

2. On November 21, 2018, CMS issued a final rule for calendar year 2019 that "continu[es] the 340B Program policies that were implemented in [calendar year] 2018," including the nearly 30% reimbursement rate reduction for drugs purchased under the 340B Program. *See* 83 Fed. Reg. 58,818, 58,981 (Nov. 21, 2018) (hereinafter "the 340B Provisions of

the 2019 OPPS Rule" or "the 2019 OPPS Rule"). Plaintiffs challenge the 2019 OPPS Rule as well.

3. Congress enacted the 340B Program in 1992 and through that Program lowered the cost of drugs purchased by certain public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. By lowering hospitals' purchase costs for patient drugs, Congress enabled these hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. No. 102–384(II), at 12 (1992). *See also* 82 Fed. Reg. at 52,493 & n.18 (quoting House report and noting that "[t]he statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients"). The 340B Provisions of the 2018 and 2019 OPPS Rules specially target the Medicare portion of this benefit of the Program for 340B hospitals that serve the poor. The 2018 and 2019 OPPS Rules eliminate nearly all of the differential between national Medicare reimbursement rates and the discounted purchase costs mandated for 340B hospitals, costing those hospitals an estimated (by CMS) $1.6 billion, in violation of both the Secretary's statutory authority under the Social Security Act to reimburse hospitals for outpatient drugs and the purpose and design of the Public Health Service Act provisions establishing the 340B program.

4. Plaintiffs American Hospital Association, Association of American Medical Colleges, and America's Essential Hospitals (the "Association Plaintiffs") are hospital associations whose members, including Plaintiffs Northern Light Health, Park Ridge Health, and Henry Ford Health System (the "Hospital Plaintiffs"), have used the 340B Program to provide critical healthcare services to their communities, including to underserved patient populations in those communities. Those hospitals and their poor and underserved patient populations have

suffered, and will continue to suffer, harm from the negation of the cost-reimbursement differential through the 340B Provisions of the 2018 and 2019 OPPS Rules. Plaintiffs are entitled to declaratory and injunctive relief, including a preliminary injunction setting aside the 340B Provisions of the 2018 and 2019 OPPS Rules pending resolution of this action.

PARTIES

5. Plaintiff American Hospital Association ("AHA") is a national not-for-profit organization headquartered in Washington, D.C. AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members (largely hospital professional staff). AHA's mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to their communities and committed to health improvement. AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It also ensures that members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters.

6. Many of AHA's member hospitals participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for the vulnerable populations they serve. These AHA members have been significantly harmed by the elimination of this differential from Medicare payments in the 2018 and 2019 OPPS Rules and will continue to be significantly harmed if those Rules remain in effect.

7. Plaintiff Association of American Medical Colleges ("AAMC") is a national not-for-profit association headquartered in Washington, D.C. AAMC is dedicated to transforming

health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its membership consists of all 151 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

8. Many of AAMC's member teaching hospitals participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for their communities, including vulnerable populations in those communities. These AAMC members have been significantly harmed by the elimination of this differential from Medicare payments in the 2018 and 2019 OPPS Rules and will continue to be significantly harmed if those Rules remain in effect.

9. Plaintiff America's Essential Hospitals ("AEH") is a national not-for-profit association headquartered in Washington, D.C. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Since 1981, AEH has initiated, advanced, and preserved programs and policies that help these hospitals ensure access to care. Its 325 hospital members are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

10. Almost all of AEH's member hospitals participate in the 340B Program and rely heavily on the price differential created by Congress through that Program to generate resources that are used to provide critical health care programs for the communities they serve, including

vulnerable populations within those communities. These AEH members have been significantly harmed by the elimination of this differential from Medicare payments in the 2018 and 2019 OPPS Rules and will continue to be significantly harmed if those Rules remain in effect.

11. Plaintiff Northern Light Health ("Northern Light") is an integrated health care system headquartered in Brewer, Maine, near Bangor, Maine, and is a member of the Plaintiff AHA. Northern Light provides services throughout virtually the entire State of Maine – including both the urban populations in south and central Maine and the rural populations residing in Maine's economically challenged northern and eastern regions. Northern Light-affiliated entities employ over 700 physicians providing access to care for the 93% of Maine's population living in Northern Light service areas.

12. Maine has the oldest population of any state and the largest percentage of Medicare eligible citizens in the nation. A large percentage of Northern Light's services is provided to elderly and disadvantaged populations.

13. The 340B Provisions of the 2018 and 2019 OPPS Rules severely threaten Northern Light's ability to provide critical healthcare programs to its communities, including the underserved populations in those communities, by depriving it of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

14. Plaintiff Henry Ford Health System ("Henry Ford") is a not-for-profit integrated health care delivery system headquartered in Detroit, Michigan. Henry Ford serves the metropolitan Detroit and Jackson areas of Michigan. The system has 30,000 employees, 26 medical centers, six acute care hospitals with a total of 2,405 inpatient beds, including its flagship hospital—Henry Ford Hospital ("HFH")—a large academic safety net hospital located

within the city of Detroit, and Henry Ford Allegiance, ("HF Allegiance") located in the city of Jackson. HFH is a member of Plaintiffs AHA, AAMC, and AEH. HF Allegiance is a member of Plaintiff AHA.

15. Located in Detroit's Midtown, HFH has served the Detroit community—which has the highest rate of concentrated poverty among the top 25 metro areas in the United States—for over 100 years. HFH is an 877-bed tertiary care hospital, education and research center, which provides comprehensive and advanced inpatient and outpatient care. HFH is also a Level I trauma center and one of the largest U.S. teaching hospitals.

16. Located in Jackson, HF Allegiance is a 475-bed healthcare organization that has served as the sole health system for the south central Michigan community since 1918. With more than 400 physicians, HF Allegiance's network of 40 facilities complements traditional acute care with mission-based services to address the health needs of its economically-challenged, underserved community. Jackson has a median income of $28,000 and a 36% poverty rate.

17. By depriving Henry Ford of millions of dollars previously generated by the differential between Medicare reimbursements and 340B discounts, the 340B Provisions of the 2018 and 2019 OPPS Rules severely threaten the ability of Henry Ford, including HFH and HF Allegiance, to provide critical healthcare programs to their communities, including the underserved populations in those communities.

18. Plaintiff Park Ridge Health ("Park Ridge") is a not-for-profit health care system headquartered in Hendersonville, North Carolina, south of Asheville, North Carolina, and is a member of the Plaintiff AHA. Park Ridge employs 119 doctors, nurses and other healthcare professionals who practice at 30 locations across Henderson, Buncombe, and Haywood

Counties. Park Ridge is part of Adventist Health System ("AHS"), a network of approximately 45 Seventh-day Adventist-affiliated hospitals, as well as skilled nursing facilities, physician offices, home health agencies, hospice providers, and urgent care facilities in nine states.

19. The communities Park Ridge serves contain a large percentage of elderly and retired persons, including a large number of Medicare beneficiaries. In fiscal year 2016, Medicare was responsible for approximately 52% of Park Ridge's gross revenues. The 340B Provisions of the 2018 and 2019 OPPS Rules severely threaten Park Ridge's ability to provide critical healthcare programs to its communities, including the underserved populations in those communities, by depriving it of millions of dollars of savings previously generated from the differential between Medicare reimbursements and 340B discounts.

20. Defendant HHS is a cabinet-level department of the United States government headquartered at 200 Independence Avenue, SW, Washington, D.C. 20201. CMS, which issued the 340B Provisions of the OPPS Rule, is an agency within HHS.

21. Defendant Alex M. Azar II ("the Secretary") is the Secretary of Health and Human Services") and maintains offices at 200 Independence Avenue, SW, Washington, D.C. 20201. In that capacity, he is responsible for the conduct and policies of HHS, including the conduct and policies of CMS. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

22. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, section 340B of the Public Health Services Act, 42 U.S.C. § 256b, and the Administrative Procedure Act, 5 U.S.C. § 701–06.

23. This Court has subject matter jurisdiction over this action under 42 U.S.C. § 405 and 28 U.S.C. § 1331.

24. This judicial district is an appropriate venue pursuant to 28 U.S.C. § 1391(e), 42 U.S.C. § 405(g), and 42 U.S.C. § 1395ff(b)(2)(C)(iii).

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

25. Congress established the 340B Program in 1992 as part of the Public Health Service Act. The 340B Program provides certain hospitals serving a disproportionate share of low-income individuals and federally-funded clinics (called "covered entities" in the statute) with outpatient prescription drug discounts comparable to those that Congress had made available to state Medicaid agencies in 1990. Under the 340B Program, private prescription drug manufacturers, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs, are required to offer covered entities discounts calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1). As the Health Resources & Services Administration ("HRSA"), the agency within HHS responsible for administering the 340B Program, has recognized, the purpose of the Program is to enable eligible public and not-for-profit hospitals and other covered institutions to use their scarce resources to reach more patients, and to provide more comprehensive services.

26. Since the 340B Program was first implemented, covered entities have retained all savings generated through the program and have used those savings to provide additional critical healthcare services for their communities, including underserved populations within those communities – for example, by increasing service locations, developing patient education programs, and providing translation and transportation services.

27. Recognizing the value of the 340B Program, Congress has increased the categories of eligible "covered entities." In 1992, when Congress first created the Program,

"covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income populations. *See* 42 U.S.C. §§ 256b(a)(4)(A)-(E), (G), (L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O).

28. Each of the Hospital Plaintiffs and many other members of the Association Plaintiffs are "covered entities" under the 340B Program and are paid under the OPPS system.

B. Medicare OPPS Reimbursement

29. In 1997, Congress acted to control Medicare expenditures for outpatient services and directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient departments, for example rehabilitation services. *See* 42 U.S.C. § 1395*l*. CMS updates the OPPS payment rates annually.

