Page 1 of 180

USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 [ORAL ARGUMENT NOT SCHEDULED]

No. 17-5018

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

AMERICAN HOSPITAL ASSOCIATION; BAXTER REGIONAL HOSPITAL, INC., d/b/a BAXTER REGIONAL MEDICAL CENTER; RUTLAND HOSPITAL, INC., d/b/a RUTLAND REGIONAL MEDICAL CENTER; COVENANT HEALTH,

Plaintiffs-Appellees,

v.

THOMAS E. PRICE, M.D., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant-Appellant.

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

JOINT APPENDIX

CATHERINE E. STETSON MORGAN L. GOODSPEED HOGAN LOVELLS US LLP 555 Thirteenth Street, N.W. Washington, D.C. 20004 (202) 637-5600

MARK B. STERN JOSHUA M. SALZMAN Attorneys, Appellate Staff Civil Division, Room 7258 U.S. Department of Justice 950 Pennsylvania Ave., N.W. Washington, D.C. 20530 (202) 532-4747

Counsel for Appellees

Counsel for Appellant

JOINT APPENDIX TABLE OF CONTENTS

Page(s)

District Court Docket EntriesJA1
Complaint and Exhibit (Dkt. No. 1)JA11
Declaration of Ivan Holleman (Dkt. No. 8-11)JA36
Declaration of John Geppi (Dkt. No. 8-12)JA40
Declaration of Caroline Steinberg (Dkt. No. 8-13)JA45
Declaration of John Wallace and Exhibits (Dkt. Nos. 8-14 to 8-17)JA49
Declaration of Nancy J. Griswold and Exhibit (Dkt. Nos. 12-1 to 12-2)JA79
Declaration of Ellen Murray and Exhibit (Dkt. No. 30-1)JA88
Order Denying Stay (Dkt. No. 37)JA114
Memorandum Opinion Denying Stay (Dkt. No. 38)JA115
Proposed Order Submitted With Plaintiffs' Motion For Summary Judgment (Dkt. No. 39-1)JA131
Defendant's Motion For Summary Judgment (Dkt. No. 41)JA133
Supplemental Declaration of Ellen Murray and Exhibits (Dkt. No. 41-1) (excerpts)JA136
Order Granting Mandamus (Dkt. No. 47)JA160
Memorandum Opinion Granting Plaintiffs' Motion For Summary Judgment (Dkt. No. 48)JA161

Second Supplemental Declaration of	
Ellen Murray (Dkt. No. 49-1)	JA168
	-
Order Denying Reconsideration (Dkt. No. 52)	JA172
	5
Notice of Appeal (Jan. 30, 2017)	IA175

Filed: 02/21/2017 Page 4 of 180

APPEAL, CLOSED, TYPE-E

U.S. District Court District of Columbia (Washington, DC) CIVIL DOCKET FOR CASE #: 1:14-cv-00851-JEB

AMERICAN HOSPITAL ASSOCIATION et al v. SEBELIUS Assigned to: Judge James E. Boasberg Case: <u>1:16-cv-02521-JEB</u> Case in other court: USCA, 15-05015 USCA, 17-05018 Cause: 28:1361 Petition for Writ of Mandamus

<u>Plaintiff</u>

AMERICAN HOSPITAL ASSOCIATION

Date Filed: 05/22/2014 Date Terminated: 12/05/2016 Jury Demand: None Nature of Suit: 890 Other Statutory Actions Jurisdiction: U.S. Government Defendant

represented by Adam K. Levin

HOGAN LOVELLS US LLP 555 13th Street, NW Washington, DC 20004 (202) 637-6846 Fax: (202) 637-5910 Email: adam.levin@hoganlovells.com LEAD ATTORNEY ATTORNEY TO BE NOTICED

Catherine Emily Stetson

HOGAN LOVELLS US LLP 555 13th Street, NW Washington, DC 20004-1109 (202) 637-5491 Fax: 202-637-5910 Email: cate.stetson@hoganlovells.com LEAD ATTORNEY ATTORNEY TO BE NOTICED

Jaclyn Lee DiLauro

HOGAN LOVELLS, LLP 555 13th Street, NW Washington, DC 20004 (202) 637-5600 Email: jaclyn.dilauro@hoganlovells.com *TERMINATED: 05/20/2016*

<u>Plaintiff</u>

BAXTER REGIONAL HOSPITAL,

represented by Adam K. Levin

JA1

Filed: 02/21/2017 Page 5 of 180

INC.

doing business as BAXTER REGIONAL MEDICAL CENTER (See above for address) LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Catherine Emily Stetson

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Jaclyn Lee DiLauro

(See above for address) *TERMINATED: 05/20/2016*

Plaintiff

RUTLAND HOSPITAL, INC.

doing business as RUTLAND REGIONAL MEDICAL CENTER

represented by Adam K. Levin

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Catherine Emily Stetson

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Jaclyn Lee DiLauro

(See above for address) *TERMINATED: 05/20/2016*

<u>Plaintiff</u> COVENANT HEALTH

represented by Adam K. Levin

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Catherine Emily Stetson

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Jaclyn Lee DiLauro

(See above for address) *TERMINATED: 05/20/2016*

V.

<u>Defendant</u>

KATHLEEN SEBELIUS

in her official capacity as SECRETARY

represented by Caroline Lewis Wolverton U.S. Department of Justice

JA2

https://ecf.dcd.uscourts.gov/cgi-bin/DktRpt.pl?894546353269488-L 1 0-1

Filed: 02/21/2017 Page 6 of 180

OF HEALTH AND HUMAN SERVICES

Civil Division 20 Massachusetts Ave., NW Suite 7150 Washington, DC 20001 (202) 514-0265 Fax: (202) 616-8470 Email: caroline.lewiswolverton@usdoj.gov LEAD ATTORNEY ATTORNEY TO BE NOTICED

Amicus

FUND FOR ACCESS TO INPATIENT REHABILITATION *agent of* FAIR FUND

represented by Ronald S. Connelly

POWERS, PYLES, SUTTER & VERVILLE 1501 M Street, NW 7th Floor Washington, DC 20005 (202) 872-6762 Fax: (202) 785-1756 Email: ron.connelly@ppsv.com LEAD ATTORNEY ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
05/22/2014	<u>1</u>	COMPLAINT against KATHLEEN SEBELIUS (Filing fee \$ 400 receipt number 0090-3724776) filed by COVENANT HEALTH, RUTLAND HOSPITAL, INC., AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC (Attachments: # 1 Exhibit, # 2 Summons, # 3 Summons, # 4 Summons)(Levin, Adam) (Additional attachment(s) added on 5/23/2014: # 5 Civil Cover Sheet) (kb). (Entered: 05/22/2014)
05/22/2014	<u>2</u>	Corporate Disclosure Statement by AMERICAN HOSPITAL ASSOCIATION. (Levin, Adam) Modified on 5/23/2014 (kb). (Entered: 05/22/2014)
05/22/2014	<u>3</u>	Corporate Disclosure Statement by BAXTER REGIONAL HOSPITAL, INC (Levin, Adam) Modified on 5/23/2014 (kb,). (Entered: 05/22/2014)
05/22/2014	<u>4</u>	Corporate Disclosure Statement by COVENANT HEALTH. (Levin, Adam) Modified on 5/23/2014 (kb). (Entered: 05/22/2014)
05/22/2014	<u>5</u>	Corporate Disclosure Statement by RUTLAND HOSPITAL, INC (Levin, Adam) Modified on 5/23/2014 (kb,). (Entered: 05/22/2014)
05/22/2014		Case Assigned to Judge James E. Boasberg. (kb) (Entered: 05/23/2014)
05/27/2014	<u>6</u>	SUMMONS (3) ISSUED ELECTRONICALLY as to KATHLEEN SEBELIUS, U.S. Attorney and U.S. Attorney General (Attachments: # <u>1</u> Summons 2nd, # <u>2</u> Summons 3rd, # <u>3</u> Notice of Consent, # <u>4</u> Consent Form)

USCA Case	#17-	5018	Document	#1662307	Filed: 02/21/2017	7 Page 7 of 180	
		(md,)	(Entered: 05/2	27/2014)			
06/05/2014	<u>7</u>	KATH SERV Attorn 5/28/1 Execut Attorn	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. KATHLEEN SEBELIUS served on 5/28/2014, RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 5/28/14., RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 5/28/2014. (Answer due for ALL FEDERAL DEFENDANTS by 7/27/2014.) (Levin, Adam) (Entered: 06/05/2014)				
07/11/2014	<u>8</u>	ASSO HEAL Exhibi 7, # <u>8</u> Declar Declar Exhibi	CIATION, BATH, RUTLAN t 2, $\# 3$ Exhibit Exhibit 8, $\# 9$ ation of Ivan H ation of Carolit t A to Decl. of	AXTER REGIC ND HOSPITAL t 3, $\# \underline{4}$ Exhibit Exhibit 9, $\# \underline{10}$ Holleman, $\# \underline{12}$ ine Steinberg, $\#$ J. Wallace, $\# \underline{12}$	by AMERICAN HOSP DNAL HOSPITAL, INC. , INC. (Attachments: # 24, # <u>5</u> Exhibit 5, # <u>6</u> E Declaration of Adam H Declaration of John Ge <u>4 14</u> Declaration of Joh <u>16</u> Exhibit B to Decl. o <u>18</u> Text of Proposed Or	C., COVENANT 1 Exhibit 1, # 2 xhibit 6, # 7 Exhibit X. Levin, # <u>11</u> eppi, # <u>13</u> n Wallace, # <u>15</u> f J. Wallace, # <u>17</u>	
07/21/2014	<u>9</u>	Motion	ı for Summary	Judgment by H	<i>Respond to Complaint</i> XATHLEEN SEBELIU a, Caroline) (Entered: 0	US (Attachments: $\# \underline{1}$	
07/22/2014	<u>10</u>	<i>and Pl</i> HOSP COVE	<i>aintiffs' Motio</i> ITAL ASSOC NANT HEAL	n for Summary IATION, BAX TH, RUTLAN	ension of Time to <i>Resp Judgment</i> filed by AM TER REGIONAL HO D HOSPITAL, INC (am) (Entered: 07/22/20	ERICAN SPITAL, INC., Attachments: # <u>1</u>	
07/22/2014		Respon Court Motion	nd to Complair ORDERS that 1 for Summary	nt and Plaintiff Defendant sha Judgment on 6	efendant's <u>9</u> Motion for 's Motion for Summary Il respond to the Comp or before September 11 014. (lcjeb3) (Entered:	Judgment. The laint and to Plaintiffs' , 2014. Signed by	
07/23/2014			n for Summary		l respond to the Compl or before 9/11/2014. (a		
08/29/2014	<u>11</u>	ASSO HEAL	CIATION, BA TH, RUTLAN	XTER REGIC	Ile by AMERICAN HC NAL HOSPITAL, INC , INC. (Attachments: # 29/2014)	C., COVENANT	
08/29/2014		The Co opposi	ourt ORDERS tion to Defend	that the Plainti lant's forthcom	ties' Joint <u>11</u> Motion fo iffs shall file a consolid ing Motion to Dismiss udgment, not to exceed	ated brief in and reply in support	

USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 8 of 180

		or before October 2, 2014; and Defendant shall file a reply brief in support of her forthcoming Motion to Dismiss on or before October 17, 2014. Signed by Judge James E. Boasberg on 08/29/14. (lcjeb1) (Entered: 08/29/2014)
08/29/2014		Set/Reset Deadlines: The Plaintiffs shall file a consolidated brief in opposition to Defendant's forthcoming Motion to Dismiss and reply in support of Plaintiffs' Motion for Summary Judgment, not to exceed forty-five pages, on or before 10/02/2014; and Defendant shall file a reply brief in support of her forthcoming Motion to Dismiss on or before 10/17/2014. (ad) (Entered: 08/29/2014)
09/11/2014	<u>12</u>	MOTION to Dismiss for Lack of Jurisdiction by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Declaration Declaration of Nancy J. Griswold, # <u>2</u> Exhibit Ex. 1 to Griswold Declaration, # <u>3</u> Exhibit Exhibit 2 to Griswold Declaration, # <u>4</u> Declaration Declaration of Constance B. Tobias, # <u>5</u> Exhibit Exhibit to Tobias Declaration, # <u>6</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 09/11/2014)
09/11/2014	<u>13</u>	Memorandum in opposition to re <u>8</u> MOTION for Summary Judgment filed by KATHLEEN SEBELIUS. (Attachments: # <u>1</u> Declaration Declaration of Nancy J. Griswold, # <u>2</u> Exhibit Exhibit 1 to Griswold Declaration, # <u>3</u> Exhibit Exhibit 2 to Griswold Declaration, # <u>4</u> Declaration Declaration of Constance B. Tobias, # <u>5</u> Exhibit Exhibit to Tobias Declaration, # <u>6</u> Text of Proposed Order) (Wolverton, Caroline) (Entered: 09/11/2014)
10/02/2014	<u>14</u>	Memorandum in opposition to re <u>12</u> MOTION to Dismiss for Lack of Jurisdiction filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Levin, Adam) (Entered: 10/02/2014)
10/02/2014	<u>15</u>	REPLY to opposition to motion re <u>8</u> MOTION for Summary Judgment filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Levin, Adam) (Entered: 10/02/2014)
10/02/2014	<u>16</u>	Unopposed MOTION for Leave to File <i>Amicus Curiae Brief</i> by FUND FOR ACCESS TO INPATIENT REHABILITATION (Attachments: # <u>1</u> Amicus Curiae Brief, # <u>2</u> Exhibit 1 to amicus brief, # <u>3</u> Exhibit 2 to amicus brief, # <u>4</u> Exhibit 3 to amicus brief, # <u>5</u> Exhibit 4 to amicus brief, # <u>6</u> Text of Proposed Order)(Connelly, Ronald) (Entered: 10/02/2014)
10/02/2014	<u>17</u>	Amicus Curiae APPEARANCE entered by Ronald S. Connelly on behalf of FUND FOR ACCESS TO INPATIENT REHABILITATION. (Connelly, Ronald) (Entered: 10/02/2014)
10/03/2014		MINUTE ORDER: The Court ORDERS that the <u>16</u> Motion for Leave to File an <i>Amicus Curiae</i> Brief by the Fund for Access to Inpatient Rehabilitation is GRANTED. Signed by Judge James E. Boasberg on 10/03/14. (lcjeb3) (Entered: 10/03/2014)
10/03/2014	18	AMICUS BRIEF by FUND FOR ACCESS TO INPATIENT

USCA Case #17-5018

Page 9 of 180

Filed: 02/21/2017

REHABILITATION. (td,) (Entered: 10/06/2014) 10/17/2014 19 REPLY to opposition to motion re 12 MOTION to Dismiss for Lack of Jurisdiction filed by KATHLEEN SEBELIUS. (Attachments: #1 Exhibit Ex. 1, Decl. of Nancy J. Griswold, Lessler v Burwell, # 2 Exhibit Ex. 2, Decl. of Lester D Cash)(Wolverton, Caroline) (Entered: 10/17/2014) 12/18/2014 ORDER: The Court ORDERS that: (1) Defendant's 12 Motion to Dismiss is 20 GRANTED; (2) Plaintiffs' 8 Motion for Summary Judgment is DENIED; and (3) Judgment is ENTERED in favor of Defendant. Signed by Judge James E. Boasberg on 12/18/14. (lcjeb2) (Entered: 12/18/2014) 12/18/2014 21 MEMORANDUM AND OPINION re 20 Motion to Dismiss. Signed by Judge James E. Boasberg on 12/18/14. (lcjeb2) (Entered: 12/18/2014) 01/16/2015 22 NOTICE OF APPEAL TO DC CIRCUIT COURT as to 20 Order on Motion to Dismiss/Lack of Jurisdiction, by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC.. Filing fee \$ 505, receipt number 0090-3966037. Fee Status: Fee Paid. Parties have been notified. (Levin, Adam) (Entered: 01/16/2015) 01/20/2015 23 Transmission of the Notice of Appeal, Order Appealed, and Docket Sheet to US Court of Appeals. The Court of Appeals fee was paid this date 1/16/15 re 22 Notice of Appeal to DC Circuit Court, (td,) (Entered: 01/20/2015) 01/21/2015 USCA Case Number 15-5015 for 22 Notice of Appeal to DC Circuit Court, filed by AMERICAN HOSPITAL ASSOCIATION, RUTLAND HOSPITAL, INC., COVENANT HEALTH, BAXTER REGIONAL HOSPITAL, INC.. (rd) (Entered: 01/22/2015) 04/04/2016 MINUTE ORDER: The Court ORDERS that a status conference is set for April 11, 2016, at 10:00 a.m. in Courtroom 19. Signed by Judge James E. Boasberg on 4/4/16. (lcjeb3) (Entered: 04/04/2016) 04/04/2016 Set/Reset Hearings: A Status Conference is set for 4/11/2016, at 10:00 AM, in Courtroom 19, before Judge James E. Boasberg. (ad) (Entered: 04/04/2016) MANDATE of USCA (certified copy) ORDERED and ADJUDGED that the 04/04/2016 26 judgment of the District Court appealed from in this cause is hereby reversed and the case is remanded for further proceedings, in accordance with the opinion of the court filed herein this date as to 22 Notice of Appeal to DC Circuit Court, filed by AMERICAN HOSPITAL ASSOCIATION, RUTLAND HOSPITAL, INC., COVENANT HEALTH, BAXTER REGIONAL HOSPITAL, INC. USCA Case Number 15-5015. (zrdj) (Entered: 04/07/2016) 04/06/2016 24 NOTICE of Appearance by Jaclyn Lee DiLauro on behalf of All Plaintiffs (Attachments: #1 Certificate of Service)(DiLauro, Jaclyn) (Entered: 04/06/2016) 25 04/06/2016 NOTICE of Appearance by Catherine E. Stetson on behalf of All Plaintiffs (Attachments: #1 Certificate of Service)(Stetson, Catherine) (Entered:

Document #1662307

Filed: 02/21/2017 Page 10 of 180

		04/06/2016)
04/11/2016		MINUTE ORDER: As discussed at today's status hearing, the Court ORDERS that Defendant shall file its Motion by May 20, 2016, with Plaintiffs' Opposition due by June 6, 2016, and Defendant's Reply by June 16, 2016. Signed by Judge James E. Boasberg on 4/11/16. (lcjeb3) (Entered: 04/11/2016)
04/11/2016		Minute Entry for proceedings held before Judge James E. Boasberg: Status Conference held on 4/11/2016. (Defendant shall file its Motion by 5/20/2016, with Plaintiffs' Opposition due by 6/06/2016, and Defendant's Reply by 6/16/2016). (Court Reporter Lisa Griffith) (ad) (Entered: 04/11/2016)
05/19/2016	<u>27</u>	MOTION for Extension of Time to File <i>Motion</i> by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 05/19/2016)
05/19/2016	<u>28</u>	RESPONSE re 27 MOTION for Extension of Time to File <i>Motion</i> filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Stetson, Catherine) (Entered: 05/19/2016)
05/19/2016		MINUTE ORDER: The Court ORDERS that Defendant's <u>27</u> Motion for Extension is GRANTED, and she shall file her Motion by May 25, 2016. Plaintiffs' Opposition shall now be due by June 13, 2016, and Defendant's Reply by June 23, 2016. (Entered: 05/19/2016)
05/20/2016		Set/Reset Deadline: If Plaintiffs oppose Defendant's <u>27</u> Motion, they shall file such opposition by 5/20/2016. (ad) (Entered: 05/20/2016)
05/20/2016	<u>29</u>	NOTICE OF WITHDRAWAL OF APPEARANCE as to AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC Attorney Jaclyn Lee DiLauro terminated. (Stetson, Catherine) (Entered: 05/20/2016)
05/25/2016	<u>30</u>	MOTION to Stay and Memorandum of Points and Authorities in Support by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Declaration of HHS Asst. Secretary Ellen Murray, # <u>2</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 05/25/2016)
06/13/2016	<u>31</u>	MEMORANDUM IN OPPOSITION re <u>30</u> MOTION to Stay <i>and</i> <i>Memorandum of Points and Authorities in Support</i> filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Attachments: # <u>1</u> Text of Proposed Order)(Stetson, Catherine) Modified text/event on 6/14/2016 (ztd). (Entered: 06/13/2016)
06/20/2016	<u>32</u>	Unopposed MOTION for Leave to File <i>Amicus Curiae Brief</i> by FUND FOR ACCESS TO INPATIENT REHABILITATION (Attachments: # <u>1</u> Amicus Curiae Brief, # <u>2</u> Exhibit 1 Zhang Decl., # <u>3</u> Exhibit 2 CMS Letter, # <u>4</u> Exhibit 3 Gittler Decl., # <u>5</u> Exhibit 4 Armstrong Decl., # <u>6</u> LCvR 7.1 Disclosure Statement, # <u>7</u> Text of Proposed Order)(Connelly, Ronald) (Entered: 06/20/2016)

USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 11 of 180

06/21/2016		MINUTE ORDER granting Unopposed <u>32</u> Motion for Leave to File <i>Amicus Brief</i> . The <i>Amicus Brief</i> and Exhibits of the Fund for Access to Inpatient Rehabilitation is deemed FILED. Signed by Judge James E. Boasberg on 6/21/16. (lcjeb3) (Entered: 06/21/2016)
06/21/2016	<u>33</u>	Unopposed MOTION for Extension of Time to File Response/Reply as to <u>30</u> MOTION to Stay <i>and Memorandum of Points and Authorities in Support</i> by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Text of Proposed Order) (Wolverton, Caroline) (Entered: 06/21/2016)
06/21/2016	<u>34</u>	AMICUS BRIEF by FUND FOR ACCESS TO INPATIENT REHABILITATION. (td) (Entered: 06/22/2016)
06/21/2016	<u>35</u>	Corporate Disclosure Statement by FUND FOR ACCESS TO INPATIENT REHABILITATION identifying Corporate Parent NONE for FUND FOR ACCESS TO INPATIENT REHABILITATION (td) (Entered: 06/22/2016)
06/22/2016		MINUTE ORDER granting Unopposed <u>33</u> Motion for Extension of Time to File. The Court ORDERS that Defendant's reply in support of her Motion to Stay shall be filed on or before July 1, 2016. Signed by Judge James E. Boasberg on 6/22/16. (lcjeb3) (Entered: 06/22/2016)
06/22/2016		Set/Reset Deadline: Defendant's reply in support of her Motion to Stay shall be filed on or before 7/1/2016. (ad) (Entered: 06/22/2016)
07/01/2016	<u>36</u>	REPLY to opposition to motion re <u>30</u> MOTION to Stay <i>and Memorandum of</i> <i>Points and Authorities in Support</i> filed by KATHLEEN SEBELIUS. (Attachments: # <u>1</u> Exhibit 1)(Wolverton, Caroline) (Entered: 07/01/2016)
09/19/2016	<u>37</u>	ORDER DENYING <u>30</u> Motion for Stay. Parties shall appear for a status conference on October 3, 2016, at 9:30 AM. Signed by Judge James E. Boasberg on 09/19/2016. (lcjeb3) (Entered: 09/19/2016)
09/19/2016	<u>38</u>	MEMORANDUM OPINION re <u>37</u> Order on Motion for Stay. Signed by Judge James E. Boasberg on 09/19/2016. (lcjeb3) (Main Document 38 replaced on 9/19/2016) (zad). (Entered: 09/19/2016)
09/19/2016		Set/Reset Hearing: A Status Conference is set for 10/3/2016, at 9:30 AM, in Courtroom 19, before Judge James E. Boasberg. (ad) (Entered: 09/19/2016)
10/03/2016		MINUTE ORDER: As discussed at today's status hearing, the Court ORDERS that: 1) Plaintiffs' Motion for Summary Judgment setting forth the specific forms a mandamus should take shall be filed by October 14, 2016; 2) Defendant's Opposition and Cross-Motion for Summary Judgment shall be filed by November 4, 2016; and 3) Plaintiffs' Reply shall be filed by November 14, 2016. If the Court believes a further Government Reply is necessary, it will so order. Signed by Judge James E. Boasberg on 10/03/16. (lcjeb3) (Entered: 10/03/2016)
10/03/2016		Minute Entry for proceedings held before Judge James E. Boasberg: Status Conference held on 10/3/2016. (Plaintiffs' Motion for Summary Judgment setting forth the specific forms a mandamus should take shall be filed by

USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 12 of 180

		10/14/2016; Defendant's Opposition and Cross-Motion for Summary Judgment shall be filed by 11/04/2016; and Plaintiffs' Reply shall be filed by 11/14/2016). (Court Reporter Lisa Griffith) (ad) (Entered: 10/03/2016)
10/14/2016	<u>39</u>	MOTION for Summary Judgment by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC. (Attachments: # <u>1</u> Text of Proposed Order)(Stetson, Catherine) (Entered: 10/14/2016)
11/04/2016	<u>40</u>	Unopposed MOTION for Extension of Time to File <i>Defendant's Motion for</i> <i>Summary Judgment and Opposition to Plaintiffs' Motion for Summary</i> <i>Judgment</i> by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 11/04/2016)
11/04/2016		MINUTE ORDER granting Defendant's <u>40</u> Motion for Extension of Time to File. The Court ORDERS that: 1) Defendant shall file her Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment on or before November 7, 2016; and 2) Plaintiffs shall file their Reply in support of their Motion for Summary Judgment by November 15, 2016. Signed by Judge James E. Boasberg on 11/4/2016.(lcjeb1) (Entered: 11/04/2016)
11/04/2016		Set/Reset Deadlines: Defendant shall file her Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment on or before 11/07/2016; and Plaintiffs shall file their Reply in support of their Motion for Summary Judgment by 11/15/2016. (ad) (Entered: 11/04/2016)
11/07/2016	<u>41</u>	Cross MOTION for Summary Judgment by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Declaration, Supplemental, of Ellen Murray, # <u>2</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 11/07/2016)
11/07/2016	<u>42</u>	Memorandum in opposition to re <u>39</u> MOTION for Summary Judgment <i>by</i> <i>Plaintiffs</i> , filed by KATHLEEN SEBELIUS. (Attachments: # <u>1</u> Declaration, Supplemental, of Ellen Murray, # <u>2</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 11/07/2016)
11/15/2016	<u>43</u>	REPLY to opposition to motion re <u>39</u> MOTION for Summary Judgment filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Stetson, Catherine) (Entered: 11/15/2016)
11/15/2016	44	Memorandum in opposition to re <u>41</u> Cross MOTION for Summary Judgment filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (See Docket Entry <u>43</u> to view document). (znmw) (Entered: 11/16/2016)
11/23/2016	<u>45</u>	MOTION for Leave to File <i>Reply Memorandum in Support of the Secretary's</i> <i>Motion for Summary Judgment</i> by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Exhibit 1 Proposed Reply Memorandum in Support of Secretary's Motion for Summary Judgment, # <u>2</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 11/23/2016)
11/28/2016	<u>46</u>	RESPONSE re <u>45</u> MOTION for Leave to File <i>Reply Memorandum in Support</i>

USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 13 of 180

		<i>of the Secretary's Motion for Summary Judgment</i> filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Attachments: # <u>1</u> Text of Proposed Order)(Stetson, Catherine) (Entered: 11/28/2016)
12/05/2016	<u>47</u>	ORDER: The Court ORDERS that: (1) Plaintiffs' <u>39</u> Motion for Summary Judgment is GRANTED; (2) Defendant's <u>45</u> Motion for Leave to File Reply is GRANTED; (3) Defendant's <u>41</u> Cross-Motion for Summary Judgment is DENIED; (4) Defendant must achieve the following reductions from the current backlog of cases pending at the ALJ level: 30% by December 31, 2017; 60% by December 31, 2018; 90% by December 31, 2019; and 100% by December 31, 2020; and (5) Defendant shall file status reports with the Court every 90 days. Signed by Judge James E. Boasberg on 12/05/2016. (lcjeb3) Modified on 12/6/2016 to include the word "order" before the entry (ad). (Entered: 12/05/2016)
12/05/2016	<u>48</u>	MEMORANDUM OPINION re <u>47</u> Order on Motion for Summary Judgment. Signed by Judge James E. Boasberg on 12/05/2016. (lcjeb3) (Entered: 12/05/2016)
12/15/2016	<u>49</u>	MOTION for Reconsideration re <u>47</u> Order on Motion for Summary Judgment,, <u>48</u> Memorandum & Opinion by KATHLEEN SEBELIUS (Attachments: # <u>1</u> Declaration of Ellen Murray, # <u>2</u> Text of Proposed Order)(Wolverton, Caroline) (Entered: 12/15/2016)
12/21/2016	<u>50</u>	RESPONSE re <u>49</u> MOTION for Reconsideration re <u>47</u> Order on Motion for Summary Judgment, <u>48</u> Memorandum & Opinion filed by AMERICAN HOSPITAL ASSOCIATION, BAXTER REGIONAL HOSPITAL, INC., COVENANT HEALTH, RUTLAND HOSPITAL, INC (Attachments: # <u>1</u> Text of Proposed Order)(Stetson, Catherine) (Entered: 12/21/2016)
12/23/2016	<u>51</u>	REPLY to opposition to motion re <u>49</u> MOTION for Reconsideration re <u>47</u> Order on Motion for Summary Judgment,, <u>48</u> Memorandum & Opinion filed by KATHLEEN SEBELIUS. (Wolverton, Caroline) (Entered: 12/23/2016)
01/04/2017	<u>52</u>	ORDER: The Court ORDERS that <u>49</u> Defendant's Motion for Reconsideration is DENIED. Signed by Judge James E. Boasberg on 1/4/2017. (lcjeb3) (Entered: 01/04/2017)
01/30/2017	<u>53</u>	NOTICE OF APPEAL TO DC CIRCUIT COURT as to <u>47</u> Order on Motion for Summary Judgment,, <u>48</u> Memorandum & Opinion, <u>52</u> Order on Motion for Reconsideration by KATHLEEN SEBELIUS. Fee Status: No Fee Paid. Parties have been notified. (Wolverton, Caroline) (Entered: 01/30/2017)
01/31/2017	<u>54</u>	Transmission of the Notice of Appeal, Order Appealed, and Docket Sheet to US Court of Appeals. The Court of Appeals docketing fee was not paid because the fee was an Appeal by the Government re <u>53</u> Notice of Appeal to DC Circuit Court. (znmw) (Entered: 01/31/2017)
02/01/2017		USCA Case Number 17-5018 for <u>53</u> Notice of Appeal to DC Circuit Court, filed by KATHLEEN SEBELIUS. (zrdj) (Entered: 02/06/2017)

JA10

https://ecf.dcd.uscourts.gov/cgi-bin/DktRpt.pl?894546353269488-L_1_0-1

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION Liberty Place, Suite 700 325 Seventh Street, NW Washington, D.C. 20004-2802

BAXTER REGIONAL HOSPITAL, INC. D/B/A/ BAXTER REGIONAL MEDICAL CENTER 624 Hospital Drive Mountain Home, Arkansas 72653

COVENANT HEALTH 100 Fort Sanders West Boulevard Knoxville, Tennessee 37922

RUTLAND HOSPITAL, INC. D/B/A RUTLAND REGIONAL MEDICAL CENTER 160 Allen Street Rutland, Vermont 05701

Plaintiffs,

v.

KATHLEEN SEBELIUS, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES 200 Independence Avenue, SW Washington, DC 20201

Defendant.

COMPLAINT

Plaintiffs the American Hospital Association ("AHA"), Baxter Regional Medical Center,

Covenant Health, and Rutland Regional Medical Center (collectively, "Plaintiffs") bring this

mandamus complaint to compel the Secretary of Health and Human Services ("HHS") to meet

the statutory deadlines for administrative review of denials of claims for Medicare

reimbursement. Lengthy, systemic delays in the Medicare appeals process, which far exceed

Civil Action No. 14-cv-851

statutory timeframes, are causing severe harm to providers of Medicare services, like the Plaintiff hospitals. HHS's unlawful delays are contrary to a clear statutory mandate requiring timely adjudication and must be eliminated.

INTRODUCTION

1. After hospitals and other healthcare providers furnish services to Medicare beneficiaries, they submit claims for payment to HHS, which processes them through the Centers for Medicare & Medicaid Services ("CMS") and its contractors. Of claims that are denied, some are denied before payment, while others are first paid and then subsequently denied during postpayment review.

2. Post-payment reviews often question the providers' medical judgment. In a growing number of cases, original payment decisions are overturned based on reviewers' findings that certain services were not medically necessary and the providers, such as Plaintiff hospitals, must pay back the funds previously reimbursed. That is so even when the review findings are incorrect.

3. Providers have a right to contest denials (whether pre- or post-payment) through a four-level appeals process within HHS. Each step of the process is governed by specific timeframes in which a decision must be rendered following receipt of the appeal.

4. Engaging in the appeals process is frequently worthwhile: When hospitals appeal the payment denials, including those made by post-payment reviewers who have a financial incentive to make findings adverse to hospitals, the decisions are very frequently reversed. Many reversals occur at the third level of the appeals process, where hospitals have a right to review of their claims by an Administrative Law Judge ("ALJ") within the HHS Office of

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Medicare Hearings and Appeals ("OMHA"). This is the first opportunity for hospitals to obtain a hearing and review by an independent adjudicator.

5. Over the past several months, however, extraordinary delays in the appeals process, particularly at the ALJ level, have effectively stymied hospitals from challenging payment denials.

6. Although an ALJ's statutory deadline for holding a hearing and rendering a decision is ninety days from a hospital's filing of its appeal with OMHA, it is taking far longer than ninety days even to *docket* new requests for an ALJ hearing, let alone decide them. Indeed, currently there is a twenty to twenty-four week delay for mere docketing into the case processing system.

7. Delays at the ALJ level of the appeals process created a massive backlog of over 460,000 claim appeals by the end of 2013. At that time, the average wait for a hearing – to say nothing of a decision – was approximately sixteen months and was expected to continue to rise as the backlog grew.

8. Now the delays will be even longer still: In December 2013, OMHA announced a moratorium on assignment of provider appeals to ALJs for at least the next two years, and possibly longer. The ALJ hearing will not occur for many months after that, with a decision date likely even later. Thus, the backlog grows as new appeals come in and old ones languish: Over 480,000 claim appeals were awaiting assignment with OMHA as of February 12, 2014, with 15,000 new appeals filed each week.

9. When these excessive delays at the ALJ level are considered in conjunction with existing delays in other steps of the appeals process, the consequences are startling: hospitals will likely have to wait up to *five years*, and possibly longer, to have their claims proceed through a

-3-JA13 four-level administrative appeals process that could otherwise conclude in less than a year according to statute.

10. The stakes for America's hospitals are high—billions of dollars in Medicare reimbursement hang in the balance. Deprived of the value of the services they already provided, hospitals are unable to use these funds to furnish patient care in their communities. For some hospitals, the situation is dire. Named Plaintiff Baxter Regional Medical Center has so much tied up in the appeals process that it cannot afford to replace a failing roof over its surgery department, purchase new beds for its Intensive Care Unit, engage in other basic upkeep, or purchase other necessary capital items.

11. Because the appeals process, as currently operating, cannot provide adequate redress, Plaintiffs have no option but to bring this mandamus lawsuit to require the Secretary's compliance with the deadlines established by law.

PARTIES

12. Plaintiff AHA is a national non-profit corporation organized and existing under the laws of the State of Illinois with offices in Chicago, Illinois, and Washington, D.C. The AHA represents more than 5,000 hospitals, health care systems, and other health care organizations, plus nearly 43,000 individual members, in matters before Congress, the executive branch, and courts. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and 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 on health care issues and trends. It also ensures that members' perspectives and needs are heard in national

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Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 5 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 18 of 180

health policy development, legislative and regulatory debates, and judicial matters. The AHA brings this suit on behalf of its members.

13. Plaintiff Baxter Regional Medical Center ("Baxter") is a 268-bed regional hospital located in Mountain Home, Arkansas—a town of only 15,000 people. Baxter prides itself on offering a broad range of services in thirty medical specialties, including open-heart surgery, to the community it serves. Without Baxter, patients living in the surrounding counties of north-central Arkansas and south-central Missouri would need to drive two to three hours for hospital care. In 2013, Baxter was named by Moody's as America's fifth-most Medicaredependent hospital, with Medicare responsible for sixty-five percent of its gross revenue. Baxter currently has approximately \$4.6 million tied up in the Medicare appeals process, more than \$1.7 million of which is pending at the ALJ level.

14. Plaintiff Covenant Health ("Covenant") is a community-owned health system located in East Tennessee, consisting of nine individual hospitals: Fort Sanders Regional Medical Center, Parkwest Medical Center, LeConte Medical Center, Methodist Medical Center of Oak Ridge, Morristown-Hamblen Healthcare System, Fort Loudoun Medical Center, Roane Medical Center (these seven hospitals collectively, "Covenant's Hospitals"), and two hospitals recently acquired in 2014. Medicare accounts for fifty-five percent of gross revenue across Covenant's Hospitals. Covenant's Hospitals have more than \$7.6 million in system-wide claims pending in the Medicare appeals process, approximately \$6.6 million of which is pending at the ALJ level.

15. Plaintiff Rutland Regional Medical Center ("Rutland") is a 133-bed, communityowned rural hospital located in Rutland, Vermont. Despite its small size, Rutland is the second largest hospital in the state of Vermont. It offers the full scope of community hospital services,

-5-JA15

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 6 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 19 of 180

including an outpatient cancer center and a cardiology department, as well as uniquely important services to the community it serves, such as an outpatient drug treatment center. Rutland also took over responsibility for provision of psychiatric health care when the state's psychiatric hospital closed after flooding from Hurricane Irene. In fiscal year 2013, Medicare was responsible for approximately forty-seven percent of Rutland's gross revenues. Rutland currently has approximately \$588,000 tied up in the Medicare appeals process, of which approximately \$554,000 is pending at the ALJ level.

16. Defendant Kathleen Sebelius is the Secretary of HHS. This action is brought against Secretary Sebelius in her official capacity. The Secretary is responsible for implementing the Medicare program, Title XVIII of the Social Security Act, as amended, 42 U.S.C. § 1395 *et seq.* The Secretary administers the Medicare program through CMS, an agency of HHS. CMS also directs its contractors, which are responsible for the first two levels of administrative review of Medicare denials. OMHA and the Departmental Appeals Board ("DAB") within HHS provide the third and fourth levels of administrative review, respectively.

JURISDICTION

17. The Court has jurisdiction in this case pursuant to 28 U.S.C. § 1361 (jurisdiction for actions in the nature of mandamus).

VENUE

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) because this is an action against an officer of the United States in her official capacity, which is being brought in the District where the Defendant resides.

FACTUAL BACKROUND

I. The Medicare Program

19. The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance primarily to individuals sixty-five years of age and older. Social Security Amendments of 1965, Pub. L. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1396v). The program's main objective is to ensure that its beneficiaries have access to health care services. *Id.* at 286. The Plaintiff hospitals qualify as providers of hospital services under Title XVIII, also known as the Medicare Act.

20. In practice, when medical providers, such as hospitals, furnish services to a Medicare beneficiary, the providers thereafter submit a claim for reimbursement to a Medicare Administrative Contractor ("MAC"). 42 U.S.C. § 1395ff(a)(2)(A). MACs are government contractors responsible for processing Medicare claims and making payments. 42 U.S.C. § 1395kk-1(a)(3).

21. Some claims that are initially paid by MACs are then subjected to an additional level of oversight. In a process known as "post-payment review," third-party contractors audit, and frequently reverse, MAC payment decisions. The post-payment review process has imposed significant burdens on the claim appeals process, particularly as the result of audits performed by one type of such contractor, known as a Recovery Audit Contractor ("RAC").

22. Permitted to audit MAC determinations on hospitals' claims dating back three years, RACs have engaged in wide-ranging audits that often question the medical judgment of the hospital and admitting physician. It is in the RACs' interests to do so: RACs themselves are paid based on the amount of Medicare reimbursement they recover from hospitals for purportedly "improper" payments. Thus, RACs have an incentive to overturn MAC payment

-7-JA17

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 8 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 21 of 180

decisions, particularly for more expensive services. One of the most common – and very lucrative – bases for a RAC reversal of a MAC's payment determination is a finding that a hospital billed for an inpatient hospital stay when, in the RAC's view, appropriate care could have been provided on an outpatient hospital basis.

23. Aggressive and widespread auditing activity by the RACs predictably has affected the number of hospital claim appeals. An increasingly large percentage of the cases received by OMHA results from RAC appeals. *See* OMHA Medicare Appellant Forum Presentation at 108 (February 12, 2014), *available at*

http://www.hhs.gov/omha/omha_medicare_appellant_forum.html (last visited May 22, 2014) (hereinafter "OMHA Forum Presentation"). For example, in fiscal year 2009, the last full fiscal year before the permanent RAC program was instituted, there were 35,831 appeals filed with OMHA for ALJ review. *Important Notice Regarding Adjudication Timeframes*, Office of Medicare Hearings and Appeals, U.S. Department of Health & Human Services, available at http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html (last visited May 22, 2014) ("*Important Notice*"). In comparison, in fiscal year 2013, well after the implementation of the RACs, 384,651 appeals were filed—more than ten times as many as only four years earlier. *Id.*; *see also* OMHA Forum Presentation at 16. The value of appealed, RAC-denied claims alone is well over \$1 billion. *See* AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 47 (June 1, 2013), *available at*

http://www.aha.org/content/13/13q1ractracresults.pdf.

24. RAC claim denials are frequently overturned on appeal. According to data provided to the AHA through the first quarter of 2013, hospitals reported that when they

appealed RAC denials, including up to an ALJ, the denials were overturned seventy-two percent of the time. *Id.* at 55.

II. The Appeals Process

25. Appeals of both pre- and post-payment claim denials are subject to a four-step process, set forth by statute. *See* 42 U.S.C. § 1395ff. The first two steps of the process are overseen by CMS; the third is overseen by OMHA; and the fourth is overseen by the DAB. The steps are as follows:

a. A denied claim is first presented to the MAC for redetermination. *Id.* § 1395ff(a)(3)(A). In cases of a RAC denial following an initial MAC approval, the hospital presents the RAC-denied claim to the MAC that originally approved and paid the claim. The MAC must render a redetermination decision within sixty days. *Id.* § 1395ff(a)(3)(C)(ii).

b. If unsatisfied with the MAC's redetermination, a hospital can appeal the MAC's decision to a Qualified Independent Contractor ("QIC") for reconsideration. *Id.*§ 1395ff(c). QICs are tasked with independently reviewing the MAC's determination and must render a decision within sixty days. *Id.* § 1395ff(c)(3)(C)(i).

c. Provided that the amount in controversy is greater than \$140 (for calendar year 2014), a hospital may next request a hearing before an ALJ. *Id.* §§ 1395ff(b)(1)(E), 1395ff(d)(1)(A). Review by an ALJ is the first opportunity for independent review of a claim. The ALJ is required both to hold a hearing and to render a decision within ninety days. *Id.*; 42 C.F.R. § 405.1016(a). When they have been granted the hearing required by law, this is the level of the appeals process at which hospitals typically have been able to obtain relief from adverse RAC determinations.

-9-JA19 d. Finally, a hospital can appeal its claim to the DAB. *Id.* § 1395ff(d)(2); 42
C.F.R.§ 405.1108(a). In that event, the DAB conducts a *de novo* review of the ALJ decision and either renders its own decision or remands to the ALJ for further proceedings. *Id.* In either event, the DAB must act within ninety days. *Id.*

26. There is also a separate "escalation" process applicable to the QIC, ALJ and DAB levels of review.

a. Specifically, if the QIC is unable to complete its review within sixty calendar days, it must notify all parties that it cannot complete the reconsideration within the statutory timeframe and offer the hospital the opportunity to "escalate" the appeal to an ALJ. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970. The QIC will continue the reconsideration process unless and until the hospital files a written escalation request. 42 C.F.R. § 405.970(c)(2).

b. Similarly, if an ALJ has not held a hearing and rendered a decision within ninety days, a hospital may bypass the ALJ level by escalating its claim to the DAB. 42 U.S.C. § 1395ff(d)(3)(A). In such situations, the QIC's decision becomes the decision subject to DAB review. 42 C.F.R. § 405.1104; 42 C.F.R. § 405.1108(d). That means that if the hospital has previously escalated from the QIC, only the record before the MAC is available for review. The DAB may conduct additional proceedings, including a hearing, but (unlike at the ALJ level) is not required to do so. 42 C.F.R. § 405.1108. In fact, OMHA has explained that, in escalation situations, the DAB will "NOT hold a hearing or conduct oral argument unless there is an extraordinary question of law/policy/fact." OMHA Forum Presentation at 117. The DAB has 180 days in which to act on an escalation request, rather than its usual ninety. 42 C.F.R. § 405.1100(c)-(d).

c. Likewise, if the DAB has not rendered a decision within ninety days on its

-10-JA20

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 11 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 24 of 180

review of an ALJ's decision, a hospital may bypass the DAB and seek judicial review. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132. In cases of an initial escalation past the ALJ level, a hospital may escalate the appeal to federal court if the DAB fails to render a decision within 180 days. 42 C.F.R. § 405.1132; 42 C.F.R. § 405.1100(d). In the event of this "double escalation," the only agency decision available to the federal court for review is the QIC's decision, made without a hearing. In the event of a "triple escalation" (from the QIC, from the ALJ, and from the DAB), only the MAC record is available for review.

III. The Delay

27. The statutory time periods governing the appeals process provide for all levels of administrative review to be completed within about one year. In practice, however, the time it takes to pursue a claim appeal through HHS far exceeds the timeframes established by the Medicare Act.

28. The moratorium declared by OMHA on assignment of appeals to ALJs will only exacerbate this problem, causing the DAB – and potentially the federal courts – to be inundated with claim appeals that never have received the benefit of a hearing

A. The ALJ Backlog

29. Enormous increases in the rates of appeal, in significant part by providers challenging inappropriate denials by over-zealous RACs, have caused a massive backlog at the ALJ level of the appeals process. In just two years (2012 and 2013), the backlog of ALJ-level appeals *quintupled*, growing from 92,000 to 460,000 pending claims. Ex. 1, Memorandum from Nancy J. Griswold, Office of Medicare Hearings & Appeals, Chief Admin. Law Judge, to OMHA Medicare Appellants (Dec. 24, 2013) ("Griswold Memorandum").

-11-JA21 30. The ALJs simply have not kept up with the prodigious and growing volume of appeals. The workload of OMHA's sixty-five ALJs increased by almost 300% from fiscal year 2012 to fiscal year 2013. *See* OMHA Forum Presentation at 16. In fiscal year 2013, of the 384,651 appeals that were filed, only 79,303 were decided – a meager twenty-one percent. OMHA Forum Presentation at 12 (reflecting decision figures); *Important Notice* (reflecting adjusted appeals receipts figures).

31. Indeed, as of December 2013, appeals had languished for an average of sixteen months – approximately thirteen months longer than the ninety-day statutory deadline for a *decision* – before an ALJ even *heard* the case. OMHA Forum Presentation at 11; see Ex. 1 (Griswold Memorandum).

