[ORAL ARGUMENT NOT YET SCHEDULED]

Nos. 19-5352, 19-5353, 19-5354

**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, in his official capacity as Secretary of Health & Human Services,

Defendant-Appellant.

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

JOINT APPENDIX

Of Counsel:

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General Counsel

BRIAN R. STIMSON
Principal Deputy General Counsel

JANICE L. HOFFMAN
Associate General Counsel

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APPEAL,CLOSED,CONSOL,TYPE-C

U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:18-cv-02841-RMC

AMERICAN HOSPITAL ASSOCIATION et al v. AZAR
Assigned to: Judge Rosemary M. Collyer
Case: 1:20-cv-00080
Case in other court: USCA, 19-05352
Cause: 28:1331 Fed. Question: Review Agency Decision

Date Filed: 12/04/2018
Date Terminated: 10/23/2019
Jury Demand: None
Nature of Suit: 151 Contract: Recovery Medicare
Jurisdiction: U.S. Government Defendant

Plaintiff

AMERICAN HOSPITAL ASSOCIATION represented by **Catherine Emily Stetson**
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ATTORNEY TO BE NOTICED

Plaintiff

ASSOCIATION OF AMERICAN MEDICAL COLLEGES represented by **Catherine Emily Stetson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Susan Margaret Cook
(See above for address)

Plaintiff

MERCY HEALTH MUSKEGON represented by

Catherine Emily Stetson
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Susan Margaret Cook
(See above for address)

Plaintiff

CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 *agent of* OLYMPIC MEDICAL CENTER	represented by	**Catherine Emily Stetson** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Susan Margaret Cook** (See above for address)

Plaintiff

YORK HOSPITAL	represented by	**Catherine Emily Stetson** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Susan Margaret Cook** (See above for address)

Plaintiff

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY *in CA 19-132*	represented by	**Joel L. McElvain** KING & SPALDING LLP 1700 Pennsylvania Avenue, NW Suite 200 Washington, DC 20006 (202) 626-2929 Fax: (202) 626-3737 Email: jmcelvain@kslaw.com *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Mark D. Polston** KING & SPALDING LLP 1700 Pennsylvania Avenue, NW Suite 200 Washington, DC 20006 (202) 626-5540 Fax: (202) 626-3737 Email: mpolston@kslaw.com *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED*

Plaintiff

COLUMBUS REGIONAL HEALTHCARE SYSTEM
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

COPLEY MEMORIAL HOSPITAL, INC.
in CA 19-132
doing business as
RUSH COPLEY MEDICAL CENTER

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

EAST BATON ROUGE MEDICAL CENTER, LLC
in CA 19-132
doing business as
OCHNER MEDICAL CENTER - BATON ROUGE

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

FAYETTE COMMUNITY HOSPITAL, INC.
in CA 19-132
doing business as
PIEDMONT FAYETTE HOSPITAL, INC.

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

FLORIDA HEALTH SCIENCES CENTER INC.
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY

doing business as
TAMPA GENERAL HOSPITAL

ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

MONTEFIORE HEALTH SYSTEM, INC.
in CA 19-132
doing business as
MONTEFIORE MEDICAL CENTER
doing business as
ST. LUKE'S CORNWALL HOSPITAL
doing business as
WHITE PLAINS HOSPITAL

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

MONTEFIORE HEALTH SYSTEM, INC.
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

MONTEFIORE HEALTH SYSTEM, INC.
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

NORTHWEST MEDICAL CENTER
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

<u>**Plaintiff**</u>

OCHSNER CLINIC FOUNDATION *in CA 19-132*	represented by	**Joel L. McElvain** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED*

<u>**Plaintiff**</u>

OSF HEALTHCARE SYSTEM *in CA 19-132* *doing business as* OSF HEART OF MARY MEDICAL CENTER *doing business as* OSF SACRED HEART MEDICAL CENTER *doing business as* OTTAWA REGIONAL HOSPITAL & HEALTHCARE CENTER *doing business as* OSF SAINT ELIZABETH MEDICAL CENTER *doing business as* SAINT ANTHONY MEDICAL CENTER *doing business as* SAINT ANTHONY'S HEALTH CENTER *doing business as* ST. JOSEPH MEDICAL CENTER	represented by	**Joel L. McElvain** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED*

<u>**Plaintiff**</u>

PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC. *in CA 19-132*	represented by	**Joel L. McElvain** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED*

Plaintiff

PIEDMONT HOSPITAL, INC.
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

PIEDMONT MOUNTAINSIDE HOSPITAL, INC.
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

PIEDMONT NEWNAN HOSPITAL, INC.
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

RUSH OAK PARK HOSPITAL, INC.
in 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

RUSH UNIVERSITY MEDICAL CENTER
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

SARASOTA MEMORIAL HOSPITAL
in CA 19-132

represented by **Joel L. McElvain**
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY
in CA 19-132
doing business as
ATRIUM HEALTH ANSON
doing business as
ATRIUM HEALTH CLEVELAND
doing business as
ATRIUM HEALTH KINGS MOUNTAIN
doing business as
ATRIUM HEALTH LINCOLN
doing business as
ATRIUM HEALTH PINEVILLE
doing business as
ATRIUM HEALTH UNION
doing business as
ATRIUM HEALTH UNIVERSITY CITY
doing business as
CAROLINA HEALTHCARE SYSTEM STANLY
doing business as
CAROLINA HEALTHCARE SYSTEM NORTHEAST
doing business as
CAROLINAS MEDICAL CENTER

represented by **Joel L. McElvain**
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

represented by

RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA
in CA 19-132
doing business as
UNIVERSITY OF VIRGINIA MEDICAL CENTER

Joel L. McElvain
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

VANDERBILT UNIVERSITY MEDICAL CENTER
in CA 19-132

represented by **Joel L. McElvain**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

SCOTLAND HEALTH CARE SYSTEM
in CA 19-132
doing business as
SCOTLAND REGIONAL

represented by **Joel L. McElvain**
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark D. Polston
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V.

Defendant

ALEX M. AZAR, II
in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES

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Amicus

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Date Filed	#	Docket Text
12/04/2018	1	COMPLAINT against ALEX M. AZAR, II (Filing fee $ 400 receipt number 0090-5822140) filed by Clallam County Public Hospital No. 2 d/b/a Olympic Medical Center, AMERICAN HOSPITAL ASSOCIATION, MERCY HEALTH MUSKEGON, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, YORK HOSPITAL. (Attachments: # 1 Civil Cover Sheet, # 2 Summons Liu, # 3 Summons Azar, # 4 Summons Whitaker)(Stetson, Catherine) (Entered: 12/04/2018)
12/04/2018	2	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by AMERICAN HOSPITAL ASSOCIATION (Stetson, Catherine) (Entered: 12/04/2018)
12/04/2018	3	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by ASSOCIATION OF AMERICAN MEDICAL COLLEGES (Stetson, Catherine) (Entered: 12/04/2018)
12/04/2018	4	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by Clallam County Public Hospital No. 2 d/b/a Olympic Medical Center (Stetson, Catherine) (Entered: 12/04/2018)
12/04/2018	5	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by YORK HOSPITAL (Stetson, Catherine) (Entered: 12/04/2018)
12/04/2018	6	

		LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by MERCY HEALTH MUSKEGON (Stetson, Catherine) (Entered: 12/04/2018)
12/04/2018	7	NOTICE of Appearance by Susan Margaret Cook on behalf of All Plaintiffs (Cook, Susan) (Entered: 12/04/2018)
12/06/2018		Case Assigned to Judge Rosemary M. Collyer. (zrdj) (Entered: 12/06/2018)
12/06/2018	8	SUMMONS (3) Issued Electronically as to ALEX M. AZAR, II, U.S. Attorney and U.S. Attorney General (Attachments: # 1 Notice and Consent)(zrdj) (Entered: 12/06/2018)
12/07/2018	9	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 12/6/2018. Answer due for ALL FEDERAL DEFENDANTS by 2/4/2019. (Stetson, Catherine) (Entered: 12/07/2018)
12/20/2018	10	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. ALEX M. AZAR, II served on 12/13/2018. (Cook, Susan); Modified text on 12/26/2018 (zth). (Entered: 12/20/2018)
12/20/2018	11	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 12/12/2018. (Cook, Susan) (Entered: 12/20/2018)
01/25/2019	12	MOTION to Stay *in Light of Lapse of Appropriations* by ALEX M. AZAR, II (Attachments: # 1 Text of Proposed Order)(Humphreys, Bradley) (Entered: 01/25/2019)
01/28/2019		MINUTE ORDER denying 12 Motion to Stay and granting extension of time to answer or otherwise respond. Defendants shall answer or otherwise respond to the Complaint no later than 2/25/2019. Signed by Judge Rosemary M. Collyer on 1/28/2019. (DAS) (Entered: 01/28/2019)
01/28/2019		Set/Reset Deadlines/Hearings: Answer or other response to Complaint due by 2/25/2019. (zcdw) (Entered: 01/30/2019)
01/29/2019	13	AMENDED COMPLAINT against All Defendants filed by CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, AMERICAN HOSPITAL ASSOCIATION, MERCY HEALTH MUSKEGON, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, YORK HOSPITAL.(Stetson, Catherine) (Entered: 01/29/2019)
02/01/2019	14	MOTION for Summary Judgment by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL (Attachments: # 1 Memorandum in Support, # 2 Declaration of AHA, # 3 Declaration of AAMC, # 4 Declaration of Olympic Medical Center, # 5 Declaration of York Hospital, # 6 Declaration of Mercy Health Muskegon, # 7 Text of Proposed Order)(Stetson, Catherine) (Entered: 02/01/2019)
02/01/2019	15	

		Joint MOTION for Briefing Schedule by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL (Attachments: # 1 Text of Proposed Order)(Stetson, Catherine) (Entered: 02/01/2019)
02/04/2019		MINUTE ORDER granting 15 Motion for Briefing Schedule. Defendant's Opposition to Motion for Summary Judgment and Motion to Dismiss shall be filed no later than March 1, 2019. Plaintiffs' Reply in Support of Motion for Summary Judgment and Opposition to Motion to Dismiss shall be filed no later than March 15, 2019. Defendant's Reply in Support of Motion to Dismiss shall be filed no later than March 29, 2019. Signed by Judge Rosemary M. Collyer on 2/4/2019. (DAS) (Entered: 02/04/2019)
02/04/2019		Set/Reset Deadlines/Hearings: Response to Motion for Summary Judgment due by 3/1/2019. Reply to Motion for Summary Judgment due by 3/15/2019. Motion to dismiss due by 3/1/2019. Response due by 3/15/2019. Reply due by 3/29/2019. (zcdw) (Entered: 02/05/2019)
02/21/2019	16	MOTION for Leave to File *Amicus Curiae Brief* by AMERICA'S ESSENTIAL HOSPITALS (Attachments: # 1 Exhibit Proposed Amicus Brief, # 2 Text of Proposed Order)(Eyman, Barbara) (Entered: 02/21/2019)
02/21/2019		MINUTE ORDER granting 16 Motion for Leave to File Amicus Curiae Brief. Signed by Judge Rosemary M. Collyer on 2/21/2019. (DAS) (Entered: 02/21/2019)
02/21/2019	17	AMICUS BRIEF by AMERICA'S ESSENTIAL HOSPITALS. (tth) (Entered: 02/26/2019)
02/27/2019		MINUTE ORDER. All parties in related case numbers 18-cv-2841 and 19-cv-132 shall meet and confer and, no later than March 6, 2019, submit a proposed schedule for consolidated dispositive briefing or show good cause why such briefing should not be consolidated. The current briefing schedules in both cases are stayed pending a decision on this issue. Signed by Judge Rosemary M. Collyer on 2/27/2019. (DAS) (Entered: 02/27/2019)
03/06/2019	18	RESPONSE TO ORDER OF THE COURT re Order, filed by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (Stetson, Catherine) (Entered: 03/06/2019)
03/08/2019		MINUTE ORDER resetting the briefing schedule after consideration of the parties' response to the Court's February 27, 2019 Minute Order. Response to Motion for Summary Judgment and Motion to Dismiss due by 3/22/2019. Reply to Motion for Summary Judgment and Opposition to Motion to Dismiss due by 4/5/2019. Reply to Motion to Dismiss due by 4/19/2019. Signed by Judge Rosemary M. Collyer on 3/8/2019. (DAS) (Entered: 03/08/2019)
03/08/2019		Set/Reset Deadlines/Hearings: Motion to Dismiss due by 3/22/2019. Response due by 4/5/2019. Reply due by 4/19/2019. Response to Motion for Summary

		Judgment due by 3/22/2019. Reply to Motion for Summary Judgment due by 4/5/2019. (zcdw) (Entered: 03/10/2019)
03/09/2019	19	NOTICE of Appearance by Susan Margaret Cook on behalf of All Plaintiffs (Cook, Susan) (Entered: 03/09/2019)
03/22/2019	20	MOTION to Dismiss *or, in the Alternative, Cross-Motion for Summary Judgment* by ALEX M. AZAR, II (Attachments: # 1 Memorandum in Support, # 2 Text of Proposed Order)(Humphreys, Bradley). Added MOTION for Summary Judgment on 3/25/2019 (tth). (Entered: 03/22/2019)
03/22/2019	21	Memorandum in opposition to re 14 MOTION for Summary Judgment filed by ALEX M. AZAR, II. (Humphreys, Bradley) (Entered: 03/22/2019)
04/05/2019	22	Memorandum in opposition to re 20 MOTION to Dismiss *or, in the Alternative, Cross-Motion for Summary Judgment* MOTION for Summary Judgment filed by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (Attachments: # 1 Text of Proposed Order)(Stetson, Catherine) (Entered: 04/05/2019)
04/05/2019	23	REPLY to opposition to motion re 14 MOTION for Summary Judgment filed by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (Stetson, Catherine) (Entered: 04/05/2019)
04/18/2019	24	NOTICE of Appearance by Justin Michael Sandberg on behalf of All Defendants (Sandberg, Justin) (Entered: 04/18/2019)
04/19/2019	25	REPLY to opposition to motion re 20 MOTION to Dismiss *or, in the Alternative, Cross-Motion for Summary Judgment* MOTION for Summary Judgment filed by ALEX M. AZAR, II. (Humphreys, Bradley) (Entered: 04/19/2019)
08/02/2019	26	Motion for Hearing by AMERICAN HOSPITAL ASSOCIATION (Stetson, Catherine); Modified event and text on 8/5/2019 (tth). (Entered: 08/02/2019)
08/15/2019	27	ORDER TO SHOW CAUSE. Plaintiffs shall show cause, by August 23, 2019, why civil cases 18-2841 and 19-132 should not be consolidated for the purposes of decision. See Order for details. Signed by Judge Rosemary M. Collyer on 8/15/2019. (lcrmc3) (Entered: 08/15/2019)
08/15/2019		Set/Reset Deadlines: Plaintiff Show Cause due by 8/23/2019. (mac) (Entered: 08/15/2019)
08/20/2019	28	RESPONSE TO ORDER OF THE COURT re 27 Order filed by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (Stetson, Catherine) (Entered: 08/20/2019)
08/26/2019		

		MINUTE ORDER consolidating cases 18-cv-2841 and 19-cv-132 for the purposes of decision. 18-cv-2841 is the leading case. Signed by Judge Rosemary M. Collyer on 8/26/2019. (lcrmc3) (Entered: 08/26/2019)
09/04/2019	29	ENTERED IN ERROR.....STIPULATION of Dismissal *(Partial)* by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COPLEY MEMORIAL HOSPITAL, INC., FAYETTE COMMUNITY HOSPITAL, INC., OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., RUSH OAK PARK HOSPITAL, INC., SCOTLAND HEALTH CARE SYSTEM. (Polston, Mark); Modified on 9/5/2019 (ztth). (Entered: 09/04/2019)
09/05/2019		NOTICE OF ERROR re 29 Stipulation of Dismissal; emailed to mpolston@kslaw.com, cc'd 10 associated attorneys -- The PDF file you docketed contained errors: 1. Incorrect header/caption/case number, 2. Please refile document (ztth,) (Entered: 09/05/2019)
09/05/2019	30	STIPULATION of Dismissal *(Partial)* by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COPLEY MEMORIAL HOSPITAL, INC., FAYETTE COMMUNITY HOSPITAL, INC., OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., RUSH OAK PARK HOSPITAL, INC., SCOTLAND HEALTH CARE SYSTEM. (Polston, Mark) (Entered: 09/05/2019)
09/10/2019		MINUTE ORDER accepting 30 Stipulation of Partial Dismissal Without Prejudice. Signed by Judge Rosemary M. Collyer on 9/10/2019. (lcrmc3) (Entered: 09/10/2019)
09/17/2019	31	MEMORANDUM OPINION. Signed by Judge Rosemary M. Collyer on 9/17/2019. (lcrmc3) (Entered: 09/17/2019)
09/17/2019	32	ORDER granting Plaintiffs' 14 Motion for Summary Judgment, and denying Defendant's 20 Cross-Motion for Summary Judgment. The parties shall submit a joint status report by October 1, 2019, regarding the need for additional briefing. See Order for details. Signed by Judge Rosemary M. Collyer on 9/17/2019. (lcrmc3) (Entered: 09/17/2019)
09/17/2019		Set/Reset Deadlines/Hearings: Joint Status Report due by 10/1/2019. (zcdw) (Entered: 09/18/2019)
09/17/2019		Set/Reset Deadlines/Hearings: Joint Status Report due by 10/1/2019. (zcdw) (Entered: 09/19/2019)
09/23/2019	33	MOTION to Modify *Order* by ALEX M. AZAR, II (Attachments: # 1 Text of Proposed Order)(Humphreys, Bradley) (Entered: 09/23/2019)
09/30/2019	34	Memorandum in opposition to re 33 MOTION to Modify *Order* filed by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (Attachments: # 1 Text of Proposed Order)(Stetson, Catherine) (Entered: 09/30/2019)

10/01/2019	35	Memorandum in opposition to re 33 MOTION to Modify *Order* filed by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC.(in CA 19-132), NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER. (Polston, Mark) (Entered: 10/01/2019)
10/01/2019	36	Joint STATUS REPORT by ALEX M. AZAR, II. (Humphreys, Bradley) (Entered: 10/01/2019)
10/07/2019	37	REPLY to opposition re 33 MOTION to Modify *Order Re-Filed Per Advice from Clerks's Office (Filed on Monday via Email)* filed by ALEX M. AZAR, II. (Sandberg, Justin) Modified on 10/9/2019 to correct filed date (jf). (Entered: 10/09/2019)
10/21/2019	38	MEMORANDUM OPINION. Signed by Judge Rosemary M. Collyer on 10/21/2019. (DAS) (Entered: 10/21/2019)
10/21/2019	39	ORDER denying 33 Motion to Modify. This case is closed. Signed by Judge Rosemary M. Collyer on 10/21/2019. (DAS) (Entered: 10/21/2019)
11/06/2019	40	NOTICE *of Intent to File Motion to Enforce Judgment* by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL (Attachments: # 1 Text of Proposed Order)(Cook, Susan) (Entered: 11/06/2019)
11/06/2019	41	MOTION for Briefing Schedule by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (See Docket Entry 40 to view document) (ztth) (Entered: 11/07/2019)
11/07/2019	42	RESPONSE re 41 MOTION for Briefing Schedule *and to Notice of Proposed Motion* filed by ALEX M. AZAR, II. (Sandberg, Justin) (Entered: 11/07/2019)
11/11/2019	43	MOTION to Enforce Judgment by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL (Attachments: # 1 Memorandum in Support, # 2 Text of Proposed Order)(Cook, Susan) (Entered: 11/11/2019)
11/12/2019		

		MINUTE ORDER setting briefing schedule. The government's opposition to Plaintiffs' 43 Motion to Enforce Judgment is due 11/25/2019. Plaintiffs' Reply is due 12/5/2019. Signed by Judge Rosemary M. Collyer on 11/12/2019. (lcrmc1) (Entered: 11/12/2019)
11/12/2019		Set/Reset Deadlines/Hearings: Response to 43 due by 11/25/2019. Reply due by 12/5/2019. (zcdw) (Entered: 11/13/2019)
11/21/2019	44	RESPONSE re 43 MOTION to Enforce Judgment filed by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC.(in CA 19-132), NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER. (McElvain, Joel) (Entered: 11/21/2019)
11/25/2019	45	RESPONSE re 43 MOTION to Enforce Judgment filed by ALEX M. AZAR, II. (Sandberg, Justin) (Entered: 11/25/2019)
12/05/2019	46	REPLY to opposition to motion re 43 MOTION to Enforce Judgment filed by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL. (Stetson, Catherine) (Entered: 12/05/2019)
12/09/2019	47	NOTICE *(Supplement)* by AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, MERCY HEALTH MUSKEGON, YORK HOSPITAL re 46 Reply to opposition to Motion, (Stetson, Catherine) (Entered: 12/09/2019)
12/12/2019	48	NOTICE OF APPEAL TO DC CIRCUIT COURT as to 38 Memorandum & Opinion, 31 Memorandum & Opinion, 32 Order, 39 Order on Motion to Modify by ALEX M. AZAR, II. Fee Status: No Fee Paid. Parties have been notified. (Humphreys, Bradley) (Entered: 12/12/2019)
12/13/2019	49	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 48 Notice of Appeal to DC Circuit Court. (ztth) (Entered: 12/13/2019)
12/13/2019		USCA Case Number 19-5352 for 48 Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR, II. (zrdj) (Entered: 12/17/2019)

12/16/2019	50	MEMORANDUM OPINION. Signed by Judge Rosemary M. Collyer on 12/16/2019. (lcrmc1) (Entered: 12/16/2019)
12/16/2019	51	ORDER denying 43 Motion to Enforce Judgment. Signed by Judge Rosemary M. Collyer on 12/16/2019. (lcrmc1) (Entered: 12/16/2019)

PACER Service Center			
Transaction Receipt			
01/14/2020 12:57:54			
PACER Login:	alisaklein	**Client Code:**	
Description:	Docket Report	**Search Criteria:**	1:18-cv-02841-RMC
Billable Pages:	14	**Cost:**	1.40

APPEAL,CLOSED,CONSOL,TYPE-C

U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:19-cv-00132-RMC

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY et al v. AZAR, II
Assigned to: Judge Rosemary M. Collyer
Case in other court: USCA, 19-05353
Cause: 05:551 Administrative Procedure Act

Date Filed: 01/18/2019
Date Terminated: 10/23/2019
Jury Demand: None
Nature of Suit: 151 Contract: Recovery Medicare
Jurisdiction: U.S. Government Defendant

Plaintiff

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY

represented by **Joel L. McElvain**
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, DC 20006
(202) 626-2929
Fax: (202) 626-3737
Email: jmcelvain@kslaw.com
ATTORNEY TO BE NOTICED

Mark D. Polston
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, DC 20006
(202) 626-5540
Fax: (202) 626-3737
Email: mpolston@kslaw.com
ATTORNEY TO BE NOTICED

Plaintiff

COLUMBUS REGIONAL HEALTHCARE SYSTEM

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

COPLEY MEMORIAL HOSPITAL, INC. *doing business as* RUSH COPLEY MEDICAL CENTER	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

EAST BATON ROUGE MEDICAL CENTER, LLC *doing business as* OCHSNER MEDICAL CENTER - BATON ROUGE	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

FAYETTE COMMUNITY HOSPITAL, INC. *doing business as* PIEDMONT FAYETTE HOSPITAL, INC.	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

FLORIDA HEALTH SCIENCES CENTER INC. *doing business as* TAMPA GENERAL HOSPITAL	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

MONTEFIORE HEALTH SYSTEM, INC. *doing business as* MONTEFIORE MEDICAL CENTER	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

MONTEFIORE HEALTH SYSTEM, INC.	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED*

doing business as
ST. LUKE'S CORNWALL HOSPITAL

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

MONTEFIORE HEALTH SYSTEM, INC.
doing business as
WHITE PLAINS HOSPITAL

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

NORTHWEST MEDICAL CENTER

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OCHSNER CLINIC FOUNDATION
doing business as
OCHSNER MEDICAL CENTER

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM
doing business as
OSF HEART OF MARY MEDICAL CENTER

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM
doing business as
OSF SACRED HEART MEDICAL CENTER

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston

(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM represented by **Joel L. McElvain**
doing business as (See above for address)
OTTAWA REGIONAL HOSPITAL & *ATTORNEY TO BE NOTICED*
HEALTHCARE CENTER
doing business as **Mark D. Polston**
OSF SAINT ELIZABETH MEDICAL (See above for address)
CENTER *ATTORNEY TO BE NOTICED*

Plaintiff

OSF HEALTHCARE SYSTEM represented by **Joel L. McElvain**
doing business as (See above for address)
SAINT ANTHONY MEDICAL *ATTORNEY TO BE NOTICED*
CENTER

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM represented by **Joel L. McElvain**
doing business as (See above for address)
SAINT ANTHONY'S HEALTH *ATTORNEY TO BE NOTICED*
CENTER

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM represented by **Joel L. McElvain**
doing business as (See above for address)
SAINT JAMES HOSPITAL *ATTORNEY TO BE NOTICED*

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM represented by **Joel L. McElvain**
doing business as (See above for address)
ST. JOSEPH MEDICAL CENTER *ATTORNEY TO BE NOTICED*

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC. represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

PIEDMONT HOSPITAL, INC. represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

PIEDMONT MOUNTAINSIDE HOSPITAL, INC. represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

PIEDMONT NEWNAN HOSPITAL, INC. represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

RUSH OAK PARK HOSPITAL, INC. represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

RUSH UNIVERSITY MEDICAL CENTER represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

		Mark D. Polston (See above for address) *ATTORNEY TO BE NOTICED*
Plaintiff		
SARASOTA MEMORIAL HOSPITAL	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*
Plaintiff		
CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY *doing business as* ATRIUM HEALTH ANSON	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*
Plaintiff		
CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY *doing business as* ATRIUM HEALTH CLEVELAND	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*
Plaintiff		
CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY *doing business as* ATRIUM HEALTH KINGS MOUNTAIN	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*
Plaintiff		
CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY *doing business as* ATRIUM HEALTH LINCOLN	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston**

(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY
doing business as
ATRIUM HEALTH PINEVILLE

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY
doing business as
ATRIUM HEALTH UNION

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY
doing business as
ATRIUM HEALTH UNIVERSITY CITY

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY
doing business as
CAROLINAS HEALTHCARE SYSTEM NORTHEAST

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY
doing business as
CAROLINAS HEALTHCARE SYSTEM STANLY

represented by **Joel L. McElvain**
(See above for address)
ATTORNEY TO BE NOTICED

Mark D. Polston
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY *doing business as* CAROLINAS MEDICAL CENTER	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA *doing business as* UNIVERSITY OF VIRGINIA MEDICAL CENTER	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

VANDERBILT UNIVERSITY MEDICAL CENTER	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

SCOTLAND HEALTH CARE SYSTEM *doing business as* SCOTLAND REGIONAL	represented by	**Joel L. McElvain** (See above for address) *ATTORNEY TO BE NOTICED* **Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

V.