30. Beginning in 2004, Congress required CMS to set reimbursement rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled into the price of an outpatient service. These drugs include outpatient drugs covered under the 340B program.

31. A provision of the statute provides CMS with two choices in setting Medicare reimbursement rates for separately payable drugs in 2006 and subsequent years. Under Subclause I of that statutory provision, CMS must set rates based on the acquisition costs of these drugs, if specified statistically sound survey data on acquisition cost are available for each drug. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Under Subclause II, if the specified acquisition cost data are not available, CMS is required to reimburse based on average sales price ("ASP")—a

defined quantity under a different statutory provision—plus 6%. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

32. In 2012, after concluding that it could not obtain the acquisition cost required in order to reimburse under Subclause I based on acquisition cost, CMS adopted the reimbursement method under Subclause II - the statutory default rate of ASP plus 6% - for all separately payable drugs. CMS applied this statutory default rate without further adjustments for each subsequent year, until January 1, 2018.

C. CMS's Proposed and Final Rule to Reduce Payment Rate for 340B Drugs

33. On July 13, 2017, CMS issued its proposed rule on OPPS and Ambulatory Surgical Center payment systems for the Calendar Year 2018. In addition to updating the OPPS with 2018 rates, CMS proposed to change how Medicare pays certain hospitals for separately payable drugs purchased under the 340B Program. 82 Fed. Reg. 33,558, 33,634 (July 20, 2017). Specifically, CMS proposed lowering the government payment rate for such drugs from the previous (statutory default) rate of ASP plus 6% to ASP minus 22.5% - a reduction in the reimbursement rate of 28.5 %. *Id.* at 33,634.

34. CMS admitted that its reason for proposing this reduction was that a lower reimbursement rate would better reflect the acquisition cost of the drugs. According to CMS, the new rate would better recognize "the significantly lower acquisition costs of such drugs incurred by a 340B hospital," *id.*, and "better represent[] the average acquisition cost for these drugs and biologicals," *id.* at 33634. On November 1, 2017, CMS issued the final version of the 340B Provisions of the 2018 OPPS rule, adopting the proposed rate of ASP minus 22.5% for drugs purchased under the 340B Program. 82 Fed. Reg. 52,356, 52,362.

35. This new reimbursement rate nearly eliminated the benefit of the 340B program for certain covered entities for Medicare/340B drugs by eliminating the difference between the purchase price paid *by* hospitals for those drugs and Medicare payments *to* hospitals for those drugs.

36. In reducing the payment rate for certain 340B drugs by nearly 30%, CMS purported to rely on its authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which allows the Secretary to "calculate" and "adjust" the statutory default rate of ASP plus 6%. *E.g.*, 82 Fed. Reg. at 52,499 (noting that "calculate and adjust" authority gives the Secretary "broad discretion" to adjust payments for drugs). The 340B Provisions of the 2018 OPPS Rule exceed the Secretary's authority because the reduction set forth in the Rule is expressly based on the estimated acquisition costs of 340B drugs, *i.e.*, a variation of the cost-based methodology set forth under Subclause I of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). *E.g.,* 82 Fed. Reg. at 52,501. Because CMS, by its own admission, cannot now and has never been able to reliably collect the statistically significant cost data for each drug required under the statute to invoke Subclause I, it improperly sought to use *aggregate* acquisition costs as estimated by the Medicare Payment Advisory Commission ("MedPAC") as a proxy for that data in issuing the OPPS Rule – even though payment under Subclause II expressly must be based on average sales price, *not* acquisition costs. In doing so, the Secretary impermissibly invoked his authority under Subclause II to circumvent the requirements under Subclause I.

37. The Secretary's authority under Subclause II of the applicable statutory provision, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), to "calculate" and "adjust" the ASP-plus-6% formula, does not allow CMS to reduce the statutory rate by nearly 30%, depriving affected hospitals of drug-price savings totaling an estimated $1.6 billion (CMS's estimate). Rather, this authority only

permits the Secretary to calculate the ASP as set forth in the statute and to fine-tune the default rate.

38. The 340B Provisions of the 2018 OPPS Rule also exceed the Secretary's authority because they undermine the 340B Program by depriving eligible hospitals of a critical portion of the resources Congress intended to provide those hospitals through 340B discounts. Elimination of these resources has and will continue to put public and not-for-profit covered entities into even more precarious financial situations, curtailing their ability to provide essential healthcare services and programs to their communities, including underserved populations within those communities. This is inconsistent with the intent of the 340B program, which was designed to help covered entities stretch scarce federal resources to reach more patients. CMS's efforts in the 340B Provisions of the 2018 OPPS Rule to "align" (82 Fed. Reg. at 52,495) the purchase price of 340B drugs with reimbursements for those drugs is directly contrary to Congress' intent to create a differential between reimbursements and purchase prices and thereby to generate resources for covered entities to use in their communities.

39. The new payment rate set forth in the 340B Provisions of the 2018 OPPS Rule has substantially impacted the day-to-day operations of many covered entities, including the Hospital Plaintiffs and other members of the Association Plaintiffs. These entities rely on the 340B savings, and the price differential Congress created through that program, to provide vital health services to their communities, including vulnerable and underserved populations within those communities. Elimination of the differential in connection with Medicare payments for 340B drugs will threaten many of these critical programs, and thus the poor and underserved populations who depend on 340B hospitals, in direct contravention of the purpose and design of the 340B program.

40. On November 21, 2018, CMS issued the 2019 OPPS Rule, which "continu[es] the 340B Program policies that were implemented in [calendar year] 2018," including the policy of "pay[ing] for separately payable Medicare Part B drugs . . . that are acquired through the 340B Program at ASP minus 22.5 percent." 83 Fed. Reg. at 58,980–81.

ADMINISTRATIVE REVIEW OF PLAINTIFFS' CLAIMS FOR PAYMENT

41. After a health-care provider performs Medicare-eligible services, it submits a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). The MAC makes an initial determination whether to pay the claim, and if so, how much to pay. 42 C.F.R. § 405.920. If the MAC denies a claim for payment in whole or in part, the Social Security Act provides a four-level administrative appeal process. First, the provider may present its claim again to the MAC for "redetermination." 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Second, the provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960. Third, the provider may seek *de novo* review by an administrative law judge in the Office of Medicare Hearings and Appeals. 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. §405.1000–58. If, however, an appeal turns on a question of law or regulation and does not present any material disputes of fact, then after or simultaneous with requesting third-level review by an administrative law judge, a provider may ask the Departmental Appeals Board to certify the appeal for expedited access to judicial review. 42 U.S.C. § 1395ff(b)(1)(A), (b)(2); 42 C.F.R. § 405.990. Fourth, the provider may seek *de novo* review by the Medicare Appeals Council, which is a part of the HHS Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 1100.

42. If HHS's final decision after this process is unfavorable, a provider may seek judicial review. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 1136.

A. Henry Ford Health System

43. On January 9, 2018, Henry Ford presented a claim for payment to WPS Government Health Administrators ("WPS"), a MAC, for separately payable drugs subject to the 340B Program. On January 25, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21800900583604MIA (hereinafter "Claim '604") and that $5,031.81 would be remitted to Henry Ford on that claim.

44. On January 10, 2018, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21801000637704MIA (hereinafter "Claim '704") and that $10,533.62 would be remitted to Henry Ford on that claim.

45. On January 10, 2018, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2018, WPS issued an initial determination advising Henry Ford that the claim would be labeled 21801000640004MIA (hereinafter "Claim '004") and that $3,734.85 would be remitted to Henry Ford on that claim.

46. Consistent with the payment reduction in the 340B Provisions of the 2018 OPPS Rule, WPS's payments on Claims '604, '704, and '004 were approximately 30% less than what it had paid Henry Ford on identical claims in 2017. On February 8, 2018, Henry Ford submitted redetermination requests to WPS for each of the three claims in which it demanded full reimbursement in the amount of $7,344.77 on Claim '604, $14,876.96 on Claim '704, and $5,451.99 on Claim '004. On each of the three redetermination request forms, Henry Ford contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(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.

47. On March 6, 2018, WPS issued unfavorable decisions on each of Henry Ford's three redetermination requests, correctly explaining in each of the three redetermination letters that the amount it had already paid was "the maximum payment allowed by Medicare" for the service at issue.

48. On March 27, 2018 (Claims '604 and '004) and April 10, 2018 (Claim '704), Henry Ford submitted reconsideration requests regarding its three claims to Maximus Federal Services ("Maximus"), a QIC. In each of its three reconsideration requests, Henry Ford raised the same argument that it had raised in its redetermination requests to WPS.

49. Maximus initially issued favorable reconsideration decisions on each of Henry Ford's three claims on May 22, 2018 (Claim '004) and June 1, 2018 (Claims '604 and '704), stating that Henry Ford "was underpaid" on each claim. However, after CMS recouped the payments on Claims '704 and '004, it reprocessed those claims and reissued payments for exactly the same lower amounts that it had issued previously in conformity with the 2018 OPPS Rule. CMS never reprocessed Claim '604. Henry Ford later learned that each of the three appeals had been reopened at the direction of CMS, which had determined that there are no administrative appeal rights for claims related to the 340B Program. Henry Ford subsequently received letters regarding each of its three reconsideration requests from Maximus, all dated July 11, 2018, in which Maximus stated that each of the three reopened appeals "ha[d] been deleted from our system" and that "MAXIMUS will not be issuing a new reconsideration decision at this time." These letters constituted dismissals of each of Henry Ford's three appeals. To date, Henry Ford has not been paid any amount of money on any of its three claims other than the deficient initial remittances made pursuant to the new OPPS Rule.