32. The backlog of appeals, and concomitant delay in adjudication, has reached a crisis point. On December 24, 2013, OMHA's Chief ALJ, Nancy Griswold, announced that OMHA had suspended the assignment of all new provider appeals to ALJs, apparently as of July 15, 2013. Ex. 1 (Griswold Memorandum). The suspension is expected to last for a minimum of two years, with additional post-assignment hearing wait times expected to exceed six months when the suspension is eventually lifted. *Id.* As recently as February 14, 2014, Judge Griswold conceded that the wait times for a hearing before an ALJ are unacceptable. Michelle M. Stein, *ALJs Lay Out Path Forward For Stakeholders As Appeals Backlog Continues*, INSIDE HEALTH POLICY, Feb. 14, 2014, *available at*

http://insidehealthpolicy.com/201402142461310/Health-Daily-News/Daily-News/aljs-lay-outpath-forward-for-stakeholders-as-appeals-backlog-continues/menu-id-212.html (last visited May 22, 2014).

> -12-JA22

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 13 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 26 of 180

33. The situation is getting only worse. OMHA received more than 15,000 appeals per week in February 2014. OMHA Forum Presentation at 53. OMHA has stated that it is currently projecting a twenty to twenty-four week delay even in *docketing* new appeals. *Important Notice*. From there, the new appeals will await assignment indefinitely, while the moratorium persists. As of February 12, 2014, 480,000 appeals were awaiting assignment to an ALJ. OMHA Forum Presentation at 57. And OMHA's self-imposed suspension in processing of appeals does not alter the requirement that a provider appeal an unfavorable QIC decision within sixty days, meaning that the backlog at the ALJ level will increase dramatically as appeals continue to roll in without being assigned or decided. *See* 42 U.S.C. § 1395ff(b)(1)(D)(ii); 42 C.F.R. § 405.1014(b)(1).

34. The more than two-year moratorium on assignment of new appeals to an ALJ, taken together with the likely additional wait times for assignment even after the moratorium is lifted and the predicted wait times to obtain a hearing once a case is assigned to an ALJ, means hospitals lodging new appeals from the QIC to the ALJ can realistically expect to wait close to three years, and probably longer, even to *obtain an ALJ hearing* – let alone to receive a decision. *See Important Notice*; Ex. 1 (Griswold Memorandum).

B. *The DAB Backlog*

35. The DAB – the last level of administrative review – is similarly inundated. At the end of fiscal year 2013, the DAB had 4,888 pending appeals, 112% more than it had at the end of fiscal year 2012. OMHA Forum Presentation at 106. OMHA projects that 7,000 DAB appeals will be received in fiscal year 2014. *Id.* That number is expected to rise to over 8,000 for fiscal year 2015. *Id.* As with the ALJs, the DAB is seeing an increased caseload due to the behavior of the RACs and other Medicare contractors.

-13-JA23

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 14 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 27 of 180

36. OMHA itself recognizes that, like the ALJs, the DAB cannot keep up with the dramatic increase in appeals. It has conceded that the DAB is "unlikely to meet the 90-day deadline for issuing decisions in most appeals." OMHA Forum Presentation at 110.

37. This concession does not even account for the increase in escalated cases the DAB will receive, where an ALJ has failed to render any decision and the DAB is forced to remand the case or begin and conclude adjudication from scratch, with only the record from the QIC (or potentially even from the MAC) as a basis for review.

38. Even if the DAB could find a way to adjudicate all of the appeals pending before it, it is not equipped to conduct the full hearing that would otherwise occur at the ALJ level in escalated cases. There are just *four* Appeals Officers within the DAB responsible for final administrative review of Medicare entitlement, managed care, and prescription drug claims in addition to the hundreds of thousands of claims from providers such as Plaintiff hospitals challenging fee-for-service payment denials. OMHA Forum Presentation at 103-104. And publicly available information about the DAB's actions in escalated cases reveals that it has not conducted a hearing in any of them.

39. Instead, the DAB can take one of only four actions, all of which are inadequate. First, it may render a summary decision on the basis of only the record established before the QIC (or, in the case of a triple escalation, the MAC), which would not provide the due process contemplated by the statute, in the form of an ALJ hearing. 42 U.S.C. § 1395ff(d)(1)(A). Second, it may remand the appeal to the ALJ, which would place the hospitals in the same position in which they started, waiting years for a relatively small number of ALJs to wade through an enormous and increasing backlog of appeals, only now at the back of the ALJ line. Third, the DAB may issue a notice that it, too, is unable to fulfill its statutory duty within the

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required timelines and thereby allow hospitals to escalate their claims to federal court. Or fourth, it may do nothing at all.

C. Impending Federal Court Involvement

40. Given the immense backlog at the ALJ level and the expected attendant increase in escalations to the DAB, itself already backlogged, hospitals are put to the difficult question whether to escalate their claims from the DAB to federal court, which cannot provide an adequate remedy in any event due to the lack of a meaningful administrative record upon which to base a decision.

41. Under the regulations, a hospital may file an action in federal district court if the DAB notifies it that no decision will be issued and if its claim meets an amount-in-controversy requirement (currently \$1,430). 42 C.F.R. § 405.1132(b); 42 C.F.R. § 405.1006(c); Notice of Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2014, 78 Fed. Reg. 59702-03 (Sept. 27, 2013). Hospitals having claims that do not meet the amount-in-controversy requirement for escalation must simply wait out the delays at the agency level.

42. Those that do meet the amount-in-controversy requirement must decide whether to undertake an attempt at escalation. As an initial matter, escalation may be thwarted by the DAB: The DAB may prevent escalation to federal court by remanding the claim to the ALJ level, 42 C.F.R. §405.1108(d)(3), where the claim will languish in a futile loop of escalation and remand. Under that scenario, hospitals that attempt to escalate may instead merely forfeit their position in the ALJ queue.

43. Alternatively, if the DAB permits escalation to federal court by providing notice that it will not issue a decision, hospitals must face the dilemma of whether to wait out the

lengthy administrative review delays or incur the cost of a federal court lawsuit that is neither an adequate remedy nor a viable alternative.

44. Federal court escalation is not an adequate remedy for Plaintiffs and other hospitals because (a) an escalating Plaintiff or other hospital will have had no hearing as contemplated by the Medicare Act; and (b) the court will have before it only the record and determination made by the QIC (or the MAC) without a hearing and will lack the benefit of an independent ALJ's findings of fact and conclusions of law.

45. In view of the undeveloped record before the federal court in the event of "double- or triple- escalation," because neither the ALJ nor the DAB (and possibly not even the QIC) rendered a timely decision on a hospital's claim, the federal court might remand the matter to the agency for fact-finding. This result would leave Plaintiffs and other hospitals stuck in an endless loop of escalation and remand with no meaningful opportunity to be heard and no merits decision.

46. Further, the cost of litigating claims in federal court may render escalation worthless in many cases. Because the amount-in-controversy requirement for escalation to federal court is relatively low, hospitals must weigh the cost of federal court litigation against the total possible recovery. In circumstances in which hospitals would pay more to litigate their claims than they could even recover, federal court escalation is not a viable alternative for Plaintiffs and other hospitals. They are thus left with no adequate remedy for HHS's unlawful delays.

III. The Impact of the Backlog on Hospitals

47. Hospitals are suffering nationwide under HHS's refusal to render decisions on appeals in a timely manner. Whether claims denials are pre-payment – in which case hospitals

-16-JA26

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 17 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 30 of 180

never receive payment for the value of their services – or post-payment – in which case hospitals must repay the amount initially reimbursed before they ever get to the ALJ level – hospitals are deeply out-of-pocket for services they already have rendered.

48. The deprivation of funds tied up in the appeals process is a profound problem. These are funds that otherwise could be dedicated to patient care or to sustaining the hospital infrastructure necessary to provide patient care. The delays in the system strain the cash flows of hospitals, many of which are already cash-strapped. HHS's delay in meeting the statutory Medicare claim appeal deadlines thus presents a serious threat to hospitals nationwide and their ability to continue to provide quality patient care while maintaining financial viability.

49. The Plaintiff hospitals have numerous claim denials delayed at various stages of the appeals process. The delays, and the concomitant deprivation of funds, have caused and are continuing to cause severe harm to the Plaintiff hospitals.

A. Baxter

50. Plaintiff Baxter currently has 144 claims at the ALJ level of the appeals process, of which 133 have been filed since July 15, 2013 and thus are subject to the moratorium on assignment of appeals to an ALJ. Thirty-eight appeals, accounting for more than \$337,000 in Medicare reimbursement, have been pending at the ALJ for longer than ninety days. All told, more than \$1.7 million in reimbursement for services that Baxter provided to Medicare beneficiaries is tied up at the ALJ level of the appeals process.

51. The delays in the appeals process have had a crippling effect on Baxter's cash flow. Funds tied up in appeals are funds that cannot be used to meet Baxter's essential needs. For example, the hospital has not been able to purchase basic equipment, like beds for its Intensive Care Unit. Instead of replacing a failing roof over its surgery department, Baxter has

> -17-JA27

been able only to patch it. The costs of Baxter's voluminous appeals of rehabilitation-related claim denials, combined with the delay in achieving resolution of those claims, has become so prohibitive that Baxter has considered whether it would be more financially prudent to *close* its rehabilitation center rather than to pursue the appeals.

B. Covenant

52. Covenant's Hospitals have approximately 1388 appeals currently pending at the ALJ level, of which approximately 812 have been filed since July 15, 2013 and are subject to the moratorium on ALJ assignment, and approximately 1350 have been pending for longer than ninety days.

53. The delays in adjudicating these pending appeals have significantly impaired Covenant's cash flow as it tries to "do more with less" across its system. Funds tied up in the appeals process are not available for allocation among Covenant's Hospitals to address patient care needs in the various communities those hospitals serve. Covenant, like Baxter, has considered whether, in light of the severe ALJ delay, it is financially prudent to continue to offer the full scope of rehabilitative services to the entire population of patients it currently serves.

C. Rutland

54. Rutland currently has 98 appeals pending at the ALJ level, of which 54 are newlyfiled appeals that are subject to the moratorium on ALJ assignment and 7 are appeals that have been pending for longer than ninety days. These pending appeals represent more than a half a million dollars in Medicare reimbursement for services that Rutland provided to its patients.

55. These are funds that Rutland could be using to advance its mission, but instead are held up in the ALJ delay. Rutland also has had to implement a number of cost-cutting

-18-JA28 measures in the wake of the ALJ delay to accommodate the cash flow deficiencies caused by the delay.

V. HHS Has Not Resolved The Unlawful Delays.

56. Despite public outcry and mounting pressure from the wide range of medical providers harmed by the unlawful delays, HHS has not taken action to remedy the situation.

57. Prior to bringing this lawsuit, Plaintiff AHA sent a letter to CMS – responsible for the first and second levels of administrative review – urging it to cooperate with OMHA to remedy the backlog, noting that the moratorium is "a direct violation of [the] Medicare statute that requires ALJs to issue a decision *within 90 days of receiving the request for hearing*." Letter from Rick Pollack, Executive Vice President of AHA, to Marilyn Tavenner, Administrator of CMS (January 14, 2014), *available at www.aha.org/letters/2014?&p=8* (last visited May 22, 2014).

58. On February 12, 2014, ninety-eight organizations sent a letter to Chief ALJ Griswold, "urg[ing] OMHA to develop a comprehensive solution to the Medicare appeal backlog problem" because "[t]he numerous appeals requirements, actual costs of filing appeals, and often lengthy delays undermine the ability of physicians to deliver patient-centered care." Letter from the American Medical Association, et al., to The Honorable Nancy J. Griswold, Chief Administrative Law Judge, Office of Medicare Hearings and Appeals (February 12, 2014), *available at* <u>http://www.aafp.org/dam/AAFP/documents/advocacy/payment/medicare/LT-HHS-</u> MedicareAppealsBacklog-021214.pdf.

59. On March 27, 2014, the Advanced Medical Technology Association ("AdvaMed") wrote to Defendant Sebelius and to the Administrator of CMS to express its concerns about the moratorium, explaining that "the policy will create significant harm for both

-19-JA29

Case 1:14-cv-00851-JEB Document 1 Filed 05/22/14 Page 20 of 22 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 33 of 180

patients and providers." Letter from Donald May, Executive Vice President of Payment & Healthcare Delivery Policy at AdvaMed, to Kathleen Sebelius, Secretary of HHS, and Marilyn Tavenner, Administrator of CMS, at 1 (March 27, 2014), *available at*

http://advamed.org/res/472/office-of-medicare-hearing-and-appeals-decision-to-suspend-

assignment-of-new-request-for-administrative-law-judge-hearings-for-adjudication-of-appeals

(last visited May 22, 2014). AdvaMed criticized OMHA's moratorium as "plainly violat[ing] the statute and contradict[ing] the purpose of the Medicare appeals process," and noted that the moratorium only "perpetuates the backlog that eliminates the statutory schedule of appeal reviews." *Id.* at 2.

60. Yet the moratorium remains in place. The ALJ backlog problem is egregious and growing more so as appeals continue to mount without resolution by HHS. OMHA has admitted that it is not meeting its statutory deadlines and will not be able to do so any time in the near future. In the meantime, hospitals are deprived of crucial funds and stuck in endless administrative holding patterns or forced to opt out of the only meaningful opportunity for hearing by undertaking attempts at escalation.

COUNT I <u>Relief Under the Mandamus Act (28 U.S.C. § 1361)</u>

61. Plaintiffs reallege and incorporate herein by reference all of the allegations contained in paragraphs 1 through 60 above as if fully set forth herein.

62. The Mandamus Act, 28 U.S.C. § 1361, vests district courts with original jurisdiction over any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to Plaintiffs.

63. Under federal law, HHS has a clear, indisputable, and non-discretionary duty to "conduct and conclude a hearing on a decision of a qualified independent contractor . . . and

-20-IA30 render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." 42 U.S.C. §1395ff(d)(1)(A).

64. HHS has breached this duty by acting in derogation of statute by, *inter alia*, permitting its delegee, OMHA, to suspend the assignment of all new provider appeals to ALJs for a minimum of twenty-four months and by failing to hold hearings and render decisions within ninety days at the ALJ level.

65. HHS's delays throughout the appeals process, and most notably at the ALJ level, plainly violate the timetables set forth by Congress in the Medicare Act.

66. HHS's delays in resolving Medicare appeals affect human health and welfare by compromising the economic well-being of hospitals across the country.

67. Absent mandamus, Plaintiffs have no adequate remedy. Neither the DAB nor the federal district courts can provide an adequate remedy to Plaintiffs. The escalation process does not provide a meaningful option for the reasons alleged above, including, *inter alia*, because it deprives Plaintiffs of their right to a hearing, while imposing costs that threaten the very value of the remedy Plaintiffs seek.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

 (a) enter a declaratory judgment that HHS's delay in adjudication of Medicare appeals violates federal law;

(b) enter an order:

(i) requiring HHS forthwith to provide Baxter Regional Medical Center, CovenantHealth, and Rutland Regional Medical Center the hearing before an ALJ and ALJ decision

required by law in each of their claim appeals pending at the ALJ level for ninety days or more;

(ii) requiring HHS forthwith to provide Baxter Regional Medical Center, Covenant

Health, and Rutland Regional Medical Center the resolution required by law in each of their claim appeals pending at the DAB for ninety days or more; and

(iii) requiring HHS to otherwise comply with its statutory obligations in administering the appeals process for all hospitals;

(c) enter a judgment for costs and reasonable attorney's fees pursuant to 28 U.S.C. § 2412; and

(d) grant such other relief at law and in equity as justice may require.

Respectfully submitted,

HOGAN LOVELLS US LLP

Dated: May 22, 2014

By: /s/ Adam K. Levin Sheree R. Kanner (D.C. Bar No. 366926) Mitchell E. Zamoff (D.C. Bar No. 439383) Adam K. Levin (D.C. Bar No. 460362) Rebecca C. Mandel (D.C. Bar No. 976808) Jaclyn L. DiLauro (D.C. Bar No. 1010951) 555 Thirteenth Street, N.W. Washington, D.C. 20004 (202) 637-5600

Melinda Reid Hatton (D.C. Bar No. 419421) Lawrence Hughes (D.C. Bar. No. 460627) American Hospital Association 325 Seventh Street, NW Washington, DC 20001 (202) 638-1100

Attorneys for Plaintiffs

-22-JA32

Exhibit 1



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Medicare Hearings and Appeals Office of the Chief Judge 1700 North Moore Street, Suite 1800 Arlington, VA 22209 (703) 235-0635 Main Line (703) 235-0700 Facsimile

DEC 2 4 2013

Memorandum to OMHA Medicare Appellants

Re: Administrative Law Judge Hearings for Medicare Claim and Entitlement Appeals

Based on a number of recent inquiries regarding delays in the processing of Medicare claim and entitlement appeals, I want to apprise you of some recent operational changes that may impact your interaction with the Office of Medicare Hearings and Appeals (OMHA). You have been chosen to receive this letter because you have a significant number of Medicare appeals currently pending before OMHA.

Due to the rapid and overwhelming increase in claim appeals, effective July 15, 2013, OMHA temporarily suspended the assignment of most new requests for an Administrative Law Judge hearing to allow OMHA to adjudicate appeals involving almost 357,000 claims for Medicare services and entitlements already assigned to its 65 Administrative Law Judges. This temporary measure was necessitated by a dramatic increase in the number of decisions being appealed to OMHA, the third level of administrative review in the Medicare claim and entitlement appeals process.

From 2010 to 2013, OMHA's claims and entitlement workload grew by 184% while the resources to adjudicate the appeals remained relatively constant, and more recently were reduced due to budgetary sequestration. Even with increased productivity from our dedicated Administrative Law Judges and their support staff, we have been unable to keep pace with the exponential growth in requests for hearing. Consequently, a substantial backlog in the number of cases pending an ALJ hearing, as well as cases pending assignment has resulted.

In just under two years, the OMHA backlog has grown from pending appeals involving 92,000 claims for services and entitlement to appeals involving over 460,000 claims for services and entitlement, and the receipt level of new appeals is continuing to rise. In January 2012, the number of weekly receipts in our Central Operations Division averaged around 1,250. This past month, the number of receipts was over 15,000 per week. Due to this rapidly increasing workload, OMHA's average wait time for a hearing before an Administrative Law Judge has risen to 16 months and is expected to continue to increase as the backlog grows.

Although assignment of most new requests for hearing will be temporarily suspended, OMHA will continue to assign and process requests filed directly by Medicare beneficiaries, to ensure their health and safety is protected. Assignment of all other new requests for hearing will resume as Administrative Law Judges are able to accommodate additional workload on their dockets. However, with the current backlog we do not expect general assignments to resume for at least 24 months and we expect post-assignment hearing wait times will continue to exceed 6 months.

Page 1 of 2 JA34 We remain committed to providing a forum for the fair and timely adjudication of Medicare claim and entitlement appeals; however, we are facing significant challenges which reduce our ability to meet the timeliness component of our mission. To address this challenge, OMHA is working closely with our colleagues within the Centers for Medicare and Medicaid Services (CMS) and the Departmental Appeals Board (DAB). We are committed to finding new ways to work smartly and more efficiently, in order to better utilize resources to address the increased demand for hearings.

In order to keep you apprised concerning our workload and to facilitate your interaction with OMHA, we will host an OMHA Medicare Appellant Forum on February 12, 2014, from 10:00 am to 5:00 pm. The event will take place in the Wilbur J. Cohen building located at 330 Independence Ave. SW, Washington DC 20024. The purpose of this event is to provide further information to OMHA appellants and providers on a number of initiatives underway and to provide information on measures we can take to make the appeals process work more efficiently. You can obtain further information and register for the event by visiting the OMHA website; http://www.hhs.gov/omha/index.html. We are pleased to offer this opportunity and hope you will be able to join us.

Although we know that this information will not alleviate your concerns with regard to delays in processing appeals, we hope that we have at least provided a backdrop for the environment in which OMHA currently processes appeals. We ask for your indulgence as we work to address these challenges and thank you in advance for your patience as we continue our efforts to serve the Medicare appellant and beneficiary communities. For additional information and updates on OMHA's adjudication timeframes, or to register for our OMHA Medicare Appellant Forum, please visit the OMHA website at: <u>http://www.hhs.gov/omha/index.html</u>.

Sincerely,

Nance Shisewood

Nancy J. Griswold Chief Administrative Law Judge

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Civil Action No. 1:14-CV-851-JEB

Defendant.

DECLARATION OF IVAN HOLLEMAN

I, Ivan S. Holleman, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If

called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Baxter County, Arkansas.

 I am submitting this declaration on behalf of Plaintiff Baxter Regional Medical Center ("Baxter") in support of Plaintiffs' Motion for Summary Judgment.

4. I am the Chief Financial Officer ("CFO") of Baxter. My responsibilities as CFO include oversight of all financial matters related to Baxter, including management of Recovery Audit Contractor ("RAC") appeals. I have a master's degree in business administration and thirty-three years of experience in hospital finance.

Baxter and the Community It Serves

5. Baxter is licensed as a 268-bed regional hospital located in Mountain Home, Arkansas. Although Mountain Home itself is a town of only 13,000 people, Baxter serves the

JA36

Case 1:14-cv-00851-JEB Document 8-11 Filed 07/11/14 Page 2 of 4 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 40 of 180

259,000 residents within a 55-mile radius. Baxter has served the residents of North-Central Arkansas and South-Central Missouri for over fifty years.

6. Baxter prides itself on offering a broad range of services in thirty medical specialties, including open-heart surgery, to the community it serves. Without Baxter, patients living in the surrounding counties of North-Central Arkansas and South-Central Missouri would need to drive one to two hours for hospital care. Baxter is located fifty to one hundred miles from hospitals providing comparable services.

In 2013, Baxter was named by Moody's Investor Service as America's fifth-most
 Medicare-dependent hospital, with Medicare responsible for 65% of its gross revenue.

8. The counties served by Baxter are expected to experience an increase of 9.5% in their over-65 population between 2013 and 2018.

Baxter's ALJ Appeals

9. Baxter currently is pursuing Medicare appeals to recover approximately \$4 million in reimbursement for services the hospital furnished to Medicare beneficiaries. Almost \$3 million of that \$4 million is pending at the Administrative Law Judge ("ALJ") level of the process.

10. Baxter currently has 230 claims pending at the ALJ level of the appeals process. Of those, 218 claims, representing \$2.95 million in reimbursement, have been filed since July 15, 2013 and thus are subject to the moratorium on assignment of appeals to an ALJ. Further, 101 appeals, accounting for more than \$1.2 million in Medicare reimbursement, have been pending at the ALJ level for longer than ninety days. Many of Baxter's appeals relate to denials of reimbursement for rehabilitation services.

Case 1:14-cv-00851-JEB Document 8-11 Filed 07/11/14 Page 3 of 4 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 41 of 180

11. Unlike at other levels of the appeal process, at ALJ hearings, Baxter has the opportunity to present oral testimony, including testimony of clinicians, in support of its claims. It also has the opportunity to respond to any questions from the ALJ in real-time through the hearing process. The ALJ level offers Baxter the first level of independent review of its claims.

12. In view of the significant advantages Baxter believes the ALJ hearing affords, Baxter does not consider escalation of its pending ALJ claims to the Departmental Appeals Board Medicare Appeals Council ("DAB") to be an adequate option. In particular, the DAB does not afford Baxter the opportunity to present testimony based on clinical factors that are critical to accurate decisions in denial of complex hospital claims.

13. Further, in all of Baxter's pending claims, the cost of litigating in federal court would far exceed the value of the claim appealed.

The Impact of the ALJ Delay on Baxter

14. The delays in the appeals process have had a crippling effect on Baxter's cash flow. Recouped funds at issue in the delayed appeals are funds that cannot be used to meet Baxter's essential needs, such as the following:

 Purchasing basic replacement equipment, like beds for its intensive care unit;

b. Replacing a failing roof over its surgery department, which Baxter has been able only to patch; and

c. Replacing its twenty-year-old catheterization laboratory. Without renovation, this laboratory will soon need to be shut down.

15. If Baxter had access to the almost \$3 million in funds that are currently subject to the ALJ delay, it would be able to address some or all of these critical needs.