Defendant

ALEX M. AZAR, II *in his official capacity as Secretary of Health & Human Services*	represented by	**Bradley P. Humphreys** U.S. DEPARTMENT OF JUSTICE Civil Division, Federal Programs Branch 1100 L Street, NW Washington, DC 20530 (202) 305-0878 Fax: (202) 639-6066 Email: bradley.humphreys@usdoj.gov *LEAD ATTORNEY*

ATTORNEY TO BE NOTICED

Justin Michael Sandberg
U.S. DEPARTMENT OF JUSTICE
Civil Division, Federal Programs Branch
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(202) 514-5838
Fax: (202) 616-8202
Email: justin.sandberg@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
01/18/2019	1	COMPLAINT against ALEX M. AZAR, II (Filing fee $ 400 receipt number 0090-5897342) filed by OSF HEALTHCARE SYSTEM, FAYETTE COMMUNITY HOSPITAL, INC., NORTHWEST MEDICAL CENTER, COLUMBUS REGIONAL HEALTHCARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, OCHSNER CLINIC FOUNDATION, CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, RUSH UNIVERSITY MEDICAL CENTER, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., MONTEFIORE HEALTH SYSTEM, INC., SCOTLAND HEALTH CARE SYSTEM, RUSH OAK PARK HOSPITAL, INC., VANDERBILT UNIVERSITY MEDICAL CENTER, COPLEY MEMORIAL HOSPITAL, INC., PIEDMONT HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., SARASOTA MEMORIAL HOSPITAL, PIEDMONT NEWNAN HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, EAST BATON ROUGE MEDICAL CENTER, LLC. (Attachments: # 1 Exhibit A, # 2 Civil Cover Sheet, # 3 Civil Cover Sheet Attachment, # 4 Summons for Acting U.S. Attorney General, # 5 Summons for U.S. Attorney for the District of Columbia, # 6 Summons for Alex M. Azar, II) (Polston, Mark) (Entered: 01/18/2019)
01/18/2019	2	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY

		MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER (Polston, Mark) (Entered: 01/18/2019)
01/18/2019	3	NOTICE OF RELATED CASE by All Plaintiffs. Case related to Case No. 18-cv-02841-RMC. (Polston, Mark) (Entered: 01/18/2019)
01/24/2019		Case Assigned to Judge Rosemary M. Collyer. (zef,) (Entered: 01/24/2019)
01/24/2019	4	SUMMONS (3) Issued Electronically as to All Defendants, U.S. Attorney and U.S. Attorney General. (Attachments: # 1 Notice and Consent)(zef,) (Entered: 01/24/2019)
02/01/2019	5	NOTICE of Appearance by Bradley P. Humphreys on behalf of ALEX M. AZAR, II (Humphreys, Bradley) (Entered: 02/01/2019)
02/15/2019	6	AMENDED COMPLAINT against ALEX M. AZAR, II filed by OSF HEALTHCARE SYSTEM, FAYETTE COMMUNITY HOSPITAL, INC., NORTHWEST MEDICAL CENTER, COLUMBUS REGIONAL HEALTHCARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, OCHSNER CLINIC FOUNDATION, CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, RUSH UNIVERSITY MEDICAL CENTER, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., MONTEFIORE HEALTH SYSTEM, INC., SCOTLAND HEALTH CARE SYSTEM, RUSH OAK PARK HOSPITAL, INC., VANDERBILT UNIVERSITY MEDICAL CENTER, COPLEY MEMORIAL HOSPITAL, INC., PIEDMONT HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., SARASOTA MEMORIAL HOSPITAL, PIEDMONT NEWNAN HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, EAST BATON ROUGE MEDICAL CENTER, LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Polston, Mark) (Entered: 02/15/2019)
02/15/2019	7	MOTION for Summary Judgment by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER (Attachments: # 1 Memorandum in Support, # 2 Exhibit A, # 3 Exhibit B, # 4

		Exhibit C, # 5 Exhibit D, # 6 Text of Proposed Order)(Polston, Mark) (Entered: 02/15/2019)
02/21/2019	8	Joint MOTION for Briefing Schedule by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER (Attachments: # 1 Text of Proposed Order)(Polston, Mark) (Entered: 02/21/2019)
02/27/2019		MINUTE ORDER. All parties in related case numbers 18-cv-2841 and 19-cv-132 shall meet and confer and, no later than March 6, 2019, submit a proposed schedule for consolidated dispositive briefing or show good cause why such briefing should not be consolidated. The current briefing schedules in both cases are stayed pending a decision on this issue. Signed by Judge Rosemary M. Collyer on 2/27/2019. (DAS) (Entered: 02/27/2019)
03/06/2019	9	RESPONSE TO ORDER OF THE COURT re Order, filed by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER. (Polston, Mark) (Entered: 03/06/2019)
03/08/2019		MINUTE ORDER granting 8 Motion for Briefing Schedule after consideration of the parties' response to the Court's February 27, 2019 Minute Order. Response to Motion for Summary Judgment and Dispositive Cross Motion due by 3/22/2019. Reply to Motion for Summary Judgment and Opposition to Dispositive Cross Motion due by 4/5/2019. Reply to Dispositive Cross Motion due by 4/19/2019. Signed by Judge Rosemary M. Collyer on 3/8/2019. (DAS) (Entered: 03/08/2019)

03/12/2019	10	NOTICE of Appearance by Joel L. McElvain on behalf of All Plaintiffs (McElvain, Joel) (Entered: 03/12/2019)
03/13/2019	11	Consent MOTION for Leave to File *SECOND AMENDED COMPLAINT* by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER (Attachments: # 1 Proposed Second Amended Complaint, # 2 Text of Proposed Order)(Polston, Mark) (Entered: 03/13/2019)
03/14/2019		MINUTE ORDER granting 11 Motion for Leave to File Second Amended Complaint. The proposed second amended complaint, attached as an exhibit to the motion, shall be filed on the docket. Signed by Judge Rosemary M. Collyer on 3/14/2019. (lcrmc3) (Entered: 03/14/2019)
03/14/2019	15	SECOND AMENDED COMPLAINT against ALEX M. AZAR, II filed by OSF HEALTHCARE SYSTEM, FAYETTE COMMUNITY HOSPITAL, INC., NORTHWEST MEDICAL CENTER, COLUMBUS REGIONAL HEALTHCARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, OCHSNER CLINIC FOUNDATION, CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, RUSH UNIVERSITY MEDICAL CENTER, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., MONTEFIORE HEALTH SYSTEM, INC., SCOTLAND HEALTH CARE SYSTEM, RUSH OAK PARK HOSPITAL, INC., VANDERBILT UNIVERSITY MEDICAL CENTER, COPLEY MEMORIAL HOSPITAL, INC., PIEDMONT HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., SARASOTA MEMORIAL HOSPITAL, PIEDMONT NEWNAN HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, EAST BATON ROUGE MEDICAL CENTER, LLC. (tth) (Entered: 03/21/2019)
03/21/2019	12	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. ALEX M. AZAR, II served on 1/30/2019 (Polston, Mark) (Entered: 03/21/2019)
03/21/2019	13	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 1/30/2019. (Polston, Mark) (Entered: 03/21/2019)
03/21/2019	14	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on

		1/30/2019. Answer due for ALL FEDERAL DEFENDANTS by 3/31/2019. (Polston, Mark) (Entered: 03/21/2019)
03/22/2019	16	Memorandum in opposition to re 7 MOTION for Summary Judgment filed by ALEX M. AZAR, II. (Humphreys, Bradley) (Entered: 03/22/2019)
03/22/2019	17	MOTION to Dismiss *or, in the Alternative, Cross-Motion for Summary Judgment* by ALEX M. AZAR, II (Attachments: # 1 Memorandum in Support, # 2 Text of Proposed Order)(Humphreys, Bradley) (Entered: 03/22/2019)
04/05/2019	18	REPLY to opposition to motion re 7 MOTION for Summary Judgment filed by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER. (Polston, Mark) (Entered: 04/05/2019)
04/05/2019	19	Memorandum in opposition to re 17 MOTION to Dismiss *or, in the Alternative, Cross-Motion for Summary Judgment* filed by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER. (Polston, Mark) (Entered: 04/05/2019)
04/18/2019	20	NOTICE of Appearance by Justin Michael Sandberg on behalf of All Defendants (Sandberg, Justin) (Entered: 04/18/2019)
04/19/2019	21	REPLY to opposition to motion re 17 MOTION to Dismiss *or, in the Alternative, Cross-Motion for Summary Judgment* filed by ALEX M. AZAR, II. (Humphreys, Bradley) (Entered: 04/19/2019)
07/29/2019	22	Joint MOTION to Consolidate Cases by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE

		SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER (Attachments: # 1 Text of Proposed Order)(Polston, Mark) (Entered: 07/29/2019)
08/02/2019	23	NOTICE OF SUPPLEMENTAL AUTHORITY by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER (Polston, Mark) (Entered: 08/02/2019)
08/15/2019		MINUTE ORDER granting 22 Joint Motion to Consolidate Cases. Case 19-cv-132 and 19-cv-1745 are consolidated, with the parties in both cases adopting their respective briefing in 19-cv-132. 19-cv-132 is the leading case. Signed by Judge Rosemary M. Collyer on 8/15/2019. (lcrmc3) (Entered: 08/15/2019)
08/15/2019	24	ORDER TO SHOW CAUSE. Plaintiffs shall show cause, by August 23, 2019, why civil cases 18-2841 and 19-132 should not be consolidated for the purposes of decision. See Order for details. Signed by Judge Rosemary M. Collyer on 8/15/2019. (lcrmc3) (Entered: 08/15/2019)
08/15/2019		Set/Reset Deadlines: Plaintiffs Show Cause due by 8/23/2019. (mac) (Entered: 08/15/2019)
08/23/2019	25	RESPONSE TO ORDER TO SHOW CAUSE by CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY, COLUMBUS REGIONAL HEALTHCARE SYSTEM, COPLEY MEMORIAL HOSPITAL, INC., EAST BATON ROUGE MEDICAL CENTER, LLC, FAYETTE COMMUNITY HOSPITAL, INC., FLORIDA HEALTH SCIENCES CENTER INC., MONTEFIORE HEALTH SYSTEM, INC., NORTHWEST MEDICAL CENTER, OCHSNER CLINIC FOUNDATION, OSF HEALTHCARE

		SYSTEM, PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., PIEDMONT HOSPITAL, INC., PIEDMONT MOUNTAINSIDE HOSPITAL, INC., PIEDMONT NEWNAN HOSPITAL, INC., RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA, RUSH OAK PARK HOSPITAL, INC., RUSH UNIVERSITY MEDICAL CENTER, SARASOTA MEMORIAL HOSPITAL, SCOTLAND HEALTH CARE SYSTEM, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, VANDERBILT UNIVERSITY MEDICAL CENTER re 24 Order *TO SHOW CAUSE*. (Polston, Mark) (Entered: 08/23/2019)
08/26/2019		MINUTE ORDER consolidating cases 18-cv-2841 and 19-cv-132 for the purposes of decision. 18-cv-2841 is the leading case. Signed by Judge Rosemary M. Collyer on 8/26/2019. (lcrmc3) (Entered: 08/26/2019)
08/26/2019		Cases Consolidated. Case 19-132 has been consolidated with case 18-2841, pursuant to an Order entered 8/26/2019. From this date forward, all pleadings shall be filed ONLY in the lead/earlier case, Civil Action No. 18-2841. The parties are advised NOT to elect the SPREAD TEXT option when filing in ECF, as this will result in repetitive docketing and emails. (ztth) (Entered: 08/27/2019)
10/21/2019		MINUTE ORDER. Pursuant to the October 21, 2019 Order in consolidated case American Hospital Association v. Azar, No. 18-2841, this case is closed. Signed by Judge Rosemary M. Collyer on 10/21/2019. (DAS) (Entered: 10/21/2019)
12/12/2019	26	NOTICE OF APPEAL TO DC CIRCUIT COURT by ALEX M. AZAR, II. Fee Status: No Fee Paid. Parties have been notified. (Humphreys, Bradley) (Entered: 12/12/2019)
12/13/2019	27	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 26 Notice of Appeal to DC Circuit Court. (ztth) (Entered: 12/13/2019)
12/13/2019		USCA Case Number 19-5353 for 26 Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR, II. (zrdj) (Entered: 12/17/2019)

PACER Service Center			
Transaction Receipt			
01/14/2020 13:10:13			
PACER Login:	alisaklein	**Client Code:**	
Description:	Docket Report	**Search Criteria:**	1:19-cv-00132-RMC
Billable Pages:	16	**Cost:**	1.60

APPEAL,CLOSED,CONSOL,TYPE-C

U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:19-cv-01745-RMC

HACKENSACK MERIDIAN HEALTH et al v. AZAR
Assigned to: Judge Rosemary M. Collyer
Case in other court: USCA, 19-05354
Cause: 05:551 Administrative Procedure Act

Date Filed: 06/14/2019
Date Terminated: 10/23/2019
Jury Demand: None
Nature of Suit: 151 Contract: Recovery Medicare
Jurisdiction: U.S. Government Defendant

Plaintiff

HACKENSACK MERIDIAN HEALTH
doing business as
JERSEY SHORE UNIVERSITY MEDICAL CENTER

represented by **Mark D. Polston**
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, DC 20006
(202) 626-5540
Fax: (202) 626-3737
Email: mpolston@kslaw.com
ATTORNEY TO BE NOTICED

Plaintiff

BARNES-JEWISH HOSPITAL

represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

BARNES-JEWISH WEST COUNTY HOSPITAL

represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

CENTRAL VERMONT MEDICAL CENTER, INC.

represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.

represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

doing business as
HEART HOSPITAL OF ACADIANA, LLC

Plaintiff

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC. *doing business as* OUR LADY OF LOURDES REGIONAL MEDICAL CENTER, INC.	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC. *doing business as* OUR LADY OF THE ANGELS HOSPITAL	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC. *doing business as* OUR LADY OF THE LAKE ASCENSION COMMUNITY HOSPITAL - ST. ELIZABETH HOSPITAL	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC. *doing business as* OUR LADY OF THE LAKE REGIONAL MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC. *doing business as* ST. FRANCIS MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

represented by

HACKENSACK MERIDIAN HEALTH *doing business as* BAYSHORE MEDICAL CENTER		**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* HACKENSACK UNIVERSITY MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* JFK MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* OCEAN MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* PALISADES MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* RARITAN BAY MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* RIVERVIEW MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HACKENSACK MERIDIAN HEALTH *doing business as* SOUTHERN OCEAN MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

HEARTLAND REGIONAL MEDICAL CENTER represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

MISSOURI BAPTIST MEDICAL CENTER represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

NYU LANGONE HEALTH SYSTEM represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

NYU WINTHROP HOSPITAL represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM
doing business as
SAINT FRANCIS MEDICAL CENTER
represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

OSF HEALTHCARE SYSTEM
doing business as
ST. MARY MEDICAL CENTER
represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

PROGRESS WEST HEALTHCARE CENTER
doing business as
PROGRESS WEST HOSPITAL
represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

SHANNON MEDICAL CENTER represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

SOUTHWEST GENERAL HEALTH CENTER represented by **Mark D. Polston**
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

STANFORD HEALTH CARE	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

TARRANT COUNTY HOSPITAL DISTRICT *doing business as* JPS HEALTH NETWORK	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

WOOSTER COMMUNITY HOSPITAL AUXILIARY, INC. *doing business as* WOOSTER COMMUNITY HOSPITAL	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

UNIVERSITY HOSPITALS HEALTH SYSTEM, INC. *doing business as* UH ELYRIA MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

UNIVERSITY HOSPITALS HEALTH SYSTEM, INC. *doing business as* UH GEAUGA MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

Plaintiff

UNIVERSITY OF VERMONT MEDICAL CENTER	represented by	**Mark D. Polston** (See above for address) *ATTORNEY TO BE NOTICED*

V.

Defendant

ALEX M. AZAR, II *in his official capacity as Secretary of Health & Human Services*	represented by	**Bradley P. Humphreys** U.S. DEPARTMENT OF JUSTICE Civil Division, Federal Programs Branch 1100 L Street, NW Washington, DC 20530 (202) 305-0878 Fax: (202) 639-6066 Email: bradley.humphreys@usdoj.gov *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED*

Date Filed	#	Docket Text
06/14/2019	1	COMPLAINT against ALEX M. AZAR, II (Filing fee $ 400 receipt number 0090-6190195) filed by HACKENSACK MERIDIAN HEALTH, FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC., SHANNON MEDICAL CENTER, UNIVERSITY OF VERMONT MEDICAL CENTER, OSF HEALTHCARE SYSTEM, THE WOOSTER COMMUNITY HOSPITAL AUXILIARY, INC., MISSOURI BAPTIST MEDICAL CENTER, UNIVERSITY HOSPITALS HEALTH SYSTEM, INC., PROGRESS WEST HEALTHCARE CENTER, STANFORD HEALTH CARE, BARNES-JEWISH HOSPITAL, NYU LANGONE HEALTH SYSTEM, TARRANT COUNTY HOSPITAL DISTRICT, BARNES-JEWISH WEST COUNTY HOSPITAL, HEARTLAND REGIONAL MEDICAL CENTER, NYU WINTHROP HOSPITAL, SOUTHWEST GENERAL HEALTH CENTER, CENTRAL VERMONT MEDICAL CENTER, INC.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Civil Cover Sheet, # 4 Civil Cover Sheet Attachment, # 5 Summons DC U.S. Attorney, # 6 Summons HHS Sec'y Azar, # 7 Summons U.S. Attorney General)(Polston, Mark) (Entered: 06/14/2019)
06/14/2019	2	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by BARNES-JEWISH HOSPITAL, BARNES-JEWISH WEST COUNTY HOSPITAL, CENTRAL VERMONT MEDICAL CENTER, INC., FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC., HACKENSACK MERIDIAN HEALTH, HEARTLAND REGIONAL MEDICAL CENTER, MISSOURI BAPTIST MEDICAL CENTER, NYU LANGONE HEALTH SYSTEM, NYU WINTHROP HOSPITAL, OSF HEALTHCARE SYSTEM, PROGRESS WEST HEALTHCARE CENTER, SHANNON MEDICAL CENTER, SOUTHWEST GENERAL HEALTH CENTER, STANFORD HEALTH CARE, TARRANT COUNTY HOSPITAL DISTRICT, THE WOOSTER COMMUNITY HOSPITAL AUXILIARY, INC., UNIVERSITY HOSPITALS HEALTH SYSTEM, INC., UNIVERSITY OF VERMONT MEDICAL CENTER (Polston, Mark) (Entered: 06/14/2019)
06/14/2019	3	NOTICE OF RELATED CASE by All Plaintiffs. Case related to Case No. 1:18-cv-02841-RMC, 1:19-cv-00132-RMC. (Polston, Mark) (Entered: 06/14/2019)
06/17/2019		Case Assigned to Judge Rosemary M. Collyer. (zef,) (Entered: 06/17/2019)
06/17/2019	4	SUMMONS (3) Issued Electronically as to ALEX M. AZAR, II, U.S. Attorney and U.S. Attorney General. (Attachments: # 1 Notice and Consent)(zef,) (Entered: 06/17/2019)
07/09/2019	5	NOTICE of Appearance by Bradley P. Humphreys on behalf of ALEX M. AZAR, II (Humphreys, Bradley) (Entered: 07/09/2019)
07/29/2019	6	Joint MOTION to Consolidate Cases by BARNES-JEWISH HOSPITAL, BARNES-JEWISH WEST COUNTY HOSPITAL, CENTRAL VERMONT MEDICAL CENTER, INC., FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC., HACKENSACK MERIDIAN HEALTH, HEARTLAND REGIONAL MEDICAL CENTER, MISSOURI BAPTIST

		MEDICAL CENTER, NYU LANGONE HEALTH SYSTEM, NYU WINTHROP HOSPITAL, OSF HEALTHCARE SYSTEM, PROGRESS WEST HEALTHCARE CENTER, SHANNON MEDICAL CENTER, SOUTHWEST GENERAL HEALTH CENTER, STANFORD HEALTH CARE, TARRANT COUNTY HOSPITAL DISTRICT, UNIVERSITY HOSPITALS HEALTH SYSTEM, INC., UNIVERSITY OF VERMONT MEDICAL CENTER, WOOSTER COMMUNITY HOSPITAL AUXILIARY, INC. (Attachments: # 1 Text of Proposed Order)(Polston, Mark) (Entered: 07/29/2019)
08/02/2019	7	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 7/10/2019. Answer due for ALL FEDERAL DEFENDANTS by 9/8/2019. (Polston, Mark) (Entered: 08/02/2019)
08/02/2019	8	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 7/10/2019. (Polston, Mark) (Entered: 08/02/2019)
08/02/2019	9	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. ALEX M. AZAR, II served on 7/10/2019 (Polston, Mark) (Entered: 08/02/2019)
08/15/2019		MINUTE ORDER granting 6 Joint Motion to Consolidate Cases. Case 19-cv-132 and 19-cv-1745 are consolidated, with the parties in both cases adopting their respective briefing in 19-cv-132. 19-cv-132 is the leading case. Signed by Judge Rosemary M. Collyer on 8/15/2019. (lcrmc3) (Entered: 08/15/2019)
08/22/2019		Cases Consolidated. Case 19-1745 has been consolidated 19-132, pursuant to a Minute Order entered 8/15/2019. From this date forward, all pleadings shall be filed ONLY in the lead/earlier case, Civil Action 19-132. The parties are advised NOT to elect the SPREAD Text option when filing in ECF, as this will result in repetitive docketing and emails. (ztth) (Entered: 08/22/2019)
10/21/2019		MINUTE ORDER. Pursuant to the October 21, 2019 Order in consolidated case American Hospital Association v. Azar, No. 18-2841, this case is closed. Signed by Judge Rosemary M. Collyer on 10/21/2019. (DAS) (Entered: 10/21/2019)
12/12/2019	10	NOTICE OF APPEAL TO DC CIRCUIT COURT by ALEX M. AZAR, II. Fee Status: No Fee Paid. Parties have been notified. (Humphreys, Bradley) (Entered: 12/12/2019)
12/13/2019	11	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 10 Notice of Appeal to DC Circuit Court. (ztth) (Entered: 12/13/2019)
12/13/2019		USCA Case Number 19-5354 for 10 Notice of Appeal to DC Circuit Court filed by ALEX M. AZAR, II. (zrdj) (Entered: 12/17/2019)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, N.W., Suite 400
Washington, D.C. 20001,

ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K Street, N.W., Suite 100
Washington, D.C. 20001,

MERCY HEALTH MUSKEGON,
1500 E. Sherman Boulevard
Muskegon, MI 49444,

CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, d/b/a OLYMPIC MEDICAL CENTER,
939 Caroline Street
Port Angeles, WA 98362,

YORK HOSPITAL,
3 Loving Kindness Way
York, ME 03909,

Plaintiffs,

v.

ALEX M. AZAR II,
in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

Defendant.

Civil Action No. 1:18-cv-2841

FIRST AMENDED COMPLAINT

Plaintiffs the American Hospital Association, Association of American Medical Colleges, Mercy Health Muskegon, Clallam County Public Hospital District No. 2, d/b/a Olympic Medical Center, and York Hospital bring this First Amended Complaint against Defendant Alex M. Azar II, in his official capacity as Secretary of Health and Human Services (HHS), and allege as follows:

PRELIMINARY STATEMENT

1. This is an action to challenge certain aspects of a final rule issued by the Centers for Medicare & Medicaid Services (CMS), an agency within HHS, published in the Federal Register on November 21. *See* Centers for Medicare & Medicaid Services, *Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, Dep't of Health and Human Servs., 83 Fed. Reg. 58,818 (Nov. 21, 2018) (Final Rule). The Final Rule, in relevant part, makes serious reductions to Medicare payment rates for certain clinic visit services provided at specified off-campus hospital provider-based departments (off-campus PBDs), commencing on January 1, 2019. Off-campus PBDs are practice locations of a hospital that are not located in immediate proximity to the main building of their affiliated hospital, but are nonetheless so closely integrated with and controlled by the main hospital as to be considered a part of the hospital.

2. In the Medicare statute, Congress has laid out a clear distinction between "excepted" off-campus PBDs, which meet specified grandfathering requirements, and "non-excepted" off-campus PBDs, which do not. The statute makes clear that services provided at excepted and non-excepted off-campus PBDs should be paid pursuant to different payment systems. 42 U.S.C. § 1395l(t)(21)(C). And yet the Final Rule effectively abolishes any

distinction between excepted and non-excepted entities by subjecting them both to the same payment system and rate. That violates the clear intent of Congress and therefore is *ultra vires*.

3. Congress also has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare. 42 U.S.C. § 1395l(t)(9)(A). Changes to payment that target only specific items or services must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). And yet in an unprecedented assertion of the agency's authority, the Final Rule purports to do precisely what Congress has expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services for calendar year (CY) 2019 by hundreds of millions of dollars by targeting a select group of services for non-budget-neutral payment adjustments. CMS cannot exercise its limited authority in a manner so flagrantly inconsistent with the Medicare statute. That, too, is textbook *ultra vires* action.

4. This Court should reject CMS's attempts to replace Congress's unequivocal directives with the agency's own policy preferences. CMS may not contravene clear congressional mandates merely because the agency wishes to make cuts to Medicare spending.

PARTIES

5. Plaintiff the American Hospital Association (AHA) is a national, not-for-profit organization headquartered in Washington, D.C. The AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, systems, and other related organizations that are accountable to the community and committed to health improvement. The 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. The AHA has a principal place of business located at 800 Tenth Street, N.W., Suite 400, Washington, D.C. 20001.

6. Plaintiff Association of American Medical Colleges (AAMC) is a national, not-for-profit association based in Washington, D.C. The AAMC represents and serves all 152 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 83,000 medical students, and 110,000 resident physicians. The AAMC works to improve the nation's health by strengthening the quality of medical education and training, enhancing the search for biomedical knowledge, advancing health services research, and integrating education and research into the provision of effective health care. In addition, it is one of the AAMC's core missions to advocate on behalf of its members and patients in connection with national health-policy matters. The AAMC has a principal place of business located at 655 K Street, N.W., Suite 100, Washington, D.C. 20001.