50. On August 2, 2018, Henry Ford submitted requests to the Office of Medicare Hearings and Appeals for review by an Administrative Law Judge ("ALJ") of Maximus's decisions on each of Henry Ford's three reconsideration requests. In each of its three ALJ hearing requests, Henry Ford raised the same argument that it had raised in its redetermination requests to WPS and in its reconsideration requests to Maximus.

51. On August 10, 2018, Henry Ford submitted a request to the Departmental Appeals Board for expedited access to judicial review pursuant to 42 C.F.R. § 405.990 on its three appeals. The request explained that there are no material facts in dispute and that Henry Ford's challenge to the remittances on its three claims turns on purely legal disputes about the whether the 2018 changes to the 340B Program exceeded Secretary's statutory authority to adjust reimbursement rates and whether administrative and judicial review of such challenges is available.

52. On January 10, 2019, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On January 30, 2019, WPS issued an initial determination advising Henry Ford that the claim would be labeled ICN 21901000533804MIA (hereinafter "Claim '804") and that $6,989.43 would be remitted to Henry Ford on that claim. On January 11, 2019, Henry Ford presented a claim for payment to WPS for separately payable drugs subject to the 340B Program. On February 1, 2019, WPS issued an initial determination advising Henry Ford that the claim would be labeled ICN 21901100534104MIA (hereinafter "Claim '104") and that $21,919.13 would be remitted to Henry Ford on that claim.

53. Consistent with the payment reduction in the 340B Provisions of the 2018 OPPS Rule that was carried forward in the 2019 OPPS Rule, WPS's payments on Claims '804 and '104 were approximately 30% less than what it had paid Henry Ford on identical claims in 2017.

54. In light of these events, Henry Ford has presented specific claims for payment to the Secretary under both the 2018 and 2019 OPPS Rules and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

B. Northern Light Health

55. On January 23, 2018, Northern Light presented a claim for payment to National Government Services ("NGS"), a MAC, for separately payable drugs subject to the 340B Program. On February 6, 2018, NGS issued an initial determination advising Northern Light that the claim would be labeled 21802300601207MEA (hereinafter "Claim '207"), and that a total of $4,826.63 would be remitted to Northern Light on that claim.

56. On February 6, 2018, Northern Light presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising Northern Light that the claim would be labeled 21803700697107MEA (hereinafter "Claim '107"), and that a total of $4,826.63 would be remitted to Northern Light on that claim.

57. On February 6, 2018, Northern Light presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising Northern Light that the claim would be labeled

21803700743607MEA (hereinafter "Claim '607") and that a total of $4,598.67 would be remitted to Northern Light on that claim.

58. On February 6, 2018, Northern Light presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 20, 2018, NGS issued an initial determination advising Northern Light that the claim would be labeled 21803700741907MEA (hereinafter "Claim '907") and that a total of $3,338.66 would be remitted to Northern Light on that claim.

59. On February 6, 2018, Northern Light presented a claim for payment to NGS for separately payable drugs subject to the 340B Program. On February 21, 2018, NGS issued an initial determination advising Northern Light that the claim would be labeled 21803700775907MEA (hereinafter "Claim '5907") and that a total of $3,083.06 would be remitted to Northern Light on that claim.

60. Consistent with the payment reduction in the 340B Provisions of the 2018 OPPS Rule, NGS's payments on Claims '207, '107, '607, '907, and '5907 were approximately 30% less than what it had paid Northern Light on identical claims in 2017. On March 19, 2018, Northern Light submitted redetermination requests to NGS for each of the five claims in which it demanded full reimbursement in the amount of $7,045.30 on Claim '207, $7,045.30 on Claim '107, $6,712.57 on Claim '607, $4,873.33 on Claim '907, and $4,500.23 on Claim '5907. On each of the five redetermination request forms, Northern Light contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(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.

61. On May 30, 2018 (Claim '607), May 31, 2018 (Claims '207 and '107), and June 1, 2018 (Claims '907 and '5907), NGS issued letters dismissing Northern Light's five redetermination requests on the grounds that "[42 U.S.C. § 1395w-4(i)(1)] prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) and 42 U.S.C. § 1395*l*(t)(12)(A). (C). (E))."

62. On July 17, 2018 Northern Light submitted reconsideration requests regarding its five claims to C2C Solutions, Inc., a QIC. In each of its five reconsideration requests, Northern Light raised the same argument that it had raised in its redetermination requests to NGS.

63. In light of these events, Northern Light has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

C. Park Ridge Health

64. On February 5, 2018, Park Ridge presented a claim for payment to First Coast Service Options, Inc. ("First Coast"), a MAC, for separately payable drugs subject to the 340B Program. On February 20, 2018, First Coast issued an initial determination advising Park Ridge that the claim would be labeled 21803603179407FLA (hereinafter "Claim '407"), and that a total of $3,685.12 would be remitted to Park Ridge on the claim.

65. On February 7, 2018, Park Ridge presented a claim for payment to First Coast for separately payable drugs subject to the 340B Program. On February 22, 2018, First Coast issued an initial determination advising Park Ridge that the claim would be labeled

21803900902607FLA (hereinafter "Claim '2607"), and that a total of $3,685.12 would be remitted to Park Ridge on the claim.

66. Consistent with the payment reduction in the 340B Provisions of the 2018 OPPS Rule, First Coast's payments on Claims '407 and '2607 were approximately 30% less than what it had paid Park Ridge on identical claims in 2017. On May 11, 2018, Park Ridge submitted redetermination requests to First Coast for both claims in which it demanded full reimbursement in the amount of $5,342.66 on Claim '407 and $5,342.66 on Claim '2607. On both of its redetermination request forms, Park Ridge contended that "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%," and that the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(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.

67. On June 1, 2018, First Coast issued letters dismissing Park Ridge's redetermination requests on the grounds that "administrative review is not available for this issue."

68. On July 23, 2018, Park Ridge submitted reconsideration requests regarding both of its two claims to C2C Solutions, Inc., a QIC. In both of its reconsideration requests, Park Ridge raised the same argument that it had raised in its redetermination requests to First Coast.

69. In light of these events, Park Ridge has presented specific claims for payment to the Secretary and any further administrative review would be futile because (a) no adjudicator within CMS has authority to invalidate a CMS regulation, and (b) CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes.

COUNT 1

2018 OPPS RULE – VIOLATION OF THE SOCIAL SECURITY ACT

70. Plaintiffs incorporate by reference the foregoing paragraphs.

71. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

72. The nearly 30% reduction in payment for 340B drugs under the2018 OPPS Rule is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 2

2019 OPPS RULE – VIOLATION OF THE SOCIAL SECURITY ACT

73. Plaintiffs incorporate by reference the foregoing paragraphs.

74. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

75. The 2019 OPPS Rule, which carries forward the nearly 30% reduction in payment for 340B drugs that was implemented in the 2018 OPPS Rule, is arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 3

HENRY FORD CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

76. Plaintiffs incorporate by reference paragraphs 1 through 54.

77. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

78. The remittances to Henry Ford for Claims '604, '704, '004, '804, and '104 reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 4

NORTHERN LIGHT CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

79. Plaintiffs incorporate by reference paragraphs 1 through 42 and 55 through 63.

80. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

81. The remittances to Northern Light for Claims '207, '107, '607, '907, and '5907 reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

COUNT 5

PARK RIDGE CLAIMS – VIOLATION OF THE SOCIAL SECURITY ACT

82. Plaintiffs incorporate by reference paragraphs 1 through 42 and 64 through 69.

83. The Social Security Act and the APA require this Court to hold unlawful and set aside any decision of the Secretary that is arbitrary and capricious or contrary to law. 42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2).

84. The remittances to Park Ridge for Claims '407 and '2607 reflected a nearly 30% reduction in payment that was arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in its favor and against Defendants:

A. Declaring that the 340B Provisions of the 2018 and 2019 OPPS Rules are an unlawful exercise of Defendants' authority, in violation of the Social Security Act and section 340B of the Public Health Service Act;

B. Directing Defendants to strike the changes in the payment methodology for section 340B drugs from the 2018 and 2019 OPPS Rules and directing Defendants to use the methodology used in calendar year 2017 for all future 340B Program payments for claims reflecting service dates in 2018 or 2019;

C. Directing Defendants to: reimburse Henry Ford $2,312.96 in connection with Claim '604, $4,343.34 in connection with claim '704, $1,717.14 in connection with claim '004, $2,572.11 in connection with claim '804, and $8066.24 in connection with claim '104; reimburse Northern Light $2,218.67 in connection with Claim '207, $2,218.67 in connection with Claim '107, $2,113.90 in connection with Claim '607, $1,534.67 in connection with Claim '907, and $1,417.17 in connection with Claim '5907; and reimburse Park Ridge $1,657.54 in connection with Claim '407 and $1,657.54 in connection with Claim '2607, plus prejudgment interest;

D. Directing Defendants to reimburse all Hospital Plaintiffs and all Organizational Plaintiffs' provider members for the difference between amounts already paid for 340B drugs pursuant to the 2018 and 2019 OPPS Rules and what would have been paid for those same drugs under the methodology used in calendar year 2017;

E. Directing Defendants to conform the payment methodology that they use for 340B drugs in 2020 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition costs to calculate prices unless Defendants have complied with 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I); and

F. Granting such other relief to which Plaintiffs may be entitled at law or in equity.

Dated: February 7, 2019

Respectfully submitted,

/s/ William B. Schultz

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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

NOTICE OF APPEAL

PLEASE TAKE NOTICE that Defendants Alex M. Azar II, Secretary of the United States Department of Health and Human Services, and the U.S. Department of Health and Human Services hereby appeal to the United States Court of Appeals for the District of Columbia Circuit from (i) the Court's December 27, 2018 Order denying Defendants' motion to dismiss, granting Plaintiffs' motion for a permanent injunction, and denying as moot plaintiffs' motion for a preliminary injunction [ECF No. 24]; and (ii) the Court's December 27, 2018 Memorandum Opinion denying Defendants' motion to dismiss, granting Plaintiffs' motion for a permanent injunction, and denying as moot plaintiffs' motion for a preliminary injunction [ECF No. 25].