JA38

Case 1:14-cv-00851-JEB Document 8-11 Filed 07/11/14 Page 4 of 4 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 42 of 180

16. In addition, the costs of Baxter's voluminous appeals of rehabilitation-related claim denials, combined with the delay in achieving resolution of those claims, has become so prohibitive that Baxter has considered whether it would be more financially prudent to close its rehabilitation center rather than to pursue the appeals.

17. Baxter's bond rating is also at risk. The unavailability of funds that remain pending in the appeals process has weakened Baxter's cash position, which plays a key role in issuance of bond ratings. Baxter's bond rating could easily fall to "junk bond" status if the ALJ delays continue.

I declare under penalty of perjury that the foregoing is true and correct. Executed this day of July, 2014.

Son Stoller

Ivan Holleman

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Civil Action No. 1:14-CV-851-JEB

Defendant.

DECLARATION OF JOHN GEPPI

I, John Geppi, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Knoxville, Tennessee.

3. I am submitting this declaration on behalf of Plaintiff Covenant Health ("Covenant") in support of Plaintiffs' Motion for Summary Judgment.

4. I am the Executive Vice President and Chief Financial Officer for Covenant. My responsibilities as Executive Vice President/CFO include oversight of substantially all non-clinical functions for Covenant including finance, patient accounting and revenue cycle management activities. I have a Bachelor's degree in business administration and over 40 years of healthcare finance experience.

Covenant's Background

5. Covenant is a community-owned health system located in East Tennessee, consisting of nine individual hospitals: Fort Sanders Regional Medical Center, Parkwest Medical

JA40

Case 1:14-cv-00851-JEB Document 8-12 Filed 07/11/14 Page 2 of 5 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 44 of 180

Center, LeConte Medical Center, Methodist Medical Center of Oak Ridge, Morristown-Hamblen Healthcare System, Fort Loudoun Medical Center, Roane Medical Center (these seven hospitals collectively, "Covenant's Hospitals"), and two hospitals recently acquired in 2014, Cumberland Medical Center and Claiborne Medical Center.

6. Covenant is the largest private employer in the region. Its member hospitals are deeply involved in community and outreach programs, special events such as the Covenant Health Knoxville Marathon, and support of local charities.

7. Covenant's mission is to serve the community by improving quality of life through better health. Its vision is for its clinical and service excellence to make it the first and best choice for patients, employees, physicians, employers, volunteers, and the community.

Covenant's ALJ Appeals

8. Delays in the Medicare appeals process are making fulfillment of Covenant's mission increasingly difficult. Medicare accounts for 55% of gross revenue across Covenant's Hospitals. Covenant is currently pursuing thousands of Medicare appeals to recover millions of dollars of Medicare reimbursement for services furnished to Medicare beneficiaries. Covenant's Hospitals have more than \$7.6 million in claims pending system-wide, over \$7 million of which is pending at the Administrative Law Judge ("ALJ") level of the Medicare appeals process.

9. Specifically, based on the information available to me as of July 11, 2014, Covenant's Hospitals have approximately 1477 appeals currently pending at the ALJ level, of which 1445 have been pending for longer than ninety days. Further, 622 of Covenant's appeals have been filed since July 15, 2013, and are thus subject to the moratorium on assignment of appeals to an ALJ.

Case 1:14-cv-00851-JEB Document 8-12 Filed 07/11/14 Page 3 of 5 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 45 of 180

10. Several of Covenant's Hospitals have particularly high numbers of pending appeals. For example, based on the information available to me as of July 11, 2014, Fort Sanders Regional Medical Center ("Fort Sanders") has 381 appeals pending at the ALJ level, representing nearly \$2.2 million in reimbursement: 379 of those appeals have been pending for longer than ninety days; 165 were filed after July 15, 2013 and are thus subject to the moratorium. Fort Sanders is a 541-bed regional hospital located in downtown Knoxville, Tennessee, which serves as a "regional referral center" for neurology, neurosurgery, orthopedics, oncology, cardiology, obstetrics, and rehabilitation medicine. Regional referral centers are hospitals to which other hospitals send their most difficult cases. Fort Sanders also offers specialized services such as one-day surgery, electrodiagnostics, a sleep disorders center, a diabetes management center, prenatal education, and sports medicine. Fifty-three percent of Fort Sanders' gross revenue is attributable to Medicare reimbursement.

11. Similarly, based on the information available to me as of July 11, 2014, Parkwest Medical Center ("Parkwest") has 399 appeals pending at the ALJ level, representing over \$2 million in reimbursement. All of those appeals have been pending longer than ninety days, and 144 of the appeals also were filed after July 15, 2013 and are thus subject to the moratorium. Parkwest, which is located in West Knoxville, is a premier medical facility and has been named among the nation's top 100 heart hospitals eight times by Solucient. In addition to providing the area's leading cardiac services, Parkwest has a nationally recognized emergency department and offers award-winning care in orthopedics, neurosurgery, and obstetrics. Over 56% of Parkwest's gross revenue comes from Medicare reimbursement.

12. The numbers of pending appeals are subject to change. Covenant regularly monitors and updates the status of its appeals.

Case 1:14-cv-00851-JEB Document 8-12 Filed 07/11/14 Page 4 of 5 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 46 of 180

13. The availability of an ALJ hearing to resolve its pending appeals is of critical importance to Covenant. The ALJ level of the Medicare appeals process is the level at which Covenant has typically been able to obtain relief from claim denials. For example, since April 2011, Parkwest has been successful in 81% of its appeals decided at the ALJ level. Fort Sanders has been successful in 72% of its appeals decided at the ALJ level during the same timeframe.

14. Unlike at other appeal levels, at ALJ hearings, Covenant has been able to present oral testimony, including testimony of clinicians, in support of its claims. It has had the opportunity to respond to any questions from the ALJ in real-time through the hearing process. This process has afforded Covenant the opportunity to explain and clarify the written arguments it has submitted to the ALJ prior to hearing.

15. In view of the significant advantages Covenant believes the ALJ hearing affords, Covenant does not consider escalation of its pending ALJ claims to the Departmental Appeals Board Medicare Appeals Council ("DAB") an adequate option. Likewise, in the vast majority of Covenant's cases, the cost of litigating in federal court could far exceed the value of the claim appealed due to the increased expense related to engagement of legal counsel and other internal administrative costs needed to pursue appeal at the federal court level.

The Impact of the ALJ Delay on Covenant

16. The extended delays in obtaining a hearing and decision by an ALJ, which have been further prolonged by the moratorium on assignment of new ALJ appeals, have harmed and are continuing to harm Covenant.

17. The delays in adjudicating these pending appeals have significantly impaired Covenant's cash flow. The over \$7 million in Medicare reimbursement associated with the claims that are pending in the Medicare appeals process is not available for Covenant's Hospitals to address patient care needs in the various communities those hospitals serve.

18. For example, Covenant is evaluating the scope of services provided to the population of patients it currently serves in light of the delays in adjudicating its appeals.

19. From January through May of 2014, Covenant's overall operating margin was negative 1.8%. The inability to recover the millions of dollars that are tied up in the appeals process is a major factor contributing to Covenant's system-wide negative operating margin.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of July, 2014.

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Civil Action No. 1:14-CV-851-JEB

Defendant.

DECLARATION OF CAROLINE STEINBERG

I, Caroline Steinberg, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Springfield, Virginia.

3. I am submitting this declaration on behalf of Plaintiff American Hospital

Association ("AHA") in support of Plaintiffs' Motion for Summary Judgment.

4. I am the Vice President of Trends Analysis for the AHA. My responsibilities as Vice President of Trends Analysis include policy research and trends analysis for purposes of AHA advocacy. Specifically, my responsibilities include collaborating with federal relations, media and policy staff to develop the policy research agenda for the AHA; overseeing a team of AHA staff and external consultants to model the impact of legislative and regulatory proposals on hospitals; and acting as spokesperson for the AHA on specific topics, such as trends affecting hospitals.

JA45

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5. I have twelve years of experience at the AHA. I joined the AHA in 2002 after fourteen years in health care consulting. I hold a Masters of Business Administration from the Tuck School of Business at Dartmouth and received my undergraduate degree from Harvard University.

6. The AHA is a national non-profit corporation organized and existing under the laws of the State of Illinois with offices in Chicago, Illinois, and Washington, D.C.

7. The AHA represents more than 5,000 hospitals, health care systems, and other health care organizations, plus nearly 43,000 individual members, in matters before Congress, the executive branch, and courts. The three hospital Plaintiffs, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center, are AHA members.

8. The AHA's mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and 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 on health care issues and trends.

9. The AHA's member hospitals are suffering harm from the delays in the Medicare appeals process, particularly at the Administrative Law Judge ("ALJ") level. Because of the AHA's mission to serve hospitals, health systems, and related organizations, and represent their interests in judicial matters, the AHA is well-positioned to pursue this lawsuit on behalf of its members. The interests sought to be protected by this lawsuit – the timely adjudication of hospital appeals of Medicare claim denials – are directly germane to the AHA's mission and purpose, which is to ensure that members' perspectives and needs are heard in judicial matters, national health policy development, and legislative and regulatory debates.

JA46

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10. As part of its mission to represent the interests of its member hospitals, the AHA created a survey to gather data regarding the impact of the Medicare Recovery Audit Contractor ("RAC") program on America's hospitals.

11. The AHA's "RACTrac" survey collects data from hospitals on a quarterly basis by asking hospital members to answer questions through an online survey tool that transmits hospitals' responses electronically to the AHA. Hospitals submit data to the AHA's RACTrac survey through their own claim tracking tools. Following the survey, the data are compiled and verified by independent consultants to the AHA, Booz Allen Hamilton and Provider Consulting Solutions. As a result, the AHA believes that RACTrac data are reliable, accurate, and consistent.

12. Attached as Exhibit 5 to Plaintiffs' Motion for Summary Judgment is a true and correct copy of the AHA's report entitled "Exploring the Impact of the RAC Program on Hospitals Nationwide" concerning the results of its RAC*Trac* survey in the first quarter of 2014. The AHA prepared and maintained its RAC*Trac* report in the regular course of AHA's business.

13. The RAC*Trac* data attached as Exhibit 5 are the most up-to-date available data on the impact of RACs on hospitals. The most recent data made publicly available by the Centers for Medicare & Medicaid Services dates from fiscal year 2012.

14. In the first quarter of 2014, 1,165 hospitals participated in the AHA's RACTrac survey. Ex. 5, RACTrac Survey Results, First Quarter 2014, at 4.

15. Ninety-three percent of reporting hospitals reported experiencing at least one delay longer than the statutory limit of ninety days for an ALJ determination to be issued. *Id.* at 51.

16. Reporting hospitals reported appealing forty nine percent of all RAC denials, with a sixty-six percent success rate in the appeals process for those RAC denials. Id. at 4.

The value of appealed, RAC-denied claims reported by the AHA's survey 17. respondents exceeds \$1.8 billion. Id. at 47. This number does not include the value of other appealed claims, which are also subject to the ALJ moratorium, but which the AHA does not separately track.

I declare under penalty of perjury that the foregoing is true and correct. Executed this Th day of July, 2014.

Caroline Steinberg

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Civil Action No. 1:14-CV-851-JEB

Defendant.

DECLARATION OF JOHN WALLACE

I, John H. Wallace, hereby declare and state the following:

1. The facts set forth in this declaration are based upon my personal knowledge. If

called upon as a witness, I could and would testify to these facts.

2. I am an adult citizen of the United States and reside in Rutland, Vermont.

3. I am submitting this declaration on behalf of Plaintiff Rutland Regional Medical Center ("Rutland Regional") in support of Plaintiffs' Motion for Summary Judgment.

4. I have served as Chief Compliance Officer for Rutland Regional since 2006. I

was admitted to the Vermont Bar in 1999 and have worked as a health care attorney for and with Vermont hospitals for fifteen years. I also teach health care ethics and compliance at the University of Vermont.

5. As the Chief Compliance Officer, I am responsible for ensuring that Rutland Regional complies with legal and ethical standards, in particular requirements associated with federal health care programs, and that we actively prevent and detect noncompliance. I also serve as in-house legal counsel. Since the development of the Medicare Recovery Audit Contractor ("RAC") program, I have been responsible for overseeing our response to external audits.

Rutland Regional and the Community It Serves

6. Rutland Regional is licensed as a 188-bed, community-owned rural hospital located in Rutland, Vermont. Despite its small size, Rutland Regional is the second largest hospital in the state of Vermont.

7. Rutland Regional offers the full scope of community hospital services, and has several outpatient specialty clinics including the Foley Cancer Center, The Rutland Heart Center, Rutland Women's health clinic, Rutland Diabetes and Endocrinology Center, the Vermont Orthopaedic Clinic, the ENT and Audiology Clinic, and Rutland Behavioral Health. Rutland Regional also provides uniquely important services to the community it serves, such as the newly opened West Ridge Center for Addiction Recovery. (Vermont ranks in the top ten of states for several measures of substance abuse. Rutland was recently featured on the front page of the *New York Times. See* Katharine Q. Seelye, *A Call to Arms on a Vermont Heroin Epidemic*, N.Y. TIMES, Feb. 27, 2014, at A1, available at http://www.nytimes.com/2014/02/28/us/a-call-to-arms-on-a-vermont-heroin-epidemic.html?_r=0.) Further, in 2011, Rutland Regional expanded its inpatient psychiatric services and assumed responsibility for patients that were displaced when the state's psychiatric hospital closed after flooding from Hurricane Irene.

8. More than 60,000 residents of Vermont and New York depend on Rutland Regional for hospital services. In fact, the Secretary of Health and Human Services ("HHS") has classified Rutland Regional as a "sole community hospital" pursuant to 42 U.S.C. § 1395ww(d)(5)(D)(iii) and 42 C.F.R. § 412.92. The "sole community hospital" program is intended to maintain access to hospital services for Medicare beneficiaries in areas of geographic isolation. HHS also has designated Rutland Regional as a "Rural Referral Center" because of the severity of cases it treats and the specialized physicians it provides to treat those cases.

9. Rutland Regional services an aging community with a large proportion of Medicare beneficiaries. In 2000, 14.9% of the population of Rutland County was age sixty-five or older. That number has grown to 16.6% in 2010 and is expected to continue to rise. By 2017, it is expected that 21.1% of Rutland County's population will be age sixty-five or older.

Moreover, in 2007, 20.9% of Rutland County's residents were Medicare
 beneficiaries, a higher percentage than the state of Vermont as a whole (17.2%). In fiscal year
 2013, Medicare was responsible for approximately 47% of Rutland Regional's gross revenues.

Rutland Regional's ALJ Appeals

11. Rutland Regional currently is pursuing Medicare appeals to recover approximately \$588,000 in Medicare reimbursement, of which approximately \$554,000 is pending at the Administrative Law Judge ("ALJ") level of the process.

12. Rutland Regional currently has ninety-eight appeals pending at the ALJ level. Ninety-six of the ninety-eight appeals have been pending for more than ninety days. Fifty-four of the ninety-eight appeals were filed on or after July 15, 2013 and are subject to HHS's moratorium on assignment of appeals to ALJs.

13. Of the ninety-six appeals that have been pending for more than ninety days, fiftyeight are appeals from denials by RACs. Most of Rutland Regional's appeals involve determinations by a Medicare contractor, such as a RAC, that a Medicare beneficiary who received treatment during an inpatient stay at Rutland Regional could have been treated as an outpatient instead. 14. Unlike at other levels of the appeal process, at ALJ hearings, Rutland Regional has the opportunity to present oral testimony, including testimony of clinicians, in support of its claims. It also has the opportunity to respond to any questions from the ALJ in real-time through the hearing process. The ALJ level offers Rutland Regional the first level of independent review of its claims.

15. Rutland Regional has also received detailed findings of fact and conclusions of law from ALJs when decisions have been rendered. Attached as Exhibits A, B, and C are true and correct copies of decisions Rutland Regional has received at the first three levels of appeal before the Medicare Administrative Contractor ("MAC"), Qualified Independent Contractor ("QIC"), and ALJ regarding the same patient care, redacted only to protect patient information. *Compare* Ex. A (MAC decision dated August 27, 2012) (offering two-paragraph explanation of decision in rendering denial) *with* Ex. B (QIC decision dated January 17, 2013) (offering approximately two-page explanation of decision in affirming denial for same patient care) *and* Ex. C (ALJ decision dated June 25, 2013) (providing eleven pages of findings of fact and conclusions of law in rendering wholly favorable decision for same patient care).

16. In view of the significant advantages Rutland Regional believes the ALJ hearing affords, Rutland Regional does not consider escalation of its pending ALJ claims to the Departmental Appeals Board Medicare Appeals Council to be an adequate option. Likewise, in all of Rutland Regional's pending cases, the cost of litigating in federal court would far exceed the value of the claim appealed.

The Impact of the ALJ Delay on Rutland Regional

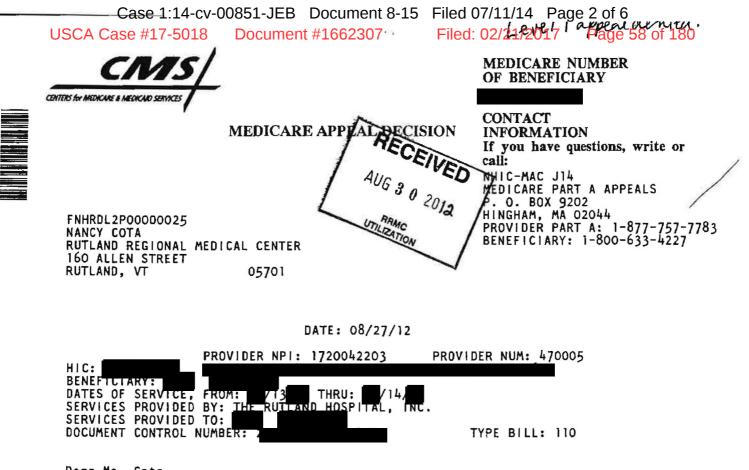
17. HHS's extended delays, which have been further prolonged by the moratorium on the assignment of new ALJ appeals, have harmed and are continuing to harm Rutland Regional. 18. If Rutland Regional had access to the over \$500,000 in funds that are subject to the ALJ delay, it could use those funds to advance its mission and enhance patient care, and create new clinics and programs.

19. Rutland Regional has had to implement a number of cost-cutting measures to accommodate the cash flow deficiencies caused, in part, by these delays. Rutland Regional initiated two rounds of cost-reductions that resulted in the elimination of thirty-two jobs. The community has been affected both through the loss of jobs and by the limitation on Rutland Regional's ability to serve its mission to improve the health of the community.

I declare under penalty of perjury that the foregoing is true and correct. Executed this // day of July, 2014.

John Wallace

EXHIBIT A



Dear Ms. Cota,

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal.

The appeal decision is unfavorable. Our decision is that your claim is not covered by Medicare.

More information on the decision is provided below. If you disagree with the decision, you may appeal to a Qualified Independent Contractor (QIC). You must file your appeal, in writing, within 180 days of receiving this letter. The Reconsideration Request Form is attached to help with this process. However, if you do not wish to appeal this decision, you are not required to take any action.

NHIC, Corp. was contracted by Medicare to review your appeal. For more information on how to appeal, see the section titled "important information About Your Appeal Rights." A copy of this letter was also sent to Mary Nickerson.

Summary of the Facts

Rutland Regional Medical Center submitted a claim for inpatient hospital services provided from 13, through 14, 14, An initial determination on the claim was made on June 7, 2012. The claim was denied because the information provided did not support the admission to the hospital as being medically necessary. On July 16, 2012, we received a request for a redetermination. A letter from a hospital representative and oncology notes were included with the appeal request. The documentation previously submitted to the Medical Review Department was also included in the redetermination process.

DATE: 08/27/12

Decision

We have decided that the above services are not covered by Medicare. We have also decided that the provider is responsible for payment of the noncovered services.

Explanation of the Decision

Our review of the records was based on the Internet-Only Manuals (10M) Pub 100-2, Medicare Benefit Policy Manual, Chapter 1, Section 10 and 100-8, Medicare Program Integrity Manual, Chapter 6, Section 6.5. Inpatient care rather than outpatient care is required only if the patient's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting. The patient's signs and symptoms must be severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis.

shortness of breath. The had a medical history that included cancer with metastasis to the liver. Upon presentation sodium level was found to be low, and was in no acute cardiopulmonary distress. The diagnostic scan of the brain was negative, and the scan of abdomen showed mild metastatic disease progression. White blood cell count was elevated, and the chest X-ray was negative for any acute infiltrates. There were also some notes indicating that the was anemic, and that a blood transfusion was to be ordered. If the treatment plan included intravenous fluids, antibiotics, and a respiratory therapy consultation. Symptoms improved, and was discharged in stable condition. The treatment provided could have been safely managed at an observation level of care. Inpatient care is only required if the patient's condition, safety, or health would be significantly threatened if care was given in a less intensive setting.

Who is Responsible for the Bill?

After reaching a decision that the service/item will not be covered by Medicare, we must decide who is liable for the denied service/item. The instructions contained in Section 1879 of the Social Security Act require two steps. First, we must decide if the beneficiary either knew or could reasonably be expected to know that the service/item would not be covered under 1862(a) (1) or 1862 (a) (9) of the Social Security Act. Next, we must decide if the provider either knew or could reasonably be expected to know that the service/item would not be covered under 1862(a) (1) or 1862(a) (9) of the Social Security Act.

By following these instructions, we have decided that the provider either knew or could be reasonably expected to know that the service/item would not be covered. 42 Code of Federal Regulations (CFR) 411.406 states that providers are presumed to have knowledge of published Medicare rules and DATE: 08/27/12

regulations, CMS rulings, Medicare coverage policies in contractor bulletins or websites and acceptable standards of medical care in the community. The provider has received notices and directives (such as bulletins, Change Requests, Medicare Memos, and Local Coverage Determinations) from CMS and this contractor. These have included instructions on how to access the Medicare Internet-Only Manuals (10Ms).

Therefore, the beneficiary is not responsible for the charges billed by the provider except for any charges for services never covered by Medicare. If the beneficiary has paid the provider for these services (including payment of co-insurance and deductible), the beneficiary may be entitled to a refund. To get this refund, please send the following items to this office:

- * A copy of this notice
- * The bill the patient received for the services, and
- * The payment receipt, the cancelled check, or any other evidence showing that the beneficiary has already paid for the services at issue.

The beneficiary should file the written request for refund within 6 months of the date of this notice.

What to Include in Your Request for an Independent Appeal

We believe we have all the evidence needed to make a decision. The documentation does not support the need for the service. However, you may still send additional information to explain why this service should be paid.

Special Note to Medicare Physicians, Providers, and Suppliers Only

Any additional evidence should be submitted with the request for reconsideration. All evidence must be presented before the reconsideration is issued. If all evidence is not submitted prior to the issuance of the reconsideration decision, you will not be able to submit any new evidence to the Administrative Law Judge or further appeal unless you can demonstrate good cause for withholding the evidence from the QIC.

NOTE: You do not need to resubmit documentation that was submitted as part of the redetermination. This information will be forwarded to the QIC as part of the case file utilized in the reconsideration process.

Sincerely,

Jennifer R. Murgia, LPN, AA

NHIC-A/B MAC J14 Medicare Part A <u>Case 1:14-cv-00851-JEB</u> Document 8-15 Filed 07/11/14 Page 5 of 6

Document #1662307

USCA Case #17-5018



Medicare Part A

Page 61 of 180

Filed: 02/21/2017

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision: If you do not agree with this decision, you may file an appeal. An appeal is a review performed by people independent of those who have reviewed your claim so far. The next level of appeal is called reconsideration. A reconsideration is a new and impartial review performed by a company that is independent from NHIC, Corp.