7. Plaintiff Mercy Health Muskegon is a Catholic nonprofit hospital that serves the greater Muskegon, Michigan area and surrounding communities. Mercy Health Muskegon operates 27 off-campus PBDs, 25 of which are excepted PBDs. These include a sleep center, a comprehensive breast high risk clinic, specialty clinics (including neurosurgery, cardiology, geriatrics, and gastroenterology), and a number of primary care facilities capable of providing x-ray, laboratory, and pharmacy services in the same building. Mercy Health Muskegon furnishes outpatient services at these excepted off-campus PBDs and will suffer immediate and concrete harm from the outpatient service payment reductions set forth in the Final Rule. Mercy Health

Muskegon has its principal place of business at 1500 E. Sherman Boulevard, Muskegon, Michigan 49444.

8. Plaintiff Clallam County Public Hospital District No. 2, d/b/a Olympic Medical Center (Olympic Medical) is a comprehensive health care provider serving the North Olympic Peninsula with a network of facilities in Clallam County, Washington. Olympic Medical is a large rural hospital and health care center designated as a Sole Community Hospital and Rural Referral Center, and which operates as a safety-net hospital, employing over 100 physicians and advanced practice clinicians. Of Olympic Medical's patients, 83% rely on Government-paid insurance and 58.3% rely on Medicare. Olympic Medical furnishes outpatient services at eight excepted off-campus PBDs, including a specialty physician clinic offering cardiology, gastroenterology, pulmonary medicine, neurology, urology and women's health, a sleep center, a primary care clinic, a coagulation clinic, a walk-in clinic, a cancer center providing medical oncology services and radiation oncology services in Sequim, which is 17 miles from the main hospital campus, and a primary care clinic in Port Angeles which is approximately one mile from the hospital. Olympic Medical will suffer immediate and concrete harm from the outpatient service payment reductions set forth in the Final Rule. Olympic Medical has its principal place of business at 939 Caroline Street, Port Angeles, Washington 98362.

9. Plaintiff York Hospital (York) is a small community hospital located in York, Maine and serving the surrounding area. York is licensed for 79 beds, and currently has only 50 beds in operation. Founded in 1906, York is dedicated to giving back to its community: among other things, it provides support programs and services to schools, civic organizations, and non-profit groups, runs an opiate treatment facility, and offers transportation and food to patients

unable to afford them. Of York's patients, almost 54% rely on Medicare. York furnishes outpatient services at 12 excepted off-campus PBDs, including three oncology clinics and specialty clinics offering psychiatry, cardiovascular care, and gynecology care. York will suffer immediate and concrete harm from the outpatient service payment reductions set forth in the Final Rule. York has its principal place of business at 3 Loving Kindness Way, York, Maine 03909.

10. Defendant Alex M. Azar II, is the Secretary of HHS and is responsible for the conduct and policies of HHS, including those relating to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. The Secretary maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201, and is sued in his official capacity only.

JURISDICTION AND VENUE

11. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiffs require a declaration of their rights by this Court and injunctive relief to prohibit the Defendants from violating laws and regulations.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (e) because this is a civil action in which the Defendant is an officer of the United States acting in his official

capacity and maintains his office and conducts business in this judicial district. Moreover, a substantial part of the events giving rise to the claims occurred within this judicial district.

13. Plaintiffs have standing to bring this lawsuit because the Plaintiff-Hospitals and the AHA's and AAMC's members are suffering and face imminent actual injury as a result of CMS's *ultra vires* decision to reduce the payment rates for targeted services furnished at members' off-campus PBDs. This lawsuit seeks to vindicate interests that are germane to the AHA's and AAMC's purposes because a critical mission of both entities is to protect their members' interests in connection with policy changes initiated by CMS. The AHA's and AAMC's members use the Medicare payments at issue in this lawsuit to provide critical health care services and will suffer a concrete and imminent injury absent judicial relief.

14. This lawsuit is ripe for judicial review. Because Plaintiffs are alleging *only* that CMS is acting well beyond the agency's statutorily granted powers, this Court has the authority to review Plaintiffs' claims, and to do so now. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 114 (D.C. Cir. 2004); *American Hospital Ass'n v. Azar*, D.E. 25, No. 18-2084-RC (D.D.C. Dec. 27, 2018).

15. After the Final Rule became effective on January 1, 2019, the Plaintiff-Hospitals presented claims to their Medicare Administrative Contractors (MACs). The Plaintiff-Hospitals also specifically requested that they be paid pursuant to the higher hospital payment rates because the clinic visit policy set forth in the Final Rule is unlawful for the reasons specified herein. Nonetheless, the Plaintiff-Hospitals are being paid at the lower rates governed by the Final Rule, rather than the rates required by the Medicare Act. Statutory requirements relating to exhaustion are not applicable in the context of a non-statutory *ultra vires* challenge. In any

event, further administrative appeal or review of the Plaintiff-Hospitals' claims would be futile, both because CMS administrative adjudicators are bound by the Final Rule, and because CMS has refused to change its position in response to these very same legal arguments.

FACTUAL BACKGROUND

Statutory Framework

16. Title XVIII of the Social Security Act establishes a program of health insurance for the aged and disabled, commonly known as Medicare. 42 U.S.C. §§ 1395 *et seq*. The Plaintiff-Hospitals and many of Plaintiffs AHA's and AAMC's members qualify as providers of hospital services under Title XVIII, commonly known as the Medicare Act.

17. Part B of the Medicare Act covers, among other things, hospital outpatient department services (OPD services), which are services that are provided to patients on an outpatient basis. OPD services include emergency or observation services, services furnished in an outpatient clinic (*e.g*., physician visits, same-day surgery), laboratory tests billed by the hospital, medical supplies (*e.g*., splints and casts), preventive and screening services, and certain drugs and biologicals.

18. Payments for OPD services are generally made under the Medicare Outpatient Prospective Payment System (OPPS) created pursuant to 42 U.S.C. § 1395l(t). The Medicare statute authorized CMS to establish the OPPS pursuant to requirements spelled out in 42 U.S.C. § 1395l(t)(2)(A) through (H).

19. The Medicare statute authorizes CMS, on an annual basis, to review and revise the "groups, the relative payment weights, and the wage and other adjustments . . . to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." 42 U.S.C. § 1395l(t)(9)(A).

20. But the Medicare statute sets clear limits on these annual adjustments, including the critical requirement that any such adjustments be budget neutral. Specifically, Congress mandated: "the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made." 42 U.S.C. § 1395l(t)(9)(A). This is a mouthful, but its meaning is plain: Any adjustments under Subsection (t)(9)(A) must be budget neutral, and CMS may not reduce Medicare Part B spending by selectively slashing the payment rates for specific types of services.

21. When Congress confers authority on CMS to make non-budget neutral changes, it has said so expressly. *See, e.g.,* 42 U.S.C. § 1395l(t)(7)(I). Indeed, if CMS wishes to make *non*-budget-neutral cuts to payments under the OPPS, the statute provides a separate mechanism for the agency to do so. First, the statute authorizes CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395l(t)(2)(F). Once the agency identifies that method, another statutory provision authorizes the agency to make non-budget-neutral adjustments to address those unnecessary increases in volume – but only through across-the-board adjustments to all items or services paid under the OPPS. Specifically, Subsection (t)(9)(C) provides that if CMS determines under Subsection (t)(2)(F) that the "volume of services . . . [has] increased beyond amounts established through those methodologies," CMS "may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395l(t)(9)(C). The conversion factor is a uniform amount that is used in the formula to calculate payment rates for *all* services or items paid under the OPPS. In other words, a conversion factor adjustment can shrink (or grow) the entire OPPS

by a percentage-factor, but it cannot reduce the relative rate of payment for a particular set of services or items.

22. The implications for CMS are clear: If CMS wants to make cuts to payment rates in order to control unnecessary increases in the volume of hospital services, it must do so across-the-board, to all services and items under the OPPS, by using the conversion factor. If CMS instead wants to make adjustments to payment rates for specific services, it must do so in a budget-neutral manner. And for good reason: The statute's structure and directives prevent the agency from engaging in cost-control measures by making draconian payment reductions targeting only specific services.

Off-Campus Provider-Based Departments

23. At issue in this lawsuit are Medicare payments for certain clinic visit services provided at off-campus PBDs. As previously noted, off-campus PBDs are practice locations of a hospital that are not in immediate proximity to the main hospital building, but are nonetheless so closely integrated with the hospital as to be considered a part of the hospital. *See* 42 C.F.R. § 413.65(e). An off-campus PBD could include a stand-alone oncology clinic, an urgent care clinic, or an office providing necessary specialty services (*e.g.*, cardiology, pulmonology, neurology, and urology). Off-campus PBDs vary significantly in function and purpose. In some cases, a hospital may lack the space on its main campus to expand, and a practice location is located off-campus as a matter of necessity. In other cases, there may be operational reasons for having a practice location off-campus. For example, a hospital might want to place an off-campus PBD in a location that is convenient to the patient population it serves. Notably, in Clallam County, where Olympic Medical Center is located, the community of Sequim (located

17 miles from the hospital) has no hospital of its own, and there are no emergency care services of any kind. The vital clinic services Olympic Medical Center offers the 28,000 residents provide essential primary, specialty and walk-in clinic services to a patient population in desperate need of those services.

24. Off-campus PBDs must be closely integrated with their main hospitals and are subject to regulatory requirements as a part of the hospital—unlike independent clinics or physician offices. *See* 42 C.F.R. § 413.65(a). As a result, off-campus PBDs often have higher costs relative to a physician office. There are many reasons for this: The patient population that visits off-campus PBDs tends to be sicker and poorer than the patient population that visits independent physician offices. *See* Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices (KNG Health Consulting LLC, 2018). In addition, off-campus PBDs are often intended to serve more functions than standalone physician offices. For example, an off-campus PBD may be an emergency department operating on nights and weekends with a team of specialist doctors and nurses on staff. In addition, CMS requires off-campus PBDs to satisfy the Medicare Conditions of Participation applicable to their main hospital, which are more demanding than the requirements imposed on physician offices or clinics. *See* Hospital Outpatient Department (HOPD) Costs Higher than Physician Offices Due to Additional Capabilities, Regulations https://www.aha.org/system/files/2018-09/info-hopd.pdf.

Section 603 of the Bipartisan Budget Act of 2015

25. Until November 2015, clinic visit services at *all* off-campus PBDs were paid under the OPPS, at the relatively higher payment rates paid to hospitals (as compared to their physician office counterparts). 83 Fed. Reg. 59,004–005.

26. The total volume of outpatient services furnished at off-campus PBDs nationwide has been increasing for years. *Id.* at 59,005–007. That increase has been necessary and appropriate. The Medicare-eligible population as a whole has increased during that same period. In addition, as medical technology has evolved, more and more services are able to be furnished on an outpatient (rather than an inpatient) basis.

27. Among the many factors contributing to the increase in volume of outpatient services furnished at off-campus PBDs is the acquisition of stand-alone physician offices by some hospitals and integration of the physician offices into hospital operations. CMS took the view that Medicare costs could be lowered if these same outpatient services were furnished in a less-expensive physician office setting. 83 Fed. Reg. 59,008–009. The off-campus PBDs could—the agency argued—be effectively de-integrated from their main hospital and operated independently, and therefore paid under the Medicare physician fee schedule rather than the OPPS. In response, commenters pointed out that off-campus PBDs have higher costs than physician offices (in some cases, exceeding even the current payment rate for such services) and that off-campus PBDs are often able to provide services that are not available in physician offices. Commenters also noted that paying off-campus PBDs at the lower rates paid to physicians would upset the reasonable expectations of hospitals that acquired or built off-campus PBDs with the understanding that they would be paid under the OPPS.

28. Congress sought to balance these competing concerns when it enacted Section 603 of the Bipartisan Budget Act of 2015. Pub. L. No 114-74 § 603, 129 Stat. 584, 598. Congress's solution was to create two classes of off-campus PBDs. Qualifying off-campus PBDs that were billing as a hospital department under the OPPS when the statute took effect on

November 2, 2015 (so-called "excepted PBDs") would continue to be paid under the OPPS. *See* 42 U.S.C. §§ 1395l(t)(1)(B)(V), (t)(21) & (t)(21)(B)(ii). But going forward, Congress required that *newly* created or acquired off-campus PBDs (so-called "non-excepted PBDs") be paid under the "applicable payment system" in order to eliminate the possibility that a payment differential could be a factor in a hospital's decision to open a new off-campus PBD. *Id.* § 1395l(t)(21)(C)); *see also id.* § 1395l(t)(21)(B)(iii)–(vi) (codifying additional exceptions, such as for off-campus PBDs that were mid-build when Section 603 was enacted, which allowed those mid-build PBDs to continue to be paid under the OPPS).

29. CMS has interpreted the statutory phrase "applicable payment system" to mean that non-excepted PBDs should be paid under the Medicare Physician Fee Schedule (PFS). 81 Fed. Reg. 79,562, 179,659 (Nov. 14, 2016). The Physician Fee Schedule has lower payment rates relative to OPPS because it is intended to reflect the costs for furnishing items or services in a physician office (as opposed to in a hospital). Thus, the payment rates for excepted PBDs (under the OPPS) are generally higher than non-excepted PBDs (under the Physician Fee Schedule).

30. In practice, CMS does not actually abide by the statutory requirement to pay non-excepted PBDs under a separate payment system from OPPS. Rather, CMS continues to pay such non-excepted PBDs under the OPPS but applies a "PFS Relativity Adjustor," which CMS says is intended to approximate what the rate of payment "would have been" if the item or service were actually paid under the Physician Fee Schedule. *See generally* 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016).

31. Common sense and the statutory structure make clear that in requiring that excepted and non-excepted PBDs be subject to different payment systems, Congress intended that they would receive different rates of payment. Congress's choice to grandfather some off-campus PBDs to permit them to continue billing under the OPPS, and thus be subject to different payment rates from other off-campus PBDs, cannot have been anything but deliberate.

The Final Rule

32. On July 31, 2018, CMS published a Proposed Rule proposing changes to the OPPS for CY 2019. As relevant here, the Proposed Rule proposed changes to the payment rate for certain clinic visit services provided at *excepted* PBDs in order to render it equal to the payment rate for services provided at *non*-excepted PBDs (the Clinic Visit Policy). Specifically, the Proposed Rule stated that the payment rate for clinic services provided by excepted PBDs in CY 2019 "would now be equivalent to the payment rate for" services provided by non-excepted PBDs. 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). CMS proposed to make this adjustment in a non-budget-neutral fashion. *Id.* In other words, the payment rate reductions proposed by CMS would *not* be offset by increases in other payment rates under the OPPS to ensure that the overall payments to hospitals would remain the same. CMS estimated that this change would result in reductions in payments to hospitals of $760 million in CY 2019 alone. *Id.* at 37,143.

33. Almost 3,000 commenters submitted comments in response to the Proposed Rule, including the AHA, the AAMC, and the Plaintiff-Hospitals or their associated health systems, either directly or through an association. Among other things, Plaintiffs pointed out that CMS was statutorily prohibited from making adjustments to payment rates in a non-budget-neutral manner under 42 U.S.C. § 1395l(t)(9)(B). Plaintiffs also explained that the Proposed Rule ran

afoul of Congress's statutory mandate that CMS treat excepted and non-excepted PBDs differently under 42 U.S.C. § 1395l(t)(21).

34. On November 2, CMS posted the Final Rule on its website. Like the Proposed Rule, the Final Rule adjusts the payment rate for services provided by excepted PBDs so that it is "equal to" the payment rate for services provided by non-excepted PBDs. 83 Fed. Reg. 58,822, 59,013. CMS explained its decision succinctly: "To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another." *Id.* at 59,008. CMS also confirmed its decision to implement the adjustment in a non-budget-neutral fashion. *Id.* at 59,014. However, CMS announced that it would be phasing in the payment reduction over a two-year period, such that the estimated reductions in payments to hospitals in CY 2019 would be approximately $380 million. *Id.*

35. The Final Rule became effective on January 1, 2019.

<u>The Final Rule Exceeds CMS's Authority Under the Medicare Act</u>

36. In promulgating the Final Rule, CMS has acted in clear violation of its statutory authority. This is so for at least two separate reasons: (i) the Clinic Visit Policy violates the Medicare statute's mandate of budget neutrality; and (ii) the Clinic Visit Policy violates the statutory mandate that excepted and non-excepted PBDs must be treated differently.

Budget Neutrality:

37. First and foremost, the Final Rule is *ultra vires* because the Clinic Visit Policy is not budget neutral, in plain violation of the statute. By CMS's own admission, the Clinic Visit Policy set forth in the Final Rule would reduce total hospital payments by $380 million in CY

2019, and $760 million in CY 2020, with no offsetting increases in payments for other services. 83 Fed. Reg. 59,014. Indeed, that was one of the *justifications* given by CMS for its proposed adjustments. *Id.*

38. But a critical element of the statute's structure is that changes in the payments for individual OPD services be made "in a budget neutral manner." 42 U.S.C. § 1395l(t)(9)(B). That is, if CMS wishes to reduce the amount of Medicare payments going to one type of service, it must increase the payments for other items or services in equal amount. *Id.*

39. While the Medicare statute allows for reductions to the total amount of Medicare payments in appropriate, limited circumstances under Subsection (t)(9)(C) through changes to the conversion factor, there is *no* statutory mechanism allowing CMS to reduce the total amount of Medicare payments by targeting only selected services. By requiring budget neutrality for payment reductions targeting specific services, the statute recognizes – and puts a check on – any incentive for CMS to employ draconian cost-control measures.

40. To get around the statutory requirement that annual adjustments be budget neutral, CMS has claimed that its authority to adopt the Clinic Visit Policy flows not from the annual adjustment authority granted in Subsection (t)(9)(A), but from the agency's separate statutory authorization to "develop a method for controlling unnecessary increases in the volume of covered OPD services." *Id.* § 1395l(t)(2)(F). CMS grounds the Clinic Visit Policy in Subsection (t)(2)(F) for a strategic purpose: that provision, unlike the rest of Subsection (t), makes no express mention of budget neutrality.

41. For good reason, though: Subsection (t)(2)(F) does not need to address budget neutrality because it does not actually authorize the agency to make any adjustments or changes

to payment rates at all. Instead, it merely authorizes CMS to "*develop a method* for controlling unnecessary increases" in the volume of services. 42 U.S.C. § 1395l(t)(2)(F). Another statutory provision governs how that method may be *used* in actual volume-control efforts.

42. Specifically, Subsection (t)(9)(C) addresses what CMS should do if it wants to make adjustments based on a finding under Subsection (t)(2)(F) that there are unnecessary increases in the volume of services: "If the Secretary determines under the methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately *adjust the update to the conversion factor* otherwise applicable in a subsequent year." *Id.* § 1395l(t)(9)(C) (emphasis added). The conversion factor applies broadly to affect the payments for all covered services and cannot be used to change the relative payment rates between and among individual services.

43. Contrary to CMS's assertion, then, Subsection (t)(2)(F) does not confer authority to modify payment rates for specific items or services in response to unnecessary increases in the volume of OPD services. Rather, as noted above, if the methodology developed by CMS under Subsection (t)(2)(F) shows that there are unnecessary increases in the volume of OPD services, Congress has said in Subsection (t)(9)(C) that CMS's recourse is to modify the conversion factor and effectuate an across-the-board reduction in payment rates under the OPPS. And to state the obvious, in the clinic visit policy portion of the Final Rule CMS has not adjusted the update to the conversion factor. Instead, it has only decreased the payments for a certain subset of services. In short, Subsection (t)(2)(F) is of little use to CMS in justifying the Final Rule.

44. In explaining its statutory authority in the Final Rule, CMS attempted to bolster its reliance on Subsection (t)(2)(F) by arguing that it had, in prior proposed rules, purported to invoke Subsection (t)(2)(F) to justify selective cuts to payment rates. 83 Fed. Reg. at 59,004–005. Not so. In fact, CMS has never actually implemented *anything* using Subsection (t)(2)(F).

45. In 1998, CMS proposed invoking Subsection (t)(2)(F) when establishing the OPPS, but that proposal – which involved modifications to *the conversion factor*—was indefinitely delayed for "further study" in another CMS action in 2000. 65 Fed. Reg. 18,434, 18,502–503 (April 7, 2000). Indeed, CMS said that "possible legislative modification" would be necessary before it could use its authority under Subsection (t)(2)(F) to adopt alternative options, which would have implemented non-conversion factor adjustments. And in 2001, both CMS and the Medicare Payment Advisory Commission (MedPAC) implicitly acknowledged that the options turned on selecting the proper contemplated methodology for triggering updates *to the conversion factor*. 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001). Thus, in every prior instance that the agency considered invoking Subsection (t)(2)(F), CMS implicitly (and correctly) acknowledged that any corresponding non-budget neutral changes to payment rates must occur pursuant to a change in the conversion factor. CMS's present assertion of sweeping authority to target only specific types of services under Subsection (t)(2)(F) in the Final Rule is unprecedented—and unlawful.

46. In any event, CMS has never made an adequate factual finding—as it must to lawfully invoke whatever authority it has under Subsection (t)(2)(F)—that any increase in the volume of covered OPD services is "unnecessary." Instead, the agency merely asserted in circular fashion that the increases in volume of covered outpatient services *must* have been

"unnecessary" simply because they occurred. 83 Fed. Reg. 59,006–008. To bolster this self-serving conclusion, CMS purports to rely upon recommendations and estimates made by MedPAC, an agency established *by Congress* to make recommendations *to Congress* regarding payment policy. *See* 42 U.S.C. § 1395b-6. And Congress has already spoken about the appropriate path forward here.

47. For the foregoing reasons, the Clinic Visit Policy is *ultra vires* because it is not budget neutral, as required by the plain language of the statute.

Statutory Distinction Between Excepted and Non-Excepted PBDs.

48. In addition, the Final Rule is *ultra vires* because it sets the same rate of payment for clinic visit services provided at both excepted and non-excepted PBDs, in violation of Congress's statutory command. Specifically, the Final Rule provides that the payment rate for services provided at excepted PBDs will be adjusted so that it would be "equal to" the payment rate for services provided at non-excepted PBDs. 83 Fed. Reg. 59,013.

49. But the Medicare statute reflects Congress's intent to treat excepted and non-excepted PBDs differently. The statute creates two distinct categories of off-campus PBDs: excepted entities, which satisfy certain grandfathering requirements and may continue billing under the OPPS, and non-excepted entities, which do not and must instead be paid under an alternative payment system. *See* 42 U.S.C. § 1395l(t)(21). Congress's clear intent in creating that distinction was to create a grandfather provision for excepted PBDs, allowing entities that had been billing before November 2015 to continue billing under the OPPS, while non-excepted entities would be subject to a different payment system (later determined by CMS to be the

Medicare Physician Fee Schedule). *See id.* § 1395l(t)(21)(C); H.R. Rep. No. 114-604, at 10 (2016).

50. Congress necessarily understood and clearly intended that these separate payment systems would entail separate payment rates. And Congress intentionally grandfathered qualifying off-campus PBDs that were already in existence at the time the different payment system for non-excepted PBDs was put in place in order to ensure that the excepted PBDs would still be paid under the OPPS. *See* 42 U.S.C. § 1395(t)(21)(B) (cross-referencing 42 C.F.R. § 413.65(a)(2)).

51. By decreeing that excepted and non-excepted entities will now be subject to the same payment rate, CMS has effectively abolished that statutory separateness, performing an end-run around the congressional mandate. But the agency lacks authority to nullify the Medicare statute in such manner.

52. The Clinic Visit Policy set forth in the Final Rule is *ultra vires* for this reason as well.

Plaintiffs Will Suffer Concrete and Imminent Harm Absent Judicial Intervention

53. The Plaintiff-Hospitals and Plaintiffs AHA's and AAMC's member hospitals rely heavily on the structure of Medicare payments established by Congress to provide critical outpatient services for the vulnerable populations in their communities, many of whom have been historically underserved.

54. As CMS itself notes, the challenged policy will result in a total reduction in payments for outpatient services of approximately $380 million in CY 2019. 83 Fed. Reg. 59,014.

55. The Plaintiff-Hospitals and Plaintiffs AHA's and AAMC's members operate excepted PBDs that are statutorily entitled to be paid differently from non-excepted PBDs. The Final Rule reduces the payment rate for covered services performed at the excepted PBDs. If the Final Rule is left in place, Plaintiff-Hospitals and Plaintiffs AHA's and AAMC's members face the prospect of serious payment reductions for affected services, and may have to make difficult decisions about whether to reduce services in response to the lowered payment rate.

56. This is particularly troubling for hospitals already operating at low or negative margins.

57. Plaintiffs and the vulnerable patients and communities they serve face concrete and imminent harms—both economic and noneconomic—if CMS's Final Rule is allowed to stand.

COUNT I
(*Ultra Vires* Agency Action)

58. Plaintiffs re-allege and incorporate by reference the allegations made in the foregoing numbered paragraphs of the Complaint.

59. This Court has the inherent power to review alleged *ultra vires* agency action when an agency patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute. *See, e.g.*, *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1168 (D.C. Cir. 2003) (agency action is *ultra vires* when it "exceed[s] the agency's delegated authority under the statute."); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988) (agency violation of "clear and mandatory" statutory provision is *ultra vires*).

60. The Clinic Visit Policy is *ultra vires* because it is not budget neutral. Annual adjustments to payment rates for ODPs must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). But by CMS's own admission, the Clinic Visit Policy would result in a net reduction in total outpatient-services payments of more than $380 million for CY 2019. 83 Fed. Reg. 59,014. Rather than providing for offsetting increases in payments for other services or adjusting the generally applicable conversion factor—as required by statutory safeguards enacted to curb the agency's discretion—CMS chose to slash the payment rate for a particular set of services and thereby reduce total expenditures. That is clearly in excess of the agency's statutory authority.

61. The Clinic Visit Policy also is *ultra vires* because it effectively eliminates the statutorily mandated distinction between excepted and non-excepted PBDs. Congress intentionally created two classes of off-campus PBDs: excepted and non-excepted ones, with the clear expectation that they would be paid differently for outpatient services. The Final Rule, premised on CMS's contrary policy preferences, effectively erases that distinction by providing that outpatient services provided at excepted and non-excepted PBMs be subject to the exact same payment rate.

62. For these and other reasons, CMS has simply ignored Congress's instructions contained in the Medicare Act. The agency's wholly unauthorized adoption of the Clinic Visit Policy is *ultra vires* and cannot stand.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the Final Rule exceeds CMS's statutory authority under the Medicare Act, 42 US.C. § 1395l, and is

unenforceable to the extent it does so;

B. Preliminary and permanent injunctive relief (i) vacating and barring Defendants from enforcing the *ultra vires* changes made to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Payment System for Calendar Year 2019; (ii) requiring CMS to conform its payment policies and conduct to the requirements of the Medicare Act; and (iii) ordering that Defendants provide immediate payment of any amounts improperly withheld as a result of the unauthorized conduct described above to Plaintiff-Hospitals and all affected members of the AHA and AAMC.