Date: February 22, 2019

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:		
Plaintiffs,	:	Civil Action No.:	18-2084 (RC)
v.	:	Re Document Nos.:	35, 40, 42
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,	:		
Defendants.	:		

ORDER

GRANTING MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF; DENYING DEFENDANTS' MOTION TO DISMISS; GRANTING IN PART PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, the Federation of American Hospitals' motion for leave to file an *amicus curiae* brief (ECF No. 40) is **GRANTED**, Plaintiffs' Motion for a Permanent Injunction (ECF No. 35) is **GRANTED IN PART**, and Defendants' Motion to Dismiss (ECF No. 42) is **DENIED**. On or before **August 5, 2019**, the parties shall submit a status report regarding the agency's progress on remand to remedy the issues raised in this litigation concerning the 2018 and 2019 OPPS Rules. The Court expects that the agency will act expeditiously to resolve these issues.

SO ORDERED.

Dated: May 6, 2019

RUDOLPH CONTRERAS
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,		
Plaintiffs,	Civil Action No.:	18-2084 (RC)
v.	Re Document Nos.:	35, 40, 42
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,		
Defendants.		

MEMORANDUM OPINION

GRANTING IN PART PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; REMANDING THE 2018 AND 2019 OPPS RULES TO HHS

I. INTRODUCTION

This Court previously held that the Department of Health and Human Services ("HHS") exceeded its statutory authority when it reduced the 2018 Medicare reimbursement rate for certain pharmaceutical drugs—those covered by the "340B Program"—by nearly 30%. In that decision, the Court asked the parties to provide supplemental briefing regarding the appropriate remedy. That briefing is now ripe for the Court's consideration. Plaintiffs, a group of hospital associations and non-profit hospitals,[1] have also filed a supplemental complaint raising a new claim. They contend that HHS once again exceeded its statutory authority when it implemented

[1] The hospital association Plaintiffs are the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH"). *See* Suppl. Compl. ¶¶ 5–10, ECF No. 39. The non-profit hospital Plaintiffs are the Henry Ford Health System ("Henry Ford Hospital"), Northern Light Health ("Northern Light"), and Park Ridge Health ("Park Ridge"). *See id.* ¶¶ 11–19.

the same 340B reimbursement rate for 2019 that the Court held was unlawfully implemented in 2018.[2]

For the reasons stated below, the Court concludes that HHS's 2019 340B reimbursement rate is unlawful, for the same reasons that the 2018 rate was unlawful. The Court also concludes that, despite the fatal flaw in the agency's rate adjustments, vacating HHS's 2018 and 2019 rules is not the best course of action, given the havoc vacatur may wreak on Medicare's administration. Rather, the Court will remand the two rules to the agency, giving it the first crack at crafting appropriate remedial measures. The Court expects HHS to resolve this issue promptly.

II. BACKGROUND

This Court's most recent opinion contains a detailed discussion of this case's background and procedural history, and the relevant statutes and regulations. *See Am. Hosp. Assoc. v. Azar ("AHA")*, 348 F. Supp. 3d 62, 66–72 (D.D.C. 2018). The Court will briefly summarize the relevant background here.

Medicare is a federal health insurance program for the elderly and disabled, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395–1395*lll*.[3] Medicare Part A provides coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. HHS's Outpatient Prospective Payment System ("OPPS"), which directly reimburses hospitals for outpatient services and pharmaceutical drugs

[2] Plaintiffs assert their claims against both HHS and the Secretary of Health and Human Services. *See* Suppl. Compl. ¶¶ 20–21. The Court will refer to HHS and the Secretary interchangeably.

[3] These provisions are commonly known as the "Medicare Act." The Court will refer to them as such.

provided to Medicare beneficiaries, is a component of Medicare Part B. *See id.* at 1395*l*(t). OPPS requires "payments for outpatient hospital care to be made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Under this system, the Secretary—through the Centers for Medicare and Medicaid Services ("CMS")—sets annual OPPS reimbursement rates prospectively, before a given year, rather than retroactively based on covered hospitals' actual costs during that year.[4]

Medicare Part B reimburses, among other products and services, "specified covered outpatient drugs" ("SCODs") provided by hospitals to Medicare beneficiaries. 42 U.S.C. § 1395*l*(t)(14)(A). SCODS are a subset of "separately payable drugs," which are not bundled with other Medicare Part B outpatient services, and are therefore reimbursed on a drug-by-drug basis. *See id.* § 1395*l*(t)(14)(B). Congress has authorized two potential methodologies for setting SCOD rates. First, if the Secretary has certain "hospital acquisition cost survey data," he must set the reimbursement rate for each SCOD according to "the *average acquisition cost* for the drug for that year . . . as determined by the Secretary taking into account" the survey data. *Id.* § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). Second, if the survey data is not available, each SCOD's reimbursement rate must be set equal to "the *average [sales] price* [("ASP")] for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales price ("ASP") of the drug plus 6%.[5]

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[4] CMS is a component of HHS and is overseen by the Secretary. *See* HHS Organizational Chart, HHS (Nov. 14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.

[5] While subsection (t)(14)(A)(iii)(II) provides two additional bases for calculating reimbursement rates—section 1395u(o) and section 1395w-3b—both parties agree that the

The Secretary applies the same methodologies used to set SCOD reimbursement rates to set rates for separately payable drugs covered by the "340B Program."[6] *See* Veterans Health Care Act of 1992, Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. The 340B Program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011); *see also* 42 U.S.C. § 256b(a)(1)–(2).[7] The statutory provisions that establish those price ceilings are independent from the statutory provisions that establish Medicare reimbursement rates. Put another way, the 340B Program caps the prices that eligible providers pay for covered drugs, but Medicare Part B sets the reimbursement rates those providers receive for prescribing covered drugs to Medicare beneficiaries. Until recently, there was a significant spread between 340B prices and Medicare reimbursement rates. 340B Program participants could purchase drugs at steeply discounted rates under the Program, then seek reimbursement for those purchases at the

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default rate for purposes of the drugs at issue here is the rate established by section 1395w-3a. *See* Defs.' Mot. to Dismiss at 6, ECF No. 14; Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. at 3–4, ECF No. 2-1; Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,501 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419) (acknowledging ASP plus 6% as the "statutory benchmark").

[6] Not all 340B drugs qualify as SCODs, to which the payment methodologies of § 1395*l*(t)(14)(A) expressly apply. The Secretary, however, "applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS." Defs.' Mot. to Dismiss at 6 n.1, ECF No. 6 (citing Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012) (codified at 42 C.F.R. pt. 419)); *see also* 82 Fed. Reg. at 52,509 (stating that the rate reduction will apply to "separately payable Part B drugs . . . that are acquired through the 340B Program"). The methodology at issue here thus applies to all 340B drugs. This "is a policy choice rather than a statutory requirement." Defs.' Mot. to Dismiss at 6 n.1 (quoting 77 Fed. Reg. at 68,383).

[7] The Program is intended to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also* 82 Fed. Reg. at 52,493 & 52,493 n.18.

higher Medicare Part B rates established by OPPS. The Secretary's attempt to narrow the spread triggered this litigation.

In mid-2017, the Secretary proposed reducing reimbursement rates for SCODs and other 340B drugs, from ASP plus 6% to ASP minus 22.5%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,634 (Jul. 20, 2017) (codified at 42 C.F.R. pt. 419). The Secretary asserted that this change was necessary to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs[,] while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care." *Id.* at 33,633.

The Secretary's statutory authority to reduce the 2018 340B rate was limited by the data available to him. Because he did not "have hospital acquisition cost data for 340B drugs," 82 Fed. Reg. at 33,634, he could not invoke his express authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, he invoked subsection (t)(14)(A)(iii)(II), which allows him to set rates according to the drugs' average sales prices, "as calculated and adjusted by the Secretary as necessary." 82 Fed. Reg. at 33,634. The Secretary proposed to "adjust the applicable payment rate as necessary" for separately payable 340B drugs, "to ASP minus 22.5[%]." *Id.* According to the Secretary, the adjustment was necessary because ASP minus 22.5% was the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC"), and thus "better represents the average acquisition cost for [340B] drugs and biologicals." *Id.* Plaintiffs objected to this adjustment, but the Secretary rejected their objections and adopted the proposal. *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment

Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419). HHS reimbursed 340B drugs at ASP minus 22.5% throughout 2018.

Having failed to defeat the 2018 340B rate adjustment during the notice and comment period, Plaintiffs challenged the 2018 OPPS Rule in this Court. *See AHA*, 348 F. Supp. 3d at 71–72. They argued that the Secretary exceeded his statutory authority in setting the 2018 340B rate, in violation of the Administrative Procedure Act ("APA") and the Social Security Act. *See id.* at 71. This Court agreed. It held that the Secretary violated subsection (t)(14)(A)(iii)(II)'s plain text when he invoked that provision to "adjust" 340B rates downward by 30%, based not on the drugs' average sales prices—as dictated by the statutory text—but on the drugs' estimated acquisition costs. *See id.* at 79–83. The Court ordered the parties to provide supplemental briefing on the proper remedy. *See id.* at 86.

The Secretary has continued to apply the same 340B rate in 2019. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2019 OPPS Rule"), 83 Fed. Reg. 58,818, 58,979 (Nov. 21, 2018) (codified at 42 C.F.R. pt. 419). And in adopting that rate, the Secretary incorporated by reference his rationale for adopting the 2018 340B rate, the rationale that this Court later held was contrary to law. *See id.* at 58,981 (referring commenters to the Secretary's "detailed response regarding [his] statutory authority to require payment reductions for [340B drugs] in the CY 2018 OPPS/ASC final rule").