How to Appeal: To exercise your right to an appeal, you must file a request in writing within 180 days of receiving this letter. Under special circumstances, you may ask for more time to request an appeal. You may request an appeal by using the form enclosed with this letter.

If you do not use this form, you may write a letter. You must include: your name, your signature, the name of the beneficiary, the Medicare number, a list of the service(s) or item(s) that you are appealing and the dates(s) of service, and any evidence you wish to attach. You must also indicate that NHIC, Corp. made the redetermination. You may also attach supporting materials, such as those listed in item 10 of the enclosed Reconsideration Request Form, or other information that explains why this service should be paid. Your doctor may be able to provide supporting materials.

If you want to file an appeal, you should send your request to :

MAXIMUS FEDERAL SERVICES MEDICARE PART A EAST 3750 MONROE AVE, SUITE 701 PITTSFORD, NY 14534-1302

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

If you want someone to act for you, you may visit http://www.medicare.gov/basics/forms/de fault.asp to download the "Appointment of Representative" form, which may be used to appoint a representative. Medicare does not require that you use this form to appoint a representative. Alternately, you may submit a written statement containing the same information indicated on the form. If you are a Medicare enrollee, you may also call 1-800MEDICARE (1-800-633-4227) to learn more about how to name a representative.



Case 1:14-cv-00851-JEB Document 8-15 Filed 07/11/14 Page 6 of 6 USCA Case #17-5018 Document #1662307

Filed: 02/21/2017 Page 62 of 180



Medicare Part A

Other Important Information: If you want copies of the statutes, regulations, policies, and/or manual instructions, we used to arrive at this decision, or if you have any questions specifically related to your appeal, please write to us at the following address and attach a copy of this letter:

> NHIC A/B MAC J14 P. O. BOX 1000 HINGHAM, MA 02044

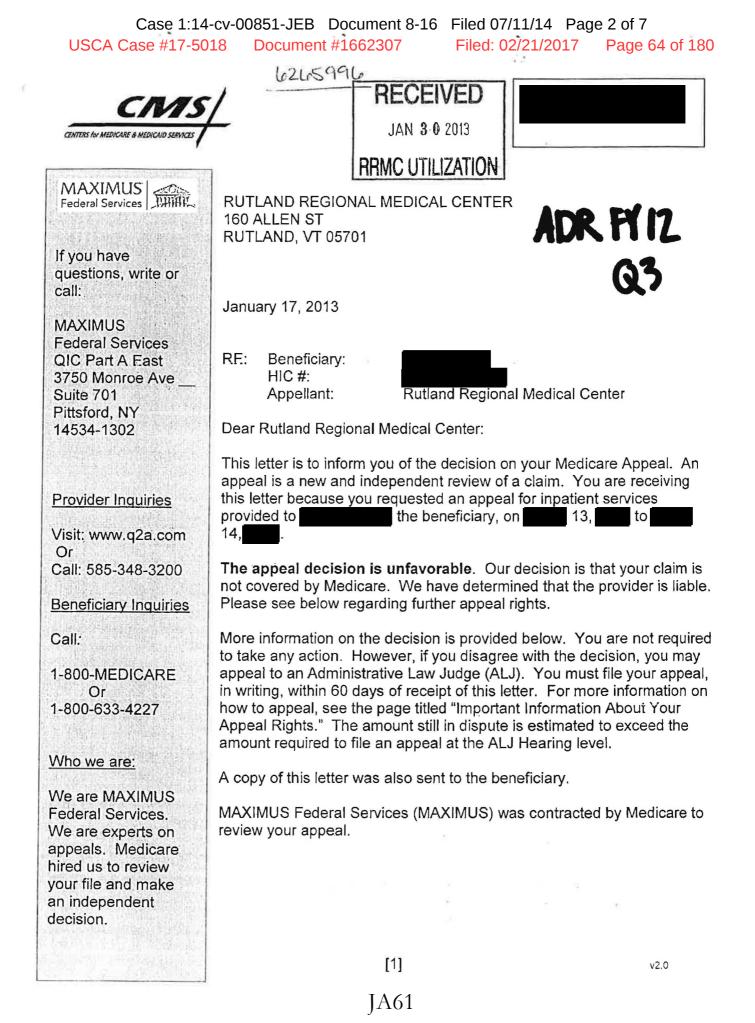
Resources for Medicare Enrollees: If you want help with an appeal, or if you have questions about Medicare, you can have a friend or someone else help you with your appeal. You can also contact your State Health Insurance Assistance Program (SHIP). You can find the phone number for your SHIP in your "Medicare & You" handbook, under the "Helpful Contacts" section of www.medicare.gov Web site, or by calling 1-800-MEDICARE (1-800-633-4227). Your SHIP can answer questions about payment denials and appeals.

For general questions about Medicare, you can call 1-800-MEDICARE (1-800-633-4227), TTY/TDD: 1-877-486-2048.

Remember that specific questions about your appeal should be directed to the contractor that is processing your appeal.

IA59

EXHIBIT B



Appeal Details at Issue

Document Control Number	Provider	Dates of Service			
	Rutland Regional Medical Center	13,	to	14	4,

Summary of the Facts

Rutland Regional Medical Center, the provider, billed for inpatient services provided to the beneficiary on **Service** 13, **Service** 14, **Service**. Upon initial determination, NHIC, Corp., the Medicare Administrative Contractor with jurisdiction, denied payment for the services. At redetermination NHIC, Corp. denied payment for services again. MAXIMUS received a request for reconsideration on September 20, 2012.

Decision

We have determined that Medicare does not cover the claim for the inpatient services provided to the beneficiary on **services** 13, **service** to **services** 14, **service**. We have also determined that the provider is responsible for payment for the inpatient services at issue.

Explanation of the Decision

Inpatient hospital care, rather than hospital outpatient care, is required only if the beneficiary's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting. For inpatient care, the medical record must indicate that inpatient care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary at any time during the stay. The beneficiary must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. (Medicare Program Integrity Manual, Publication 100-8, Chapter 6, Section 6.5.2)

For inpatient hospital care, admitting physicians or other practitioners should use a 24-hour period as a benchmark, i.e., they should order inpatient admission for patients who are expected to need such care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision whether to admit as an inpatient is a complex medical judgment, which includes consideration of a variety of factors, including:

· The patient's medical history and current medical needs;

• The types of facilities available to inpatients and outpatients, the hospital's bylaws and admission policies, and the relative appropriateness of treatment in each setting;

• The severity of the signs and symptoms exhibited by the beneficiary;

· The medical probability of something adverse happening to the beneficiary;

• The need for diagnostic studies that are appropriately outpatient services to assist in assessing the need for inpatient admission; and

• The availability of diagnostic procedures at the time when and at the location where the beneficiary presents.

(Medicare Benefit Policy Manual, Publication 100-2, Chapter 1, Section 10).

Outpatient observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether a patient will require further treatment as a hospital inpatient, or if s/he can be discharged from the hospital. Thus, a patient receiving hospital observation services may improve and be released, or be admitted as an inpatient. In the majority of cases, the decision whether to admit as an inpatient or discharge can be made in less than 48 hours, usually in less than 24 hours. (Medicare Benefit Policy Manual, Publication 100-2, Chapter 6, Section 20.6; Medicare Claims Processing Manual, Publication 100-4, Chapter 4, Section 290).

In this case, NHIC, Corp. determined that argued that the beneficiary did not require an inpatient level of care. When requesting this appeal, the appellant argued that the beneficiary required an inpatient admission.

A panel of licensed healthcare professionals reviewed this case and determined that the services at issue did not meet Medicare coverage criteria.

The beneficiary has a medical history significant for asthma, malignant neoplasm of the [diagnosed in 2006] with metastasis to the liver, six year history of multiple chemotherapeutic treatments. Most recently, the beneficiary received chemotherapy on [diagnosed], 2012 with Carboplantin and Gemcitabine followed by 1.5 mg of Pegfilgrastim. It is reported that the beneficiary was seen in clinic [cancer center] the day before and received intravenous hydration for volume depletion and anemia. The beneficiary was scheduled to receive two units of packed red blood cells on [diagnosed], 2012.

On 2012 Section 2012 the beneficiary was brought into clinic for evaluation of increased abdominal pain and confusion. On presentation the beneficiary was awake, alert, orientated in no acute distress, febrile [100,76], review of systems was noncontributory, white blood cell count was 16 k/ul. The beneficiary was admitted as an inpatient on 2012 With orders for intravenous hydration, pain management, blood transfusions [two units of packed red blood cells], radiological studies to assess metastatic disease or other etiology [computed tomography (CT) scan showed some mild disease progression], oncology social worker and case management.

Medicare criteria for inpatient admission was not met since the services rendered to the beneficiary were not high acuity services and none of the beneficiary's testing results revealed pathology that required complex therapy or that prompted urgent intervention. Finally, no complicating event occurred during the course of the hospital stay to require an escalation in the beneficiary's level of care, or to necessitate more intense monitoring. The beneficiary was discharged from the hospital on 2012 with plans to follow up at a later date.

The denial is upheld.

The inpatient hospital services at issue were not reasonable and medically necessary. The beneficiary must demonstrate signs and/or symptoms severe enough to warrant medical care and must receive services of such intensity that they could be furnished safely and effectively only on an inpatient basis. The documentation submitted for review did not support that the beneficiary required an inpatient level of care. Therefore, Medicare cannot cover the inpatient hospital services at issue.

Additional Information

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

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

Who is Responsible for the Bill?

Because we determined that the services in question did not meet Medicare coverage criteria, under the Social Security Act, Title 18, Section 1879, we must determine whether the beneficiary and/or provider knew or could reasonably have been expected to know that the services would not be covered under Medicare.

The case file did not include an Advance Beneficiary Notice or any other documentation that the beneficiary had been given prior written notice that Medicare would not pay for the inpatient services at issue. Therefore, we have concluded that the beneficiary in this case did not know, or could not reasonably have known, that any of these items or services would not be covered by Medicare, and the beneficiary is not financially responsible for these noncovered charges.

Since we have found that the beneficiary is not liable, we must next determine whether the provider should be held liable for any of these noncovered items or services. The provider has received or has access to CMS notices, including manual issuances, bulletins, or other written guides or directives from Medicare contractors, describing the basis for excluding certain services from Medicare coverage. Similarly, the provider has access to Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service. Therefore, we have determined that the Rutland Regional Medical Center is responsible for payment of the inpatient services because it knew, or could reasonably have been expected to know, that Medicare payment for the service or

item would be denied. (CMS Medicare Claims Processing Manual, Publication 100-4, Chapter 30, Section 40.1).

If you have any questions, please call the phone number on the front of this letter. For information on how to appeal this decision, please see the page entitled "Important Information About Your Appeal Rights."

Sincerely, Hen he getimories

Barbara M. Yakimowicz, J.D., M.H.A., PMP Project Director

BMY/MKR

cc:



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IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may file an appeal. An appeal is a review performed by people independent of those that have reviewed your claim so far. The next level of appeal is called an Administrative Law Judge (ALJ) Hearing. At this hearing, you or your representative may present your case before a judge.

If you appeal before January 1, 2013, you must have at least \$130 still in dispute. If you appeal after January 1, 2013, you must have at least \$140 still in dispute. This appeal can be combined with others to reach this total, if the other claims were appealed and dismissed within 60 day of this new request for an appeal, and involve similar or related services.

How to Appeal

To exercise your right to appeal, you must file a request in writing within **60 days** of receiving this letter. You must send your request to:

HHS OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, OH 44114-2316

You should use FORM CMS-20034 A/B, available at:

http://www.hhs.gov/omha/forms/index.html

Your written request must include: (1) The name, address, and Medicare health insurance claim number of the beneficiary, (2) The name and address of the person appealing, if the person is not the beneficiary, (3) The name and address of the representative, if any, (4) The appeal number listed on the front page of this notice, (5) The dates of service, (6) The reasons why you disagree with the decision, (7) Any and all evidence you wish to submit and the date it will be submitted, (8) A statement that you have sent a copy of this request to the other parties to the appeal, and (9) If you wish to combine claims to meet the ALJ Hearing minimum amount in dispute, include a list of the claims.

Under special circumstances, you may ask for more time to request an appeal.

Upon receipt of your request, the ALJ may decide a hearing is necessary for your appeal. ALJ hearings are usually held by telephone or videoteleconference (VTC) to make sure you get a hearing and decision as fast as possible. Telephone or VTC hearings reduce travel time for you, ALJs, and witnesses. If you do not want a telephone or VTC hearing, you may ask for a hearing in person, which the ALJ may grant for good cause. Your request must be in writing. Your request must explain why you believe an in-person hearing is necessary.

Who May File an Appeal

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

If you want someone to act for you, you and your appointed representative must sign, date and send us a statement naming that person to act for you. Call 1-800-MEDICARE to learn more about how to name a representative.

Help With Your Appeal

If you want help with an appeal, or if you have questions about Medicare, you can have a friend or someone else help you with your appeal. You can also contact your State Health Insurance Assistance Program (SHIP). You can call 1-800-MEDICARE (1-800-633-4227) for information on how to contact your local SHIP. Your SHIP can answer questions about payment denials and appeals.

Other Important Information

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

> MAXIMUS Federal Services QIC Fart A East 3750 Monroe Ave, Suite 701 Pittsford, NY 14534-1302

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

Other Resources To Help You

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

EXHIBIT C

Case 1:14-cv-00	D851-JEB Document 8-17	Filed 07/11/14 Page	e 2 of 12
USCA Case #17-5018	Document #1662307	Filed: 02/21/2017	Page 71 of 180



Department of Health and Human Services OFFICE OF MEDICARE HEARINGS AND APPEALS Midwestern Region Cleveland, Ohio

WHOLLY FAVORABLE DECISION

Appeal of: E.H.R. o.b.o. Rutland Regional Medical Center

ALJ Appeal No.:

Medicare Part A

Beneficiary:

HICN:

Before: James S. O'Leary U.S. Administrative Law Judge

Summary of Decision

Executive Health Resources is the Authorized Representative of Appellant. Rutland Regional Medical Center (Provider, Appellant) provided medical services (Part A Inpatient Hospital Admission) to (Beneficiary) for dates of service (DOS) 13, to 14, 14, 15, in satisfaction of Medicare coverage criteria, thus warranting this Wholly Favorable decision.

Procedural History

Issues

The Carrier denied the claims stating the records do not show why the services (Part A Inpatient Hospital Admission) could not have been safely provided in another setting (e.g. observation status or as an outpatient). The QIC denied the claim with similar reasoning (Exhs. 1-2; Exh. 2, pp. 20-26; Exh. 2, pp. 6-11). The issues to be decided by this Appeal are:

• Did Appellant prove the **13**, **13**, **10** to **14**, **14**, **14**, **15** inpatient hospital admission of Beneficiary was medically reasonable and necessary, thus warranting Medicare coverage and reimbursement at the level claimed?

Findings of Fact

The following facts were established by a preponderance of the evidence: These claims have been denied by the Carrier and the QIC. Appellant's appeal is now before this ALJ on a

Page 1 of 11

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timely filed appeal (Exh. 2, pp. 20-26; Exh. 2, pp. 6-11; Exh. 2, pp. 1-4; 42 C.F.R. §405.1002; 42 C.F.R. §405.1004; 42 C.F.R. §405.1014), which satisfies the amount in controversy (Exhs. 1-2; Exh. 2, p. 31; 42 C.F.R. §405.1006; 77 Federal Register (Fed.Reg.) No. 189, §59618-§59619 (September 28, 2012)).

Appellant, in furtherance of making their position better appreciated, has provided a Position Paper which argues:

This inpatient hospital admission was medically necessary, appropriate and consistent with the best local and national standards of medical practice. The medical record documents the following evidence which unquestionably shows that this admission fulfilled the Medicare requirements for an inpatient hospital admission under the CMS *Medicare Benefit Policy Manual (MBPM)*, pub. 100-02, Ch. 1, §10, as well as other noted CMS regulations and guidance. (Exh. 1, pp. 1-101; Exh. 2, pp. 18-19).

No Advanced Beneficiary Notice (ABN) appears in the file (Exbs. 1-2; §1879(a) of the Act, 42 USCA §1395pp; 42 C.F.R.§411.400- §411.408). Appellant has submitted additional records for consideration, including a Position Paper (Exbs. 1-2; Exb. 2, pp. 18-19; Exb. 2, pp. 1-32; 42 C.F.R. §405.1028; 42 C.F.R. §405.1018).

Legal Framework

I. ALJ Review Authority A. Jurisdiction

An individual or organization that is dissatisfied with the reconsideration of a Qualified Independent Contractor (QIC) or of a Medicare Quality Improvement Organization (QIO) is entitled to a hearing before the Secretary of the Department of Health and Human Services (hereinafter "HHS" and the "Secretary"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner (Social Security Act (hereinafter Act) §1869(b)(1)(A), 42 USCA §1395ff). The Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals ("OMHA") (§1869 of the Act, 42 USCA §1395ff; 42 C.F.R. §405.904; 70 Federal Register (Fed.Reg.) §36386, §36387 (06/23/05)). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council or Federal District Courts (See 42 C.F.R. §405.1048).

Page 2 of 11

JA69

B. Scope of and Standard of Review

The issues before the ALJ include all the issues brought out in the initial determination, Redetermination, or Reconsideration decisions that were not decided entirely in Appellant's favor. An ALJ may also consider and rule on issues not appealed by Appellant, if evidence causes the ALJ to question a previously wholly favorable decision. The ALJ may consider and rule on this issue as a 'new issue' provided the ALJ notifies all of the parties before the Hearing (42 C.F.R. §405.1032). ALJs are empowered to conduct *de novo* considerations of the facts and the law (See §1869 of the Act, 42 USCA §13955ff; 42 C.F.R. §405.904; 70 Fed. Reg. §36386, §36387 (June 23, 2005)).

II. Principles of Law A. Statutes & Regulations

Benefits for Medicare Part A include services provided to a Beneficiary as an inpatient in a hospital. Benefits for Medicare Part B include "medical and other health services" which includes diagnostic services which are (1) furnished to people as outpatients by a hospital or under arrangements with them made by a hospital and (2) such services are ordinarily furnished by the hospital to its patients for diagnostic study. Coverage for 'outpatient' observation services provided by hospitals to patients not yet admitted as 'inpatients' or discharged, is included in this grouping of services (\$1861(s)(2)(B)(C), 42 USCA \$1395x).

All Medicare coverage must always be measured by the standard that no payment may be made under Part A (hospital insurance) or Part B (supplementary medical insurance) for any expenses incurred for items or services that are not 'reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member' (\$1862(a)(1)(A) of the Act, 42 USCA \$1395y). Any potential payment of benefits must always be supported by sufficient information and documentation (\$1833(e) of the Act, 42 USCA \$13951).

A party requesting an ALJ Hearing must do so within 60 days of receipt of the notice of the QIC's Reconsideration Decision. The party is presumed to have received the QIC's decision 5 days after the date of the Reconsideration Decision, unless there is evidence to the contrary. The Request for ALJ Hearing is considered filed when it is received by the entity specified in the QIC's Reconsideration Decision or if it is filed in a timely manner with another entity by virtue of a good faith mistake (42 C.F.R. §405.1002; 42 C.F.R. §405.1014). If a party files a RFH after the 60 days have elapsed, they may request an extension of time to file and be considered timely if the ALJ finds good cause for the delayed filing (42 C.F.R. §405.1014(c); 42 C.F.R. 405.942).

Appellants must submit the evidence to be considered in a timely manner. Absent a finding of good cause by the ALJ, the evidence is late unless it was submitted before the issuance of the QIC's Reconsideration Decision (42 C.F.R. §405.966; 42 C.F.R. §405.1018; 42 C.F.R. §405.1028; 42 C.F.R. §405.942).

Providers are presumed to know the rules of Medicare, and what will or will not be covered. If neither the Provider nor the Beneficiary could reasonably have been expected to know something would not have been covered, then Medicare may cover it. If it is not covered, the Provider is presumed to be responsible, since they should have known it would not be covered. A Beneficiary can be held liable for payment for non-covered services if a valid written

Page 3 of 11

JA70

notice, Advanced Beneficiary Notice (ABN) or Notice of Non-Coverage, is provided to them in accordance with law (42 C.F.R. §411.400-§411.408; §1879 of the Act, 42 USCA §1395pp; *Medicare Claims Processing Manual (MCPM)* pub. 100-04, Ch. 30).

Section 1879 of the Act, provides for shifting of liability and for payment in cases where neither the Beneficiary or the Provider knew or had reason to know the goods and services would not be covered (§1879 of the Act, 42 USCA §1395pp).

B. Policy and Guidance

The Act states that unless promulgated as a regulation by the Secretary, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare Program (§1871(a)(2) of the Act, 42 USCA §1395hh; 42 C.F.R. §405.860). The Centers for Medicare and Medicaid Services (CMS) provide manuals for guidance in the administration of the Medicare Program. CMS approved contractors issue Local Medical Review Policies (LMRPs) and Local Coverage Determinations (LCDs). The Medicare manuals, LMRPs, and LCDs are not binding on ALJs, but are entitled to "substantial deference" (42 C.F.R. §405.1062; Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 102 (1995). No LCD was cited by the Carrier or the QIC.

The Medicare Benefit Policy Manual (MBPM) provides that Outpatient Observation Services are a well-defined, specific set of services used to decide a patient's treatment regimen. The services commonly include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation status is commonly assigned to patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. In most cases, the decision to admit as an inpatient or to discharge can be made within 24 hours. Only in rare and exceptional cases should the observation period last 48 hours or mnre. All hospital observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient. (MBPM, pub. 100-02, Ch. 6, §20.6; Medicare Claims Processing Manual (MCPM), pub. 100-04, Ch. 4, §290.1).

A person is considered a "hospital outpatient" if they have not been admitted by the hospital as an "inpatient", but are registered on the hospital records as an "outpatient" and receives services (rather than supplies alone) from the hospital or CAH (*MBPM*, pub. 100-02, Ch. 6, $\S20.2$). A service is "diagnostic" if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury (*MBPM*, pub. 100-02, Ch. 6, $\S20.4.1$).

While outpatient observation services can last for 48 hours; the true limit that is used and suggested appears to be the 24 hour limitation. By 24 hours, many authorities suggest a decision

Page 4 of 11

to either admit the patient for further observation/treatment or to discharge the patient should be able to be made (*MBPM*, pub. 100-02, Ch. 6, §20.6; *MCPM*, pub. 100-04, Ch. 4, §290.1 & Ch. 12, §30.6.8-§30.6.9.2).

CMS's Hospital Guidelines for Outpatient Observation Services states:

"Outpatient Observation is for: Evaluating a patient for possible inpatient admission; Treating patients expected to be stabilized and released in 24 hours (With appropriate documentation, patients can stay in observation more than 24 hours.); Extended recovery following a complication of an outpatient procedure (e.g., abnormal postoperative bleeding, poor pain control, intractable vomiting, delayed recovery from anesthesia). Outpatient Observation is NOT: A substitute for an inpatient admission; For continuous monitoring " (Exhs. 1-2; CMS Medical Director's Corner, Hospital Guidelines for Outpatient Observation Services (CMS GUIDELINES), by Richard K. Baer MD, Medical Director, 02/03/12. viewed Medicare Part A: See link. last at http://myedutrax2.com/docs/CMS_observation_services.pdf).

There is an *LCD*, *LCD L27548* addressing Acute Care: Inpatient, Observation and Treatment Room Services, which provides:

The determination of an inpatient or outpatient status for any given patient is specifically reserved to the admitting physician. The decision must be based on the physician's expectation of the care that the patient will require. The general rule is that the physician should order an inpatient admission for patients who are expected to need hospital care for 24 hours or longer and treat other patients on an outpatient basis. An inpatient admission is not covered when the care can be provided in a less intensive setting without significantly and indirectly threatening the patient's safety or health. Although in many institutions there is no difference between the actual medical services provided in inpatient and outpatient observation settings, in such cases the designation still serves to assign patients to an appropriate billing category.