C. An order awarding Plaintiffs their costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

D. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Catherine E. Stetson
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Dated: January 29, 2019

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL
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d/b/a AnMed Health Medical Center
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ANMED HEALTH SYSTEM
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d/b/a AnMed Health Cannon
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Civil Action No. 19-CV-132

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MONTEFIORE HEALTH SYSTEM, INC.)
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d/b/a OSF Sacred Heart Medical Center)

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RUSH UNIVERSITY MEDICAL CENTER)
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UNIVERSITY HOSPITALS HEALTH SYSTEM, INC.
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VANDERBILT UNIVERSITY MEDICAL CENTER	)
1211 Medical Center Drive	)
Nashville, TN 37232	)
	)
Plaintiffs,	)
	)
v.	)
	)
ALEX M. AZAR II, in his official capacity	)
as Secretary of Health & Human Services	)
United States Department of	)
Health & Human Services,	)
200 Independence Avenue, S.W.	)
Washington, D.C. 20201	)
	)
Defendant.	)
	)

[PROPOSED] SECOND AMENDED COMPLAINT

Plaintiffs, 46 hospitals that participate in the Medicare program, bring this complaint against Defendant Alex M. Azar II, in his official capacity as Secretary of Health and Heath Human Services ("Secretary"), and allege as follows:

INTRODUCTION

1. In Section 603 of the Bipartisan Budget Act of 2015 ("BBA 2015"), Congress amended the Social Security Act so that the Medicare program now pays the same rates for medical services regardless of whether they are provided in a physician's office or in a hospital department that is located away from or "off" the main campus of the hospital. At the same time, Congress excepted from this amendment all off-campus hospital outpatient departments that were providing services *before* the enactment of Section 603. Pursuant to the line drawn by Congress, those pre-existing departments would continue to be paid for their services at the higher hospital rates that pre-dated Section 603. But the Secretary believes that Congress did not go far enough, and under a rule that went into effect January 1, 2019, the Secretary is now paying the lower, physician office rate to the very hospital departments that Congress protected from this change. The Secretary's rule is irrational, a patent misconstruction of the Social Security Act and a blatant attempt to circumvent the will of Congress clearly expressed in Section 603.

2. Many hospitals, including Plaintiffs, operate off-campus hospital departments which the Medicare program commonly refers to as "provider-based departments" ("PBDs"). Medicare defines an off-campus PBD as a facility not located on a hospital's main campus but operated by and integrated with the main hospital to such a degree that services furnished there are considered furnished by the hospital itself. *See generally* 42 C.F.R. § 413.65. Many hospitals locate off-campus PBDs throughout the community so that they are closer to and more convenient

for patients to visit for care as compared to traveling to the hospital's main campus. Off-campus PBDs provide outpatient hospital services, which are those services that do not require a patient to stay overnight in a hospital bed, sometimes referred to as ambulatory or same-day services. *See e.g.*, Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 6 § 20.2 (defining "outpatient"). Evaluation and management services, or E/M services, are a common outpatient service. E/M services involve the assessment and treatment of a patient by a physician. *See* Medicare Learning Network, *Evaluation and Management Services*, ICN 006764 available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf (overviewing E/M services). Off-campus PBDs that offer E/M and other services help improve quality and access to hospital-level care, particularly for underserved communities that may not otherwise have access to these services at other nonhospital sites such as independent physician offices.

3. In general, medical services provided in hospital outpatient departments are more resource-intensive—and therefore more costly—than those furnished in an independent physician's office. *See* 73 Fed. Reg. 66,187, 66,191 (Nov. 7, 2008) (recognizing the "high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital . . ."). Hospitals are required to provide a wider range of services and meet much stricter regulatory requirements than freestanding physician offices. For example, hospitals must offer 24-hour nursing care, maintain discharge planning protocols, and meet various health and safety requirements. 42 U.S.C. § 1395x(e)(3)-(9). Hospitals must maintain a formal "institutional plan and budget" that "provide[s] for capital expenditures for at least a 3-year period" and is subject to State review. 42 C.F.R. § 482.12(d). Hospitals must also maintain a pharmacy overseen by a licensed pharmacist, as well as ensure security for prescription

drugs. *Id.* at § 482.25. Hospitals must maintain or have available diagnostic radiologic and laboratory services, as well as food and dietetic services. *Id.* at § 482.26–28. Hospitals must ensure that they have emergency sources of electricity, water and gas, and that the physical plant meets all applicable building and fire code standards. *Id.* at § 482.41. None of these conditions for participating in Medicare and other Federal healthcare programs apply to an independent physician's office.

4. Because these statutory and regulatory requirements create additional operating and capital expenditures that other healthcare entities do not incur, Medicare pays hospitals more for services, including outpatient services, than it pays for comparable services provided by an independent physician office. *See* 83 Fed. Reg. at 59,008 (comparing Medicare payment for a certain clinic visit furnished under the Medicare Outpatient Prospective Payment System ("OPPS") and under the Medicare Physician Fee Schedule ("MPFS")). The higher payment rates for hospitals, however, raised concerns as to whether some hospitals have been motivated to purchase independent physician offices and convert them into hospital departments to capture the higher payment rates without incurring the corresponding increase in costs to provide comparable services. *See, e.g.*, 83 Fed. Reg. 37,046, 37,148 (July 31, 2018). The Medicare Payment Advisory Commission ("MedPAC"), a body established by statute to make recommendations to Congress regarding healthcare policy, has recommended that Congress consider legislation to address this possibility, such as eliminating the payment difference between all hospital outpatient departments and physician offices. 83 Fed. Reg. 58,818, 59,006–07 (Nov. 21, 2018) (citing 2012 and 2014 reports).

5. Congress recognized that it was not necessary to adopt such broad proposals into law to address this concern. Instead, Congress enacted Section 603 of the BBA 2015, which

creates clear, specific and narrowly-tailored rules governing how the Medicare program will pay for medical services provided at off-campus PBDs. Pub. L. No. 114-74 § 603, 129 Stat. 584, 598. Rather than lower rates for all off-campus PBDs, for example, Congress determined that only those off-campus PBDs that began operations on or after November 2, 2015 would be paid according to a different, lower-paying rate system. These off-campus PBDs are often called "nonexcepted" PBDs because they are not excepted by the payment changes Congress made in Section 603. 42 U.S.C. § 1395l(t)(21)(C). In contrast, Congress determined that off-campus PBDs that were operating before November 2, 2015 would continue to receive higher rates determined under the hospital OPPS. These off-campus PBDs are referred to as "excepted" or "grandfathered" PBDs because Congress excepted them from the changes in Section 603. As for the rates paid to new, nonexcepted PBDs, Congress authorized the Secretary to determine which reimbursement system to use to calculate payments for those off-campus PBDs. *See* 42 U.S.C. § 1395l(t)(21)(C) (identifying that payment be made for nonexcepted PBDs under an "applicable payment system").

6. The Secretary ultimately chose to calculate payment rates for nonexcepted PBDs using the MPFS, the same methodology he uses to set payment rates for independent physician practices. *See* 81 Fed. Reg. 79,562, 79,570 (Nov. 14, 2016). At that time, he acknowledged that Congress intended to preserve the ability of excepted off-campus PBDs to continue to receive those higher rates so that they could serve their communities effectively without any disruptions in care. *Id.* at 79,704 ("we believe that section 603 applies to off-campus PBDs as they existed at the time the law was enacted. That is, we believe that the statutory language provides for payment to continue under the OPPS for such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of [Section 603]").

7. However, on November 21, 2018, the Secretary reversed course and issued a final rule, effective January 1, 2019, that eliminates the higher, OPPS reimbursement rate for E/M services provided by excepted off-campus PBDs. The Secretary, instead, will only reimburse for E/M services at the lower, MPFS rate that nonexcepted off-campus PBDs receive. *See* Centers for Medicare & Medicaid Services, Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Dep't of Health and Human Servs., 83 Fed. Reg. 58,818 (Nov. 21, 2018) ("Final Rule"). In other words, notwithstanding Congress's decision that excepted off-campus PBDs were exempt from Section 603's payment changes and would continue to be reimbursed at OPPS rates, the Secretary has blatantly disregarded a specific and unambiguous statutory directive, acted well beyond his authority and nullified that statutory exemption.

8. The Secretary's actions are no garden variety error of law; they are *ultra vires*. He has left no doubt that he is substituting his will for Congress's. In the Final Rule, the Secretary expressed his opinion that Section 603 only "address[ed] *some* of [his] concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting." *Id.* at 59,012 (emphasis added). He criticized Congress's decision to allow many "hospital off-campus departments [to] continue to receive full OPPS payment," referring to those off-campus PBDs Congress specifically exempted from Section 603's payment rate changes. *Id.*

9. The Secretary has cited 42 U.S.C. § 1395l(t)(2)(F)—a provision enacted nearly 20 years before Section 603—as authority that allows him to override Congress's mandate. But Section (t)(2)(F) allows for no such thing. It authorizes the Secretary to "develop a method for controlling unnecessary increases" in the volume of hospital outpatient department services, but it does not authorize the Secretary to set payment rates contrary to those established by statute, nor

does it allow the Secretary to override Congress's more recent and specific statutory mandate in Section 603 to continue to pay excepted off-campus PBDs at hospital OPPS rates. No provision of law—not Section (t)(2)(F) or any other—permits the Secretary to ignore a clearly expressed mandate of Congress simply because the Secretary disagrees with Congress's legislative choices.

10. The Secretary's Final Rule is also *ultra vires* because it violates 42 U.S.C. § 1395l(t)(9)(B) (Section 1833(t)(9)(B) of the Social Security Act). Section (t)(9)(B) requires the Secretary to "budget neutralize" any changes he makes in the amounts paid for specific outpatient department items or services. Any increases (or decreases) in payment rates must be offset by a corresponding reduction (or increase) in the rates for other services so that aggregate payments for outpatient department services remains the same. The Secretary admits that the initial rate cut for E/M services in 2019 alone will reduce Medicare payments for hospital outpatient department services by $300 million—and even more in future years when the E/M rate cut is fully implemented. However, rather than offset that payment cut by increasing funding to the providers of those services elsewhere, the Secretary intends to retain this amount in direct defiance of Congress's instructions.

11. The Secretary's unlawful rate cut directly contravenes clear congressional directives and will impose significant harm on affected off-campus hospital outpatient departments and the patients they serve. Accordingly, this Court should declare the Secretary's Final Rule to be *ultra vires* and enjoin the agency from implementing any payment methodology other than OPPS rates for all E/M services provided by excepted off-campus PBDs.

PARTIES

12. Plaintiffs operate excepted off-campus PBDs that participate in the Medicare program and are affected by the unlawful rate cut in E/M services that became effective January 1, 2019.

13. The plaintiffs in this action are:

- UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, Medicare Provider No. 17-0040;
- ANMED HEALTH SYSTEM d/b/a AnMed Health d/b/a AnMed Health Medical Center, Medicare Provider No. 42-0027;
- ANMED HEALTH SYSTEM d/b/a Cannon Memorial Hospital, Inc. d/b/a AnMed Health Cannon, Medicare Provider No. 42-0011;
- BLUE RIDGE HEALTHCARE SYSTEM, INC. d/b/a CHS Blue Ridge, Medicare Provider No. 34-0075;
- CARILION MEDICAL CENTER, Medicare Provider No. 49-0024;
- COLUMBUS REGIONAL HEALTHCARE SYSTEM, INC., Medicare Provider No. 34-0068;
- COPLEY MEMORIAL HOSPITAL, INC. d/b/a Rush Copley Medical Center, Medicare Provider No. 14-0029;
- EAST BATON ROUGE MEDICAL CENTER, LLC d/b/a OCHSNER MEDICAL CENTER - BATON ROUGE, Medicare Provider No. 19-0202;
- FAYETTE COMMUNITY HOSPITAL, INC. d/b/a Piedmont Fayette Hospital, Inc, Medicare Provider No. 11-0215;

- FLORIDA HEALTH SCIENCES CENTER INC d/b/a Tampa General Hospital, Medicare Provider No. 10-0128;
- LIMA MEMORIAL HEALTH SYSTEM, Medicare Provider No. 36-0009;
- MERCY MEDICAL CENTER, INC., Medicare Provider No. 36-0070;
- MONTEFIORE HEALTH SYSTEM, INC. d/b/a Montefiore Medical Center, Medicare Provider No. 33-0059;
- MONTEFIORE HEALTH SYSTEM, INC. d/b/a St. Luke's Cornwall Hospital, Medicare Provider No. 33-0264;
- MONTEFIORE HEALTH SYSTEM, INC. d/b/a White Plains Hospital, Medicare Provider No. 33-0304;
- THE MEDICAL CENTER OF CENTRAL GEORGIA, INC., Medicare Provider No. 11-0107;
- NORTHWEST MEDICAL CENTER, Medicare Provider No. 04-0022;
- OCHSNER CLINIC FOUNDATION d/b/a OCHSNER MEDICAL CENTER, Medicare Provider No. 19-0036;
- OSF HEALTHCARE SYSTEM d/b/a OSF Heart of Mary Medical Center, Medicare Provider No. 14-0113;
- OSF HEALTHCARE SYSTEM d/b/a OSF Sacred Heart Medical Center, Medicare Provider No. 14-0093;
- OSF HEALTHCARE SYSTEM d/b/a Ottawa Regional Hospital & Healthcare Center d/b/a OSF Saint Elizabeth Medical Center, Medicare Provider No. 14-0110;

- OSF HEALTHCARE SYSTEM d/b/a Saint Anthony Medical Center, Medicare Provider No. 14-0233;
- OSF HEALTHCARE SYSTEM d/b/a Saint Anthony's Health Center, Medicare Provider No. 14-0052;
- OSF HEALTHCARE SYSTEM d/b/a Saint James Hospital, Medicare Provider No. 14-0161;
- OSF HEALTHCARE SYSTEM d/b/a St. Joseph Medical Center, Medicare Provider No. 14-0162;
- PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., Medicare Provider No. 11-0074;
- PIEDMONT HOSPITAL, INC, Medicare Provider No. 11-0083;
- PIEDMONT MOUNTAINSIDE HOSPITAL, INC., Medicare Provider No. 11-0225;
- PIEDMONT NEWNAN HOSPITAL, INC., Medicare Provider No. 11-0229;
- RUSH OAK PARK HOSPITAL, INC., Medicare Provider No. 14-0063;
- RUSH UNIVERSITY MEDICAL CENTER, Medicare Provider No. 14-0119;
- SARASOTA MEMORIAL HOSPITAL, Medicare Provider No. 10-0087;
- SCOTLAND HEALTH CARE SYSTEM d/b/a Scotland Regional, Medicare Provider No. 34-0008;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Anson, Medicare Provider No. 34-0084;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Cleveland, Medicare Provider No. 34-0021;

- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Kings Mountain, Medicare Provider No. 34-0037;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Lincoln, Medicare Provider No. 34-0145;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Pineville, Medicare Provider No. 34-0098;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Union, Medicare Provider No. 34-0130;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health University City, Medicare Provider No. 34-0166;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Carolinas HealthCare System NorthEast, Medicare Provider No. 34-0001;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Carolinas HealthCare System Stanly, Medicare Provider No. 34-0119;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Carolinas Medical Center, Medicare Provider No. 34-0113;
- THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA d/b/a University of Virginia Medical Center, Medicare Provider No. 49-009;
- UNIVERSITY HOSPITALS HEALTH SYSTEM, INC. d/b/a UH Cleveland Medical Center, Medicare Provider No. 36-0137; and
- VANDERBILT UNIVERSITY MEDICAL CENTER, Medicare Provider Number 44-0039.

14. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services, which administers the Medicare program established under title XVIII of the Social Security Act. Defendant Azar is sued in his official capacity only. The Centers for Medicare & Medicaid Services ("CMS") is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs, including issues relating to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

JURISDICTION AND VENUE

15. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, each of the Plaintiffs has been paid an amount for E/M services provided at excepted off-campus PBDs at the MPFS rate rather than the hospital department OPPS rate as required by Section 603. Each of the Plaintiffs has presented claims to the Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the Secretary's authority to pay excepted off-campus PBDs at rates contrary to Section 603. Further administrative appeal and review of Plaintiffs' claims is futile because the Secretary's administrative adjudicators are bound by the Secretary's Final Rule, and the Secretary has already determined that he will not revise the Final Rule leaving Plaintiffs with no recourse other than federal court review.

16. Alternatively, this Court has subject-matter jurisdiction under 42 U.S.C. § 1331 because Plaintiffs' claims arise under the laws of the United States.

17. Venue is proper in this district under 28 U.S.C. § 1391 because Defendant resides in the District of Columbia and a substantial part of the events giving rise to this action occurred in this district.

18. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201 & 2202 and 5 U.S.C. §§ 705 & 706.

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

19. Medicare is a federal health insurance program for eligible disabled individuals and senior citizens. 42 U.S.C. §§ 1395 *et seq*. Plaintiffs provide hospital services to Medicare beneficiaries that qualify for reimbursement through Medicare.

20. Medicare provider-based status is a decades-old mechanism that hospitals nationwide use to furnish outpatient hospital services to their patients, particularly at locations beyond a hospital's main campus and closer to where patients live. CMS has acknowledged that the concept has been active "[s]ince the beginning of the Medicare program," as large hospital facilities "have functioned as a single entity while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes." 67 Fed. Reg. 49982, 50,078 (Aug. 1, 2002). Specifically, hospitals' transformation into "integrated delivery systems" has led many of them to "acquire control of nonprovider treatment settings, such as physician offices." 65 Fed. Reg. 18,434, 18,504 (April 7, 2000).

21. The requirements for provider-based status are set out at 42 C.F.R. § 413.65. The regulation generally requires that an off-campus hospital department operate on the main hospital's license; that its clinical services and staff are supervised by and integrated with those of the main

provider; that the hospital retain ultimate managerial and administrative control over the department; that the department is held out to the public as part of the main provider; and that the department's income and expenses are accounted together with those of the main hospital. If a hospital can demonstrate that it meets these requirements, then the department "is clearly and unequivocally an integral part of a [hospital] provider." 65 Fed. Reg. at 18,506.

22. Payment for medical services provided by *all* off-campus PBDs prior to November 2015 were reimbursed under the OPPS, whereas services rendered at physician offices were reimbursed at lower rates set by the MPFS. As the Secretary himself has recognized, off-campus PBDs have higher costs than physician offices and offer "enhanced" services; therefore, the difference in pay rates was warranted.

23. Because of the important and unique role played by PBDs, the volume of services provided at off-campus PBDs has increased over the years. 83 Fed. Reg. at 59,005–07. This trend reflects developments in medical technology that have increased treatment options that were previously unavailable on an outpatient basis and that have allowed PBDs to offer increased access to hospital care to many outlying communities. *See, e.g.*, OIG Rep. No. OEI-04-97-00090 at 27 (Aug. 2000) ("We . . . believe that provider-based entities can improve access to care. In fact, many provider-based entities provide services that are enhanced relative to free-standing entities and that are virtually identical to those provided in the main portion of the hospitals.").

24. MedPAC has documented the increases in hospital outpatient services and the practice of hospitals purchasing physician offices—also referred to as "vertical integration." MedPAC has recommended to Congress that it reform the payment differences for services provided in hospital outpatient departments and physicians' offices, including a 2012 report in which MedPAC recommended that Congress eliminate payment differences in rates for E/M

services. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 71 (March 2012). In 2014, MedPAC expanded the list of services it recommended Congress target for payment rate equalization. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 83 (March 2014).

25. Many hospitals opposed MedPAC's proposals as extreme and having failed to consider the negative effects such rate reductions would have on hospitals' ability to provide safety-net services for vulnerable populations. If adopted, MedPAC's proposals would "result in the closure of some [PBDs] and the reduction of services in others, greatly affecting the vulnerable populations—especially those with complex medical problems—that receive care there, and limiting the ability to train the next generation of health professionals in these outpatient settings." Letter from Atul Grover, Chief Pub. Policy Officer, Association of American Medical Colleges, to The Honorable John Barrasso et al., (Jan. 13, 2012) https://www.aamc.org/download/271334/data/aamccommentletteronproposedhopdcuts.pdf.

26. Amid this ongoing debate, Congress enacted Section 603 of the BBA 2015. Contrary to MedPAC's recommendations, Congress *did not* equalize the payment rates between all PBDs and physician offices for E/M services or any others. Instead, Congress addressed the financial incentives that were generating *new* off-campus PBDs by equalizing the payment rates for all newly created off-campus PBDs with those paid to physician offices. In the same enactment, Congress preserved the ability of *existing* off-campus PBDs to continue treating patients under the OPPS reimbursement framework by excepting them from the changes in Section 603.

27. Congress left no room for doubt when it directed the Secretary to continue to pay excepted off-campus PBDs at OPPS rates. The Medicare statute requires the Secretary to develop

an outpatient prospective payment system—OPPS—to pay for "covered OPD [outpatient department] services." 42 U.S.C. § 1395l(t)(1)(A). When it enacted Section 603, Congress amended Section (t)(1)(A) to exclude from the definition of "covered OPD services" those "applicable items and services" provided by "an off-campus outpatient department of a provider." 42 U.S.C. § 1395l(t)(1)(B)(v). The impact of Section 603 on an "off-campus outpatient department" is clear: all of the "items and services" it furnishes are no longer "covered OPD services" paid under OPPS. Instead, they must be paid under an "applicable payment system" that is not OPPS.

28. Section 603 is just as clear that if OPD services are furnished by a department that is *not* "an off-campus outpatient department of a provider," then Section 1833(t)(1)(A) and OPPS rates still apply. And Section 603 excludes from the definition of "off-campus outpatient department of a provider" a "department of a provider . . . that was billing under [subsection (t)] with respect to covered OPD services furnished prior to" November 2, 2015. 42 U.S.C. § 1395l(t)(21)(B)(ii.). Therefore, Section 603 mandates that the Medicare program must continue to pay for *all* services furnished by excepted off-campus PBDs under OPPS.

B. Proposed Rule

29. Notwithstanding this clear, specific and unambiguous statutory directive, the Secretary on July 31, 2018 issued a proposed rule that would "apply an amount equal to the site-specific MPFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the MPFS payment rate) for [E/M] services . . . when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act." 83 Fed. Reg. at 37,142. In other words, contrary to Section 603, the Secretary proposed to cut the payment rate for E/M services provided

at excepted off-campus PBDs by applying the lower, MPFS rate reserved for such services provided at new off-campus PBDs that are subject to Section 603's changes.

30. The Secretary reasoned that this rate cut was necessary to equalize payment between excepted and nonexcepted facilities to address what he regarded as an unnecessary "shift of services from the physician office to the hospital outpatient department" caused by the difference in payment rates. *Id.* Fully aware that Congress had already addressed this issue three years earlier, the Secretary determined that Section 603 only "address[ed] some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting." *Id.* at 37,141. Unsatisfied with the fact that Congress rejected MedPAC's recommendation to equalize payment rates between *all* hospital outpatient departments and physicians' offices, the Secretary proposed a rule to override Congress's mandate to exempt pre-existing off-campus PBDs from Section 603.

31. Notably, the Secretary does not claim that he has the authority to reduce E/M rates pursuant to any authorization under Section 603. In the proposed rule, the Secretary instead identified Section 1833(t)(2)(F) of the Medicare statute as the authority that permits him to implement this rate cut. When it created the OPPS system in 1997, Congress required the Secretary to reimburse hospitals for "covered outpatient department services" using a precise formula set forth in statute to set prospective rates for these services. *See* 42 U.S.C. § 1395l(t)(3). Section (t)(2)(F), enacted at the same time, directs the Secretary to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." The Secretary has, until now, never interpreted Section (t)(2)(F) as permitting him to selectively override the precise formula in Section 1833(t)(3) to create his own, preferred payment rate for a specific outpatient hospital department service.

32. Although Section (t)(2)(F) directs the Secretary to develop a "method" to "control unnecessary increases in the volume" of services, E/M services provided in excepted off-campus PBDs are not "unnecessary" merely because they are reimbursed at a higher rate. The fact that the Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary."

33. Even if Section (t)(2)(F) allowed the Secretary to set his own payment rates (and it does not), the Secretary has acted far in excess of any such authority by implementing a new payment rate without any data to support it. None of the evidence or data cited by the Secretary in the proposed rule showed any ongoing "shift of services from the physician office to the hospital outpatient department" setting that post-dates the enactment of Section 603. In fact, the annual MedPAC reports and other commentary referenced by the Secretary in the proposed rule analyzed data from periods *before* the statutory changes imposed by Section 603 went into effect and do not support the Secretary's decision. Any "shift of services" cannot possibly increase Medicare expenditures because any newly-acquired physician practice would still be paid under the MPFS as a nonexcepted PBD. Therefore, even if the Secretary had the authority to override Congress's decision in Section 603 (which he does not), he cited no evidence to support it.

34. The Secretary also proposed to make this payment cut in a non-budget-neutral manner, meaning that the decreased payments to nonexcepted off-campus PBDs would not be offset by positive adjustments to OPPS rates elsewhere to achieve the same overall funding to hospitals under Medicare. *See* 83 Fed. Reg. at 37,142. Again, the Secretary acted contrary to clear and controlling legislative directives, as Section 1833(t)(9) requires that changes to the group of covered OPD services and "adjustments," including the "relative payment weights" under OPPS,

must be implemented in a budget-neutral manner. *See* Section 1833(t)(9)(B). This provision encompasses rate changes such as the substitution of MPFS rates for E/M services instead of the statutorily-required OPPS rates for excepted off-campus PBDs.

35. Despite this clear language, the Secretary reasoned that exercises of his authority to develop "method[s]" for controlling "volume" increases are not subject to the same budget neutrality restrictions. This reasoning ignores the fact that his proposed "method" for restricting volume increases was to directly lower rates for one-type of service (E/M services), the very sort of "adjustment" that is plainly subject to budget neutrality requirements. Moreover, Section (t)(9)(F) authorizes the Secretary to "adjust the update to the conversion factor"—*i.e.*, budget neutralize—when implementing "the methodologies described in paragraph (2)(F)."

36. In 2019 alone, CMS estimated the impact of making this payment cut in a non-budget-neutral manner would result in $610 million less Medicare funding to hospitals.