Plaintiffs have filed a supplemental complaint, *see* Suppl. Compl., ECF No. 39, and moved to permanently enjoin the 2019 OPPS Rule, *see* Pls.' Mot. Permanent Inj. Covering 2019 OPPS Rule ("Pls.' Mot. Inj."), ECF No. 35. That motion, and the parties' remedies briefing, is

now ripe for the Court's review. The Court will first consider Plaintiffs' motion to enjoin the 2019 OPPS Rule, then the parties' remedies briefing. It grants Plaintiffs' motion in part, and remands both the 2018 and 2019 OPPS Rules to HHS, giving the Secretary the first crack at crafting an appropriate remedy.

III. MOTION FOR PERMANENT INJUNCTION

Rather than fully briefing Plaintiffs' motion to enjoin the 2019 OPPS Rule, the parties have elected to incorporate by reference their arguments regarding the 2018 OPPS Rule. [8] Plaintiffs proffer that "[f]or all of the reasons that the Court has already articulated with respect to the 2018 OPPS Rule, the 2019 OPPS Rule is *ultra vires* and unlawful."[9] Pls.' Mot. Inj. at 2. Defendants respond that their arguments for denying Plaintiffs' challenge to the 2018 OPPS Rule "provide ample bases for rejecting" Plaintiffs' challenge to the 2019 OPPS Rule. Defs.' Opp'n Pls.' Mot. Inj. at 1, ECF No. 42. Recognizing that the Court "rejected those arguments in the context of the 2018 OPPS Rule," Defendants "respectfully request that the Court reconsider its conclusion." *Id.* at 2. The Court declines Defendants' invitation. It enjoins the 2019 OPPS Rule for the same reason that it enjoined the 2018 OPPS Rule. In the interest of thoroughness, the Court will briefly summarize that reasoning.

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[8] In evaluating Plaintiffs' challenge to the 2018 OPPS Rule, the Court consolidated the parties' pleading-stage briefing with a decision on the merits. *See AHA*, 348 F. Supp. 3d at 83–85. The Court does the same here. This case raises pure questions of law that do not turn on the administrative record or any other facts that may emerge at the summary judgment stage. *See id.* Proceeding to summary judgment, rather than reaching a decision now, would thus be redundant and unnecessary. *See Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Neither party contests this approach.

[9] Plaintiffs' challenge is grounded in the APA. The APA provides for judicial review of a "final agency action for which there is no other adequate remedy in a court[,]" 5 U.S.C. § 704, except when "statutes preclude judicial review" or the "agency action is committed to agency discretion by law[,]" *id.* § 701(a). The APA permits a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A).

First, Plaintiffs have sufficiently exhausted their administrative remedies, such that they may challenge the 2019 OPPS Rule in federal court. To seek judicial review, a plaintiff challenging a Medicare-related agency action must satisfy two requirements established by 42 U.S.C. § 405(g). *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12–15 (2000). First, a jurisdictional, non-waivable "requirement that a claim for benefits shall have been presented to the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). Second, a non-jurisdictional "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id.* This second requirement may be waived by the agency or a court. *See id.* at 330. Together, the two requirements serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13.

Plaintiffs satisfied § 405(g)'s first, non-waivable requirement when Henry Ford Hospital presented HHS with two claims for reimbursement for 340B drugs prescribed under the 2019 OPPS Rule. *See* ECF Nos. 34–1 & 34-2. In response, HHS dutifully applied the 2019 340B reimbursement rate challenged by Plaintiffs: ASP minus 22.5%.[10] *Id.* Defendants do not contest that Henry Ford Hospital's 2019 claims satisfy § 405(g)'s presentment requirement.

Plaintiffs need not satisfy § 405(g)'s second requirement, that they fully exhaust the administrative process, because exhaustion would be futile. As this Court previously noted, plaintiffs need not exhaust their administrative remedies when "(1) the issue raised is entirely

[10] Henry Ford Hospital technically presented its claims to a Medicare administrative contractor (also known as a "fiscal intermediary"), which processes reimbursements on behalf of HHS. *See* 42 C.F.R. § 424.32. "If dissatisfied with the contractor's initial determination, the hospital then may pursue within HHS various other avenues for redetermination, reconsideration, hearings, and appeals." *Amgen*, 895 F.3d at 824 (citing 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904); *see also* Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. at 11, ECF No. 2-1 (describing the Secretary's four-level administrative appeal process).

collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; [or] (3) exhaustion would be futile." *AHA*, 348 F. Supp. 3d at 75 (alteration in original) (quoting *Triad at Jeffersonville I, LLC v. Leavitt*, 563 F. Supp. 2d 1, 16 (D.D.C. 2008)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In such circumstances, a "district court may, in its discretion, excuse exhaustion if 'the litigant's interests in immediate judicial review outweigh the government's interests in the efficiency or administrative autonomy that the exhaustion doctrine is designed to further.'" *Avocados Plus Inc. v. Veneman*, 370 F.3d 1243, 1247 (D.C. Cir. 2004) (quoting *McCarthy v. Madigan*, 503 U.S. 140, 146 (1992)). More specifically, the court must consider whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. *See Tataranowicz*, 959 F.2d at 275 (citing *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975)).

As with Plaintiffs' challenge to the 2018 OPPS Rule, *see AHA*, 348 F. Supp. 3d at 75–76, it would be futile for Plaintiffs to exhaust their administrative remedies here, because their challenge raises pure questions of law that cannot be decided through the administrative process. Plaintiffs argue that the Secretary lacked statutory authority to set the 2019 340B reimbursement rate at ASP minus 22.5%. *See* Pls.' Mot. Inj. at 2. The Court does not need a factual record to decide that question. And no administrative body has authority to rule in Plaintiffs' favor, even if Plaintiffs are correct on the law. *See* 42 C.F.R. § 405.1063(a) (stating that "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council"); HHS Expedited Access to Judicial Review Ruling at 6, ECF No. 19-1 (stating that "neither the ALJ nor the [Medicare Appeals]

Council has the authority to find the 2018 OPPS Rule invalid"). Plus, it is unlikely that further administrative appeals would cause the Secretary to rethink his position that he has authority to "adjust" 340B rates from ASP plus 6% to ASP minus 22.5%, based on the drugs' estimated acquisition costs. *See Tataranowicz*, 959 F.2d at 275. Even after this Court held the 2018 OPPS Rule unlawful, the Secretary left the identical 2019 OPPS Rule in place. Thus, because Plaintiffs have presented claims for reimbursement to the Secretary under the 2019 OPPS Rule, and because Plaintiffs' exhaustion of their administrative remedies would be futile, the Court waives Plaintiffs' exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).

Second, on the merits, the Secretary acted *ultra vires* in setting the 2019 340B reimbursement rate. *Ultra vires* review "is 'quite narrow.'" *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)). To successfully mount an *ultra vires* challenge, a plaintiff "must show a 'patent violation of agency authority.'" *AHA*, 348 F. Supp. 3d at 79 (quoting *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016)). "A violation is 'patent' if it is '[o]bvious' or 'apparent.'" *Fla. Health Scis. Ctr*, 830 F.3d at 522 (quoting Black's Law Dictionary (10th ed. 2014)). The Secretary's violation here is apparent.

The Secretary set the 2019 340B rate using his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("subsection II"). *See* 83 Fed. Reg. at 58,981 (incorporating the 2018 OPPS Rule's discussion of the Secretary's authority to reimburse 340B drugs at ASP minus 22.5%). Under that provision, a given drug's reimbursement rate "shall be equal . . . [to] the *average [sales] price for the drug* in the year established under . . . section 1395w-3a of this title

. . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* (emphasis added). This Court previously held, based on the D.C. Circuit's decision in *Amgen*, that subsection II's plain text limits the Secretary's authority to adjust rates.[11] *See AHA*, 348 F. Supp. 3d at 79–81. Adopting the Circuit's reasoning, the Court concluded that "because the term adjustments" does not "encompass the power to make basic and fundamental changes in the [statutory] scheme . . . a more substantial departure from the default amounts would, at some point . . . cease to be an adjustment[]." *Id.* at 80 (internal quotation marks omitted) (quoting *Amgen*, 357 F.3d at 117). Put simply, because subsection II "only authorizes adjustments," it cannot not be read to permit the "total elimination or severe restructuring of the statutory scheme." *Id.* (quoting *Amgen*, 357 F.3d at 117). To do so would be *ultra vires.*

In "adjusting" the 2019 340B rate under subsection II, the Secretary made basic and fundamental changes to the statutory scheme. The rate covers reimbursement for potentially thousands of pharmaceutical products. *See* 82 Fed. Reg. at 52,494 (discussing the number of 340B "covered products" available to 340B Program participants). The Secretary expressly based that rate on the products' estimated acquisition costs. *See* 82 Fed. Reg. at 52,496, 52,500. That methodology—setting a drug's rate based on its acquisition cost—is contained in a

[11] In *Amgen*, the Circuit considered the Secretary's authority to adjust reimbursement rates under a different, but related, Medicare provision: 42 U.S.C. § 1395*l*(t)(2)(E). *See Amgen*, 357 F.3d at 107. Like subsection (t)(14)(A)(iii)(II), subsection (t)(2)(E) authorizes the Secretary to make "adjustments" to certain hospital reimbursement rates "as determined to be necessary to ensure equitable payments" under the OPPS scheme. 42 U.S.C. § 1395*l*(t)(2)(E). In addressing the *Amgen* plaintiff's claim that the Secretary exceeded his adjustment authority under subsection (t)(2)(E), the Circuit observed that "[l]imitations on the Secretary's equitable adjustment authority inhere in the text of § (t)(2)(E)." *Amgen*, 357 F.3d at 117. Thus, though the slight adjustment at issue in *Amgen* was not *ultra vires*, the Circuit left open the possibility that an adjustment of much greater magnitude could, in fact, "cease to be an 'adjustment[]'" at all. *Id.* (alteration in original) (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994)).