A person is considered an inpatient if he is formally admitted based on the physician's expectation of a need for an appropriate inpatient stay. If the patient dies, is transferred, leaves AMA or recovers in a shorter period of time, an inpatient admission is still appropriate. The justification for the admission, then, is based on the information available at the time of admission. Subsequent information may support a physician's "hunch" that the patient needed inpatient care, but never serves to refute that original determination.

When the admitting physician orders observation services, the patient is considered an outpatient. While specific medical necessity for both inpatient admissions and outpatient observation is always determined on a case-by-case basis, certain diagnoses and procedures generally do not support an inpatient admission, and fall within the definitions of outpatient observation.

Uncomplicated presentations of chest pain (rule out MI), mild asthma/COPD, mild CHF, syncope and decreased responsiveness, atrial arrhythmias and renal colic are all frequently associated with the expectation of a brief (less than 24-

Page 5 of 11

hour) stay unless serious pathology is uncovered. Routine diagnostic cardiac catheterization, electrophysiologic mapping, and renal dialysis are usually performed with a similar short stay expectation and are thus usually outpatient procedures (LCD L27548).

The Medicare Program Integrity Manual (MPIM) addresses screening tools used to review Medicare claims and provides:

6.5.1 - Screening Instruments: The reviewer shall use a screening tool as part of their medical review of acute IPPS and LTCH claims. CMS does not require that you use a specific criteria set. In all cases, in addition to screening instruments, the reviewer applies his/her own clinical judgment to make a medical review determination based on the documentation in the medical record.

The following shall be utilized as applicable, for each case: Admission criteria; Invasive procedure criteria; CMS coverage guidelines; Published CMS criteria; DRG validation guidelines; Coding guidelines; and Other screens, criteria, and guidelines (e.g., practice guidelines that are well accepted by the medical community) Contractors shall consult with physician or other specialists if necessary to make an informed medical review determination. (*MPIM*, pub. 100-08, Ch. 6, §6.5.1).

On July 13, 2012 CMS issued *Technical Direction Letter (TDL) No.: 12309* which provides for the adjustment of hospital admission claims when the claims were initially submitted as inpatient Part A claims which are denied coverage at that level (Part A inpatient) and the claim is to be paid as a Part B outpatient observation level of hospital admission (See link, last viewed 10/18/12 at http://www.wachler.com/files/cms_memorandum_re_effectuating_part_b_reimbursement.pdf).

On March 13, 2013, the Centers for Medicare & Medicaid Services (CMS) issued Ruling 1455-R. The Ruling addresses a hospital's Medicare Part B billing options when a Medicare Part A claim was submitted. The Ruling essentially provides that if a Part A claim is submitted, the Part A claim is all that may be ruled on; and a Part A claim may not be denied but ruled on as favorable as a Part B claim. If no Part B claim was submitted by the hospital, there is no appealable initial determination on Part B services. If the Part A claims are withdrawn there are limited Part B claims which may be considered (See link, last viewed 03/22/13 at http://www.hhs.gov/omha/Data/cmsruling.html).

The Medicare Benefit Policy Manual (MBPM), pub. 100-02, Ch. 6, \$20.6 addresses Hospital Outpatient Observation Services and provides:

When a physician orders that a patient receive observation care, the patient's status is that of an outpatient. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient (see Pub. 100-02, Medicare Benefit Policy Manual, Chapter I, Section 10 "Covered Inpatient Hospital Services Covered Under Part A" at http://www.cms.hhs.gov/manuals/Downloads/bp102c01.pdf). For more information on correct reporting of observation services, see Pub. 100-04, Medicare Claims Processing Manual, chapter 4, section 290.2.2.) All hospital observation services,

Page 6 of 11

regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare (*MBPM*, pub. 100-02, Ch. 6, \$10, \$20.6).

Overpayments are discussed in the Medicare Financial Management Manual (MFMM) which provides:

Overpayments are Medicare payments a provider or beneficiary has received in excess of amounts due and payable under the statute and regulations. Once a determination of an overpayment has been made, the amount is a debt owed by the debtor to the United States Government.

The Federal Claims Collection Act requires timely and aggressive efforts to recover overpayments, including efforts to locate the debtor where necessary, demands for repayment, and establishment of repayment schedules, suspension of interim payments by intermediaries to institutional providers, and recoupment or setoff, where appropriate. (Medicare Financial Management Manual (MFMM), pub. 100-06, Ch. 3, §10).

The MCPM provides a Provider will be responsible for non-covered services if the Provider knew or should have known the services would not be covered. A provider may be able to limit the liability or shift liability with Advanced Beneficiary Notices (ABNs) or similar documents. Beneficiaries remain liable for services that are denied as technical or categorical denials, because the service may not meet the definition of a Medicare covered benefit; regardless of the presence of an ABN or not (42 C.F.R.§411.406; MCPM, pub. 100-04, Ch. 30, §30,2.1 & §40.1.2).

Analysis

Appellant has provided additional documents with the RFH. To the extent these documents are duplicates or summaries of previously submitted records, like a Position Paper, or they address the issue of good cause for late filing, they are admitted. To the extent the newly submitted records are new evidence they are denied as there has been no showing of good cause (Exhs. 1-2; Exh. 2, pp. 18-19; Exh. 2, pp. 1-32; 42 C.F.R. §405.1028; 42 C.F.R. §405.1018).

The claims at issue include Provider's provision of medical services (Part A Inpatient Hospital Admission) to Beneficiary on DOS 13, 14, 14, Any other claims, other than as stated hereinabove, will not be addressed by or ruled on in this decision, as they are not properly before the undersigned (Exhs. 1-2; Exh. 2, pp. 20-26; Exh. 2, pp. 6-11; Exh. 2, pp. 1-4; 42 C.F.R. §405.1032).

This is a de novo review and decision. The undersigned is not bound by the prior decisions. However, the prior decisions are a useful reference point as to how the appeal developed. The Carrier denied the claims stating the records do not show why the services (Part A Inpatient Hospital Admission) could not have been safely provided in another setting (e.g. observation status or as an outpatient). The QIC denied the claim with similar reasoning (Exhs. 1-2; Exh. 2, pp. 20-26; Exh. 2, pp. 6-11). Coverage of the claims at issue, and liability if applicable, will be examined and discussed below.

"An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that

Page 7 of 11

he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight....The decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as: (1) The severity of the signs and symptoms exhibited by the patient; (2) The medical predictability of something adverse happening to the patient; (3) The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and (4) The availability of diagnostic procedures at the time when and at the location where the patient presents." (MBPM, pub. 100-02, Ch. 1, §10).

Reviewing the factors set forth above, admission was appropriate because: (1) These signs and symptoms were severe, suggesting admission was appropriate. Beneficiary was admitted as an inpatient for IV Hydration, Pain Management, and Blood Transfusions (scheduled to receive 2 units on /14/10, or some combination of them with severe signs and symptoms of: (e.g. 66 year old presented to ER complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical history includes: Recurrent Cancer with Multiple Metastases (including to the liver); Asthma: Last Chemotherapy was //06/ (needed IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on 1/14/11). These were severe signs and symptoms; (2) The medical predictability of adverse consequences happening. Beneficiary was admitted with symptoms that suggested adverse consequences (e.g. 66 year old presented to ER complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical history includes: Recurrent Cancer with Multiple Metastases (including to the liver); Asthma; Last Chemotherapy was /06/ (needed IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on). Coupled with Beneficiary's age and medical history, the probability of something adverse happening had Beneficiary not received proper medical care promptly was good for an adverse event to occur. Beneficiary had high risk level for complications, serious injury or death; (3) The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted: This Beneficiary should not have been treated and tested as an outpatient. Beneficiary needed diagnosed and the acute problem(s) brought under control. Then Beneficiary would need intense close monitoring of Beneficiary's potentially changing conditions and reactions to any attempted treatments. Monitoring would help them adjust Beneficiary's medications and follow Beneficiary's recovery while in the hospital. Admitting Beneficiary as an inpatient provided the intense concentrated services to make complex decisions about treatments as quickly as possible. Inpatient services were exactly what Beneficiary needed. This suggested the problem will not be resolved within 24 hours, so conducting the tests on an observation level admission is not appropriate. Appellant argues the admission was entirely appropriate and medically reasonable and necessary because Beneficiary required closer monitoring in a setting that would provide access to emergent

Page 8 of 11

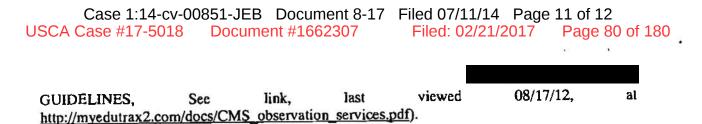
intervention if necessary; (4) The availability of diagnostic procedures at the time when and at the location where the patient presents: The ER and the observation status rooms do not have the availability of all of the equipment to test and continue to monitor all of Beneficiary's systems with the ease that an inpatient admission to the hospital would provide, nor is the observation unit staffed with nurses having as much higher training and certifications. The telemetry unit is staffed by nurses trained to watch critical care patients, has a smaller staff to patient ratio, and has more specialized equipment more readily available than other units of the hospital. Again, Appellant states the admission afforded this Beneficiary the required closer monitoring in a setting that would provide access to emergent intervention if necessary. These factors all suggest the inpatient admission was medically reasonable and necessary and at the level claimed by Appellant (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, p. 31; *MBPM*, pub. 100-02, Ch. 1, §10).

The QIC suggested a lesser level of care would have worked, such as an observation only status admission. There are several flaws with this option.

First, if one does no not admit Beneficiary but uses outpatient observation status to treat, then one runs into the limitation that outpatient observation status is to be used for 24 hours in order to decide if the person needs to be admitted or if the problem has resolved itself. If the problem does not resolve itself in 24 hours, then the person is usually admitted as an inpatient. Beneficiary was being admitted for suspected ACS, TIA/Stroke or Systemic Problem(s), or some combination of them with complicating factors (i.e. age, medical history and clinical presentation). Predicting this to be resolved in less than 24 hours was anything but a sure thing.

Second, using outpatient observation here would have been contrary to CMS Guidelines for Outpatient Observation Services, which states outpatient observation services are for three (3) situations, none of which was present here. CMS GUIDELINES provides outpatient observation services are appropriate for: (1) Evaluating a patient for possible inpatient admission; (2) Treating patients expected to be stabilized and released in 24 hours (With appropriate documentation, patients can stay in observation more than 24 hours.); (3) Extended recovery following a complication of an outpatient procedure (e.g., abnormal postoperative bleeding, poor pain control, intractable vomiting, delayed recovery from anesthesia). None of these three situations was what Beneficiary presented because: (1) the urgency of Beneficiary's symptoms suggested admission was appropriate; (2) Beneficiary was not expected to be stabilized within 24 hours; (3) Beneficiary was not recovering from any procedure; rather Beneficiary needed stabilized and treatment of the acute medical problem(s) because of Beneficiary's medical condition, as Beneficiary was admitted for IV_Hydration, Pain Management, and Blood Transfusions (scheduled to receive 2 units on 14/ or some presented to ER combination of them with complicating factors: (e.g. 66 year old complaining of Shortness of Breath (SOB) and Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical history includes: Recurrent Cancer with IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on 14/14/14). This required urgent treatment and inpatient hospital admission to isolate the reason(s) for the suspected ACS, TIA/Stroke or Systemic Problem(s), or some combination of them with severe signs and symptoms; then treat the causes and the symptoms. The physicians were anticipating what complications would arise and what additional procedures Beneficiary would need as the physicians tried to resolve this problem. Therefore, Beneficiary was more appropriately admitted and treated as an inpatient (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, p. 31; CMS

Page 9 of 11



Finally, this admission should be covered under the *LCD* because this Beneficiary was not experiencing:

Uncomplicated presentations of chest pain (rule out MI), mild asthma/COPD, mild CHF, syncope and decreased responsiveness, atrial arrhythmias and renal colic are all frequently associated with the expectation of a brief (less than 24-hour) stay unless serious pathology is uncovered. Routine diagnostic cardiac catheterization, electrophysiologic mapping, and renal dialysis are usually performed with a similar short stay expectation and are thus usually outpatient procedures (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, pp. 1-4; Exh. 2, p. 31; Exh. 5; LCD L27548).

This Beneficiary presented for IV Hydration, Pain Management, and Blood Transfusions (scheduled to receive 2 units on 14/14), or some combination of them with complicating presented to ER complaining of Shortness of Breath (SOB) and factors: (e.g. 66 year old Fatigue; ER tests showed: Hypotensive (80/40); Febrile (WBC count 16,000); Past medical Cancer with Multiple Metastases (including to the liver); histnry includes: Recurrent Asthma; Last Chemotherapy was /06/ (needed IV hydration the day before for volume depletion and anemia); admitted for IV Hydration, Pain Management, and to receive Blood Transfusions (scheduled to receive 2 units on 1/14/1). This was not anticipated to be an uncomplicated diagnostic admission with no need for complex care required. Rather, this was anticipated to be complicated and risky for this Beneficiary. That the physicians reacted to the complications that arose, managed the co-morbidities and managed to safely discharge the Beneficiary after such a brief stay shnuld be to their credit for a job well done. This is compliance with nr substantial deference to the LCD (Exhs. 1-2; Exh. 1, pp. 1-101; Exh. 2, pp. 18-19; Exh. 2, pp. 1-4; LCD L27548). For all of the above reasons, the undersigned finds admitting Beneficiary as an inpatient (Part A Inpatient Hospital Admission) was medically reasonable and necessary. As to the DRG claimed, Appellant's inpatient admission of Beneficiary was correct on these DOS, so Appellant's claims should be covered as claimed; including the claimed DRG (Exhs. 1-2).

ALJs are bound to follow statutes, regulations and NCDs. ALJs give substantial deference to LMRPs, LCDs and Medicare Manuals. InterQual is not sanctioned or officially recognized as authoritative by CMS. InterQual and its use is not sanctioned in a statute, regulation or NCD, a LMRP, LCD or part of the Medicare Manual series. The undersigned is required to give InterQual no weight at all. (Exhs. 1-2; §1871(a)(2) of the Act, 42 USCA §1395hh; 42 C.F.R. §405,860; 42 C.F.R. §405,1062; Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 102 (1995); 71 Fed. Reg. §51050 - §51085, at §51061 (08/28/2006)). The undersigned finds the services are covered by Medicare and liability is now moot (Exhs. 1-2).

Case 1:14-cv-00851-JEB Document 8-17 Filed 07/11/14 Page 12 of 12 USCA Case #17-5018 Document #1662307 Filed; 02/21/2017 Page 81 of 180

Conclusions of Law

Order

The Medicare Contractor is DIRECTED to process the claim in accordance with this decision.

decision.	8	
Dated: _	JUN 2 5 2013	(James 5 0 Ming
		James S O'Leary U.S. Administrative Law Judge

JA78

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,¹ Civil Action No. 14-cv-00851 (JEB)

Defendant.

DECLARATION OF NANCY J. GRISWOLD

I, Nancy J. Griswold, declare as follows:

1. I am the Chief Administrative Law Judge for the Office of Medicare Hearings and

Appeals (OMHA) within the Department of Health and Human Services (HHS), which, organizationally, is located within the Office of the Secretary. I have held this position since March 1, 2010. Among my duties, I oversee the third level of administrative review for individual Medicare claim and entitlement appeals within HHS, which is also known as the Administrative Law Judge (ALJ) level of review. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties.

2. On July 10, 2014, I submitted a written statement on OMHA workloads before the United States House Committee on Oversight & Government Reform Subcommittee on Energy Policy, Health Care & Entitlements, and I read that statement into the record under oath.

¹ Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell, the current Secretary of Health and Human Services, is automatically substituted as the named defendant for Kathleen Sebelius, the former Secretary of Health and Human Services.

Case 1:14-cv-00851-JEB Document 12-1 Filed 09/11/14 Page 2 of 2 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 83 of 180

A true and correct copy of that written statement is attached as Exhibit 1. *See also* http://www.hhs.gov/asl/testify/2014/07/t20140710a.html. To the best of my knowledge, the information contained in that written statement continues to be true and accurate.

3. OMHA requires significant additional funding to procure the resources needed to meet the 90-day timeframe for issuing ALJ decisions for all appeals. OMHA has a fixed amount of resources and must set priorities for how it will utilize those limited resources in light of the unprecedented number of appeals that are currently pending, and that continue to be filed, at the ALJ-level of administrative review.

4. Attached as Exhibit 2 is a true and correct copy of a December 24, 2013 letter I sent to appellants who had a significant number of Medicare appeals pending at the ALJ-level of administrative review.

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

Executed this 11th day of September, 2014, in Alexandria, Virginia.

Vancy J. Chiswold

EXHIBIT 1

STATEMENT OF

NANCY J. GRISWOLD

CHIEF ADMINISTRATIVE LAW JUDGE OFFICE OF MEDICARE HEARINGS AND APPEALS

ON

"OFFICE OF MEDICARE HEARINGS AND APPEALS WORKLOADS"

BEFORE THE

UNITED STATES HOUSE COMMITTEE ON OVERSIGHT & GOVERNMENT REFORM

SUBCOMMITTEE ON ENERGY POLICY, HEALTH CARE & ENTITLEMENTS

JULY 10, 2014

U.S. House Committee on Oversight & Government Reform Subcommittee on Energy, Health Care & Entitlements Hearing on Office of Medicare Hearings and Appeals Workloads July 10, 2014

Chairman Lankford, Ranking Member Speier and members of the Subcommittee, thank you for the invitation to discuss the workloads at the Office of Medicare Hearings and Appeals (OMHA). OMHA, a staff division within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claims and entitlement appeals under sections 1869 and 1155, of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries, and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicaid State Agencies, have a fair and impartial forum to address disagreements with Medicare claim determinations. This includes determinations related to Medicare eligibility and entitlement, as well as income-related premium surcharges made by the Social Security Administration (SSA). In addition, OMHA provides hearings on appeals of coverage determinations made by Medicare Advantage Organizations, health maintenance organizations, competitive medical plans, and Part D plan sponsors under sections 1876(c)(5)(B), 1852(g)(5), and 1860D-4(h) of the Act.

The Medicare claims appeals process consists of four levels of administrative review within HHS, and a fifth level of review with the federal district courts after administrative remedies within HHS have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors. The third level of review is administered by OMHA and is conducted by Administrative Law Judges. Subsequent reviews are conducted at the fourth level of appeal within the Departmental Appeals Board (DAB), and at the fifth level by the federal district courts.

The Medicare entitlement appeals process consists of three levels of administrative review, and a fourth level of review with the federal district courts after administrative remedies have been exhausted. The first level is the reconsideration level conducted by the SSA. The second level of review is administered by OMHA and is conducted by Administrative Law Judges. Subsequent reviews are conducted at the third level of appeal within the DAB and at the fourth level by the federal district courts.

The Department established OMHA in June, 2005, pursuant to section 931 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) which required the transfer of responsibility for the Administrative Law Judge hearing

function of the Medicare claims and entitlement appeals process from the SSA to the Department of Health and Human Services. OMHA was established to improve service to appellants and to reduce the average 368-day waiting time for a hearing decision that appellants experienced with SSA to the 90-day time frame for issuing dispositions established in the Medicare, Medicaid, and SCHIP Benefits and Improvement Act of 2000 (BIPA) (Pub. L. 106-554). In order to ensure that OMHA's adjudicators would have decisional independence from CMS, OMHA was established as a separate agency within the Department of Health and Human Services, reporting directly to the Secretary. Accordingly, OMHA operates under a separate appropriation and is both functionally and fiscally separate from CMS.

At the time OMHA was established, Congress envisioned that OMHA would receive:

- Claim and entitlement appeals workload from the Medicare Part A and Part B programs:
- Coverage appeals from the Medicare Advantage (Part C) program;
- A new workload of appeals from the Medicare Prescription Drug (Part D) program; and
- Appeals of Income Related Monthly Adjustment Amount (IRMAA) premium surcharges assessed by SSA.

With this mix of work at the expected levels, OMHA was for the most part able to meet the 90day time frame that Congress contemplated for most appeals. However, starting in FY 2010, OMHA began to experience an upward trend in the number of requests for hearings and delays in the average processing times for appeals.

From FY 2011 thru FY 2013, the upward trend in receipt levels took an unexpectedly sharp turn and OMHA experienced an overall 545% growth in appeals (from 59,600 in FY 2011 to 384,151 in FY 2013). This rise in the number of appeals resulted both from increases in the number of beneficiaries utilizing services covered by Medicare (CMS now processes more than one billion claims annually) and from the expansion of OMHA's responsibility to adjudicate appeals resulting from new audit workloads, including the nationwide implementation of the Recovery Audit Program in 2010. The Recovery Audit Program, established by Congress, has been very successful, returning billions in improper payments to the Medicare Trust Fund. Only 7% (99,492) of the 1.419 million Recovery Auditors claims identified as overpayments were challenged and overturned on appeal as published in the Centers for Medicare and Medicaid Services (CMS) FY 2012 Report to Congress. There have also been increases in Medicaid State Agency (MSA) appeals of Medicare coverage denials for beneficiaries enrolled in both Medicaid and Medicare. Although ALJ team productivity (dispositions per ALJ) more than doubled from FY 2009 through FY 2013 (from an average of 534 dispositions per ALJ team per year in FY 2009 to 1260 in FY 2013), the magnitude of these increases in workload has exceeded OMHA's ability to adjudicate incoming appeals within the 90-day time frame that Congress contemplated for most appeals. As a result of the significant disparity between workload and capacity, adjudication time frames have increased to their current level of 387 days (as of June 30, 2014).

OMHA has been able to maximize its productivity by supporting each of its ALIs with assigned processing teams consisting of attorneys and other support staff. This has allowed

3

each ALJ to focus on hearing and deciding appeals—functions which can only be performed by ALJs. However, OMHA's adjudication capacity is still limited by the number of ALJ teams on board. Under the 2014 continuing resolution, OMHA's funding level supported 65 ALJ teams. OMHA's 2014 enacted funding level allowed for the hiring of 7 additional teams, who will report on August 25, 2014. This will bring OMHA's adjudication capacity to approximately 72,000 appeals per year. However, this capacity pales in comparison to the adjudication workload. In FY 2013 alone, OMHA received 384,151 appeals, and in FY 2014 receipt levels through July 1 are approximately 509,124 appeals. Weekly appeal levels have ranged between 10,000 and 16,000 throughout FY 2014. As a result, OMHA had over 800,000 appeals pending on July 1, 2014. At current receipt and adjudication capacity levels, OMHA's Central Operations, which is the focal point for all incoming appeals, is receiving one year's worth of appeals every four to six weeks.

Due to the rapid and persistent influx of appeals, OMHA's four field offices faced significant challenges in their ability to safely store the high number of files pending hearing. As a consequence, OMHA began deferring its requests for case files from the lower appeal levels, and deferred the assignment of most requests for hearing to an Administrative Law Judge (ALJ), until they could be accommodated on an ALJ's docket. The decision to defer assignment of appeals was a management decision related to the geography of case storage and did not cause any additional delays in the hearing and decision of appeals. Although the assignment of most vulnerable appellants, comprise less than 2% of our workload and continue to be given priority assignment to ALJs. In February, 2014, OMHA began to assign a limited number of non-beneficiary appeals to judges who were able to accommodate additional appeals on their dockets. Throughout this time, OMHA has continued to conduct hearings and issue decisions on appeals already assigned.

Recognizing the impact the growing workload would have on our appellant community and the need for transparency with regard to its growing workloads, OMHA held an Appellant Forum on February 12, 2014, to inform stakeholders of its operating status. Over 800 individuals attended the forum either in person or by webinar. In addition to presentations by OMHA, both CMS and the DAB presented information concerning their workloads and processes. OMHA's next Appellant Forum is tentatively scheduled for October 29, 2014, and will be formally announced on our website in the near future.