C. Comments

37. During the comment period following the release of the proposed rule, thousands of stakeholders submitted written comments, many stating that the Secretary's proposed rate cut for E/M services provided at excepted off-campus PBDs violated clear statutory directives and was unsupported by evidence. In particular, the commenters stated:

a. Congress was unambiguous in the choice it made in Section 603: pre-existing off-campus PBDs would continue to be paid at OPPS rates while new off-campus PBDs would be paid lesser rates. Further, the general authority in Section (t)(2)(F), enacted nearly *twenty* years before Section 603, to adopt "methods" to control unnecessary volume increases does not override this explicit mandate. Under well-established principles of statutory construction, a "later federal statute" setting forth

a "specific policy"—*i.e.*, Section 603—"control[s]" any "construction of the earlier statute" that could arguably conflict with that later-adopted specific policy. Ex. A (Comment of Sarasota Memorial Hospital) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (citations omitted)).

b. The fact that the Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary." *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) ("As written, the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all."). Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" does not authorize the Secretary to deviate from this fundamental structure of the Medicare statute to pay for medically necessary services at statutory prescribed rates. To read (t)(2)(F) as the Secretary does would "permit an end-run around the statute" and violate the judicial cannon that "Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Association*, 531 U.S. 457, 468 (2001). *See* Ex. A (Comment of Sarasota Memorial Hospital).

c. The Secretary failed to make the requisite showing of "unnecessary" increases in medical services to trigger whatever actual authority the Secretary could properly exercise under (t)(2)(F). The Secretary merely theorized about the purported shift in location where E/M visits were taking place, not that the visits themselves were

in any way "unnecessary." Therefore, not only did the Secretary fundamentally misconstrue (t)(2)(F) to assume powers not delegated to him by Congress—*i.e.*, modifying statutorily-prescribed rates for services provided by excepted off-campus PBDs—the Secretary failed to fulfill the basic threshold requirements of (t)(2)(F). *See* Ex. A (Comment of Sarasota Memorial Hospital).

d. The Secretary's proposal to implement the rate cut for excepted off-campus PBDs in a non-budget neutral manner also exceeded the agency's authority. Section 1833(t)(9) requires adjustments to be implemented in a budget-neutral manner which includes rate changes such as the substitution of MPFS rates instead of OPPS rates paid E/M services at excepted off-campus PBDs. If permitted to implement this rate cut in a non-budget-neutral manner, the Secretary could invoke (t)(2)(F) to justify the application of every rate reduction for any OPPS service in a non-budget neutral manner and thereby circumvent the budget neutrality requirement in (t)(9) altogether. Given the express statutory command that "adjustments" must be budget neutral, it would defy well-established canons of statutory construction for the Secretary to ignore, yet again, a specific legislative command in favor of the Secretary overly expansive reading of (t)(2)(F). *See* Ex. A (Comment of Sarasota Memorial Hospital).

D. Final Rule

38. On November 21, 2018, the Secretary issued a Final Rule that, among other things, finalized the rate cut for excepted off-campus PBDs effective January 1, 2019. 83 Fed. Reg. 58,818. In other words, as of January 1, excepted off-campus PBDs no longer receive OPPS rates for E/M services, but rather are reimbursed based at MPFS rates. The only substantive change

made by the Secretary in the Final Rule was phasing-in full implementation of the rate cut over a two-year period, meaning that affected hospitals will receive $300 million less in Medicare funding in 2019 and $610 million less in 2020 when the rate cut is fully implemented.

39. The Secretary dismissed the commenters' legal challenges out of hand. As to the concern that the Secretary was overturning Congress's mandate to except pre-existing off-campus PBDs from Section 603, the Secretary reiterated his view that Congress had not gone far enough: the "action Congress took in 2015 to address certain off-campus PBDs helped stem the tide of these increases in the volume of OPD services," but many "off-campus PBDs continue to be paid the higher OPPS amount for these services." 83 Fed. Reg. at 59,012. The Secretary did not engage with these comments in any meaningful way and stated: "We do not believe that the section 603 amendments to section 1833(t) of the Act, which exclude applicable items and services furnished by nonexcepted off-campus PBDs from payments under the OPPS, preclude us from exercising our authority in section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services under the OPPS." *Id.*

40. The Secretary also failed to engage meaningfully with commenters' concerns that the agency lacked the authority to implement the rate cut in a non-budget-neutral manner. With no analysis whatsoever, the Secretary simply repeated his position in the proposed rule that budget-neutrality was not required because he was invoking his authority under (t)(2)(F). *See id.* ("we maintain that the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act.").

E. Plaintiffs Are Suffering Substantial Harm

41. The rate cut, which lowers payment rates for clinic visits by 30 percent in 2019 (and an additional 30 percent in 2020) went into effect on January 1, 2019, thereby depriving critical funding to Plaintiffs that is necessary for these institutions to effectively serve their communities.

42. As the Secretary has forecasted, the total reduction in payments to affected hospital providers will be approximately $380 million in 2019, and $760 million in 2020. 83 Fed. Reg. at 59014.

43. Even prior to this rate cut, Plaintiffs were under significant financial strain from steadily increasing costs in the healthcare marketplace and reimbursement cuts from the government and private insurers alike.

44. Hospital outpatient departments, including those formed and operated by Plaintiffs before enactment of Section 603, play an important role serving members of their communities who otherwise may face increased barriers to receiving timely care.

45. Plaintiffs, both at the time they created their affiliated outpatient departments and when Section 603 was enacted, reasonably expected they would continue to be reimbursed under the OPPS as they had been for many years and as mandated by Congress. The Secretary's Final Rule implementing this rate cut for E/M services, which was only first proposed five months before the January 1, 2019 effective date, was a severe and unexpected financial hit to the operations of Plaintiffs that jeopardizes their ability to care for the medically vulnerable populations often treated in PBDs.

46. Plaintiffs raised these concerns to the Secretary during the comment period preceding the Final Rule. Plaintiff Sarasota Memorial Hospital ("SMH") noted that it "established

PBDs to provide necessary services that are *not commonly provided by Part B physicians in our community*, such as radiology, bone density, mammography, ultrasound, nuclear medicine, CT scan, MRI, cardiopulmonary rehab, cardiac rehab, anti-coagulation, a COPD clinic, a heart failure clinic, and, most importantly, urgent care services. Urgent care, in particular, is one of SMH's most significant outpatient service lines because it fills a significant gap between physician offices that offer limited services during limited hours, and costly hospital emergency departments." Sarasota Memorial Hospital, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 24, 2018) (emphasis added). Urgent care and many specialty services are billed as E/M services. As a result, "CMS's proposals to reduce payments to excepted departments for E/M services will result in an annual estimated impact to SMH of $3.7 million" and would "dramatically erode[] SMH's ability to provide services to [its] growing and aging patient population and will instead have the likely effect of increasing more costly visits to the ED." *Id.*

47. Plaintiff Tampa General Hospital noted that it "operate[s] two offsite clinics which primarily serve the most vulnerable patient populations in the greater Tampa metropolitan area. The services provided, and patients seen, in these clinics are substantially different from those treated in [the] average physician's office[]. These patients are more medically complex and have a substantially higher proportion of social determinants of health—such as housing, transportation, literacy, and nutrition—which provide additional challenges and add to the complexity of care." Tampa General Hospital, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 24, 2018). Once again, many of the services

furnished to these patients are classified as E/M visits, and "CMS' proposed reimbursement cut for these … facilities would have a disastrous impact" on the hospital's ability to continue treating these costly patients. *Id.*

48. Plaintiff University of Virginia Medical Center noted that the proposed payment rate reduction would be particularly devastating to academic medical centers that "operate centers of excellence … based in hospital settings and provide outstanding team-based, patient centered care" with additional benefits such as "translators and other social services" that independent physician offices generally do not offer. Office of the Chief Executive Office of the Medical Center, University of Virginia Health System, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 21, 2018). Indeed, the hospital said, low-income and vulnerable patients turn to PBDs because they "face difficulty being seen in physician offices" at all. *Id.* The hospital noted that it already incurs "negative margins when we treat Medicare patients in [PBDs], and these cuts will hurt our ability to continue to provide the full range of quality safety net services that we currently offer. This is not a sustainable financial model for public institutions like UVA Medical Center who serve[] all citizens regardless of their ability to pay for care." *Id.*

49. The Secretary nonetheless adopted the rate reduction and Plaintiffs, and the patients they care for, face immediate harm and will continue to suffer these harms as long as the Secretary's unlawful Final Rule is allowed to remain in place.

50. The Plaintiff hospitals have submitted claims for payment to the Medicare program for their excepted off-campus E/M services that were affected by the Final Rule, asserting their view that the Final Rule is invalid. *See* Ex. B at 1–8. Additionally, Medicare has paid E/M claims

submitted by the Plaintiff hospitals at the lower MPFS rate set by the Secretary's Final Rule. *See id.* at 9–16. The Plaintiff hospitals have filed Requests for Redetermination that take an administrative appeal of Medicare's failure to pay them the statutorily-prescribed rate for their services. *Id.*

FIRST CAUSE OF ACTION
(Administrative Procedure Act)

The Secretary Has Violated Congress's Clear And Unambiguous Directive That Excepted Off-Campus PBDs Are To Be Reimbursed Under The OPPS Methodology

51. Plaintiffs re-allege and incorporate by reference the allegations made in the foregoing paragraphs of the Complaint.

52. Congress enacted a direct mandate under Section 603 of the BBA 2015 that excepted off-campus PBDs would continue to be paid at OPPS rates, and not at different, lower payment rates that the Secretary applies, at Congress's direction, to nonexcepted PBDs.

53. Congress left no gaps for the Secretary to fill as its command was clear and unequivocal that excepted off-campus PBDs were exempt from any such payment changes. This legislative action ensured that grandfathered off-campus PBDs in operation before the enactment of Section 603 would not be adversely affected by the changes in payment methodology that would apply to newly formed off-campus PBDs.

54. However, the Secretary's Final Rule disregards a specific and unambiguous statutory directive by denying OPPS rates for E/M services at off-campus PBDs, and instead reimbursing for these services at lower MPFS rates, the exact same methodology the Secretary has adopted for nonexcepted off-campus PBDs following enactment of Section 603. The Secretary's actions are *ultra vires,* and he has acted well beyond his statutory authority simply to pursue his preferred policy of cutting payment rates at excepted off-campus PBDs.

55. Contrary to his assertions in the Final Rule, Section 1395l(t)(2)(F) adopted in 1997 does not permit the Secretary to make an end run around Section 603 adopted in 2015. Section 603, which sets forth an unambiguous and "specific policy" to continue OPPS payment for excepted off-campus PBD services, is a "later federal statute" setting forth a "specific policy," and the Secretary's "construction of" (t)(2)(F)—the "earlier statute"—is impermissible because it conflicts with Congress's later-adopted specific policy.

56. Further, Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" does not authorize the Secretary to deviate from Congress's command that the Secretary pay for medically necessary services at statutory prescribed rates. The fact that the Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary." The Secretary's reliance on section (t)(2)(F) to set aside those payment rates and pay at the least costly alternative exceeds his statutory authority.

57. For these and other reasons, the Secretary's rate cut for E/M visits at off-campus PBDs is unlawful.

SECOND CAUSE OF ACTION
(Administrative Procedure Act)

The Secretary Has Further Exceeded Its Statutory Authority By Not Making the Payment Cut In A Budget Neutral Manner That Congress Required For All Adjustments To Payment Rates For OPD Services

58. Plaintiffs re-allege and incorporate by reference the allegations made in the foregoing paragraphs of the Complaint.

59. Even assuming the Secretary has authority to impose MPFS rates for E/M visits at excepted off-campus PBDs, which he clearly does not under Section 603 of the BBA 2015, the

Secretary acted unlawfully in the Final Rule by not implementing the rate cut in a "budget neutral" manner.

60. Section 1833(t)(9) of the Social Security Act requires that "adjustments" of this sort must be implemented in a budget-neutral manner.

61. The Secretary, however, in the Final Rule chose not to make any funding increases to offset the anticipated loss of $300 million in Medicare funding in 2019 to excepted off-campus PBDs (and even more in future years) resulting from this rate cut. Instead, directly contravening the budget neutrality requirements of Section 1833(t)(9), CMS will retain that money in its coffers.

62. In so doing, the Secretary has acted in an *ultra vires* manner well beyond his delegated authority.

63. For these and other reasons, the Secretary's rate cut for E/M visits at off-campus PBDs is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request an Order:

a. Declaring that the Final Rule Exceeds the Secretary's statutory authority in that CMS must reimburse Excepted Off-Campus PBDs under the OPPS methodology;

b. Declaring that the Final Rule Exceeds the Secretary's statutory authority in that rate cuts for OPD services must be done in a budget neutral manner;

c. Vacating and setting aside the Final Rule;

d. Enjoining the Secretary from enforcing, applying, or implementing the Final Rule, and ordering that the Secretary provide prompt payment of any amounts improperly withheld as a result of the Final Rule;

e. Requiring the Secretary to pay legal fees and costs of suit incurred by the Plaintiffs; and

f. Providing such other just and proper relief as the Court may consider appropriate.

Respectfully submitted,

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Date: March 13, 2019

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FOR THE DISTRICT OF COLUMBIA

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HACKENSACK MERIDIAN HEALTH)
d/b/a Riverview Medical Center)
343 Thornall Street)

Edison, NJ, 08837)
)
HACKENSACK MERIDIAN HEALTH)
d/b/a Southern Ocean Medical Center)
343 Thornall Street)
Edison, NJ, 08837)
)
HEARTLAND REGIONAL MEDICAL CENTER)
5325 Faraon Street)
St. Joseph, MO 64506)
)
MISSOURI BAPTIST MEDICAL CENTER)
3015 North Ballas Road)
Saint Louis, MO 63131)
)
NYU LANGONE HEALTH SYSTEM)
550 First Avenue)
New York, NY 10016)
)
NYU WINTHROP HOSPITAL)
259 First Street Mineola)
New York, 11501)
)
OSF HEALTHCARE SYSTEM)
d/b/a Saint Francis Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a St. Mary Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
PROGRESS WEST HEALTHCARE CENTER)
d/b/a Progress West Hospital)
2 Progress Point Parkway)
O'Fallon, MO 63368)
)
SHANNON MEDICAL CENTER)
120 East Harris Avenue)
P.O. Box 1879)
San Angelo, TX 76902)
)
SOUTHWEST GENERAL HEALTH CENTER)
18697 Bagley Road)
Middleburg Heights, OH 44130)

STANFORD HEALTH CARE
450 Serra Mall Main Quad
Bldg 170 3rd Floor
Stanford, California 94305

TARRANT COUNTY HOSPITAL DISTRICT
d/b/a JPS Health Network
1500 South Main Street
Fort Worth, Texas 76104

THE WOOSTER COMMUNITY HOSPITAL
AUXILIARY, INC.
d/b/a Wooster Community Hospital
1761 Beall Avenue Wooster, OH 44691

UNIVERSITY HOSPITALS HEALTH SYSTEM, INC.
d/b/a UH Elyria Medical Center
3605 Warrensville Center Road
Shaker Heights, OH 44122

UNIVERSITY HOSPITALS HEALTH SYSTEM, INC.
d/b/a UH Geauga Medical Center
3605 Warrensville Center Road
Shaker Heights, OH 44122-5203

UNIVERSITY OF VERMONT MEDICAL CENTER
111 Colchester Avenue
Burlington, VT 05401

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity
as Secretary of Health & Human Services
United States Department of
Health & Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendant.

COMPLAINT

Plaintiffs, thirty-three hospitals that participate in the Medicare program, bring this complaint against Defendant Alex M. Azar II, in his official capacity as Secretary of Health and Heath Human Services ("Secretary"), and allege as follows:

INTRODUCTION

1. In Section 603 of the Bipartisan Budget Act of 2015 ("BBA 2015"), Congress amended the Social Security Act so that the Medicare program now pays the same rates for medical services regardless of whether they are provided in a physician's office or in a hospital department that is located away from or "off" the main campus of the hospital. At the same time, Congress excepted from this amendment all off-campus hospital outpatient departments that were providing services *before* the enactment of Section 603. Pursuant to the line drawn by Congress, those pre-existing departments would continue to be paid for their services at the higher hospital rates that pre-dated Section 603. But the Secretary believes that Congress did not go far enough, and under a rule that went into effect January 1, 2019, the Secretary is now paying the lower, physician office rate to the very hospital departments that Congress protected from this change. The Secretary's rule is irrational, a patent misconstruction of the Social Security Act and a blatant attempt to circumvent the will of Congress clearly expressed in Section 603.

2. Many hospitals, including Plaintiffs, operate off-campus hospital departments which the Medicare program commonly refers to as "provider-based departments" ("PBDs"). Medicare defines an off-campus PBD as a facility not located on a hospital's main campus but operated by and integrated with the main hospital to such a degree that services furnished there are considered furnished by the hospital itself. *See generally* 42 C.F.R. § 413.65. Many

hospitals locate off-campus PBDs throughout the community so that they are closer to and more convenient for patients to visit for care as compared to traveling to the hospital's main campus. Off-campus PBDs provide outpatient hospital services, which are those services that do not require a patient to stay overnight in a hospital bed, sometimes referred to as ambulatory or same-day services. *See e.g.*, Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 6 § 20.2 (defining "outpatient"). Evaluation and management services, or E/M services, are a common outpatient service. E/M services involve the assessment and treatment of a patient by a physician. *See* Medicare Learning Network, *Evaluation and Management Services*, ICN 006764 available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf (overviewing E/M services). Off-campus PBDs that offer E/M and other services help improve quality and access to hospital-level care, particularly for underserved communities that may not otherwise have access to these services at other nonhospital sites such as independent physician offices.

3. In general, medical services provided in hospital outpatient departments are more resource-intensive—and therefore more costly—than those furnished in an independent physician's office. *See* 73 Fed. Reg. 66,187, 66,191 (Nov. 7, 2008) (recognizing the "high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital . . ."). Hospitals are required to provide a wider range of services and meet much stricter regulatory requirements than freestanding physician offices. For example, hospitals must offer 24-hour nursing care, maintain discharge planning protocols, and meet various health and safety requirements. 42 U.S.C. § 1395x(e)(3)-(9). Hospitals must maintain a formal "institutional plan and budget" that "provide[s] for capital expenditures for at least a 3-year period" and is subject to State review.

42 C.F.R. § 482.12(d). Hospitals must also maintain a pharmacy overseen by a licensed pharmacist, as well as ensure security for prescription drugs. *Id.* at § 482.25. Hospitals must maintain or have available diagnostic radiologic and laboratory services, as well as food and dietetic services. *Id.* at § 482.26–28. Hospitals must ensure that they have emergency sources of electricity, water and gas, and that the physical plant meets all applicable building and fire code standards. *Id.* at § 482.41. None of these conditions for participating in Medicare and other Federal healthcare programs apply to an independent physician's office.

4. Because these statutory and regulatory requirements create additional operating and capital expenditures that other healthcare entities do not incur, Medicare pays hospitals more for services, including outpatient services, than it pays for comparable services provided by an independent physician office. *See* 83 Fed. Reg. at 59,008 (comparing Medicare payment for a certain clinic visit furnished under the Medicare Outpatient Prospective Payment System ("OPPS") and under the Medicare Physician Fee Schedule ("MPFS")). The higher payment rates for hospitals, however, raised concerns as to whether some hospitals have been motivated to purchase independent physician offices and convert them into hospital departments to capture the higher payment rates without incurring the corresponding increase in costs to provide comparable services. *See, e.g.*, 83 Fed. Reg. 37,046, 37,148 (July 31, 2018). The Medicare Payment Advisory Commission ("MedPAC"), a body established by statute to make recommendations to Congress regarding healthcare policy, has recommended that Congress consider legislation to address this possibility, such as eliminating the payment difference between all hospital outpatient departments and physician offices. 83 Fed. Reg. 58,818, 59,006–07 (Nov. 21, 2018) (citing 2012 and 2014 reports).

5. Congress recognized that it was not necessary to adopt such broad proposals into law to address this concern. Instead, Congress enacted Section 603 of the BBA 2015, which creates clear, specific and narrowly-tailored rules governing how the Medicare program will pay for medical services provided at off-campus PBDs. Pub. L. No. 114-74 § 603, 129 Stat. 584, 598. Rather than lower rates for all off-campus PBDs, for example, Congress determined that only those off-campus PBDs that began operations on or after November 2, 2015 would be paid according to a different, lower-paying rate system. These off-campus PBDs are often called "nonexcepted" PBDs because they are not excepted by the payment changes Congress made in Section 603. 42 U.S.C. § 1395l(t)(21)(C). In contrast, Congress determined that off-campus PBDs that were operating before November 2, 2015 would continue to receive higher rates determined under the hospital OPPS. These off-campus PBDs are referred to as "excepted" or "grandfathered" PBDs because Congress excepted them from the changes in Section 603. As for the rates paid to new, nonexcepted PBDs, Congress authorized the Secretary to determine which reimbursement system to use to calculate payments for those off-campus PBDs. *See* 42 U.S.C. § 1395l(t)(21)(C) (identifying that payment be made for nonexcepted PBDs under an "applicable payment system").

6. The Secretary ultimately chose to calculate payment rates for nonexcepted PBDs using the MPFS, the same methodology he uses to set payment rates for independent physician practices. *See* 81 Fed. Reg. 79,562, 79,570 (Nov. 14, 2016). At that time, he acknowledged that Congress intended to preserve the ability of excepted off-campus PBDs to continue to receive those higher rates so that they could serve their communities effectively without any disruptions in care. *Id.* at 79,704 ("we believe that section 603 applies to off-campus PBDs as they existed at the time the law was enacted. That is, we believe that the statutory language provides for

payment to continue under the OPPS for such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of [Section 603]").

7. However, on November 21, 2018, the Secretary reversed course and issued a final rule, effective January 1, 2019, that eliminates the higher, OPPS reimbursement rate for E/M services provided by excepted off-campus PBDs. The Secretary, instead, will only reimburse for E/M services at the lower, MPFS rate that nonexcepted off-campus PBDs receive. *See* Centers for Medicare & Medicaid Services, Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Dep't of Health and Human Servs., 83 Fed. Reg. 58,818 (Nov. 21, 2018) ("Final Rule"). In other words, notwithstanding Congress's decision that excepted off-campus PBDs were exempt from Section 603's payment changes and would continue to be reimbursed at OPPS rates, the Secretary has blatantly disregarded a specific and unambiguous statutory directive, acted well beyond his authority and nullified that statutory exemption.

8. The Secretary's actions are no garden variety error of law; they are *ultra vires*. He has left no doubt that he is substituting his will for Congress's. In the Final Rule, the Secretary expressed his opinion that Section 603 only "address[ed] *some* of [his] concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting." *Id.* at 59,012 (emphasis added). He criticized Congress's decision to allow many "hospital off-campus departments [to] continue to receive full OPPS payment," referring to those off-campus PBDs Congress specifically exempted from Section 603's payment rate changes. *Id.*

9. The Secretary has cited 42 U.S.C. § 1395l(t)(2)(F)—a provision enacted nearly 20 years before Section 603—as authority that allows him to override Congress's mandate. But Section (t)(2)(F) allows for no such thing. It authorizes the Secretary to "develop a method for

controlling unnecessary increases" in the volume of hospital outpatient department services, but it does not authorize the Secretary to set payment rates contrary to those established by statute, nor does it allow the Secretary to override Congress's more recent and specific statutory mandate in Section 603 to continue to pay excepted off-campus PBDs at hospital OPPS rates. No provision of law—not Section (t)(2)(F) or any other—permits the Secretary to ignore a clearly expressed mandate of Congress simply because the Secretary disagrees with Congress's legislative choices.

10. The Secretary's Final Rule is also *ultra vires* because it violates 42 U.S.C. § 1395l(t)(9)(B) (Section 1833(t)(9)(B) of the Social Security Act). Section (t)(9)(B) requires the Secretary to "budget neutralize" any changes he makes in the amounts paid for specific outpatient department items or services. Any increases (or decreases) in payment rates must be offset by a corresponding reduction (or increase) in the rates for other services so that aggregate payments for outpatient department services remains the same. The Secretary admits that the initial rate cut for E/M services in 2019 alone will reduce Medicare payments for hospital outpatient department services by $300 million—and even more in future years when the E/M rate cut is fully implemented. However, rather than offset that payment cut by increasing funding to the providers of those services elsewhere, the Secretary intends to retain this amount in direct defiance of Congress's instructions.

11. The Secretary's unlawful rate cut directly contravenes clear congressional directives and will impose significant harm on affected off-campus hospital outpatient departments and the patients they serve. Accordingly, this Court should declare the Secretary's Final Rule to be *ultra vires* and enjoin the agency from implementing any payment methodology other than OPPS rates for all E/M services provided by excepted off-campus PBDs.

PARTIES

12. Plaintiffs operate excepted off-campus PBDs that participate in the Medicare program and are affected by the unlawful rate cut in E/M services that became effective January 1, 2019.

13. The plaintiffs in this action are:

- HACKENSACK MERIDIAN HEALTH,
  d/b/a Jersey Shore University Medical Center, Medicare Provider No. 31-0073;
- BARNES-JEWISH HOSPITAL, Medicare Provider No. 26-0032;
- BARNES-JEWISH WEST COUNTY HOSPITAL,
  Medicare Provider No. 26-0162;
- CENTRAL VERMONT MEDICAL CENTER, INC.,
  Medicare Provider No. 47-0001;
- FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.,
  d/b/a Heart Hospital of Acadiana, LLC, Medicare Provider No. 19-0263;
- FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.,
  d/b/a Our Lady of Lourdes Regional Medical Center, Inc., Medicare Provider No. 19-0102;
- FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.,
  d/b/a Our Lady of the Angels Hospital, Medicare Provider No. 19-0312;
- FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.,
  d/b/a Our Lady of the Lake Ascension Community Hospital—St. Elizabeth Hospital, Medicare Provider No. 19-0242;
- FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.,
  d/b/a Our Lady of the Lake Regional Medical Center, Medicare Provider No. 19-0064;
- FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.,
  d/b/a St. Francis Medical Center, Medicare Provider No. 19-0125;
- HACKENSACK MERIDIAN HEALTH,
  d/b/a Bayshore Medical Center, Medicare Provider No. 31-0112;

- HACKENSACK MERIDIAN HEALTH,
d/b/a Hackensack University Medical Center, Medicare Provider No. 31-0001;

- HACKENSACK MERIDIAN HEALTH,
d/b/a JFK Medical Center, Medicare Provider No. 31-0108;

- HACKENSACK MERIDIAN HEALTH,
d/b/a Ocean Medical Center, Medicare Provider No. 31-0052;

- HACKENSACK MERIDIAN HEALTH,
d/b/a Palisades Medical Center, Medicare Provider No. 31-0003;

- HACKENSACK MERIDIAN HEALTH,
d/b/a Raritan Bay Medical Center, Medicare Provider No. 31-0039;

- HACKENSACK MERIDIAN HEALTH,
d/b/a Riverview Medical Center, Medicare Provider No. 31-0034;

- HACKENSACK MERIDIAN HEALTH,
d/b/a Southern Ocean Medical Center, Medicare Provider No. 31-0113;

- HEARTLAND REGIONAL MEDICAL CENTER,
Medicare Provider No. 26-0006;

- MISSOURI BAPTIST MEDICAL CENTER,
Medicare Provider No. 26-0108;

- NYU LANGONE HEALTH SYSTEM,
Medicare Provider No. 33-0214;

- NYU WINTHROP HOSPITAL,
Medicare Provider No. 33-0167;

- OSF HEALTHCARE SYSTEM,
d/b/a Saint Francis Medical Center, Medicare Provider No. 14-0067;

- OSF HEALTHCARE SYSTEM,
d/b/a St. Mary Medical Center, Medicare Provider No. 14-0064;

- PROGRESS WEST HEALTHCARE CENTER,
d/b/a Progress West Hospital, Medicare Provider Number 26-0219;

- SHANNON MEDICAL CENTER,
Medicare Provider No. 45-0571;

- SOUTHWEST GENERAL HEALTH CENTER,
Medicare Provider No. 36-0155;

- STANFORD HEALTH CARE,
  Medicare Provider No. 05-0441;

- TARRANT COUNTY HOSPITAL DISTRICT,
  d/b/a JPS Health Network, Medicare Provider No. 45-0039;

- THE WOOSTER COMMUNITY HOSPITAL AUXILIARY, INC.,
  d/b/a Wooster Community Hospital, Medical Provider No. 36-0036;

- UNIVERSITY HOSPITALS HEALTH SYSTEM, INC.,
  d/b/a UH Elyria Medical Center; Medicare Provider No. 36-0145;

- UNIVERSITY HOSPITALS HEALTH SYSTEM, INC.,
  d/b/a UH Geauga Medical Center, Medicare Provider No. 36-0192; and

- UNIVERSITY OF VERMONT MEDICAL CENTER, INC.,
  Medicare Provider No. 47-0003.

14. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services, which administers the Medicare program established under title XVIII of the Social Security Act. Defendant Azar is sued in his official capacity only. The Centers for Medicare & Medicaid Services ("CMS") is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs, including issues relating to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

JURISDICTION AND VENUE

15. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, each of the Plaintiffs has been paid an amount for E/M services provided at excepted off-campus PBDs at the MPFS rate rather than the hospital department OPPS rate as required by Section 603. Each of the Plaintiffs has presented claims to the

Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the Secretary's authority to pay excepted off-campus PBDs at rates contrary to Section 603. Further administrative appeal and review of Plaintiffs' claims is futile because the Secretary's administrative adjudicators are bound by the Secretary's Final Rule, and the Secretary has already determined that he will not revise the Final Rule leaving Plaintiffs with no recourse other than federal court review.

16. Alternatively, this Court has subject-matter jurisdiction under 42 U.S.C. § 1331 because Plaintiffs' claims arise under the laws of the United States.

17. Venue is proper in this district under 28 U.S.C. § 1391 because Defendant resides in the District of Columbia and a substantial part of the events giving rise to this action occurred in this district.

18. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201 & 2202 and 5 U.S.C. §§ 705 & 706.

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

19. Medicare is a federal health insurance program for eligible disabled individuals and senior citizens. 42 U.S.C. §§ 1395 *et seq*. Plaintiffs provide hospital services to Medicare beneficiaries that qualify for reimbursement through Medicare.

20. Medicare provider-based status is a decades-old mechanism that hospitals nationwide use to furnish outpatient hospital services to their patients, particularly at locations beyond a hospital's main campus and closer to where patients live. CMS has acknowledged that the concept has been active "[s]ince the beginning of the Medicare program," as large hospital

facilities "have functioned as a single entity while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes." 67 Fed. Reg. 49982, 50,078 (Aug. 1, 2002). Specifically, hospitals' transformation into "integrated delivery systems" has led many of them to "acquire control of nonprovider treatment settings, such as physician offices." 65 Fed. Reg. 18,434, 18,504 (April 7, 2000).

21. The requirements for provider-based status are set out at 42 C.F.R. § 413.65. The regulation generally requires that an off-campus hospital department operate on the main hospital's license; that its clinical services and staff are supervised by and integrated with those of the main provider; that the hospital retain ultimate managerial and administrative control over the department; that the department is held out to the public as part of the main provider; and that the department's income and expenses are accounted together with those of the main hospital. If a hospital can demonstrate that it meets these requirements, then the department "is clearly and unequivocally an integral part of a [hospital] provider." 65 Fed. Reg. at 18,506.

22. Payment for medical services provided by *all* off-campus PBDs prior to November 2015 were reimbursed under the OPPS, whereas services rendered at physician offices were reimbursed at lower rates set by the MPFS. As the Secretary himself has recognized, off-campus PBDs have higher costs than physician offices and offer "enhanced" services; therefore, the difference in pay rates was warranted.

23. Because of the important and unique role played by PBDs, the volume of services provided at off-campus PBDs has increased over the years. 83 Fed. Reg. at 59,005–07. This trend reflects developments in medical technology that have increased treatment options that were previously unavailable on an outpatient basis and that have allowed PBDs to offer increased access to hospital care to many outlying communities. *See, e.g.*, OIG Rep. No. OEI-

04-97-00090 at 27 (Aug. 2000) ("We . . . believe that provider-based entities can improve access to care. In fact, many provider-based entities provide services that are enhanced relative to free-standing entities and that are virtually identical to those provided in the main portion of the hospitals.").

24. MedPAC has documented the increases in hospital outpatient services and the practice of hospitals purchasing physician offices—also referred to as "vertical integration." MedPAC has recommended to Congress that it reform the payment differences for services provided in hospital outpatient departments and physicians' offices, including a 2012 report in which MedPAC recommended that Congress eliminate payment differences in rates for E/M services. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 71 (March 2012). In 2014, MedPAC expanded the list of services it recommended Congress target for payment rate equalization. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 83 (March 2014).

25. Many hospitals opposed MedPAC's proposals as extreme and having failed to consider the negative effects such rate reductions would have on hospitals' ability to provide safety-net services for vulnerable populations. If adopted, MedPAC's proposals would "result in the closure of some [PBDs] and the reduction of services in others, greatly affecting the vulnerable populations—especially those with complex medical problems—that receive care there, and limiting the ability to train the next generation of health professionals in these outpatient settings." Letter from Atul Grover, Chief Pub. Policy Officer, Association of American Medical Colleges, to The Honorable John Barrasso et al., (Jan. 13, 2012) https://www.aamc.org/download/271334/data/aamccommentletteronproposedhopdcuts.pdf.

26. Amid this ongoing debate, Congress enacted Section 603 of the BBA 2015. Contrary to MedPAC's recommendations, Congress *did not* equalize the payment rates between all PBDs and physician offices for E/M services or any others. Instead, Congress addressed the financial incentives that were generating *new* off-campus PBDs by equalizing the payment rates for all newly created off-campus PBDs with those paid to physician offices. In the same enactment, Congress preserved the ability of *existing* off-campus PBDs to continue treating patients under the OPPS reimbursement framework by excepting them from the changes in Section 603.

27. Congress left no room for doubt when it directed the Secretary to continue to pay excepted off-campus PBDs at OPPS rates. The Medicare statute requires the Secretary to develop an outpatient prospective payment system—OPPS—to pay for "covered OPD [outpatient department] services." 42 U.S.C. § 1395l(t)(1)(A). When it enacted Section 603, Congress amended Section (t)(1)(A) to exclude from the definition of "covered OPD services" those "applicable items and services" provided by "an off-campus outpatient department of a provider." 42 U.S.C. § 1395l(t)(1)(B)(v). The impact of Section 603 on an "off-campus outpatient department" is clear: all of the "items and services" it furnishes are no longer "covered OPD services" paid under OPPS. Instead, they must be paid under an "applicable payment system" that is not OPPS.

28. Section 603 is just as clear that if OPD services are furnished by a department that is *not* "an off-campus outpatient department of a provider," then Section 1833(t)(1)(A) and OPPS rates still apply. And Section 603 excludes from the definition of "off-campus outpatient department of a provider" a "department of a provider . . . that was billing under [subsection (t)] with respect to covered OPD services furnished prior to" November 2, 2015. 42 U.S.C. §

1395l(t)(21)(B)(ii.). Therefore, Section 603 mandates that the Medicare program must continue to pay for *all* services furnished by excepted off-campus PBDs under OPPS.

B. Proposed Rule

29. Notwithstanding this clear, specific and unambiguous statutory directive, the Secretary on July 31, 2018 issued a proposed rule that would "apply an amount equal to the site-specific MPFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the MPFS payment rate) for [E/M] services . . . when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act." 83 Fed. Reg. at 37,142. In other words, contrary to Section 603, the Secretary proposed to cut the payment rate for E/M services provided at excepted off-campus PBDs by applying the lower, MPFS rate reserved for such services provided at new off-campus PBDs that are subject to Section 603's changes.

30. The Secretary reasoned that this rate cut was necessary to equalize payment between excepted and nonexcepted facilities to address what he regarded as an unnecessary "shift of services from the physician office to the hospital outpatient department" caused by the difference in payment rates. *Id.* Fully aware that Congress had already addressed this issue three years earlier, the Secretary determined that Section 603 only "address[ed] some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting." *Id.* at 37,141. Unsatisfied with the fact that Congress rejected MedPAC's recommendation to equalize payment rates between *all* hospital outpatient departments and physicians' offices, the Secretary proposed a rule to override Congress's mandate to exempt pre-existing off-campus PBDs from Section 603.

31. Notably, the Secretary does not claim that he has the authority to reduce E/M rates pursuant to any authorization under Section 603. In the proposed rule, the Secretary instead

identified Section 1833(t)(2)(F) of the Medicare statute as the authority that permits him to implement this rate cut. When it created the OPPS system in 1997, Congress required the Secretary to reimburse hospitals for "covered outpatient department services" using a precise formula set forth in statute to set prospective rates for these services. *See* 42 U.S.C. § 1395l(t)(3). Section (t)(2)(F), enacted at the same time, directs the Secretary to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." The Secretary has, until now, never interpreted Section (t)(2)(F) as permitting him to selectively override the precise formula in Section 1833(t)(3) to create his own, preferred payment rate for a specific outpatient hospital department service.

32. Although Section (t)(2)(F) directs the Secretary to develop a "method" to "control unnecessary increases in the volume" of services, E/M services provided in excepted off-campus PBDs are not "unnecessary" merely because they are reimbursed at a higher rate. The fact that the Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary."

33. Even if Section (t)(2)(F) allowed the Secretary to set his own payment rates (and it does not), the Secretary has acted far in excess of any such authority by implementing a new payment rate without any data to support it. None of the evidence or data cited by the Secretary in the proposed rule showed any ongoing "shift of services from the physician office to the hospital outpatient department" setting that post-dates the enactment of Section 603. In fact, the annual MedPAC reports and other commentary referenced by the Secretary in the proposed rule analyzed data from periods *before* the statutory changes imposed by Section 603 went into effect and do not support the Secretary's decision. Any "shift of services" cannot possibly increase

Medicare expenditures because any newly-acquired physician practice would still be paid under the MPFS as a nonexcepted PBD. Therefore, even if the Secretary had the authority to override Congress's decision in Section 603 (which he does not), he cited no evidence to support it.

34. The Secretary also proposed to make this payment cut in a non-budget-neutral manner, meaning that the decreased payments to nonexcepted off-campus PBDs would not be offset by positive adjustments to OPPS rates elsewhere to achieve the same overall funding to hospitals under Medicare. *See* 83 Fed. Reg. at 37,142. Again, the Secretary acted contrary to clear and controlling legislative directives, as Section 1833(t)(9) requires that changes to the group of covered OPD services and "adjustments," including the "relative payment weights" under OPPS, must be implemented in a budget-neutral manner. *See* Section 1833(t)(9)(B). This provision encompasses rate changes such as the substitution of MPFS rates for E/M services instead of the statutorily-required OPPS rates for excepted off-campus PBDs.

35. Despite this clear language, the Secretary reasoned that exercises of his authority to develop "method[s]" for controlling "volume" increases are not subject to the same budget neutrality restrictions. This reasoning ignores the fact that his proposed "method" for restricting volume increases was to directly lower rates for one-type of service (E/M services), the very sort of "adjustment" that is plainly subject to budget neutrality requirements. Moreover, Section (t)(9)(F) authorizes the Secretary to "adjust the update to the conversion factor"—*i.e.*, budget neutralize—when implementing "the methodologies described in paragraph (2)(F)."

36. In 2019 alone, CMS estimated the impact of making this payment cut in a non-budget-neutral manner would result in $610 million less Medicare funding to hospitals.

C. Comments

37. During the comment period following the release of the proposed rule, thousands of stakeholders submitted written comments, many stating that the Secretary's proposed rate cut for E/M services provided at excepted off-campus PBDs violated clear statutory directives and was unsupported by evidence. In particular, the commenters stated:

a. Congress was unambiguous in the choice it made in Section 603: pre-existing off-campus PBDs would continue to be paid at OPPS rates while new off-campus PBDs would be paid lesser rates. Further, the general authority in Section (t)(2)(F), enacted nearly *twenty* years before Section 603, to adopt "methods" to control unnecessary volume increases does not override this explicit mandate. Under well-established principles of statutory construction, a "later federal statute" setting forth a "specific policy"—*i.e.*, Section 603—"control[s]" any "construction of the earlier statute" that could arguably conflict with that later-adopted specific policy. Ex. A (Comment of Sarasota Memorial Hospital) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (citations omitted)).

b. The fact that the Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary." *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) ("As written, the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all."). Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" does

not authorize the Secretary to deviate from this fundamental structure of the Medicare statute to pay for medically necessary services at statutory prescribed rates. To read (t)(2)(F) as the Secretary does would "permit an end-run around the statute" and violate the judicial cannon that "Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Association*, 531 U.S. 457, 468 (2001). *See* Ex. A (Comment of Sarasota Memorial Hospital).

c. The Secretary failed to make the requisite showing of "unnecessary" increases in medical services to trigger whatever actual authority the Secretary could properly exercise under (t)(2)(F). The Secretary merely theorized about the purported shift in location where E/M visits were taking place, not that the visits themselves were in any way "unnecessary." Therefore, not only did the Secretary fundamentally misconstrue (t)(2)(F) to assume powers not delegated to him by Congress—*i.e.*, modifying statutorily-prescribed rates for services provided by excepted off-campus PBDs—the Secretary failed to fulfill the basic threshold requirements of (t)(2)(F). *See* Ex. A (Comment of Sarasota Memorial Hospital).

d. The Secretary's proposal to implement the rate cut for excepted off-campus PBDs in a non-budget neutral manner also exceeded the agency's authority. Section 1833(t)(9) requires adjustments to be implemented in a budget-neutral manner which includes rate changes such as the substitution of MPFS rates instead of OPPS rates paid E/M services at excepted off-campus PBDs. If permitted to implement this rate cut in a non-budget-neutral manner, the Secretary could invoke

(t)(2)(F) to justify the application of every rate reduction for any OPPS service in a non-budget neutral manner and thereby circumvent the budget neutrality requirement in (t)(9) altogether. Given the express statutory command that "adjustments" must be budget neutral, it would defy well-established canons of statutory construction for the Secretary to ignore, yet again, a specific legislative command in favor of the Secretary overly expansive reading of (t)(2)(F). *See* Ex. A (Comment of Sarasota Memorial Hospital).

D. Final Rule

38. On November 21, 2018, the Secretary issued a Final Rule that, among other things, finalized the rate cut for excepted off-campus PBDs effective January 1, 2019. 83 Fed. Reg. 58,818. In other words, as of January 1, excepted off-campus PBDs no longer receive OPPS rates for E/M services, but rather are reimbursed based at MPFS rates. The only substantive change made by the Secretary in the Final Rule was phasing-in full implementation of the rate cut over a two-year period, meaning that affected hospitals will receive $300 million less in Medicare funding in 2019 and $610 million less in 2020 when the rate cut is fully implemented.

39. The Secretary dismissed the commenters' legal challenges out of hand. As to the concern that the Secretary was overturning Congress's mandate to except pre-existing off-campus PBDs from Section 603, the Secretary reiterated his view that Congress had not gone far enough: the "action Congress took in 2015 to address certain off-campus PBDs helped stem the tide of these increases in the volume of OPD services," but many "off-campus PBDs continue to be paid the higher OPPS amount for these services." 83 Fed. Reg. at 59,012. The Secretary did not engage with these comments in any meaningful way and stated: "We do not believe that the

section 603 amendments to section 1833(t) of the Act, which exclude applicable items and services furnished by nonexcepted off-campus PBDs from payments under the OPPS, preclude us from exercising our authority in section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services under the OPPS." *Id.*

40. The Secretary also failed to engage meaningfully with commenters' concerns that the agency lacked the authority to implement the rate cut in a non-budget-neutral manner. With no analysis whatsoever, the Secretary simply repeated his position in the proposed rule that budget-neutrality was not required because he was invoking his authority under (t)(2)(F). *See id.* ("we maintain that the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act.").

E. Plaintiffs Are Suffering Substantial Harm

41. The rate cut, which lowers payment rates for clinic visits by 30 percent in 2019 (and an additional 30 percent in 2020) went into effect on January 1, 2019, thereby depriving critical funding to Plaintiffs that is necessary for these institutions to effectively serve their communities.

42. As the Secretary has forecasted, the total reduction in payments to affected hospital providers will be approximately $380 million in 2019, and $760 million in 2020. 83 Fed. Reg. at 59014.

43. Even prior to this rate cut, Plaintiffs were under significant financial strain from steadily increasing costs in the healthcare marketplace and reimbursement cuts from the government and private insurers alike.

44. Hospital outpatient departments, including those formed and operated by Plaintiffs before enactment of Section 603, play an important role serving members of their communities who otherwise may face increased barriers to receiving timely care.

45. Plaintiffs, both at the time they created their affiliated outpatient departments and when Section 603 was enacted, reasonably expected they would continue to be reimbursed under the OPPS as they had been for many years and as mandated by Congress. The Secretary's Final Rule implementing this rate cut for E/M services, which was only first proposed five months before the January 1, 2019 effective date, was a severe and unexpected financial hit to the operations of Plaintiffs that jeopardizes their ability to care for the medically vulnerable populations often treated in PBDs.

46. Hospitals across the industry raised these concerns to the Secretary during the comment period preceding the Final Rule. Sarasota Memorial Hospital ("SMH") noted that it "established PBDs to provide necessary services that are *not commonly provided by Part B physicians in our community*, such as radiology, bone density, mammography, ultrasound, nuclear medicine, CT scan, MRI, cardiopulmonary rehab, cardiac rehab, anti-coagulation, a COPD clinic, a heart failure clinic, and, most importantly, urgent care services. Urgent care, in particular, is one of SMH's most significant outpatient service lines because it fills a significant gap between physician offices that offer limited services during limited hours, and costly hospital emergency departments." Sarasota Memorial Hospital, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and

Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 24, 2018) (emphasis added). Urgent care and many specialty services are billed as E/M services. As a result, "CMS's proposals to reduce payments to excepted departments for E/M services will result in an annual estimated impact to SMH of $3.7 million" and would "dramatically erode[] SMH's ability to provide services to [its] growing and aging patient population and will instead have the likely effect of increasing more costly visits to the ED." *Id*.

47. Tampa General Hospital noted that it "operate[s] two offsite clinics which primarily serve the most vulnerable patient populations in the greater Tampa metropolitan area. The services provided, and patients seen, in these clinics are substantially different from those treated in [the] average physician's office[]. These patients are more medically complex and have a substantially higher proportion of social determinants of health—such as housing, transportation, literacy, and nutrition—which provide additional challenges and add to the complexity of care." Tampa General Hospital, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 24, 2018). Once again, many of the services furnished to these patients are classified as E/M visits, and "CMS' proposed reimbursement cut for these … facilities would have a disastrous impact" on the hospital's ability to continue treating these costly patients. *Id.*

48. University of Virginia Medical Center noted that the proposed payment rate reduction would be particularly devastating to academic medical centers that "operate centers of excellence … based in hospital settings and provide outstanding team-based, patient centered care" with additional benefits such as "translators and other social services" that independent physician offices generally do not offer. Office of the Chief Executive Office of the Medical

Center, University of Virginia Health System, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 21, 2018). Indeed, the hospital said, low-income and vulnerable patients turn to PBDs because they "face difficulty being seen in physician offices" at all. *Id.* The hospital noted that it already incurs "negative margins when we treat Medicare patients in [PBDs], and these cuts will hurt our ability to continue to provide the full range of quality safety net services that we currently offer. This is not a sustainable financial model for public institutions like UVA Medical Center who serve[] all citizens regardless of their ability to pay for care." *Id.*

49. The Secretary nonetheless adopted the rate reduction and Plaintiffs, and the patients they care for, face immediate harm and will continue to suffer these harms as long as the Secretary's unlawful Final Rule is allowed to remain in place.

50. The Plaintiff hospitals have submitted claims for payment to the Medicare program for their excepted off-campus E/M services that were affected by the Final Rule. Medicare has paid E/M claims submitted by the Plaintiff hospitals at the lower MPFS rate set by the Secretary's Final Rule. *See* Ex. B. The Plaintiff hospitals have filed Requests for Redetermination that take an administrative appeal of Medicare's failure to pay them the statutorily-prescribed rate for their services. *Id.*

FIRST CAUSE OF ACTION
(Administrative Procedure Act)

The Secretary Has Violated Congress's Clear And Unambiguous Directive That Excepted Off-Campus PBDs Are To Be Reimbursed Under The OPPS Methodology

51. Plaintiffs re-allege and incorporate by reference the allegations made in the foregoing paragraphs of the Complaint.

52. Congress enacted a direct mandate under Section 603 of the BBA 2015 that excepted off-campus PBDs would continue to be paid at OPPS rates, and not at different, lower payment rates that the Secretary applies, at Congress's direction, to nonexcepted PBDs.

53. Congress left no gaps for the Secretary to fill as its command was clear and unequivocal that excepted off-campus PBDs were exempt from any such payment changes. This legislative action ensured that grandfathered off-campus PBDs in operation before the enactment of Section 603 would not be adversely affected by the changes in payment methodology that would apply to newly formed off-campus PBDs.

54. However, the Secretary's Final Rule disregards a specific and unambiguous statutory directive by denying OPPS rates for E/M services at off-campus PBDs, and instead reimbursing for these services at lower MPFS rates, the exact same methodology the Secretary has adopted for nonexcepted off-campus PBDs following enactment of Section 603. The Secretary's actions are *ultra vires,* and he has acted well beyond his statutory authority simply to pursue his preferred policy of cutting payment rates at excepted off-campus PBDs.

55. Contrary to his assertions in the Final Rule, Section 1395l(t)(2)(F) adopted in 1997 does not permit the Secretary to make an end run around Section 603 adopted in 2015. Section 603, which sets forth an unambiguous and "specific policy" to continue OPPS payment for excepted off-campus PBD services, is a "later federal statute" setting forth a "specific policy," and the Secretary's "construction of" (t)(2)(F)—the "earlier statute"—is impermissible because it conflicts with Congress's later-adopted specific policy.

56. Further, Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" does not authorize the Secretary to deviate from Congress's command that the Secretary pay for medically necessary services at statutory prescribed rates. The fact that the

Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary." The Secretary's reliance on section (t)(2)(F) to set aside those payment rates and pay at the least costly alternative exceeds his statutory authority.

57. For these and other reasons, the Secretary's rate cut for E/M visits at off-campus PBDs is unlawful.

SECOND CAUSE OF ACTION
(Administrative Procedure Act)

The Secretary Has Further Exceeded Its Statutory Authority By Not Making the Payment Cut In A Budget Neutral Manner That Congress Required For All Adjustments To Payment Rates For OPD Services

58. Plaintiffs re-allege and incorporate by reference the allegations made in the foregoing paragraphs of the Complaint.

59. Even assuming the Secretary has authority to impose MPFS rates for E/M visits at excepted off-campus PBDs, which he clearly does not under Section 603 of the BBA 2015, the Secretary acted unlawfully in the Final Rule by not implementing the rate cut in a "budget neutral" manner.

60. Section 1833(t)(9) of the Social Security Act requires that "adjustments" of this sort must be implemented in a budget-neutral manner.

61. The Secretary, however, in the Final Rule chose not to make any funding increases to offset the anticipated loss of $300 million in Medicare funding in 2019 to excepted off-campus PBDs (and even more in future years) resulting from this rate cut. Instead, directly contravening the budget neutrality requirements of Section 1833(t)(9), CMS will retain that money in its coffers.

62. In so doing, the Secretary has acted in an *ultra vires* manner well beyond his delegated authority.

63. For these and other reasons, the Secretary's rate cut for E/M visits at off-campus PBDs is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request an Order:

a. Declaring that the Final Rule Exceeds the Secretary's statutory authority in that CMS must reimburse Excepted Off-Campus PBDs under the OPPS methodology;

b. Declaring that the Final Rule Exceeds the Secretary's statutory authority in that rate cuts for OPD services must be done in a budget neutral manner;

c. Vacating and setting aside the Final Rule;

d. Enjoining the Secretary from enforcing, applying, or implementing the Final Rule, and ordering that the Secretary provide prompt payment of any amounts improperly withheld as a result of the Final Rule;

e. Requiring the Secretary to pay legal fees and costs of suit incurred by the Plaintiffs; and

f. Providing such other just and proper relief as the Court may consider appropriate.

Respectfully submitted,

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Date: June 14, 2019

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, **Plaintiffs,** **v.** **ALEX M. AZAR II,** **Secretary of the Department of Health and Human Services,** **Defendant.**	)	**Civil Action No. 18-2841 (RMC)**

MEMORANDUM OPINION

Under Medicare Part B, the Centers for Medicare & Medicaid Services (CMS) pays hospital outpatient departments at predetermined rates for patient services, and Congress has established the Outpatient Prospective Payment System by which CMS is to set and pay those rates. CMS came to believe that the rate for certain clinic-visit services at a specific subset of these outpatient departments—familiarly, off-campus provider-based departments—was too high and that patients could receive similar services from free-standing physician offices at lower cost to the government and to taxpayers. Accordingly, CMS promulgated a rule in 2018 lowering the payment rate for clinic-visit services at off-campus provider-based departments to match the rate for similar services at physician offices, in order to shift patients towards the latter.

Plaintiffs are hospital organizations which have seen their payment rates cut. They argue that the method by which CMS has cut their rates has no place in the statutory scheme established by Congress, and further that Congress has already decided as a matter of policy and practicality that off-campus provider-based departments should be paid at *higher* rates

than physician offices for similar services. In short, Plaintiffs argue that CMS' 2018 rule is *ultra vires*. CMS opposes. Both parties move for summary judgment.

The Court has given close attention to the parties' arguments and the statutory scheme, which, as relevant, is both simple and detailed. For the reasons below, the Court finds that CMS exceeded its statutory authority when it cut the payment rate for clinic services at off-campus provider-based clinics. The Court will grant Plaintiffs' motion, deny CMS' cross-motion, vacate the rule, and remand.

I. BACKGROUND

The Medicare program, established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides federally funded medical insurance to the elderly and disabled. Medicare Part A addresses insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B addresses supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k.