Medicare subsection on which the Secretary could not rely, because he did not gather the necessary data—he did not have the "hospital acquisition cost survey data under subparagraph (D)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("subsection I"). The subsection on which the Secretary did rely sets a drug's rate based on its average sales price, rather than its acquisition cost. *See id.* § (t)(14)(A)(iii)(II) ("subsection II").[12] The Secretary thus "adjusted" the 2019 340B rate using a methodology entirely decoupled from that established by the Medicare subsection on which he relied. Not to mention, the rate adjustment is not modest; it is a nearly 30% reduction from the default statutory formula. "When viewed together, the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to 'adjust[]' SCOD rates under § (t)(14)(A)(iii)(II)."[13] *AHA*, 348 F. Supp. 3d at 81 (alteration in original).

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[12] Again, subsection II allows the secretary to set each 340B drug's reimbursement rate equal to "the average price for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. § (t)(14)(A)(iii)(II).

[13] The Secretary argues that his "adjustment" of the 2019 340B reimbursement rate is shielded by 42 U.S.C. § 1395*l*(t)(12). That provision precludes judicial review of certain types of Medicare rate adjustments. *See, e.g.*, 42 U.S.C. § 1395*l*(t)(12)(C) (barring judicial review of "periodic adjustments made under paragraph [(t)(9)]"). However, "the preclusion on review of" those adjustments "extends no further than the Secretary's statutory authority to make them." *Amgen*, 357 F.3d at 112. In other words, if the Secretary makes an "adjustment" within that term's meaning, subsection (t)(12) bars a court from reviewing the reasons underlying that adjustment. But if the Secretary's action is so extreme that it ceases to be an "adjustment," a court may review and strike down that action. *See id.* at 112–14; *AHA*, 348 F. Supp. 3d at 78–79; *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20–21 (D.D.C. 2014). Here, because the Secretary exceeded his statutory authority to make an "adjustment" under subsection (t)(14)(A)(iii)(II), subsection (t)(12) does not preclude the Court from reviewing that action. *Cf. H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11–12 (D.D.C. 2018) (holding that the court would have jurisdiction, "under *ultra vires* review," to hear the plaintiff's claim that the agency was statutorily required to make an adjustment under subsection (t)(2)(E)). The Court thus need not determine whether subsection (t)(12) would preclude review of a lawful adjustment made under subsection (t)(14).

IV. REMEDIES

Having concluded that both the 2018 and 2019 340B reimbursement rates were unlawful, the Court must determine how to "unscramble the egg," so to speak. Determining the proper remedy is no easy task, given Medicare's complexity. The parties, unsurprisingly, take wildly divergent positions on this issue. Plaintiffs seek injunctive relief. *See* Pls.' Suppl. Remedies Br. ("Pls.' Remedy Br.") at 10–11, ECF No. 32. They ask this Court to (1) order the Secretary to pay Plaintiffs "the difference between the amount they received [under the 2018 and 2019 OPPS Rules] and the amount to which they are entitled (based on the ASP plus 6% methodology)"; and (2) order that Plaintiffs that have not yet received reimbursement for 340B drugs prescribed in 2018 and 2019 be paid "the amount they would have received under the 2017 OPPS rule."[14] *Id.* Defendants, on the other hand, ask this Court to remand the 2018 and 2019 OPPS Rules to HHS, without vacating the rules or imposing specific duties on the agency. *See* Defs.' Remedy Br. at 1–2, ECF No. 31.

The Secretary also argues that his adjustment is "committed to agency discretion by law," and is thus unreviewable under the APA. 5 U.S.C. § 701(a)(2). That argument fails for the same reason that the Secretary's statutory preclusion argument fails. A matter is committed to agency discretion when "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). The D.C. Circuit indicated in *Amgen*, however, that the statute at issue here *does* impose a meaningful standard: The Secretary may not use his adjustment authority to make fundamental changes to the statutory scheme. *See Amgen*, 357 F.3d at 117. "[A] court may not inquire into the 'necessity' of an 'adjustment' made by the Secretary, but that does not prevent the Court from inquiring into whether the Secretary's actions were, in fact, an 'adjustment' or something more." *AHA*, 348 F. Supp. 3d at 83 n.20.

[14] Plaintiffs' remedies briefing does not specifically discuss the 2019 OPPS Rule. However, in their motion for a permanent injunction, Plaintiffs ask this Court to (1) require the Secretary to amend the 2019 rule and implement a 340B rate of ASP plus 6%, and (2) "implement the same retrospective remedy that [P]laintiffs have proposed for 2018." Pls.' Mot. Inj. at 3–4.

The parties' briefing raises two questions regarding the appropriate remedy. First, should the Court issue an injunction or remand the issue to the agency? Second, if remand is appropriate, should the Court vacate the 2018 and 2019 OPPS Rules? Having reviewed the parties' briefing and the relevant case law, the Court concludes that remand without vacatur is most appropriate.

A. Remand is Appropriate

Remand, rather than an injunction, is the better course of action here. As Defendants note, "[w]hen a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal." *N. Air Cargo v. USPS*, 674 F.3d 852, 861 (D.C. Cir. 2012) (citing *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). Thus, when a plaintiff brings an APA claim "to set aside an unlawful agency action . . . it is the prerogative of the agency to decide in the first instance how best to provide relief." *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013) (citing *N. Air Cargo*, 674 F.3d at 861). Indeed, in certain circumstances, "to order the agency to take specific actions is reversible error." *Flaherty v. Pritzker*, 17 F. Supp. 3d 52, 57 (D.D.C. 2014) (citing *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999)). If the plaintiffs are "dissatisfied with [the agency's] remedy [on remand], they would always have the option to seek review" of that remedy under the APA. *Bennett*, 703 F.3d at 589 (citing 5 U.S.C. § 706(2)(A)).

At least one other court in this jurisdiction has followed this course under similar circumstances. *See Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 19. In *Moffitt Cancer Center*, the plaintiff challenged the Secretary's decision *not* to make an OPPS rate adjustment under 42

U.S.C. § 1395*l*(t)(2)(E), arguing that the adjustment was required by statute. *Id.* at 10–11. The plaintiff sought an order requiring HHS to (1) vacate and amend a particular rule, and (2) "adjust [the plaintiff's] payments . . . accordingly." *Id.* at 18–19. The court agreed with the plaintiff on the merits, holding that the statute unambiguously required the Secretary to raise the plaintiff's OPPS rates under subsection (t)(2)(E). *See id.* at 13–14. But the court declined to grant the specific relief sought. *See id.* at 19. Instead, it "simply remand[ed] to HHS so that it c[ould] consider and adopt an 'appropriate adjustment.'" *Id.* The Court will take the same approach here.

Plaintiffs' arguments for injunctive relief are unpersuasive, and the case law weighs against them. Plaintiffs note that there are multiple ways for HHS to remediate its underpayments, some more complicated than others. *See* Pls.' Remedy Br. at 2–4, 7–8. This discussion illustrates why remand is best: Injunctive relief is typically appropriate when "there is 'only one rational course' for the [a]gency to follow upon remand." *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2013) (quoting *Am. Fed'n of Gov't Emps., AFL-CIO v. Fed. Labor Relations Auth.*, 778 F.2d 850, 862 n.19 (D.C. Cir. 1985)). As the parties' briefing makes clear, HHS has multiple courses on remand, including Plaintiffs' proposed mechanism.[15] Plaintiffs also note "recent examples of cases in which HHS has paid hospitals to compensate for past underpayments." Pls.' Remedy Br. at 4–7. But in each of those cases, the agency reached its own decision on remand; the courts did not grant injunctive relief. *See Cape Cod Hosp. v.*

[15] For example, HHS indicates that it could potentially adjust reimbursement rates in future years to make up for its underpayments in 2018 and 2019. *See* Defs.' Remedy Br. at 11. Or, it also indicates that it could amend the 2018 and 2019 OPPS Rules, and issue retroactive payments accordingly. *See id.* And as discussed below, there is some question as to whether the agency's actions must be budget neutral. The path forward is not sufficiently clear cut that this Court should chart it in the first instance.

Sebelius, 630 F.3d 203, 216 (D.C. Cir. 2011); *Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 18–19; *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 267–71 (D.D.C. 2015). Finally, Plaintiffs express concern that the Secretary may use remand to "further delay resolution of this matter" or even deny relief altogether. Pls.' Resp. Br. Remedies ("Pls.' Resp.") at 1, ECF No. 37. But the Court will retain jurisdiction over this matter, and the Court may reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner. In short, Plaintiffs have provided no sound reason or case law to support deviating from the normal course in this jurisdiction under these circumstances: remand.

B. Vacatur is not Warranted

While it is a close question, the Court concludes that it is best to remand the 2018 and 2019 OPPS Rules without vacating them. In deciding whether vacatur is warranted, the Court turns to the standard articulated by the D.C. Circuit in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146, 150–51 (D.C. Cir. 1993).[16] Under this standard, the Court must weigh "the seriousness of the [agency] order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Id.* (quoting *Int'l Union, United Mine Workers of Am. v. Fed. Mine Safety & Health Admin.*, 920 F.2d 960, 967 (D.C. Cir. 1990)). "There is no rule requiring either the proponent or opponent of vacatur to prevail on both factors." *Shands*, 139 F. Supp. 3d at 270 (listing cases). "[R]esolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives." *Id.*

[16] Both parties agree that this standard is applicable. *See* Defs.' Remedy Br. at 5; Pls.' Resp. at 2.