In the face of dramatically increasing workloads, OMHA recognizes the need to deliver high quality and timely decisions on benefits and services to the Medicare community with greater efficiency. By the end of the fiscal year we will release our adjudicative business process manual, which will utilize best practices to standardize our business processes. We are using information technology to convert our process from paper to electronic. This effort will culminate in the first release of our Electronic Case Adjudication Processing Environment (ECAPE) in the summer of 2015. We have also developed a Medicare Appeals Template System (MATS), which simplifies the work of our staff by providing standardized fillable formats for routine word processing.

4

Recognizing the gravity of its workload challenges, OMHA proposed and former Secretary Sebelius established a departmental interagency workgroup in 2013, which included leaders from each of the three agencies involved in the Medicare appeals process (CMS, OMHA, and DAB). This interagency group conducted a thorough review of the appeals process and developed a series of initiatives that both OMHA and CMS are implementing to reduce the current backlog of pending appeals and the number of appeals that reach OMHA.

As a result of this cross-component cooperation and the assistance we have received from departmental leaders, OMHA is now implementing a number of pilot programs. On June 30, OMHA posted on its website two new options for appellants seeking resolution of their appeals. The first allows appellants to have their claims adjudicated using statistical sampling and extrapolation. This initiative facilitates resolution of large numbers of claims based upon resolution of a statistically valid sample. The second new option for appellants uses alternative dispute resolution techniques during a facilitated settlement conference conducted by OMHA attorneys who have been trained in mediation techniques. OMHA will be monitoring the performance of these pilots and, if successful, will roll them out nationally as funding allows. Finally, to bolster the processing of beneficiary appeals as our first priority, OMHA has redirected the efforts of its senior attorneys to assist in the prioritization of these appeals. Any beneficiary who believes their case is not receiving priority consideration at OMHA may contact us directly by e-mail at Medicare.Appeals@hhs.gov or at OMHA's toll free number, 855-556-8475.

OMHA is, by Congressional design, functionally and organizationally separate from CMS and its review processes. I understand, however, that in addition to the initiatives OMHA has undertaken to mitigate workload challenges, CMS also has taken a number of steps intended to substantially reduce the number of appeals submitted to OMHA. While CMS would be in the best position to address the specifics of those initiatives, I can provide a general outline. These initiatives include: a) beginning global settlement discussions involving similarly-situated claimants; b) under the new fee for service recovery audit contracts, requiring the new Recovery Auditors to offer providers and suppliers a 30-day discussion period to allow an opportunity for resolution before the Recovery Auditor refers a claim to the Medicare Administrative Contractor for collection; c) under the new fee for service recovery audit contracts, allowing for payment only after CMS' Qualified Independent Contractor (QIC) has made a determination supporting the recovery auditor's determination of an overpayment; d) issuing a proposed rule requiring prior authorization for certain durable medical equipment frequently subject to overutilization; and e) using CMS's demonstration authority to require prior authorization for two particular Part B services.

OMHA is privileged to have an extremely dedicated workforce of both Administrative Law Judges and staff who remain committed to processing Medicare appeals in both a quality and timely fashion. While the Department is working to address the backlog and the number of prospective appeals with current resources and authorities, the initiatives discussed today are

5

insufficient to close the gap between workload and resources at OMHA. Although all workloads at OMHA have experienced rapid growth, a significant portion of the increase is a consequence of the Department's efforts to implement legislation designed to combat Medicare fraud and reduce improper payments. The Department is committed to bringing these efforts and the resulting appeal workload into balance. With that goal in mind OMHA continues to work with departmental leaders to develop comprehensive solutions to its growing workloads and we also look forward to working with this committee and our stakeholders to develop and implement these solutions.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

Civil Action No. 14-cv-00851 (JEB)

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

DECLARATION OF ELLEN MURRAY

I, Ellen Murray, declare as follows:

1. I am the Assistant Secretary for Financial Resources and Chief Financial Officer of the Department of Health and Human Services (HHS or Department). I have held this position since February 2010. Among my duties, I provide advice and guidance to the Secretary on all aspects of budget, financial management, grants and acquisition management, and provide for the direction and implementation of these activities across the Department. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties.

2. Over the last several years, a significant backlog has developed in the number of appeals pending before the Department's Office of Medicare Hearings and Appeals (OMHA). A number of factors have contributed to the growth of this backlog, including the growth in the number of Medicare claims due to an increase in the number of Medicare beneficiaries, and a marked increase in the number of appeals brought by certain providers. Appeals generated from the denial of claims through the Department's statutorily mandated Recovery Audit (RA)

program have also contributed to the growth of the backlog. RA-related appeals, however, are only a portion of the appeals pending before OMHA. As of April 25, 2016, RA-related appeals constituted 31% of the pending appeals at OMHA, and non-RA-related appeals constituted 69% of the pending appeals at OMHA. That percentage is dropping, due at least in part to refinements to the RA program.

3. HHS recognizes that the appeals backlog is a matter of great significance, and it has made it a priority to adopt measures that are designed to reduce that backlog. As described below, HHS has adopted a series of measures, and is in the process of implementing additional measures, that are projected to eliminate the backlog in its entirety by the end of fiscal year (FY) 2021. HHS monitors the appeals backlog continuously and annually projects its size and the impact of the measures the Department has adopted, with quarterly updates. However, given the variance in when providers submit appeals and the time required to implement administrative initiatives and see results, we believe that the Department's progress is more meaningfully measured on a semi-annual and annual basis. Appellants have up to 120 days to submit requests for redetermination, 180 days to request reconsideration of a redetermination decision, and 60 days to request an ALJ hearing on a reconsideration decision. Some large institutional appellants submit appeals daily, while some providers may not submit any appeals in a given month, but wait to submit them in large groups.

4. Attached as Exhibit 1 is a true and correct copy of a table showing data and projections as of March 31, 2016 as to the number of pending OMHA cases from the end of FY 2014 to the end of FY 2020 under different scenarios. As shown in the table, at the end of FY 2014, the number of pending OMHA cases was 767,422. The table illustrates anticipated changes in the number of pending cases based on the projected impact of the current

administrative actions for which data is available and the projected impact of the proposed legislative actions described below. Based on the projected impacts of both types of actions, HHS expects the number of pending OMHA cases to fall to just 50,000 by the end of FY 2020, and the number of pending OMHA cases over 90 days old to be eliminated completely by FY 2021.

Background

5. The Centers for Medicare & Medicaid Services (CMS) processes an estimated 1.2 billion Medicare Fee-For-Service (FFS) claims annually for over 33.9 million beneficiaries whose health care benefits are provided through the Medicare program. Accurate and efficient payment and processing of claims for the services those beneficiaries receive is critical to ensuring the integrity of the Medicare program.

6. When Medicare beneficiaries or providers disagree with coverage or payment decisions made by Medicare, a Medicare health plan, or a Medicare Prescription Drug Plan, they have the right to appeal. In general, there are five levels in the appeals process: (1) redetermination by a Medicare Administrative Contractor (MAC); (2) reconsideration by a Qualified Independent Contractor (QIC) or Independent Review Entity (IRE); (3) hearing by an Administrative Law Judge (ALJ) in OMHA; (4) review by the Medicare Appeals Council (Council) within the Departmental Appeals Board (DAB); and (5) judicial review in federal district court.

7. The Department has statutory responsibilities both to protect the Medicare Trust Funds and to provide for a fair appeals process for Medicare beneficiaries and stakeholders. The Medicare statute charges the Department with the responsibility to ensure that payment from the Trust Funds is made only for valid claims for reimbursement. *See, e.g.*, 42 U.S.C. §§ 1395f(a), 1395g(a), 1395i(h). In fulfillment of this duty, the Department continues to strengthen Medicare program integrity to combat fraud, abuse, and improper payments to help protect the Medicare Trust Funds for current and future generations. The Medicare statute also charges the Department with the responsibility to provide a fair appeals system for its stakeholders. *See, e.g.*, 42 U.S.C. § 1395ff(b). The Department is committed to protecting the rights of Medicare beneficiaries and stakeholders through the Medicare appeals process. Several factors, including the growth in Medicare claims – largely driven by the aging population – and HHS' focus on combatting fraud, abuse, and improper payments have led to more appeals than HHS has the capacity to adjudicate. However, while the volume of appeals has increased dramatically, funding has remained relatively stagnant.

8. As of March 31, 2016, there were 761,318 appeals pending at OMHA and 19,302 appeals pending at the Council. As of March 31, 2016, OMHA was receiving approximately 3,500 new appeals per week, and the Council was receiving approximately 250 new appeals per week. As of March 31, 2016, the average time to obtain a decision for non-beneficiary appeals decided in FY 2016 at OMHA was 819.4 days.

Sources of the Backlog

The backlog in appeals pending before OMHA began to grow substantially in FY
 2010. The growth in the backlog is due to a number of factors.

10. First, beginning in 2011, Medicare began experiencing a large increase in the number of new beneficiaries as members of the "baby boom" generation began to reach age 65 and become eligible for Medicare. There have also been recent increases in the number of younger disabled individuals enrolling in Medicare. These increases, coupled with the increase in life expectancy of Medicare beneficiaries, have caused increases in the frequency of services

4 JA91 provided, in claims submitted to Medicare, and in the total number of denials of claims and resulting appeals.

11. Second, the Department's continued efforts to strengthen the integrity of the Medicare program have contributed to a growth in appeals. Between FY 2010 and FY 2015, OMHA's traditional workload (non-RA-related, non-State Medicaid Agency appeals) increased by 316%. CMS has contracted with claims review contractors to perform analysis of Medicare fee-for-service claims in order to identify atypical billing patterns and to identify inappropriate payments. CMS has also taken steps to refine and improve coverage policies and documentation requirements to protect against inappropriate payments where data analysis uncovers vulnerabilities to the Medicare Trust Funds. The result of the increased program integrity efforts and additional scrutiny of Medicare claims has been an increase in the number of claims subject to appeal.

12. Third, in recent years there has been a growing sense, among at least some members of the provider community, that it is a good business practice to appeal every denied claim. The absence of filing fees in the administrative appeals process has fostered the notion in the provider community that there is a low risk and potentially high reward associated with pursuing appeals. In addition, the amount in controversy required for an ALJ hearing (currently \$150) is substantially lower than the amount in controversy of \$1,500 required for judicial review. The amount-in-controversy requirement represents a very low barrier for access to the ALJ hearing process. As a result, a small number of appellants are responsible for a substantial portion of the appeals filed at OMHA in the absence of any disincentive to filing appeals. In FY 2015, of the more than 20,000 appellants that filed appeals with OMHA, including approximately 5,000 individual beneficiaries, three appellants filed nearly 40 percent of the

appeals (over 92,500 appeals). Additionally, since 2012, there has also been a marked increase in companies specializing in the handling of Medicare appeals, fueling increases in appeal filings.

13. Fourth, there has been a significant increase in appeals filed by Medicaid state agencies. Differences in Medicare and Medicaid coverage and payment rules for home health care services has led to an increase in appeals to determine the covered level of care and, in turn, the appropriate primary payer for dually-eligible beneficiaries. These factors have led certain states to seek post-payment review in almost every case where a dual-eligible beneficiary has services billed to Medicaid.

14. Fifth, although adjudication delays at OMHA have affected all categories of appellants, OMHA has recognized that the beneficiary population comprises its most vulnerable stakeholders. Because the issues presented in beneficiary appeals often involve emergent pre-treatment or continuation of care issues, this population is less able to absorb delays in case processing. For this reason, on July 15, 2013, OMHA's Chief ALJ directed the agency to prioritize appeals filed by beneficiaries. This policy has been responsible for the reduction in wait times for beneficiary appeals from a high of 259 days for appeals decided in FY 2013 to the current wait time of 68.4 days for appeals decided in FY 2016 (as of April 30, 2016).

15. Sixth, the number of appeals generated from the denial of claims through the RA program has also contributed to the backlog. However, OMHA's workload has also increased because of an increase in the number of non-RA-related appeals. As of April 25, 2016, RA-related appeals constituted 31% of the pending appeals at OMHA, but that percentage is dropping, due at least in part to the refinements to the RA program that are described below.

Based on trends in receipts at this time, HHS projects that RA-related appeals currently constitute only 20% of incoming appeals, and non-RA-related appeals constitute 80% of incoming appeals.

16. The non-RA-related workload at OMHA is composed of appeals by Medicaid State Agencies for Medicare claim denials for dually enrolled Medicare-Medicaid beneficiaries; appeals by providers, suppliers, and beneficiaries of pre- and post-payment Part A and Part B claim denials by MACs, Zone Program Integrity Contractors (which conduct data analysis to identify patterns of fraud and make appropriate referrals to law enforcement), and the Comprehensive Error Rate Testing Contractor (which measures and reports improper payments in Medicare fee-for-service); appeals by beneficiaries of Part A and Part B Medicare eligibility, entitlement, and premium determinations made by the Social Security Administration; and appeals of Medicare Advantage (Part C) organization determinations made by Medicare Advantage Organizations and Medicare prescription drug coverage determinations made by Part D Plan Sponsors.

Medicare Appeals Process Improvement and Backlog Reduction Plan

17. The Department's Medicare Appeals Process Improvement and Backlog Reduction Plan includes a three-pronged strategy to restore balance to the Medicare appeals process:

a. Take multiple administrative actions to reduce the number of pending appeals and encourage resolution of cases earlier in the process.

b. Request new resources from Congress to invest at all levels of appeal to increase adjudication capacity and to implement new strategies and expand existing activities to alleviate the current backlog.

7 JA94 c. Propose legislative reforms that provide additional funding and new authorities to address the volume of appeals.

18. HHS anticipates that the actions described below will reduce, and eventually eliminate, the backlog in OMHA's processing of appeals and allow OMHA to return to appropriate pending levels and processing times. However, given current workload trends, legislative and regulatory authorities, and funding levels, it is not possible to implement an immediate solution to the backlog at OMHA. HHS anticipates that the time to obtain a decision for non-beneficiary appeals will increase before it improves because the number of appeals that OMHA is receiving currently exceeds OMHA's capacity to decide them. But, as noted, HHS anticipates that the actions described below will succeed in eliminating the backlog and returning OMHA to appropriate pending levels and processing times by the end of FY 2021.

I. Administrative Actions

19. To date, the administrative actions being taken by the Department to reduce the backlog include:

a. <u>CMS Hospital Settlements</u>: In August 2014, CMS offered hospitals an option to administratively resolve appeals of certain inpatient hospital claim denials. The deadline for hospitals to request settlement was October 31, 2014. Under this option, hospitals received timely partial payment of the disputed claims in exchange for withdrawing a pending appeal and/or not further appealing the claim. The settlement provided an opportunity for the government to reduce the pending appeals by resolving a large number of homogeneous claims in a short period. In addition, settling the appeals allowed hospitals to obtain payment for rendered services, rather than waiting an extended time for an ALJ hearing or having to escalate an appeal, and allowed all parties to avoid the risk and expense of continued appeals. All

settlement agreements have been signed by the hospitals and CMS, and all payments have been made. CMS, OMHA, and the Council are currently removing the settled appeals from the system, and expect to complete this action by the end of FY 2016. When complete, the settlements will remove approximately 260,000 appeals that were pending at OMHA and the Council prior to the settlements.

Recovery Audit Program Contract Modifications: CMS has made several b. changes to the RA program to decrease the number of RA contractor-identified claims that are incorrectly denied and enter the Medicare appeals system. First, CMS has modified the RA contracts to require RA contractors, before they refer a claim they have identified as improper for recoupment, to first offer providers the opportunity to discuss the basis of the claim with the RA contractor and to submit additional information to substantiate payment of their claim. Second, CMS has limited the number of reviews the RA contractors may initially conduct under an approved topic, and no additional RA reviews may occur until CMS investigates the RA reviews already conducted and provides approval for additional reviews. Third, when CMS awards new RA contracts (expected in the summer of 2016), CMS will pay RA contractors only after a reconsideration decision by a OIC at the second level of appeal if the RA contractors' decisions are upheld at that level, or after the timeframe to file an appeal at the second level has expired. These contract modifications are expected to improve the accuracy of RA reviews and decrease the number of RA contractor-identified claims that enter the Medicare appeals system. HHS estimates that these actions will reduce the number of appeals that reach OMHA by more than 22,000 appeals by the end of FY 2020.

c. <u>Prior Authorization Initiatives</u>: CMS has initiated a series of demonstration projects, under which CMS requires that providers and suppliers obtain prior

9 JA96

authorization from the MACs for certain items or services in certain jurisdictions before the provider or supplier furnishes the item or service and bills for it. The prior authorization process encourages providers and suppliers to assess Medicare coverage criteria and meet documentation requirements before they furnish the service or item and before submitting a claim. The process also gives providers and suppliers the opportunity to correct errors and omissions because the provider or supplier may resubmit a request for prior authorization an unlimited number of times. It also reduces the number of appeals entering the appeals process by allowing providers to address issues with their documentation before submitting the claim, thereby reducing the number of claim denials. CMS currently has prior authorization demonstrations in nineteen states for power mobility devices, in eight states and the District of Columbia for non-emergent ambulance transport, and in three states for non-emergent hyperbaric oxygen. CMS has also recently finalized a prior authorization regulation for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 80 Fed. Reg. 81,674 (Dec. 30, 2015). HHS estimates that these initiatives will reduce the number of appeals that would have otherwise reached OMHA by more than 269,000 appeals by the end of FY 2020.

d. <u>QIC Demonstration – DMEPOS Discussions and Reopenings:</u> In January 2016, CMS launched a demonstration with DMEPOS suppliers that submit Medicare FFS claims in two DMEPOS MAC jurisdictions for diabetic testing supplies and oxygen equipment. These MAC jurisdictions cover 37 states and territories. Under this demonstration, suppliers have the opportunity to discuss their claim by telephone with the QIC at the second "reconsideration" level of appeal, submit additional documentation to support their claim, and receive feedback and education on CMS policies and requirements. HHS projects that, as a result of the discussions and educational outreach, new appeals for the DMEPOS items tested under the

demonstration will decrease by 10% due to suppliers submitting accurate Medicare claims to the MAC at the outset, thus reducing the number of claims that denied and then appealed to OMHA.

i. Under the demonstration, the QIC will also reopen certain QIC reconsideration decisions that are pending at OMHA, that could be resolved favorably using the information gained through the formal telephone discussion. Reopening these QIC decisions will reduce the number of appeals currently pending at OMHA.

ii. HHS projects that by the end of FY 2020, the supplier-education aspect of the demonstration will reduce the number of appeals that would have otherwise reached OMHA by more than 13,000 appeals. HHS further projects that the reopening aspect of the demonstration will reduce the number of appeals that reach OMHA by more than 63,000 appeals and resolve more than 202,000 appeals that are currently pending at OMHA. Thus, in total, HHS estimates that this action will reduce the number of appeals either pending at OMHA or that would otherwise reach OMHA by more than 278,000 appeals by the end of FY 2020.

iii. CMS anticipates expanding the scope of this demonstration in the future to include additional types of services, items, and supplies. CMS is not in a position at this time, however, to determine how quickly or to what extent the demonstration should be expanded. These determinations will depend on CMS' empirical experience with the current demonstration as it develops.

e. <u>OMHA Settlement Conference Facilitations</u>: OMHA staff who have been trained in mediation techniques are facilitating settlement conferences between CMS and appellants that currently have at least 20 claims, or \$10,000, at issue in appeals pending before OMHA for most Part B appeals; or that currently have at least 50 claims and \$20,000 at issue in appeals pending before OMHA for most Part A appeals. These conferences bring those appellants and CMS together to discuss administratively settling the appeals. As of May 18, 2016, of the 63 requests for facilitation that it has closed, OMHA has facilitated the settlement of 7,924 appeals for 17 appellants through this project – the equivalent of almost eight Administrative Law Judge (ALJ) teams' annual workload. In addition, OMHA is processing expressions of interest from 50 additional appellants for settlement conference facilitation. HHS estimates that, at current funding levels, this action will reduce the number of appeals that are currently pending at OMHA by more than 27,000 appeals by the end of FY 2020.

f. <u>OMHA Voluntary Statistical Sampling</u>: Under this pilot project, appellants with 250 or more claims filed before December 31, 2014 pending at OMHA may choose to have OMHA adjudicate their claims using statistical sampling and extrapolation. This allows the appellants to have large volumes of claims decided based on a statistically valid sample of the appellant's appealed claims, reducing the time and cost to obtain a decision. At this time, OMHA has over 6,000 appeals in this process and plans to open the project in summer 2016 to more claims by removing the date limitation that OMHA adopted while it assessed the pilot and balanced available resources. HHS estimates that this project will allow OMHA to process an additional 25,000 appeals by the end of FY 2020.

g. <u>OMHA On-the-Record Adjudication</u>: Under this program, OMHA senior attorney advisors review cases in which the appellant has waived its right to an oral hearing and requested that OMHA decide the merits of the case on the existing record. An OMHA senior attorney advisor reviews the record to verify that a decision can be issued without a hearing and drafts a recommended decision. An ALJ then reviews the record and the recommended decision, and if he or she concurs, issues the decision. An ALJ may also return the case to the senior attorney advisor with decision instructions. Since the program was initiated in July 2015, in addition to their other duties, OMHA senior attorneys have been responsible for resolving over 1,000 appeals – the equivalent of one ALJ team's annual workload. The program frees ALJ time to prepare for additional hearings, rather than conducting the initial review and assessment of records for cases in which the appellant has waived the oral hearing, and then issuing case development and/or decision instructions to a decision writer. The program also results in a faster decision because the appeal need not wait in the hearing queue. HHS estimates that, at current funding levels, this program will allow OMHA to process an additional 15,000 appeals by the end of FY 2020.

h. <u>Senior ALJ Program</u>: The Senior ALJ Program is administered by the Office of Personnel Management and allows agencies to reemploy retired ALJs on a temporary and intermittent basis, to work part-time conducting hearings and issuing decisions. The reemployment of retired ALJs allows OMHA to add temporary ALJ adjudication capacity to assist with the processing of delayed appeals. In FY 2016, OMHA will complete the hiring of 11 Senior ALJs through this program. HHS estimates that this action will increase the number of appeals that OMHA can adjudicate by more than 16,000 appeals by the end of FY 2020.

20. HHS estimates that by the end of FY 2020, the administrative actions described above in \P 19(a)-(h) will result in an OMHA backlog of nearly 50% fewer appeals than if the Department had not taken these administrative actions.