A. The Outpatient Prospective Payment System

Under Medicare Part B, CMS directly reimburses hospital outpatient departments for providing outpatient department (OPD) services to Medicare beneficiaries, which payments are made through the elaborate Outpatient Prospective Payment System (occasionally, OPPS). *See generally* 42 U.S.C. § 1395*l*(t). Implemented as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, the Outpatient Prospective Payment System does not reimburse hospitals for their actual costs of providing OPD services. Rather, as with Medicare generally and in an effort to control costs, the Outpatient Prospective Payment System pays for OPD services at pre-determined rates. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Those payment rates are determined as follows: OPD services which are clinically comparable or which require similar resource usage are grouped together and assigned an

Ambulatory Payment Classification (occasionally, APC). 42 U.S.C. § 1395*l*(t)(2)(B). A formula is used to calculate the relative payment weight of each Ambulatory Payment Classification against other APCs, based on the average cost of providing OPD services in previous years. *See id.* § 1395*l*(t)(2)(C). Each Ambulatory Payment Classification's relative payment weight is then multiplied by an Outpatient Prospective Payment System "conversion factor"—which is the same for, and applies uniformly to, all APCs—to reach the fee schedule amount for each APC. *Id.* § 1395*l*(t)(3)(D). Ultimately, the actual amount paid to the hospital is the calculated fee schedule amount adjusted for regional wages, transitional pass-through payments, outlier costs, "and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals," *id.* § 1395*l*(t)(2)(D)-(E), less an applicable deductible and modified by a "payment proportion." *See id.* § 1395*l*(t)(4).

Every year, CMS must review the groups, relative payment weights, and wage and other adjustments for each Ambulatory Payment Classification to account for changes in medical practice or technology, new services, new cost data, and other relevant information and factors. *Id.* § 1395*l*(t)(9)(A). This annual review is conducted with an important caveat: any adjustment to the groups, relative payment weights, or adjustments must be budget neutral, meaning that it cannot cause a change in CMS' estimated expenditures for OPD services for the year. *See id.* § 1395*l*(t)(9)(B); *cf. id.* § 1395*l*(t)(9)(D)-(E) (requiring initial wage, outlier, and other adjustments also be budget neutral). Thus, decreases or increases in spending caused by one adjustment must be offset with increases or decreases in spending by another.

CMS must also update annually the Outpatient Prospective Payment System conversion factor, generally to account for the inflation rate for the cost of medical services, *see id.* § 1395*l*(t)(3)(C)(iv), but sometimes for other reasons, as discussed below. Unlike

adjustments to Ambulatory Payment Classifications under paragraph (t)(9)(A), adjustments to the conversion factor do *not* need to be budget neutral. *See generally id.* § 1395*l*(t)(3)(C) (describing conversion factor inputs). However, because the same conversion factor applies equally to all Ambulatory Payment Classifications, adjustments to the conversion factor cannot be used to change the fee schedule for specific APCs. In other words, changes to the conversion factor affect total spending and not spending on specific services.

The Outpatient Prospective Payment System controls overall costs by incentivizing hospital outpatient departments to provide OPD services at or below the average cost for such services. That said, while the Outpatient Prospective Payment System limits the amount Medicare will pay for each service, it does not limit the volume or mix of services provided to a patient. Concerned that fee schedule limits would not adequately limit increases in overall expenditures, Congress included as part of the Outpatient Prospective Payment System two provisions at issue here. Under paragraph (t)(2)(F), "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services." *Id.* § 1395*l*(t)(2)(F). Further, under paragraph (t)(9)(C), "[i]f the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395*l*(t)(9)(C).

B. Off-Campus Provider-Based Departments, Physician Offices, and the Bipartisan Budget Act of 2015

Many medical services that were once only offered in an inpatient hospital setting can now be provided by hospital outpatient departments whereby the patient does not spend the night. Medicare traditionally welcomed these cheaper alternatives to inpatient care and, to meet

the growing demand for these services, some hospitals have established off-campus provider-based departments (occasionally, PBDs), which are outpatient departments at facilities separated by a specific distance (or more) from the physical campus of the hospital with which they are affiliated. *See* 42 C.F.R. § 413.65(e). Although not physically proximate to their affiliated hospital's main campus,[1] off-campus provider-based departments are so closely integrated into the same system that they are considered part of the hospital itself. This allows off-campus provider-based departments to offer more comprehensive services to their patients but also subjects off-campus provider-based departments to the same regulatory requirements as the main hospital. *See* 42 C.F.R. § 413.65 (describing regulatory requirements for off-campus provider-based departments). Because they are part of the same system and face the same regulatory requirements and regulatory costs as hospitals, off-campus provider-based departments have generally been paid at the same rates hospitals are paid for OPD services.[2]

That said, some comparable outpatient medical services can also be provided by free-standing physician offices, which are medical practices not integrated with, or part of, a hospital. *See* 42 C.F.R. § 413.65(a)(2). While physician offices do not provide the same array of services as off-campus provider-based departments, they also do not bear the same regulatory requirements and costs as hospitals. Accordingly, CMS pays physician offices for outpatient medical services according to the lower-paying Medicare Physician Fee Schedule instead of the Outpatient Prospective Payment System. As relevant to this case, in 2017 the Outpatient Prospective Payment System rate for the most voluminous OPD service provided by off-campus

[1] For example, an off-campus provider-based department may be located away from the main hospital because of space constraints at the main campus, or because the hospital wants to have an affiliated facility in a different (oftentimes underserved) neighborhood.

[2] Not all are paid the same amounts, for reasons described below.

provider-based departments, "evaluation and management of a patient" (E&M),[3] was $184.44 for new patients and $109.46 for established patients while the Physician Fee Schedule rate for the comparable service at a physician office was $109.46 for a new patient and $73.93 for an established patient. *See* 83 Fed. Reg. 37,046, 37,142 (July 31, 2018) (Proposed Rule).

Until 2015, all off-campus provider-based departments were paid according to the Outpatient Prospective Payment System. At that time, the volume of OPD services had increased by 47 percent over the decade ending in calendar year 2015 and, in the five years from 2011 to 2016, combined program spending and beneficiary cost-sharing (*i.e.*, co-payments) rose by 51 percent, from $39.8 billion to $60.0 billion. *See* Proposed Rule at 37,140. There are many possible explanations for this increase. For one, the Medicare-eligible population grew substantially during the same time period. *See* Medicare Board of Trustees, 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 181 (2018), *available at* https://go.cms.gov/2m5ZCok. For another, advances in medical technology shifted services from inpatient settings to outpatient settings. *See* Ken Abrams, Andreea Balan-Cohen & Priyanshi Durbha, Growth in Outpatient Care, Deloitte (Aug. 15, 2018), *available at* https://bit.ly/2nOkG05.

However, the Medicare Payment Advisory Commission (MedPAC), an independent congressional agency which advises Congress on issues related to Medicare, long believed that another major reason for this increase was the financial incentive created by the Outpatient Prospective Payment System compared to the Physician Fee Schedule. *See* MedPAC, Report to the Congress: Medicare Payment Policy 69-70 (Mar. 2017). That is, because off-

[3] Technically, E&M services fall under Healthcare Common Procedure Coding System (HCPCS) code G0463, billed under APC 5012 (Clinic Visits and Related Services).

campus provider-based departments are paid at higher rates than physician offices, MedPAC advised that hospitals were buying existing physician offices and converting them into off-campus provider-based departments, sometimes without a change of location or patients, unnecessarily causing CMS to incur higher costs. *See id.* To combat this trend, MedPAC repeatedly recommended that Congress authorize CMS to equalize payment rates under both the Outpatient Prospective Payment System and Physician Fee Schedule for certain services, including E&M services, at all off-campus provider-based departments. *See id.* at 70-71; *see also id.* at 69 ("One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services."). Hospitals responded by advising Congress that MedPAC's recommendation ignored the higher costs required to operate a hospital and would force some existing off-campus provider-based departments, which relied on the rates set by the Outpatient Prospective Payment System, to reduce their services or close completely. *See, e.g.*, Letter from Atul Grover, Chief Pub. Policy Officer, Ass'n of Am. Med. Colls., to The Hon. John Barrasso, *et al*. (Jan. 13, 2012), *available at* http://bit.ly/2LVEXOT.

Congress ended the debate, at least momentarily, when it adopted Section 603 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597 (2015). That 2015 statute neither equalized payment rates for physicians offices and off-campus provider-based departments, as MedPAC had recommended, nor left the Outpatient Prospective Payment System untouched, as the hospitals requested. Instead, Congress chose a middle path: Off-campus provider-based departments that were billing under the Outpatient Prospective Payment System as of November 2, 2015 (now "excepted off-campus PBDs") were permitted to continue that practice. *See* 42 U.S.C. § 1395*l*(t)(21)(B)(ii). However, off-campus provider-based

departments which were not billing under the Outpatient Prospective Payment System as of November 2, 2015, *i.e.*, *new* off-campus provider-based departments (or "nonexcepted off-campus PBDs"), would be paid according to a different rate system to be selected by CMS. *See id.* § 1395*l*(t)(21)(C). In practice, CMS continues to pay nonexcepted off-campus PBDs under the Outpatient Prospective Payment System but applies a "[Physician Fee Schedule] Relativity Adjustor" which approximates the rate the operative Physician Fee Schedule would have paid. *See* 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016).

C. The Final Rule and Plaintiffs' Challenge

Despite these changes, the volume of OPD services provided by excepted off-campus provider-based departments grew. When Congress passed the Bipartisan Budget Act of 2015, expenditures by the Outpatient Prospective Payment System were approximately $56 billion and increasing at an annual rate of about 7.3 percent, with the volume and intensity of outpatient services increasing by 3.5 percent. *See* Proposed Rule at 37,139. In 2018, CMS estimated that, without intervention, expenditures in 2019 would rise to $75 billion (an increase of 8.1 percent over 2018), with the volume and intensity increasing by 5.3 percent. *See id.* at 37,139.

CMS thus proposed to implement a "method for controlling unnecessary increases in the volume of covered OPD services." *See generally id.* at 37,138-143; *cf.* 42 U.S.C. § 1395*l*(t)(2)(F). Specifically, CMS determined that many of the E&M services provided by off-campus provider-based departments were "unnecessary increases in the volume of outpatient department services." Such services were not deemed *medically* "unnecessary" but *financially* "unnecessary" because "these services could likely be safely provided in a lower cost setting,"

i.e., at physician offices.[4] Proposed Rule at 37,142. More specifically, CMS determined that the growth of E&M services provided by off-campus provider-based departments was due to the higher payment rate available to excepted off-campus provider-based departments under the Outpatient Prospective Payment System. *Id.* CMS proposed to solve its financial problem by applying the corresponding Physician Fee Schedule rate for E&M services to excepted off-campus PBDs, thereby equalizing the payment rate for E&M services provided by excepted off-campus PBDs, nonexcepted off-campus PBDs, and physician offices alike. *Id.* at 37,142.

CMS also determined that it could not control the volume of financially "unnecessary" OPD services in a budget-neutral fashion, since this would "simply shift the movement of the volume within the OPPS system in the aggregate." *Id.* at 37,143. Therefore, CMS proposed to implement its new approach in a *non*-budget-neutral manner, asserting that the budget neutrality requirements of paragraphs (t)(2)(D)-(E) and (t)(9)(B) do not apply to "methods" developed under paragraph (t)(2)(F) and that its new approach constituted such a method. *Id.* CMS estimated that this approach would save approximately $610 million in 2019 alone. *Id.*

CMS received almost 3,000 comments on the Proposed Rule, many of which argued that CMS lacked statutory authority to implement the proposed method. Nonetheless, on November 21, 2018, CMS issued a Final Rule implementing the proposed method effective

[4] As a general matter, CMS uses expenditures over targeted levels to measure "unnecessary" increases in the volume of OPD services, albeit not without criticism. *See, e.g.*, 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998) ("[W]e are examining a number of mechanisms to control unnecessary increases, as reflected by expenditure levels, in the volume of covered outpatient department services."); 65 Fed. Reg. 18,434, 18,503 (Apr. 7, 2000) ("Others argued that an expenditure target is not a reliable way to distinguish the growth of necessary versus unnecessary services."); 66 Fed. Reg. 44,672, 44,707 (Aug. 24, 2001) (noting MedPAC's recommendation that CMS "not use an expenditure target to update the conversion factor").

January 1, 2019. *See generally Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 83 Fed. Reg. 58,818, 59,004-15 (Nov. 21, 2018) (Final Rule). The only substantive change between the Proposed Rule and the Final Rule was that implementation of the full E&M rate cut was staggered over two years, saving an estimated $300 million in 2019, with additional savings subsequent. *Id.* at 59,004.

Plaintiffs are hospital organizations and related trade groups that have provided services with payment rates affected by the Final Rule, have submitted claims for payment by Medicare, and have appealed determinations on those claims to CMS. The Defendant is Alex M. Azar, in his official capacity as the Secretary of the Department of Health and Human Services. Plaintiffs argue that the Final Rule is contrary to both the Medicare statutory scheme and the policy decision reached by Congress under Section 603 of the Bipartisan Budget Act of 2015 and is therefore *ultra vires*. Both parties have moved for summary judgment; the matter is now ripe.[5]

II. LEGAL STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *accord Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "In a case involving review of a final agency action under the Administrative Procedure Act, however, the standard set forth in Rule 56[] does

[5] On August 26, 2019, the Court consolidated two cases challenging the same Final Rule: *Am. Hosp. Ass'n v. Azar*, No. 18-2841 (RMC), and *Univ. of Kansas Hosp. Auth. v. Azar*, No. 19-132 (RMC). *See* 8/26/2019 Minute Order. Although each set of plaintiffs asserts a different legal vehicle to bring their claim—non-statutory review and APA review, respectively—both challenge the same Final Rule on purely legal grounds with largely overlapping, and not inconsistent, legal arguments. Both legal theories are addressed herein.

not apply because of the limited role of a court in reviewing the administrative record." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006) (internal citation omitted); *see also Charter Operators of Alaska v. Blank*, 844 F. Supp. 2d 122, 126-27 (D.D.C. 2012). Under the APA, the agency's role is to resolve factual issues to reach a decision supported by the administrative record, while "'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" *Sierra Club*, 459 F. Supp. 2d at 90 (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Id*. (citing *Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)).

Plaintiffs' argument that the Secretary acted *ultra vires* is premised on three basic tenets of administrative law. First, "an agency's power is no greater than that delegated to it by Congress." *Lyng v. Payne*, 476 U.S. 926, 937 (1986); *see also Transohio Sav. Bank v. Dir., Office of Thrift Supervision*, 967 F.2d 598, 621 (D.C. Cir. 1992). Second, agency actions beyond delegated authority are *ultra vires* and should be invalidated. *Transohio*, 967 F.2d at 621. Third, courts look to an agency's enabling statute and subsequent legislation to determine whether the agency has acted within the bounds of its authority. *Univ. of D.C. Faculty Ass'n/NEA v. D.C. Fin. Responsibility & Mgmt. Assistance Auth.*, 163 F.3d 616, 620-21 (D.C. Cir. 1998) (explaining that *ultra vires* claims require courts to review the relevant statutory materials to determine whether "Congress intended the [agency] to have the power that it exercised when it [acted]").

When reviewing an agency's interpretation of its enabling statute and the laws it administers, courts are guided by "the principles of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)." *Mount Royal Joint Venture v. Kempthorne*, 477 F.3d 745, 754 (D.C. Cir. 2007) (internal citations omitted). *Chevron* sets forth a two-step inquiry. The initial question is whether "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 843. If so, then "that is the end of the matter" because both courts and agencies "must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. To decide whether Congress has addressed the precise question at issue, a reviewing court applies "'the traditional tools of statutory construction.'" *Fin. Planning Ass'n v. SEC*, 482 F.3d 481, 487 (D.C. Cir. 2007) (quoting *Chevron*, 467 U.S. at 843 n.9). It analyzes "the text, structure, and the overall statutory scheme, as well as the problem Congress sought to solve." *Id.* (citing *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 796 (D.C. Cir. 2004); *Sierra Club v. EPA*, 294 F.3d 155, 161 (D.C. Cir. 2002)). When the statute is clear, the text controls and no deference is extended to an agency's interpretation in conflict with the text. *Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195 (2011).

If the statute is ambiguous or silent on an issue, a court proceeds to the second step of the *Chevron* analysis and determines whether the agency's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843; *Sherley v. Sebelius*, 644 F.3d 388, 393-94 (D.C. Cir. 2011). Under *Chevron* Step Two, a court determines the level of deference due to the agency's interpretation of the law it administers. *See Mount Royal Joint Venture*, 477 F.3d at 754. Where, as here, "an agency enunciates its interpretation through notice-and-comment rule-making or formal adjudication, [courts] give the agency's interpretation *Chevron* deference." *Id.* at 754 (citing *United States v. Mead Corp.*, 533 U.S. 218,

230-31 (2001)). That is, an agency's interpretation that is permissible and reasonable receives controlling weight,[6] *id.*, "even if the agency's reading differs from what the court believes is the best statutory interpretation," *see Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005). Such broad deference is particularly warranted when the regulations at issue "concern[] a complex and highly technical regulatory program." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotation marks and citation omitted).

III. ANALYSIS

A. Reviewability

The government contends that this Court lacks jurisdiction to review the Final Rule under the APA because Congress has precluded judicial review of the development of the Outpatient Prospective Payment System, including its methods and adjustments, and because Plaintiffs have failed to exhaust their administrative remedies under the Medicare statute.

1. Preclusion of Judicial Review

Agency action is subject to judicial review under the APA unless the statute precludes review, or the agency action is committed to agency discretion by law. *See COMSAT Crop. v. FCC*, 114 F.3d 223, 226 (D.C. Cir. 1997) (citing 5 U.S.C. § 701(a)). The statute specifies one such limitation:

> There shall be *no administrative or judicial review* under section 1395ff of this title, 1395oo of this title, or otherwise *of*—
>
> (A) 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)*.

[6] An interpretation is permissible and reasonable if it is not arbitrary, capricious, or manifestly contrary to the statute. *Mount Royal Joint Venture*, 477 F.3d at 754.

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). The government argues here that the Final Rule imposed a rate cut as a "method" developed under paragraph (t)(2)(F) and so court review is barred. *Cf. id.* § 1395*l*(t)(2)(F) ("[T]he Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services.").

Despite the bar against Medicare review in some contexts, "[t]here is a strong presumption that Congress intends judicial review of administrative action, and it can only be overcome by a clear and convincing evidence that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111 (internal citations and quotations omitted). "The presumption is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority." *Id.* "Such review is favored . . . 'if the wording of a preclusion clause is less than absolute.'" *Id.* (quoting *Dart v. United States*, 848 F.2d 217, 221 (D.C. Cir. 1988)). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 346 (1984).

Applied to this case, paragraph (t)(12)(A) plainly shields a "method" to control volume in outpatient departments from judicial review. To determine whether that shield applies, though, the Court must ascertain, consistent with Plaintiffs' *ultra vires* claims, whether what CMS calls a "method" satisfies the statute. That is, CMS cannot shield any action from judicial review merely by calling it a "method," even if it is not that. Accordingly, "the 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." *Id.* at 113; *see also COMSAT*, 114 F.3d at 227 ("The no-review provision . . . merges consideration of the legality of the [agency's] action with consideration of this 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."). Because, as explained below, the Court finds that CMS' action here does not constitute a "method" within the meaning of the statute, the Court also finds that paragraph (t)(12)(A) does not preclude judicial review of Plaintiffs' claims.[7]

2. Exhaustion

As argued by the government, Section 405(g) of the Medicare statute requires a plaintiff to obtain administrative review of its claims before filing suit in court. *See* 42 U.S.C. § 405(g); *see also Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018) (describing the Medicare statute channeling provisions). Specifically, Section 405(g) has two requirements: (1) "presentment" of the claim; and (2) exhaustion of administrative remedies. *See Am. Hosp. Ass'n*, 895 F.3d at 825-26. The government does not substantially argue that Plaintiffs have failed to present their claim. But the government does argue that Plaintiffs have not fully availed themselves of the administrative review process. Plaintiffs concede that they have not exhausted their administrative remedies fully but argue that the requirement of exhaustion should be waived because further administrative review would be futile.

[7] Certain plaintiffs argue that they may bring a non-statutory *ultra vires* claim, even if review under the APA is precluded. *See* Reply in Supp. of Pls.' Mot. for Summ. J. [Dkt. 25] at 11-14. True, "the case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Luterans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir 2003). But non-statutory claims may also be precluded and the standard for determining whether non-statutory review is limited is the same as under the APA. *See Dart*, 848 F.2d at 221 ("If the wording of a preclusion clause is less than absolute, the presumption of judicial review . . . is favored when an agency is charged with acting beyond its authority."). Thus, the analysis and outcome are the same.

"Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with other factors." *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015) (citing *Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992)). Futility applies where exhaustion would be "clearly useless," such as where the agency "has indicated that it does not have jurisdiction over the dispute, or because it has evidenced a strong stand on the issue in question and an unwillingness to reconsider the issue." *Randolph-Sheppard Vendors v. Weinberger*, 795 F.2d 90, 106 (D.C. Cir. 1986). That said, the ordinary standard for futility in administrative law cases is inapplicable 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"). In the context of Medicare, courts also look to 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." *Nat'l Ass'n for Home Care & Hospice*, 77 F. Supp. 3d at 111 (citing *Tataranowicz*, 959 F.2d at 275); *see also Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 72, 75 (D.D.C. 2018), *appeal docketed*, No. 19-5048 (D.C. Cir. Feb. 28 2019).

Consideration of these factors makes clear that requiring Plaintiffs to exhaust their administrative remedies here would be a "wholly formalistic" exercise in futility. *Tataranowicz*, 959 F.2d at 274. The government does not argue that further administrative review is necessary for the agency's efficient functioning. Nor does the government argue that administrative review will give the agency the opportunity to self-correct. To the contrary, CMS' interpretation here is "even more embedded" since it was promulgated through notice-and-comment rulemaking whereby CMS has already considered and rejected Plaintiffs' specific arguments. *Nat'l Ass'n for*

Home Care & Hospice, 77 F. Supp. 3d at 112; Final Rule at 59,011-13. Finally, additional administrative review would do nothing to develop the factual record or provide the Court with further benefits of agency expertise, since this case concerns a purely legal challenge to the scope of the Secretary's statutory authority. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 23-24 (D.D.C. 2009) ("[E]xhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law." (internal quotations omitted)). Indeed, it does not appear that further expertise can be brought to bear since no administrative review body has the authority to override CMS' binding regulations. *See* 42 C.F.R. § 405.1063(a) ("All laws and regulations pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council."); *see, e.g.*, Noridian Healthcare Solutions, *G0463 Has No Appeal Rights* (Mar. 22, 2019), *available at* http://bit.ly/2K2Yw4W ("CMS has provided direction to the Medicare Administrative Contractors (MACs) to dismiss requests appealing the reimbursement of HCPCS G0463. No further appeal rights will be granted at subsequent levels due to the statutory guidance supporting the pricing of this HCPCS code."). In short, the government "gives no reason to believe that the agency machinery might accede to plaintiffs' claims," even as it recites the formal steps involved in administrative review. *Tataranowicz*, 959 F.2d at 274.

B. The Outpatient Prospective Payment System Statutory Scheme

Plaintiffs argue that if CMS wants to reduce the payment rate for a particular OPD service, it must change the relative payment weights and adjustments through the annual review process, *see* 42 U.S.C. § 1395*l*(t)(9)(A), in a budget neutral manner, *see id.* § 1395*l*(t)(9)(B). Alternatively, if CMS wants to reduce Medicare costs by addressing "unnecessary increases in the volume of services," it must first develop a method to do so, *id.* § 1395*l*(t)(2)(F), which it may then implement across-the-board by adjusting the conversion factor, *see id.*

§ 1395*l*(t)(9)(C). This statutory scheme, Plaintiffs argue, is intended to prevent exactly what happened here: a selective cut to Medicare funding which targets only certain services and providers.

The government responds that CMS has authority to "develop a method for controlling unnecessary increases" in volume under paragraph (t)(2)(F) and that this authority is independent of its authority under paragraph (t)(9)(C) to adjust the conversion factor. It argues that these two actions are different and independent cost-control tools in its regulatory belt. Further, the government argues that CMS may develop a "method" to set payment rates for a particular service which is causing an "unnecessary" increase in cost (and volume) without regard to budget neutrality, because there is no logical reason Congress would want CMS to penalize all outpatient departments—by reducing rates for all OPD services—for the spike in volume (as measured by total expenditures) if only one such service caused the spike.

The government emphasizes that "method" is not explicitly defined in the statute and argues that its approach satisfies generic definitions of the term. *See, e.g.*, *Method*, Black's Law Dictionary (11th ed. 2019) ("A mode of organizing, operating, or performing something, esp. to achieve a goal."). But "reasonable statutory interpretation must account for both 'the specific context in which . . . language is used' and 'the broader context of the statute as a whole.'" *Util. Air Regulatory Grp.*, 573 U.S. at 321 (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). "A statutory 'provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.'" *Id.* (quoting *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)); *see also King v. Burwell*, 135 S. Ct. 2480, 2483 (2015) ("[O]ftentimes the meaning—or ambiguity—of

certain words or phrases may only become evident when placed in context.”). As such, the Court must “read the words ‘in their context and with a view to their place in the overall statutory scheme.’” *King*, 135 S. Ct. at 2483 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)); *see also Util. Air Regulatory Grp.*, 573 U.S. at 320. That context does not make clear what a “method” is, but it does make clear what a “method” is *not*: it is not a price-setting tool, and the government’s effort to wield it in such a manner is manifestly inconsistent with the statutory scheme. There are two reasons.

First, Congress established an elaborate statutory scheme which spelled out each step for determining the amount of payment for OPD services under the Outpatient Prospective Payment System. As detailed in 42 U.S.C. § 1395*l*(t)(4), titled “Medicare payment amount,” the amount paid “is determined” by: the fee schedule amount “computed under paragraph (3)(D)” for the OPD service’s Ambulatory Payment Classification, adjusted for wages and other factors “as computed under paragraphs (2)(D) and (2)(E),” *see* 42 U.S.C. § 1395*l*(t)(4)(A); less applicable deductibles under § 1395*l*(b), *see id.* § 1395*l*(t)(4)(B); and modified by a “payment proportion,” *see id.* § 1395*l*(t)(4)(C). The applicable deductible and “payment proportion” are fixed by statute and are not relevant to this case, but the Ambulatory Payment Classification fee schedule amount is. That amount is the product of the conversion factor “computed under subparagraph [(3)(C)]” and the relative payment weight for the Ambulatory Payment Classification “determined under paragraph (2)(C).” *See id.* § 1395*l*(t)(3)(D). The base ingredients of an Outpatient Prospective Payment System payment over which CMS has discretion are, therefore, the Ambulatory Payment Classification groups and relative payment weights; the conversion factor; and the wage adjustment and other adjustments.