Plaintiffs state that they "are not urging this Court to vacate the portions of the 2018 OPPS Rule that the Court held unlawful." Pls.' Resp. at 2.[17] Yet, Plaintiffs also argue that the *Allied-Signal* factors weigh in favor of vacatur. *See* Pls.' Remedy Br. at 7 n.6; Pls. Resp. at 2. And their supplemental complaint expressly seeks vacatur. *See* Suppl. Compl. at 24 (asking this Court to "strike the changes in the payment methodology for section 340B drugs from the 2018 and 2019 OPPS Rules"). Regardless, the Court concludes that the *Allied-Signal* factors weigh, ever so slightly, against vacatur.

The Secretary's deficiencies here were substantial. He patently violated the Medicare Act's text. Unlike cases in which the agency's decision may have been lawful, but was inadequately explained, *see Am. Great Lakes Ports Ass'n v. Zukunft*, 301 F. Supp. 3d 99, 103 (D.D.C. 2018), no amount of reasoning on remand will allow the Secretary to re-implement the 340B rates in the same manner, *see Shands*, 139 F. Supp. 3d at 268 (holding that the first *Allied-Signal* factor weighed in favor of vacatur where the "flaw in the notice and comment process was substantial," and the court was not convinced that HHS would be able to justify its decision on remand). Rather, the Secretary would need to justify those rates under a different statutory provision—a nearly impossible task, given the Secretary's lack of relevant data. The Secretary argues that "there remains some 'doubt about whether the agency chose correctly,'" given that the D.C. Circuit could reverse this Court's decision on appeal. Defs.' Remedy Br. at 5 (quoting *Allied-Signal*, 988 F.2d at 150). That may be true. But the Secretary cites no case in which a court considered the losing party's potential success on appeal in determining the proper trial-

[17] This may be an eleventh-hour strategic decision. Perhaps Plaintiffs have decided that vacatur will increase the likelihood that HHS corrects its underpayments in a budget neutral manner, clawing back payments made to Plaintiffs for other Medicare-related services. *See* Pls.' Resp. at 10–11.

level remedy. Possible success on appeal would weigh against vacatur in every case, given that reversal is always a possibility. The Court will not consider it here. The first *Allied-Signal* factor thus weighs in favor of vacatur.

On the other hand, vacatur would likely be highly disruptive. If the Court were to vacate the 2018 and 2019 OPPS Rules, it could order the Secretary to reinstate the rule previously in effect—the 2017 OPPS Rule—or leave it to the Secretary to issue new rules. *See Am. Great Lakes Ports*, 301 F. Supp. 3d at 103–04; *Oceana, Inc. v. Evans*, 389 F. Supp. 2d 4, 6 (D.D.C. 2005). Under either scenario, 340B reimbursement rates would presumably be higher than ASP minus 22.5%. While those higher rates would address Plaintiffs' harm, they would raise the following potentially serious administrative problems.

In general, OPPS payments must remain budget neutral, which could throttle the Secretary's ability to retroactively adjust reimbursement rates in the event of vacatur. *See, e.g.*, 42 U.S.C. § 1395*l*(t)(9)(B) (stating that OPPS rate "adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made"); *id.* § 1395*l*(t)(14)(H) (stating that "[a]dditional expenditures resulting from" subsection (t)(14), after 2005, "shall be taken into account" in "establishing the conversion, weighting, and other adjustment factors" under subsection (t)(9)). Budget neutrality dictates that any increase in spending on certain aspects of Medicare Part B must be offset by decreases elsewhere in the program. *See Cape Cod*, 630 F.3d at 206 (noting that budget neutrality required the Secretary to implement a rate adjustment "in a manner that would have no effect on the annual total of Medicare payments made to all hospitals throughout the country for inpatient services").

The Secretary issued the 2018 and 2019 340B rates according to this principle: Because he decreased reimbursement rates for 340B drugs, he increased rates for other Medicare Part B products and services. *See* 82 Fed. Reg. at 52,623 (stating that HHS implemented the 340B "payment reduction in a budget neutral manner within OPPS," allowing HHS to "increase OPPS payment rates for non-drug items and services by approximately 3.2[%]"). Thus, if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services. And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect. *See* Decl. of Elizabeth Richter ¶¶ 5–9, ECF No. 31-1 (estimating that recoupment would take a year, require between $25 and $30 million in administrative costs, and adversely impact Medicare beneficiaries who would owe different amounts under their cost-sharing obligations).

The parties, and the Federation of American Hospitals,[18] strongly debate whether the Secretary's remedial rate adjustments must be budget neutral. *See* Pls.' Remedy Br. at 8–10; Defs.' Remedy Br. at 7–9; Amicus Br. at 4–7, ECF No. 38. Some courts in this jurisdiction have hypothesized, without concluding, that HHS's remedial adjustments need not be budget neutral. *See Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15–16. The D.C. Circuit, on the other hand, has

[18] The Federation of American Hospitals filed an amicus brief on behalf of "more than 1,000" non-340B hospitals, addressing remedies. *See* Unopposed Mot. Leave File Amicus Curiae Br. at 1–2, ECF No. 33. The Federation also seeks leave to respond to the parties' briefing on this issue. *See* Mot. Leave File Amicus Curiae Br. at 1, ECF No. 40. Because the Court finds the Federation's briefing helpful, it exercises its "inherent authority" to allow the Federation's participation as amicus curiae. *Jin v. Ministry of State Sec.*, 557 F. Supp. 2d 131, 136 (D.D.C. 2008) (quoting *Smith v. Chrysler Fin. Co., LLC*, No. Civ.A. 00-6003, 2003 WL 328719, at *8 (D.N.J. Jan.15, 2003)). The Court will consider the Federation's response brief.

suggested the opposite, *see Amgen*, 357 F.3d at 112 (noting that "judicially mandated changes in one [OPPS] payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year"), although it does not appear to have definitively weighed in. At this stage, it suffices to say that the uncertainty surrounding this issue all but guarantees its resolution would be highly disruptive, should the Court vacate the 2018 and 2019 OPPS Rules.[19]

Relatedly, the presumption against retroactive rulemaking would also complicate vacatur, given that vacatur would force the Secretary to retroactively issue rules for 2018 and 2019. *See* Pls.' Response at 10. Under this presumption, "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). "Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant." *Id.* at 208–09.

Other courts grappling with this issue in the Medicare context have found that it weighs against vacatur. For instance, in *Shands*, another court in this jurisdiction considered whether to vacate an HHS rule reducing a particular reimbursement rate by 0.2% without adequate explanation. *See Shands*, 139 F. Supp. 3d at 263, 269. There, as here, it was "unclear whether the presumption against retroactive rulemaking would apply" if HHS were required to issue a new rule upon vacatur. *Id.* at 269. The Court held that the presumption's applicability weighed

[19] Budget neutrality is likely to cause disruption regardless of whether the Court vacates the 2018 and 2019 OPPS Rules. But remand without vacatur will allow the agency more flexibility to determine the least disruptive means of correcting its underpayments to Plaintiffs, including possibly making remedial payments in a non-budget neutral manner.

against vacatur, because it would impact the agency's ability to navigate the proper remedial action. *See id.*; *cf. Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) ("[W]e think it sufficient for the purpose of the second *Allied–Signal* factor that vacatur of the rural location requirement would have raised substantial doubt about HHS's ability to recoup payments it made for years prior to reinstatement of that requirement."); *Am. Great Lakes Ports*, 301 F. Supp. 3d at 104 (holding that vacatur was inappropriate where "it would appear that the Coast Guard would be unable to reinstate the 2016 rates through a properly justified new rule due to the presumption against retroactive rulemaking"). The same concern applies here: The Secretary may not be able to retroactively adjust 340B payments, at least not in a budget neutral manner, should the 2018 and 2019 OPPS Rules be vacated. Any attempt to do so would almost certainly trigger litigation. *See* Amicus Br. at 10 (asking this Court to determine that the Secretary "lacks authority to recoup any or all of the 3.2[%] budget neutrality adjustment" made in the 2018 OPPS Rule). Remand may allow the agency to avoid the issue altogether.[20]

It is true that, as Plaintiffs note, courts most commonly remand without vacatur agency decisions that suffer from procedural, rather than substantive, deficiencies. *See, e.g*, *Am. Great Lakes Ports*, 301 F. Supp. 3d at 104. But Plaintiffs cite no case law indicating that remand without vacatur is *never* appropriate for agency decisions suffering from severe deficiencies. Nor could they. *See North Carolina v. EPA*, 550 F.3d 1176, 1177–78 (D.C. Cir. 2008) (per curiam) (remanding an agency rule without vacatur, despite "more than several fatal flaws in the

[20] For instance, the Secretary may be able to raise 340B rates in future years to compensate for the 2018 and 2019 underpayments. *See Shands Jacksonville Med. Ctr., Inc. v. Azar*, No. 14-cv-263 *et al.*, 2018 WL 6831167, at *16 (D.D.C. Dec. 28, 2018) (affirming the Secretary's decision to implement a one-time, prospective rate increase to address underpayments in previous years). The Federation of American Hospitals contends that the Medicare Act does not authorize this type of prospective remedial adjustment in a budget neutral manner. *See* Amicus Br. at 9–10. But the Court need not decide that at this stage.

rule" (quoting *North Carolina v. EPA*, 531 F.3d 896, 901 (D.C. Cir. 2008) (per curiam))); *Shands*, 139 F. Supp. 3d at 270 (remanding the Secretary's rate reduction without vacatur, despite the action's serious deficiencies); *cf. Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) ("[W]hen equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy."). Given the "complex prospective payment system" at issue here, *Amgen*, 357 F.3d at 112, the Court concludes that vacating the 2018 and 2019 OPPS Rules would do more harm than good, despite the fatal flaws in the Secretary's 340B rate adjustments.

V. CONCLUSION

For the foregoing reasons, the Court concludes that the 340B drug reimbursement rate contained in the 2019 OPPS Rule is unlawful, because it was implemented in contravention of the Medicare Act's plain text. That said, the Court declines to grant the injunctive relief requested by Plaintiffs. Instead, the Court remands the 2018 and 2019 OPPS Rules to the Secretary without vacatur. Thus, Plaintiffs' Motion for a Permanent Injunction (ECF No. 35) is **GRANTED IN PART**, and Defendants' Motion to Dismiss (ECF No. 42) is **DENIED**. On or before **August 5, 2019**, the parties shall submit a status report regarding the agency's progress on remand to remedy the issues raised in this litigation concerning the 2018 and 2019 OPPS Rules. The Court expects that the agency will act expeditiously to resolve these issues. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: May 6, 2019

RUDOLPH CONTRERAS
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,		
Plaintiffs,	Civil Action No.:	18-2084 (RC)
v.	Re Document Nos.:	51, 54
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,		
Defendants.		

ORDER

GRANTING DEFENDANTS' MOTION FOR ENTRY OF FINAL JUDGMENT; DENYING AS MOOT PLAINTIFFS' MOTION FOR A FIRM DATE

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Defendants' motion for entry of final judgment (ECF No. 54) is **GRANTED** and Plaintiffs' motion for a firm date (ECF No. 51) is **DENIED** as moot.

SO ORDERED.

Dated: July 10, 2019

RUDOLPH CONTRERAS
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,		
Plaintiffs,	Civil Action No.:	18-2084 (RC)
v.	Re Document Nos.:	51, 54
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,		
Defendants.		

MEMORANDUM OPINION

GRANTING DEFENDANTS' MOTION FOR ENTRY OF FINAL JUDGMENT; DENYING AS MOOT PLAINTIFFS' MOTION FOR A FIRM DATE

I. BACKGROUND[1]

On May 6, 2019, this Court held that the Department of Health and Human Services ("HHS") exceeded its statutory authority when it reduced the 2019 Medicare reimbursement rate for pharmaceutical drugs covered by the "340B Program" by nearly 30%. *See Am. Hosp. Ass'n v. Azar ("AHA II")*, No. CV 18-2084 (RC), 2019 WL 1992868 (D.D.C. May 6, 2019). This holding followed the Court's December 2018 conclusion that HHS exceeded its statutory authority in reducing the 2018 Medicare reimbursement rate. *See Am. Hosp. Ass'n v. Azar ("AHA I")*, 348 F. Supp. 3d 62, 79–83 (D.D.C. 2018). In *AHA II*, this Court also specified the remedy for the agency's unlawful rate adjustments: remand of both the 2018 and 2019 rules to

[1] Because the December 2018 Opinion and May 2019 Opinion contain extensive discussion of the relevant background, procedural history, and the relevant statutes and regulation, *see AHA II*, 2019 WL 1992868 at *1–4; *AHA I*, 348 F. Supp. 3d at 66–72, and because the instant order addresses the remedy and not the merits in this dispute, the Court will not recapitulate the facts previously reported in detail.

the agency, without vacatur. *AHA II*, 2019 WL 1992868 at *7–10. In specifying the remedy, the Court stated that it would "retain jurisdiction over this matter" so that it could "reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner." *Id.* at *7.

Both parties soon filed further motions. Plaintiffs moved for a firm date by which Defendants must propose a remedy to the Court. Pls.' Mot. for Firm Date, ECF No. 51 ("Pls.' Mot."). Defendants moved for reconsideration of the May 6, 2019 Order and requested entry of final judgment pursuant to Federal Rule of Civil Procedure Rule 58(a), contending that the Court's retention of jurisdiction was "clear error." Defs.' Mot. for Recons., Entry of Final J., and Expedited Briefing, ECF No. 54 ("Defs.' Mot."). In this motion, Defendants also argue that entry of final judgment is necessary for expeditious review on the merits in the D.C. Circuit. *Id.* at 1. These motions are ripe for the Court's consideration. For the reasons stated below, the Court will grant Defendant's motion for entry of final judgment and dismiss as moot Plaintiff's motion for a firm date.

II. ANALYSIS

Defendants ask this Court to revisit the remedy specified in the May 6, 2019 Order, ECF No. 49, specifically requesting that the Court, first, reconsider its retention of jurisdiction following remand to HHS and, second, enter final judgment. Defs.' Mot. 1. Defendants argue that the Court has both the authority and the imperative to reconsider the May 6 Order. The Court agrees.

A court has authority to reconsider an interlocutory order like the May 6 Order "at any time before the entry of judgment adjudicating all the claims and the rights and liabilities of all the parties." *Lewis v. District of Columbia*, 736 F. Supp. 2d 98, 101 (D.D.C. 2010) (quoting Fed. R. Civ. P. 54(b)); *see also Bayshore Cmty. Hosp. v. Azar*, 325 F. Supp. 3d 18, 22 (D.D.C. 2018)

(quoting *Ofisi v. BNP Paribas, S.A.*, 285 F. Supp. 3d 240, 243 (D.D.C. 2018)). "Relief under Rule 54(b) is available 'as justice requires,' a standard that reflects the flexibility afforded courts under the rule." *Bayshore Cmty. Hosp.*, 325 F. Supp. 3d at 22 (quoting *Cobell v. Jewell*, 802 F.3d 12, 25 (D.C. Cir. 2015) (internal quotation mark omitted)). For a court to grant a motion for reconsideration of an interlocutory order, the movant must generally demonstrate: "(1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error in the first order." *Zeigler v. Potter*, 555 F. Supp. 2d 126, 129 (D.D.C. 2008), *aff'd*, No. 09-5349, 2010 WL 1632965 (D.C. Cir. Apr. 1, 2010) (quoting *Keystone Tobacco Co. v. U.S. Tobacco Co.*, 217 F.R.D. 235, 237 (D.D.C. 2003)).

Here, Defendants argue that the Court's retention of jurisdiction upon remand to HHS constitutes clear error. They contend that the proper remedy is remand to the agency—and remand alone. *See* Defs.' Mot. at 2. Defendants aver that this is an open and shut issue: because this Court reviewed the agency's action and found that the agency made an error of law, "the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *Id.* (quoting *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005)). Plaintiffs counter with a different view of what remand requires, asserting that this Court nonetheless has *discretion* in certain circumstances to retain jurisdiction. Pls.' Opp'n Defs.' Mot. 3, ECF No. 56. Thus, even Plaintiffs acknowledge that, although the Court may retain jurisdiction over this case, it is not *required* to do so. The Court thus reconsiders the issue and determines that it should not exercise its discretion in that fashion.

As a general matter, Plaintiffs are correct that the Court has discretion to retain jurisdiction, and it aligns with other courts in this Circuit in "recogniz[ing] that it has the discretion to retain jurisdiction over a case pending completion of a remand and to order the

filing of progress reports." *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 41 (D.D.C. 2008) (citing *Cobell*, 240 F.3d at 1109). But "this discretion is typically reserved for cases alleging unreasonable delay of agency action or failure to comply with a statutory deadline, or for cases involving a history of agency noncompliance." *Id.* (citing *Cobell,* 240 F.3d at 1109). In the instant case, there is no evidence of unreasonable agency delay or noncompliance on par with the decades-long recalcitrance evidenced in cases such as *Cobell*. And in such instances, "[t]he norm is to vacate agency action that is held to be arbitrary and capricious and remand for further proceedings consistent with the judicial decision, without retaining oversight over the remand proceedings." *Baystate Med. Ctr.*, 587 F. Supp. 2d at 41. Here, of course, the Court concluded that vacatur was inappropriate, *see AHA II*, 2019 WL 1992868 at *7, so its retention of jurisdiction cuts against this norm.

Moreover, pragmatic considerations call for reconsideration of the Court's original stance. Both parties wish to resolve the dispute expeditiously. And this Court is sympathetic to Defendants' argument that retention of oversight over remand to the agency "calls into question the finality of the remand order" and thereby risks delaying the ability to appeal to the D.C. Circuit. Defs.' Mot. 3. Although Plaintiffs would prefer that this Court retain jurisdiction and resolve the merits and the remedy at once, Defendants correctly note in a separate filing that the Administrative Procedure Act does not permit this Court to review a *proposed* rule before it is final. Defs.' Opp'n Pls.' Mot. 4–5, ECF No. 53 (discussing 5 U.S.C. § 704 and associated case law). Accordingly, retention of jurisdiction risks delaying prompt resolution of this suit, pending a final agency rule. To afford the parties the opportunity for expedited review by the D.C. Circuit, this Court will grant Defendants' motion for entry of final judgment. This resolution moots Plaintiffs' motion for a firm date.

III. CONCLUSION

For the foregoing reasons, Defendants' motion for reconsideration and motion for entry of final judgment is **GRANTED** and Plaintiffs' motion for entry of a firm date is **DENIED** as moot. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: July 10, 2019

RUDOLPH CONTRERAS
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

NOTICE OF APPEAL

PLEASE TAKE NOTICE that Defendants Alex M. Azar II, Secretary of the United States Department of Health and Human Services, and the U.S. Department of Health and Human Services hereby appeal to the United States Court of Appeals for the District of Columbia Circuit from the order entering final judgment [ECF No. 58] and related opinion [ECF No. 59], and all prior rulings that merged with the final judgment.

Date: July 11, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2019, I electronically filed the foregoing Joint Appendix with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Laura E. Myron
LAURA E. MYRON