The Court recounts these cross-referencing provisions—even the irrelevant ones—to make one thing clear: nowhere is a "method" developed under paragraph (t)(2)(F) referenced. CMS cannot shoehorn a "method" into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference. *See Util. Air Regulatory Grp.*, 573 U.S. at 328. ("We reaffirm the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."). As such, if CMS wishes to reduce Outpatient Prospective Payment System payments for E&M services, it must make budget-neutral adjustments to either that service's relative payment weight or to other adjustments under paragraph (t)(9)(A). Alternatively, CMS may update the conversion factor to apply across-the-board cuts under paragraph (t)(9)(C). But nothing in the adjustment or payment scheme permits service-specific, non-budget-neutral cuts.

CMS apparently understood this limitation when it considered other "methods" in the past. For example, when the Outpatient Prospective Payment System was first being developed in 1998, CMS evaluated three possible methods of volume control, all based on the Sustainable Growth Rate formula which was enacted by Congress to control the growth of "physician services" under, ironically, the Physician Fee Schedule, which is itself also a prospective payment system. *See* 63 Fed. Reg. at 47,586. Much like payment rates for OPD services under the Outpatient Prospective Payment System, payment rates for physician services are prospectively set through a combination of relative resource use, regional adjustments, and an across-the-board Physician Fee Schedule conversion factor. The Sustainable Growth Rate formula set overall target expenditure levels for physician services based on changes in enrollment, changes in physician fees, changes in the legal and regulatory landscape, and total economic growth, and then manipulated the Physician Fee Schedule conversion factor to achieve

that targeted level. Two of CMS' proposals in 1998 would have modified the Sustainable Growth Rate formula to also account for a measure of OPD service efficiency as well, while the third proposal would have developed a similar, independent formula for the Outpatient Prospective Payment System. All three proposals would have operated through updates to the relevant conversion factors under paragraph (t)(9)(C).[8] *Id.* at 47,586-87. None of these methods, based upon a conversion factor calculated using a Sustainable Growth Rate formula, was implemented. *See* Final Rule at 59,005.

Instead, CMS considered and implemented a different method of volume control known as "packaging," whereby "ancillary services associated with a significant procedure" are "packaged into a single payment for the procedure." 72 Fed. Reg. 66,580, 66,610 (Nov. 27, 2007); *see also* Final Rule at 58,854 ("Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging . . . has been a fundamental part of OPPS since its implementation in August 2000."). Packaging incentivizes providers "to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment." 72 Fed. Reg. at 66,611; *see also* 63 Fed. Reg. at 47,586 ("We believe that greater packaging of these services might provide volume control."); 79 Fed. Reg. 66,770, 66,798-99 (Nov. 10, 2014) (introducing conceptually similar "comprehensive APCs"). Unlike the proposed methods based on a Sustainable Growth Rate formula that were considered in 1998, packaging does not control

[8] Plaintiffs argue that here CMS acknowledged "possible legislative modification" would be necessary to implement any method other than adjustment to the conversion factor. *See* Mem. of P. & A. in Supp. of Pls.' Mot. for Summ. J. [Dkt. 14-1] at 15; *see also* 63 Fed. Reg. at 47,586. As noted in the text, all three "methods" proposed in 1998 would have adjusted the conversion factor. Possible legislative modification was discussed because, for two of the proposed methods, CMS did not itself have the authority to modify the Sustainable Growth Rate, which Congress implemented by statute. *See* 42 U.S.C. 1395w-4(f) (1999)).

volume by changing the conversion factor and thereby obviates the need to rely on paragraph (t)(9)(C), and packaging is implemented in a budget neutral manner. *See, e.g.*, 72 Fed. Reg. at 66,615 ("Because the OPPS is a budget neutral payment system[,] . . . the effects of the packaging changes we proposed resulted in changes to scaled weights and . . . to the proposed payments rates for all separately paid procedures."); *cf.* 42 U.S.C. § 1395*l*(t)(9)(A)-(B).

This history makes it clear that CMS can adopt volume-control methods under paragraph (t)(2)(F) which affect payment rates indirectly, even if those methods cannot affect them directly. Moreover, it demonstrates that the Court's interpretation does not render paragraph (t)(2)(F) mere surplusage, since some methods do not depend on manipulation of the conversion factor.

Second, Congress provided great detail in directing how CMS should develop and adjust relative payment weights. For example, Congress required that the initial relative payment weights for OPD services be rooted in verifiable data and cost reports. *Id.* § 1395*l*(t)(2)(C). Congress also required CMS to develop a wage adjustment attributable to geographic labor and labor-related costs, *id.* § 1395*l*(t)(2)(D); an outlier adjustment to reimburse hospitals for particularly expensive patients, *id.* § 1395*l*(t)(2)(E) and (t)(5) (detailing further the outlier adjustment); a transitional pass-through payment scheme for innovative medical devices, drugs, and biologicals, *id.* § 1395*l*(t)(2)(E) and (t)(6) (detailing further the pass-through adjustment); and catch-all "other adjustments as determined to be necessary to ensure equitable payments," *id.* § 1395*l*(t)(2)(E). This extraordinarily detailed scheme results in a relative payment system which ensures that payments for one service are rationally connected to the payments for another and satisfies specific policies considered by Congress. And so that this system retains its integrity, CMS is required to review annually the relative payment weights of

OPD services and their adjustments based on changes in cost data, medical practices and technology, and other relevant information. *See id*. § 1395*l*(t)(9)(A). Further, CMS is required to consult with "an expert outside advisory panel" to ensure the "clinical integrity of the groups and weights." *Id.*

Congress also required that adjustments to the Outpatient Prospective Payment System be made in a budget-neutral fashion (with specified exceptions). Congress itself set the first conversion factor so that the estimated expenditures for the first year of payments under the Outpatient Prospective Payment System would match estimated expenditures for the same year under the previous system. *Id.* § 1395*l*(t)(3)(C)(i). Congress further specified that the wage adjustment, outlier adjustment, pass-through adjustment, and the "other adjustments" all be budget neutral. *Id.* § 1395*l*(t)(2)(D)-(E). And Congress directed CMS to make any changes to the groups, their relative payment weights, or the adjustments resulting from its mandatory annual review in a budget-neutral fashion. *Id.* § 1395*l*(t)(9)(B).

Notwithstanding this granularity in the statute, CMS posits that in a single sentence Congress granted it parallel authority to set payment rates in its discretion that are neither relative nor budget neutral. *Cf. id.* § 1395*l*(t)(2)(F). But "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001); *cf. Air Alliance Houston v. EPA*, 906 F.3d 1049, 1061 (D.C. Cir. 2018) ("[I]t is well established that an agency may not circumvent specific statutory limits on its actions by relying on separate, general rulemaking authority."). If CMS reads the statute correctly, its new-found authority would supersede Congress' carefully crafted relative payment system by severing the connection between a service's payment rate and its relative resource use. In the context of the

similarly-designed Physician Fee Schedule system, Congress expressly denounced this disconnect. *See* H.R. Rep. No. 105-149, at 1347-48 (1997) ("As a result, relative value units have become seriously distorted. This distortion violates the basic principle underlying the resource-based relative value scale (RBRVS), namely that each services [sic] should be paid the same amount regardless of the patient or service to which it is attached."). Further, the structure of the Outpatient Prospective Payment System makes clear that Congress intended to preserve "the clinical integrity of the groups and weights." 42 U.S.C. § 1395*l*(t)(9)(A). There is no reason to think that Congress with one hand granted CMS the authority to upend such a "basic principle" of the Outpatient Prospective Payment System while working with the other to preserve it.[9]

The government also argues that Congress knew how to require budget neutrality when it wanted to, and that its silence in the context of paragraph (t)(2)(F) is telling. Not only does this argument fail to address damage to the integrity of the relative payment system, but in the context of the Outpatient Prospective Payment System, the reverse is also true: for decisions within CMS' discretion that might affect overall expenditures, Congress made clear when budget neutrality was *not* required. *See id.* § 1395*l*(t)(7)(I) (exempting transitional payments from budget neutrality); *id.* § 1395*l*(t)(16)(D)(iii) (exempting special payments from budget neutrality); *id.* § 1395*l*(t)(20) (exempting the effects of certain incentives from budget neutrality); *cf. id.* § 1395*l*(t)(3)(C) (permitting negative conversion factors); *id.* § 1395*l*(t)(14)(H) (exempting specific expenditure increases from consideration under paragraph (t)(9)). As CMS

[9] CMS' interpretation would also swallow paragraph (t)(9)(C) in its entirety: why would the agency go through the annual hassle of updating the conversion factor if it could use paragraph (t)(2)(F) to decrease or increase payment rates for disfavored or favored services whenever desired?

has said, "the OPPS is a budget neutral payment system." 72 Fed. Reg. at 66,615. Given how pervasively the statute requires budget neutrality in the Outpatient Prospective Payment System, Congress clearly considered effects on total expenditures critical to that system. Yet Congress did not mention the budgetary impact of paragraph (t)(2)(F) at all. The Court concludes that no such reference was made because Congress did not intend CMS to use an untethered "method" to directly alter expenditures independent of other processes. To the contrary, Congress directed that any "methods" developed under paragraph (t)(2)(F) be implemented through other provisions of the statute.[10]

Finally, the government argues that there is no reason Congress would have wanted CMS to penalize all outpatient departments in order to control unnecessary increases in the volume of a single type of service. Of course, that is exactly what Congress did when it applied the Sustainable Growth Rate formula to the Physician Fee Schedule under the Balanced Budget Act of 1997—the same Act which created the Outpatient Prospective Payment System—to disastrous results. *See* Jim Hahn & Janemarie Mulvey, Congressional Research Service, Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System 8 (2012) ("There is a growing consensus among observers that the SGR system is fundamentally flawed and is creating instability in the Medicare program for providers and beneficiaries."); *id.* ("One commonly asserted criticism is that the SGR system treats all services and physicians equally . . . to the detriment of physicians who are 'unduly' penalized."). Congress recognized its error and

[10] Paragraph (t)(9)(C) explicitly provides that methods developed under paragraph (t)(2)(F) may result in adjustments to the conversion factor because subsection (t)(3), governing the conversion factor, does not already provide CMS such authority. *Cf.* 42 U.S.C. § 1395*l*(t)(9)(A) (requiring CMS to review and adjust groups and relative payments weights and adjustments for OPD services). Put another way, the provision is permissive, not mandatory, because CMS may choose to implement its methods through other means.

repealed the Sustainable Growth Rate formula, *see* Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87, and it has demonstrated that it retains for itself the authority to make these and similarly selective funding decisions in this highly complicated intersection of patient needs, medical care, and government funding through the relative payment weight system. *See, e.g.*, Bipartisan Budget Act § 603 (establishing different payment schemes for excepted and non-excepted PBDs). Here, Congress has developed a multi-factored, complicated annual process whereby CMS is to pre-set relative payments for OPD services. This annual process would be totally ignored and circumvented if CMS could unilaterally set OPD service-specific rates without regard to their relative position or budget neutrality.

For these reasons, the Court finds that the "method" developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention. The Court find that the Final Rule is *ultra vires*.[11]

C. Remedies

A brief note on remedies. Plaintiffs not only ask for *vacatur* of the Final Rule, but also for a court order requiring CMS to issue payments improperly withheld due to the Final Rule. Plaintiffs' request will be denied. "'Under settled principles of administrative law, when a court reviewing agency action determines that an 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.'" *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400 (D.C. Cir. 2005) (quoting *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999)). That said,

[11] Because the Court concludes that service-specific unilateral price setting by CMS is not a "method" within the meaning of the statute, the Court does not reach Plaintiffs' other arguments.

Outpatient Prospective Payment System reimbursements are complex and a third set of plaintiffs in another case challenging the same rule has raised the spectre of complications resulting from an order to vacate. *See* Opposition to Defendant's Motion to Stay Proceedings, *Sisters of Charity Hospital of Buffalo, New York v. Azar*, No. 19-1446 (RMC) (July 25, 2019) Dkt. 13. Other courts in this district have wrestled with the ripple effects of *vacatur* caused by Medicare budget neutrality provisions and interest payments. *See Am. Hosp. Ass'n*, 348 F. Supp. 3d at 85-86 (requiring further briefing on remedies related to OPPS adjustments); *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2019 WL 1228061, at *2 (D.D.C. Mar. 15, 2019) (addressing plaintiff-specific interest payments on improper reimbursement determinations); *see also Amgen*, 357 F.3d at 112 ("Other circuits have noted the havoc piecemeal review of OPPS payments could bring about."). The Final Rule is less than one year old and did not apply budget neutrality principles. These factors should lessen the burden on reconsideration. Nonetheless, the Court will require a joint status report to determine if additional briefing is appropriate.

IV. CONCLUSION

CMS believes it is paying millions of taxpayer dollars for patient services in hospital outpatient departments that could be provided at less expense in physician offices. CMS may be correct. But CMS was not authorized to ignore the statutory process for setting payment rates in the Outpatient Prospective Payment System and to lower payments only for certain services performed by certain providers. Plaintiffs' Motion for Summary Judgment, Dkt. 14, will be granted. The government's Cross-Motion for Summary Judgment, Dkt. 20, will be denied. The Court will vacate the applicable portions of the Final Rule and remand the matter for further proceedings consistent with this Memorandum Opinion. The parties will be required to submit a joint status report by October 1, 2019, to determine if additional briefing on remedies

is required, along with the CMS estimate as to the duration of further proceedings. A memorializing Order accompanies this Memorandum Opinion.

Date: September 17, 2019

ROSEMARY M. COLLYER
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, **Plaintiffs,** **v.** **ALEX M. AZAR II,** **Secretary of the Department of Health and Human Services,** **Defendant.**	**Civil Action No. 18-2841 (RMC)**

ORDER

For the reasons articulated in the Memorandum Opinion issued contemporaneously with this Order, it is hereby

ORDERED that Plaintiffs' Motion for Summary Judgment, Dkt. 14, is **GRANTED**; and it is

FURTHER ORDERED that the Secretary's Cross-Motion for Summary Judgment, Dkt. 20, is **DENIED**; and it is

FUTHER ORDERED that the Secretary's Method to Control for Unnecessary Increases in the Volume of Outpatient Services, 83 Fed. Reg. 58,818, 59,004-15 (Nov. 21, 2018) (Section X.B), is **VACATED** and this matter **REMANDED** to the Secretary for further proceedings consistent with the Memorandum Opinion; and it is

FURTHER ORDERED that the parties shall submit a joint status report by no later than October 1, 2019, discussing whether additional briefing regarding remedies is necessary.

Date: September 17, 2019

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ROSEMARY M. COLLYER
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, **Plaintiffs,** **v.** **ALEX M. AZAR II,** **Secretary of the Department of Health and Human Services,** **Defendant.**	)	**Civil Action No. 18-2841 (RMC)**

MEMORANDUM OPINION

Previously, the Court held that the Centers for Medicare & Medicaid Services (CMS) exceeded its statutory authority when it selectively reduced by Final Rule reimbursement rates under the Outpatient Prospective Payment System (OPPS) to off-campus provider-based departments for certain outpatient department (OPD) services. *See Am. Hosp. Ass'n v. Azar*, No. 18-2841, 2019 WL 4451984 (D.D.C. Sept. 17, 2019); 83 Fed. Reg. 58,818 (Nov. 21, 2018) (Final Rule). Specifically, the Court determined that the addition of a non-budget-neutral rate reduction for Evaluation and Management (E&M) services at such facilities—separate from the normal OPPS reimbursement schedule—conflicted with the overall statute. *Am. Hosp. Ass'n*, 2019 WL 4451984, at *8-12. Accordingly, the Court vacated the relevant portions of the Final Rule, left intact the rest of the OPPS reimbursement schedule, and remanded the matter back to the agency for proceedings consistent with its decision. *Id.* at *12. However, given the complexities of setting and administering Medicare payments rates, the Court also ordered the parties to submit a status report to determine if additional briefing was required. *Id.*

CMS now asks the Court to modify its Order and to instead remand the matter to the agency to develop a remedy in the first instance, without vacatur. Alternatively, CMS asks for a 60-day stay of the Order while it considers whether or not to appeal. Plaintiffs oppose.[1] For the reasons below, the Court will neither modify nor stay the Order.

I. ANALYSIS

A. Vacatur

The D.C. Circuit has "made clear that '[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated.'" *Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)). That said, a court has discretion to remand an unlawful rule without vacatur depending on (1) "the seriousness of the [rule]'s deficiencies (and thus the extent of doubt whether the agency chose correctly)" and (2) "the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear-Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). Neither factor is dispositive. "Rather, resolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives." *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 270 (D.D.C. 2015) (*Shands I*).

As to the first factor, CMS "respectfully disagrees" with the Court's decision and maintains that its rate cut was a permissible "method for controlling unnecessary increases in the volume of covered OPD services." *See* 42 U.S.C. § 1395*l*(t)(2)(F). CMS thus argues that there is a live question regarding "whether the agency chose correctly" that may be resolved on appeal.

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[1] *See* 9/17/2019 Order [Dkt. 32]; Mot. to Modify Order (Mot.) [Dkt. 33]; Pls.' Opp'n to Def.'s Mot. to Modify Order [Dkt. 34]; Mem. of the Univ. of Kansas Hosp. Auth. Pls. in Opp'n to Mot. to Modify [Dkt. 35]; Reply in Supp. of Mot. to Modify Order (Reply) [Dkt. 37].

CMS devotes little space to this argument. This factor may weigh in the government's favor when a decision within the agency's discretion was potentially lawful but insufficiently explained. *See Heartland Reg'l Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) ("When an agency may be able readily to cure a defect in its explanation of a decision, the first factor in *Allied-Signal* counsels remand without vacatur."); *see, e.g.*, *Allied Signal*, 988 F.2d at 151 ("It is conceivable that the Commission may be able to explain how the principles supporting an exemption for education institutions do not justify a similar exemption for domestic UF_6 converters."); *cf. Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1, 13 (D.D.C. 2019) (finding a CMS rule could not be justified because the necessary data did not exist). But here the Court determined that CMS put forth an impermissible interpretation of the statutory scheme; no amount of new data or reasoning on remand can save its interpretation. *See Humane Soc'y of the U.S. v. Jewell*, 76 F. Supp. 3d 69, 137 (D.D.C. 2014) ("[T]he Court is certain that the agency cannot arrive at the same conclusions reached in the Final Rule because the actions taken were not statutorily authorized."). Nor does its hope of reversal on appeal help because "[p]ossible success on appeal would weigh against vacatur in every case, given that reversal is always a possibility." *Am. Hosp. Ass'n*, 385 F. Supp. 3d at 13. The first factor clearly favors vacatur.

As to the second factor, CMS argues more forcefully that for several reasons the disruption caused by vacating the rule weighs heavily in favor of remand only. First, CMS contends that without the rule "there is currently no extant methodology under which the Secretary may pay off-campus provider-based departments for the . . . services that the challenged portion of the Rule addressed." Mot. at 5. CMS similarly contends that "there is no methodology available for affected off-campus provider-based departments to calculate appropriate patient co-payments." *Id.*

These contentions fail to convince. Because CMS believed that it had authority to implement the E&M rate reduction independent of its authority to review and adjust OPPS relative payment weights, it developed underlying OPPS reimbursement rates and then tacked the E&M rate reduction on at the end. *See* Final Rule at 59,014 (applying the reduced E&M rates to the "final payment rates" for OPPS). As Plaintiffs describe it, CMS created an exception to OPPS reimbursement rates for only E&M services and only at applicable off-campus provider-based departments; vacating the rate reduction for E&M services at off-campus provider-based departments merely reverted such off-campus provider-based departments to the general rule. Indeed, CMS admits that there are extant OPPS reimbursement rates for *on*-campus provider-based departments which the relevant off-campus provider-based departments would have been subject to but for the Final Rule.[2] *See* Mot. at 6.

Anticipating this, CMS argues that vacatur leaves behind no OPPS reimbursement rates because the rate reduction for E&M services "cannot be severed from the rest of the OPPS rates set forth in the [Final] Rule." *Id.* at 5. The D.C. Circuit has held that "[s]everance and affirmance of a portion of an administrative regulation is improper if there is 'substantial doubt' that the agency would have adopted the severed portion on its own." *Davis Cty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir 1997). CMS asserts that it accounted for its projected $300 million in projected savings when developing the underlying OPPS

[2] CMS argues that payments to off-campus provider-based departments for E&M services would not revert to the general rule because such services have been carved out and reduced. *See* Reply at 3. Only the challenged rate reduction carved E&M services out of the general rule; all other patient services at off-campus provider-based departments continue to be paid at OPPS rates. The rate reduction was vacated as beyond the authority of CMS; therefore, such selected services are no longer carved out and should be paid according to the general rule.

reimbursement rates, and that without the rate reduction for E&M services it might have utilized other statutory means to accomplish the same ends or cut reimbursement rates across the board.

There is not nearly enough evidence to find "'substantial doubt' that the agency would have adopted the severed portion on its own." *Id.* To start, that the rate reduction for E&M services can be so easily severed from the Final Rule as a practical matter strongly suggests that severance is appropriate as a legal matter. *See Am. Petroleum Inst. v. EPA*, 862 F.3d 50, 72 (D.C. Cir. 2017) ("Thus we have severed provisions when 'they operate[d] entirely independently of one another.'") (quoting *Davis Cty.*, 108 F.3d at 1459). That is, unlike other cases, the underlying OPPS reimbursement rates here were not "expressly conditioned" on rate reduction for E&M services. *North Carolina v. FERC*, 730 F.2d 790, 796 (D.C. Cir. 1984). Further, this is not a case where the remaining rule starts to lose meaning without the severed portion. *See MD/DC/DE Broadcasters Ass'n v. FCC*, 253 F.3d 732, 740 (D.C. Cir. 2001) (examining "whether a *statute's* function would be impaired if, after invaliding a portion of an implementing regulation, the Court left the rest of the regulation in place"). Indeed, there is no evidence at all that CMS considered the underlying OPPS reimbursement scheme when it decided to reduce rates for E&M services at off-campus provider-based departments, other than to note that the OPPS reimbursement rates were higher than comparable rates at physician offices. Rather, the reduced rate for E&M services "operate[d] entirely independently" of the underlying OPPS reimbursement scheme and was "not in any way 'intertwined'" with CMS's obligation to review and set those underlying OPPS reimbursement rates. *Davis Cty.*, 108 F.3d at 1459 (quoting *Tel. & Data Sys., Inc. v. FCC*, 19 F.3d 42, 50 (D.C. Cir. 1994)). In fact, that independence was CMS's explanation for why budget neutrality did not apply. *See* Def.'s Opp'n to Pls.' Mot. for Summ. J. & Mem. in Supp. of Mot. to Dismiss or, in the Alternative, Cross-

Mot. for Summ. J. [Dkt. 20-1] at 14-15. Regardless of what CMS hypothetically might have done, nothing in the Final Rule implies that the E&M rate reduction and underlying OPPS reimbursement rates were intended to be inseparable.

The Court further notes that the only material difference between the Proposed Rule and the Final Rule is that CMS chose to implement the rate reduction for E&M services over two years instead of one. *Compare* 83 Fed. Reg. 37,046, 37,143 (July 31, 2018) (Proposed Rule), *with* Final Rule at 59,013-14. CMS thus projected it would save only $300 million due to the Final Rule, or half of the $600 million originally projected. *See* Final Rule at 59,014. Yet CMS did not change the underlying OPPS reimbursement rates in the Final Rule to account for the $300 million shortfall caused by phased implementation. CMS does not explain why the $300 million shortfall caused by vacatur should be treated differently. CMS's silence in the Final Rule indicates that it would have implemented the underlying OPPS reimbursement rates even without a rate reduction for E&M services and also favors vacatur. *Cf. North Carolina*, 730 F.2d at 796 (severing a regulation despite resulting "nominal effects").

Second, CMS argues that vacating the Final Rule would prove disruptive if CMS were to succeed on appeal because, as a practical matter, it would be difficult for CMS to claw back any overpayments due to the administrative costs of doing so. *See* Mot. at 6. However, if CMS were to lose on appeal, this disruption would not come to pass. That may seem obvious, but the point is that CMS's argument has nothing to do with the appropriateness of vacatur in this case, only its timing; CMS's argument better supports its request for a stay pending appeal and is addressed below.[3]

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[3] Although the D.C. Circuit has noted "the havoc that piecemeal review of OPPS payments could bring about," *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004), that havoc is born of the

Finally, CMS argues that the Court should grant CMS the opportunity to develop a remedy in the first instance, in recognition of the "substantial deference that Courts owe to the Secretary in the administration of such a 'complex statutory and regulatory regime.'" *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 366 F. Supp. 3d 32, 54 (D.D.C. 2018) (quoting *Good Samartian Hosp. v. Shalala*, 508 U.S. 402, 404 (1993)); *see also N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012). But in each of the cases cited by CMS, deference was not an independent reason to remand without vacatur. Rather, remand without vacatur was found appropriate only after application of the *Allied-Signal* factors. *See N. Air Cargo*, 674 F.3d at 860-61; *Am. Hosp. Ass'n*, 385 F. Supp. 3d at 12-15; *Shands I*, 139 F. Supp. at 269-70. For the reasons above, those factors do not favor CMS here.

B. Stay of the Order

District courts generally have the authority to stay their orders pending appeal. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); Fed. R. Civ. P. 62(c). But in determining whether to grant a stay, courts consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton*, 481 U.S. at 776. At most, CMS has only hinted at irreparable harm. *But cf. Tataranowicz v. Sullivan*, No. 90-0935, 1991 WL 57005, at *1 (D.D.C. Feb. 26, 1991) (finding disbursement of

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prospective and budget neutral elements of the statutory scheme, neither of which is implicated here. Vacating the select rate reduction does not directly affect the broader reimbursement scheme. *Cf. Am. Hosp. Ass'n*, 385 F. Supp. 3d at 12-15 (declining to vacate an *ultra vires* budget neutral rule).

Medicare payments and administrative costs of recoupment are not irreparable harm). It has completely ignored the other factors. Without more, CMS has not satisfied its burden.

II. CONCLUSION

The *ultra vires* consequences of the Final Rule are not so complex that they cannot be directly redressed or undone. Vacatur and remand are the correct remedies and CMS has not established that a stay is appropriate at this time. The government's Motion to Modify Order, Dkt. 33, will be denied. The Court will enter final judgment. A memorializing Order accompanies this Memorandum Opinion.

Date: October 21, 2019

ROSEMARY M. COLLYER
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, **Plaintiffs,** **v.** **ALEX M. AZAR II,** **Secretary of the Department of Health and Human Services,** **Defendant.**	)	**Civil Action No. 18-2841 (RMC)**

ORDER

For the reasons in the Memorandum Opinion issued contemporaneously with this Order, it is hereby

ORDERED that Defendant's Motion to Modify Order, Dkt. 33, is **DENIED**.

This is a final appealable Order. *See* Fed. R. App. P. 4. This case is closed.

Date: October 21, 2019

ROSEMARY M. COLLYER
United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that on January 23, 2020, I electronically filed the foregoing joint appendix with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Alisa B. Klein
Alisa B. Klein