21. The Department has taken, or is in the process of taking, several additional administrative actions designed to reduce the backlog and increase adjudicative efficiency. The Department believes that these additional actions are contributing and will contribute to a reduction in the backlog and increase adjudicative efficiency at all levels, but it is not currently possible to quantify the extent of their impact. The estimated impact of these administrative

actions will be revisited as the actions are implemented and results from the administrative actions are evaluated. These actions include:

a. <u>Expanding the Medicare Appeals System (MAS)</u>: CMS continues to prioritize expanding the utilization of MAS to additional MACs. Currently, over 70 percent of the Part A redetermination workload is processed in MAS. MAS is a web-based system designed to support the management, execution, and administration of first, second and third level appeals. MAS is an integral part of CMS' management and oversight of MAC and QIC appeals. Access to real-time appeals data allows CMS to closely monitor workload trends and contractor performance. Implementing the system at additional MACs will improve accuracy, timeliness, and efficiency in the appeals process and provide electronic appeals case files and consistent processes in appeals activities across MACs and QICs.

b. <u>Accuracy Review Process</u>: CMS uses a comprehensive strategy to promote consistency and accuracy among all Medicare review contractors (including MACs, RA contractors, and others). To this end, CMS has established an Accuracy Review Team to verify that Medicare review contractors make accurate medical review determinations and apply Medicare policies consistently across the program. The Accuracy Review Team conducts monthly reviews of Medicare review contractors' review decisions, looking at varying items and services, including those that are currently part of new medical review initiatives, as well as on an ad hoc basis in response to specific concerns. Additionally, CMS continues to use a validation contractor to assess the accuracy of RA contractor determinations. The validation contractor establishes an annual accuracy score for each RA contractor, which is identified in the annual Recovery Auditing in Medicare Report to Congress. CMS uses the information gained through both of these activities to reexamine and clarify Medicare payment polices, furthering the effort to improve review consistency while addressing improper payment vulnerabilities. HHS expects that increasing consistency in review decisions and providing policy clarification where needed will result in a decrease in inappropriate denials, and therefore a decrease in appeals.

c. Judicial Education Training for OMHA ALJs and Adjudication Staff: Training sessions provide consistent training to adjudicators on Medicare coverage law and policy and Medicare administrative appeal procedures. The sessions routinely involve collaborative training using policy experts from OMHA, CMS, and the Council. Special sessions have also included participation from the HHS Offices of the Inspector General and General Counsel. This joint training increases decisional consistency between adjudicators at all levels of appeal, which may contribute to lower appeal rates by resolving issues at the lower levels of appeal and affecting appellants' business decisions whether to appeal to higher levels of appeal. After the Department implemented this joint training, the percentage of appeals (including dismissals) in which OMHA ALJs fully or partially reverse claim denials decreased from 63.2% in FY 2010 to the current rate of 28.4% as of March 31, 2016.

d. <u>Field Office Reorganization</u>: OMHA re-engineered its field office staffing structure, which streamlines and centralizes many administrative functions, serves as a template for future offices, and allows OMHA to use more of its funding on direct case-support functions.

e. <u>Field Office of the Future Initiative</u>: This is a collaborative effort between OMHA, the General Services Administration, and the Center for Legal and Courtroom Technology at the College of William & Mary. The initiative concurrently addresses expiring leases in existing agency offices, evaluates expanding business operations, and modernizes the agency's workspace for transition to an electronic system, while reducing OMHA's overall footprint at significant cost savings, which can be redirected to support case processing.

f. <u>Case Grouping Initiative</u>: This initiative uses data reports to identify appellants with a large number of filings (at least 200 appealed reconsiderations) and group them for assignment to an ALJ as a unit for potential consolidated proceedings and more efficient adjudication.

g. <u>Electronic Case Adjudication Processing Environment (ECAPE)</u>: OMHA

is in the process of transitioning to an electronic case adjudication processing system that will allow OMHA to process appeals electronically from filing to closure. ECAPE will modernize most aspects of OMHA's business process, especially in the areas of managing and handling documents, exhibiting case records, generating correspondence, scheduling and managing hearings, support the decision process by adding tools such as decision templates to make the decision writing process more efficient, and produce statistics on appeals and appeal trends for evaluation by management. It will also provide a public portal for appellants to file an appeal electronically and to submit evidence and access information about their appeal. ECAPE will also interface with CMS' electronic system, MAS, to retrieve MAC and QIC appeal data and documents and pass OMHA data and documents back to MAS for viewing by other appeal levels. OMHA expects to release phase I of ECAPE, which will allow most appellants to file their requests for hearing online, in summer 2016, and has begun scanning pending requests for an ALJ hearing in anticipation of a full electronic processing of cases in phase II, expected in winter 2017, followed by an expanded public portal in phase III, expected in spring 2017. The goal of ECAPE is to make the case processing and adjudication process more efficient, which will contribute to improving the timeliness of decisions.

h. <u>ALJ Appeal Status Information System (AASIS)</u>: AASIS is a website (accessed through OMHA's website) that provides public access to appeal status information, allowing users to obtain appeal data such as the date the request for an ALJ hearing was received, the appeal status, and the assigned field office and ALJ with team contact information. AASIS was introduced on December 30, 2014. This system provides an informational tool for appellants to look up their cases and reduces the number of inquiries that have to be addressed by OMHA staff, freeing that staff to focus on case processing work.

i. <u>Improvement and Formalization of Communications from the Council and</u> <u>OMHA to CMS and its Contractors</u>: Council, OMHA, and CMS staff meet bi-weekly to discuss operational and programmatic concerns and issues. This forum has been a useful tool for sharing information and identifying and resolving issues at all levels of the appeals process. CMS staff relay information they obtain through meetings with CMS contractors to OMHA and the Council. Likewise, OMHA and Council staffs share information from their levels of the appeals process with CMS and each other. These efforts improve case processing times by resolving administrative issues that slow down the adjudication process. For example, staff may identify, discuss, and resolve an operational issue related to the production of a particular group of case files for adjudication on appeal.

j. <u>OMHA Quality Assurance Program:</u> OMHA continues to focus on adjudication quality through an internal peer review program of closed ALJ decisions. The program has been instrumental in identifying areas for training and case processing policy development to enhance decisional quality, and contributed to the increasing consistency in case processing practices, as well as increasing decisional consistency among adjudicators. k. <u>Expanding Adjudicatory Capacity</u>: By streamlining space requirements and renegotiating leases in its existing offices, and through additional appropriations from Congress, OMHA was able to open a new office in Kansas City, Missouri in summer 2014, increase the size of its office in Arlington, Virginia, and will open a new office in Seattle, Washington, in summer 2016. As these offices open and expand, OMHA has brought on more staff to process appeals.

II. Legislative Proposals for Reforms and Additional Resources

22. Congress is currently considering several legislative proposals included in the FY 2017 President's Budget and in the Audit & Appeal Fairness, Integrity, and Reforms in Medicare (AFIRM) Act, S. 2368 – a bill that is under consideration in the Senate -- to address the increasing number of appeals and increase resources to reduce the size of the backlog, including several proposals that would expand administrative actions currently being implemented. These legislative proposals include:

a. Use of Medicare Magistrates and Increase Amount-in-Controversy

<u>Required for an ALJ Hearing</u>: Both the FY 2017 President's Budget and the AFIRM Act include proposals that would allow OMHA to use lower cost Medicare Magistrates (senior attorneys), rather than ALJs, to adjudicate cases in which the appealed claims meet the current amount-incontroversy requirement for an ALJ hearing (\$150 in 2016), but are below the Federal district court amount in controversy threshold (\$1,500 in 2016), and would increase the amount-incontroversy threshold for an ALJ hearing to that required for Federal district court review. Currently, the Social Security Act requires a hearing by an ALJ for a Medicare claim or coverage determination with an amount in controversy of \$150 or more. These proposals would reserve ALJs for more complex and higher amount in controversy appeals, and align the amount at issue

18 JA105

with the amount OMHA spends to adjudicate the claim. This action will increase the number of appeals that OMHA can adjudicate because more adjudicators can be hired to decide appeals based on the written record. If the measure becomes law and is fully funded, HHS estimates that 294,000 future appeals will be diverted from the ALJ hearing queue to the new Medicare magistrates by the end of FY 2020.

b. Additional Funding from RA Reimbursement or AFIRM Act: The FY 2017 President's Budget includes a proposal that would allow HHS to use RA program recoveries to supplement the annual appropriations for OMHA and DAB for the workload associated with RA-related appeals. The AFIRM Act also proposes increasing OMHA and DAB appropriations. Either authority would provide OMHA and DAB with an additional \$1.3 billion total in funding over 10 years. These additional resources would fund 101 additional ALJ teams who could adjudicate an additional 101,000 appeals per year, as well as additional adjudication capacity at DAB. HHS estimates that this action would increase the number of appeals that OMHA can adjudicate by more than 319,000 appeals by the end of FY 2020.

c. <u>Prior Authorization for Any Non-Emergent Medicare Item or Service</u>: The FY 2017 President's Budget includes a proposal to give the Secretary the authority to require prior authorization for any non-emergency Part A or Part B item or service. HHS estimates that this action would reduce the number of appeals that reach OMHA by more than 90,000 appeals by the end of FY 2020.

d. <u>Refundable Filing Fee</u>: The FY 2017 President's Budget includes a proposal to institute a refundable per-claim filing fee for providers, suppliers, and Medicaid State Agencies, including those acting as a representative of a beneficiary, at each level of appeal. The fee would not apply to appeals filed by beneficiaries (unless the beneficiary was represented by the provider, supplier, or Medicaid State Agency). Fees would be returned to appellants who receive a fully favorable determination. Under current law, there is no administrative fee paid to the adjudicating entity for filing an appeal; an appellant's cost for utilizing the appeals process is limited to the appellant's costs associated with appeal preparation. Filing fees would partially offset appeals costs and allow HHS to reinvest funds in order to improve responsiveness in the appeals process. In addition, a filing fee would encourage potential appellants to assess the merits of their appeals more carefully before filing. Currently, a small number of appellants file a significant number of appeals in part because their preparation cost is minimal. As noted above, in FY 2015, of the more than 20,000 appellants that filed appeals with OMHA, including approximately 5,000 individual beneficiaries, three appellants filed nearly 40 percent of the appeals (over 92,500 appeals). HHS has not estimated the impact of this action on the backlog. The Department would need to review the program after Congress enacts the legislation before it could reasonably estimate an impact.

e. <u>Sample and Consolidate Similar Claims for Administrative Efficiency</u>: Both the FY 2017 President's Budget and the AFIRM Act include proposals that would allow the Secretary to adjudicate appeals through the use of sampling and extrapolation techniques. Additionally, these proposals would authorize the Secretary to consolidate related appeals into a single administrative appeal at all levels of the appeals process for purposes of administrative efficiency. In addition, parties would be required to file one appeal request to appeal all claims included within an extrapolated overpayment or consolidated previously within the appeals process. Currently, when parties appeal claim determinations that are part of an extrapolated overpayment or a consolidated appeal, they are not required to appeal those determinations together, leading to inefficiencies in appeals processing. HHS has not estimated the impact of this action on the backlog. The Department would need to review the program after Congress enacts the legislation before it could reasonably estimate an impact.

f. Remand Appeals to the Redetermination Level with the Introduction of New Evidence: Both the FY 2017 President's Budget and the AFIRM Act include proposals that would require an adjudicator to remand an appealed claim to the first level of appeal when a party to the appeal (other than a beneficiary or CMS or its contractors) submits new documentary evidence at the second level of appeal or above. The adjudicator may choose not to remand if the evidence was provided to the lower level adjudicator but erroneously omitted from the record on appeal, or if the adjudicator denies the claim on a new and different basis from earlier determinations. This proposal provides a strong incentive for appellants to produce all evidence early in the appeals process and promotes the goal of having the same record reviewed and considered at the second and subsequent levels of appeal. There continues to be a propensity on the part of providers and suppliers to submit evidence in the administrative appeals process after the reconsideration (second) level. By submitting evidence late, these appellants create situations in which the redetermination and reconsideration levels of appeals correctly uphold claim denials based on the evidence before them, but the ALJ or Council overturns these denials because the appellant has submitted new evidence into the record. This proposal would also deter later submission of evidence, as submissions after the redetermination level would only serve to restart the appeals process and potentially delay payment to the appellant. HHS has not estimated the impact of this action on the backlog. The Department would need to review the program after Congress enacts the legislation before it could reasonably estimate an impact.

g. <u>Expedited Procedure for Claims with No Material Facts in Dispute</u>: Both the FY 2017 President's Budget and the AFIRM Act include proposals allowing OMHA to issue decisions without holding a hearing if no material facts are in dispute and the ALJ determines that binding authority controls the decision in the matter. These cases include, for example, denials of drug coverage under Medicare Part D because the drug does not qualify as a Part D drug under the statute, or denials of items or services because they do not fall within a Medicare benefit category. Appeals of these "technical denials," as well as appeals that involve only procedural issues, could be resolved without a hearing. This proposal would increase the efficiency of the Medicare appeals system and result in faster adjudications of appeals at the ALJ level. HHS has not estimated the impact of this action on the backlog. The Department would need to review the program after Congress enacts the legislation before it could reasonably estimate an impact.

h. <u>Expanded OMHA Settlement Conference Facilitations</u>: With additional discretionary funding requested in the FY 2017 President's Budget, OMHA could expand the settlement conference facilitation described in paragraph 19(e) above. HHS estimates that this action would reduce the number of appeals that would otherwise be pending at OMHA by 180,000 appeals by the end of FY 2020.

i. <u>Expanded On-the-Record Adjudication</u>: With additional discretionary funding requested in the FY 2017 President's Budget, OMHA could expand the on-the-record adjudication described in paragraph 19(g) above. HHS estimates that this action would increase the number of appeals that OMHA can adjudicate by 69,000 appeals by the end of FY 2020.

Medicare Appeals Council Initiatives

23. Many of the administrative and legislative initiatives discussed above for reducing the backlog at OMHA have the effect of increasing the number of appeals received by the Council. This is because appellants appeal some of the claims OMHA adjudicates (currently

approximately 10%) to the Council. Therefore, additional funding and authorities that increase adjudications by OMHA will also increase the number of cases appealed to the Council. For this reason, one of the Department's main strategies is to address appeals at the lower CMS levels (MAC and QIC) in order to prevent certain appeals from ever entering the system. These initiatives, described in paragraphs 19(a) -19(e), not only decrease the number of appeals received by OMHA, but they also decrease the number of appeals OMHA adjudicates that are then appealed to the Council.

24. The Department has implemented additional initiatives to help reduce the present and anticipated backlog at the Council. Those initiatives include:

a. <u>Case Processing Support</u>: In June 2015, the Council began using contract paralegal support to perform essential case functions including processing incoming mail and docketing incoming appeals. In addition, the contract paralegals draft basic orders, such as CMS Hospital Settlement dismissals and select remand orders, for an AAJ's review, which increases the adjudicative capacity of the Council.

b. <u>Medicare Operations Division (MOD) Process Management Attorney</u>: The Council has identified one of its existing attorney-advisors to act as the MOD Process Management Attorney. The role of the MOD Process Management Attorney is to analyze the backlog, identify beneficiary and other priority cases, such as pre-service cases, and look for potential consolidations to increase case processing efficiencies with the DAB's current resources. The MOD Process Management Attorney will continue to implement process improvements to better accommodate the increased number of new appeals received per week, including reorganization of its pending cases, to increase efficiencies and economize work efforts. Finally, the MOD Process Management Attorney coordinates with other levels of review to resolve systemic issues that increase case processing times. For example, the MOD Process Management Attorney has established processes with OMHA to quickly address claim file deficiencies, which permits the Council to review cases in a timelier manner.

Electronic Case and Record Initiatives: The Council has implemented a c. series of initiatives that will allow it to process appeals electronically from filing to case closure. The Council began receiving electronic claim files in cases referred by CMS in FY 2014. The use of electronic records improved case processing time by reducing the wait time to correct deficiencies in administrative records and allowing multiple analysts to review records at one time. Beginning in FY 2015, the Council began receiving electronic records in other types of cases and currently receives approximately 35% of its claim files in a digital format. In addition, the Council has developed an electronic filing system that will be tested and deployed in the beginning of FY 2017. The electronic filing system is designed to automate the docketing process, which will further reduce case processing times and allow the Council to identify deficiencies with new appeal requests at an earlier stage. Finally, the Council automated the incoming mail log on April 1, 2016. Automation of the mail log has decreased case intake time and has improved case tracking abilities. In the future, to streamline the review process further, the Council plans to develop a module with interoperability to OMHA's ECAPE case management system.

d. The Department is continuing to explore other initiatives to manage the increase in appeals to the Council that will result from the actions taken to reduce OMHA's backlog.

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

Executed on May 25, 2016 in Washington, D.C.

Mus

Ellen Murray

		FY14	FY15	FY16	FY17	FY18	FY19	FY20
	Beginning Workload Balance	380,696	767,422	928,901	1,085,984	1,269,930	1,474,558	1,690,789
Projections with No Action New Receipts	New Receipts	474,063	240,360	241,583	275,946	296,628	308,231	317,920
Taken	Disposition	(87,337)	(78,881)	(84,500)	(92,000)	(92,000)	(92,000)	(92,000)
	Cumulative Backlog - No Action Taken	767,422	928,901	1,085,984	I,269,930	1,474,558	1,690,789	1,916,709
	CMS Hospital Settlement	•	(42,483)	(215,863)	•	•	•	3
	Recovery Audit Program Contract Modifications	'	ı	(974)	(3,894)	(5,355)	(5,841)	(6,085)
	Prior Authorization (Administrative Actions)	'	,	(22,601)	(50,552)	(74,818)	(61,124)	(60,152)
	QIC Demonstration - Provider Education Impact	1	•	(1,396)	(2,871)	(2,951)	(3,034)	(3,122)
Dunitations with Toward of	QIC Demonstration - Appeals Resolved before Reaching OMHA	•	•	(160'L)	(14,183)	(14,183)	(14,183)	(14,183)
	OMHA Settlement Conferences	•	(2,401)	(2,000)	(2,000)	(2,000)	(5,000)	(5,000)
Administrative	On-the-Record adjudication	'	•	(3,000)	(3,000)	(3,000)	(3,000)	(3,000)
ACCIUIS	Senior ALJ Program	'	ı	(585)	(3,960)	(3,960)	(096(0)	(096'E)
	Statistical Sampling (Administrative Actions under Current Authorities and Budget)	•	•	(5,000)	(2,000)	(2,000)	(5,000)	(2,000)
	QIC Demonstration - Reopening of Appeals Pending at OMHA		•	(22,500)	(45,000)	(45,000)	(45,000)	(45,000)
	Administrative Actions Impact Total	,	(44,884)	(284,010)	(133,460)	(159,267)	(146,142)	(145,502)
	Cumulative Backlog - With Current Actions Taken	767,422	884,017	757,090	807,576	852,937	923,026	1,003,444
	Legislation: Magistrates; Procedural Issues and Revised AIC	•	•	•	(42,000)	(84,000)	(84,000)	(84,000)
Becientione with Immedia of	Device instant and the second of the second	ı	ı	1	(16,833)	(101,000)	(000'101)	(101,000)
r rojecualis with inipacts of	OMHA Settlement Conference Facilitations (Additional Capacity - Budget Dependent)	ı	,		(45,000)	(45,000)	(45,000)	(45,000)
Commentional Actions And	On-the-Record Adjudication (Additional Capacity - Budget Dependent)	ı	•	•	(3,000)	(22,000)	(22,000)	(22,000)
Congressional Actions (notin Ionislation and hudsoft)	Prior Authorization for any non-emergent Medicare Item or Service Legislative Proposal	•	•		(8,230)	(15,949)	(32,813)	(33,776)
	Legislative/Budget Dependent Actions Impact Total	ł	I	1	(115,063)	(267,949)	(284,813)	(285,776)
	Cumulative Backlog - Legislative/Budget Dependent Actions Taken	767,422	884,017	757,090	692,513	469,925	255,201	49,843

Case 1:14-cv-00851-JEB Document 30-1 Filed 05/25/16 Page 27 of 27 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 116 of 180

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 14-851 (JEB)

ORDER

For the reasons set forth in the accompanying Memorandum Opinion, the Court

ORDERS that:

- 1. Defendant's Motion for Stay is DENIED; and
- 2. Parties shall appear for a status conference on October 3, 2016, at 9:30 AM.

SO ORDERED.

<u>/s/ James E. Boasberg</u> JAMES E. BOASBERG United States District Judge

Date: September 19, 2016

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 14-851 (JEB)

MEMORANDUM OPINION

The best medicine can sometimes be hard to swallow. More than two years ago, a set of Medicare service providers asked the Court to issue a writ of mandamus to compel the Secretary of Health and Human Services to process their long-pending claim-reimbursement appeals in accordance with statutory timelines. The Court declined to do so, believing the matter best left to the political process. The Court of Appeals disagreed, holding that this Court has jurisdiction to grant mandamus relief and remanding the case here for a determination on the merits. In response, the Secretary now moves to stay the proceedings until September 30, 2017, to allow HHS to move forward on various administrative and legislative efforts designed to tackle the backlog of reimbursement appeals. As was true two years ago, the Court is reluctant to intervene. But the backlog and delays have only worsened since Plaintiffs first sought the

Court's help, and the Secretary's proposed solutions are unlikely to turn the tide. The Court accordingly will deny the Secretary's Motion for Stay.

I. Background

The Court offered a primer on Medicare reimbursement in its first Opinion in this case. <u>See Am. Hosp. Ass'n v. Burwell</u> (<u>AHA I</u>), 76 F. Supp. 3d 43, 46-48 (D.D.C. 2014), <u>rev'd</u>, <u>Am.</u> <u>Hosp. Ass'n v. Burwell</u> (<u>AHA II</u>), 812 F.3d 183 (D.C. Cir. 2016). It now briefly reviews the aspects of the administrative-appeals process relevant to the instant Motion.

Health-care providers and suppliers submit an extraordinary number of Medicare fee-forservice claims on behalf of the program's beneficiaries — 1.2 billion in fiscal year 2014. <u>See</u> Gov't Accountability Office, <u>Medicare Fee-for-Service: Opportunities Remain to Improve</u> <u>Appeals Process</u> 1 (May 2016), http://www.gao.gov/assets/680/677034.pdf (GAO Report). A Medicare Administrative Contractor (MAC) processes each claim for reimbursement and decides whether to pay it or deny it as invalid or improper. <u>See</u> 42 U.S.C. § 1395kk-1(a). If the claim is denied, the provider may appeal.

The Medicare Act sets out a sequential four-step administrative-appeal process, each of which must be completed within a statutorily provided deadline: (1) redetermination by the MAC, which must be completed within 60 days, <u>id.</u> § 1395ff(a)(3)(A), (a)(3)(C)(ii); (2) on-the-record reconsideration by a Qualified Independent Contractor (QIC), which must be completed within 60 days, <u>id.</u> §1395ff(c)(3)(C)(i); (3) review, including a hearing, by an administrative law judge in HHS's Office of Medicare Hearings and Appeals (OMHA), which, absent a waiver, must be completed within 90 days, <u>id.</u> § 1395ff(d)(1)(A); and (4) review by the Medicare Appeals Council within the Departmental Appeals Board (DAB), which must render a decision or remand to the ALJ within 90 days. <u>Id.</u> § 1395ff(d)(2)(A). If the provider's claim is worth at

2

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 3 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 120 of 180

least \$1,500, the DAB's decision is subject to judicial review. <u>Id.</u> § 1395ff(b)(1)(E)(i), (b)(1)(E)(iii); 42 C.F.R. § 405.1006(c); 80 Fed. Reg. 57,827 (Sept. 25, 2015). When a statutory deadline lapses before a decision has been made, moreover, a provider may leapfrog its appeal to the next stage through a process referred to as "escalation." <u>See</u> 42 U.S.C. §§

1395ff(c)(3)(C)(ii), (d)(3)(A), (d)(3)(B); 42 C.F.R. §§ 405.1104, 405.1108(d), 405.1132(b).

Taking the statutory deadlines together, a Medicare-reimbursement claim should proceed through all four steps of the administrative-appeal process within one year — "and for years they did." <u>AHA I</u>, 76 F. Supp. 3d at 46. Recently, however, a massive accumulation of backlogged cases has triggered significant delays, particularly at step three — ALJ review. Between fiscal years 2010 and 2014, the number of appeals filed at step three grew 936% — from 41,733 to 432,534. <u>See</u> GAO Report at 11. By the end of FY2014, 767,422 appeals were pending at step three, <u>see</u> Mot., Exh. 1 (Projections Chart) at 26, and 96% of ALJ decisions were issued well after the 90-day statutory deadline. <u>See</u> GAO Report at 18. In FY2014, it took OMHA an average of 415 days to process a step three appeal; it now takes <u>935</u> days. <u>See</u> HHS, <u>Office of Medicare Hearings and Appeals (OMHA): Current Workload — Decision Statistics</u> (July 25, 2016), http://www.hhs.gov/omha/Data/Current% 20W orkload/index.html.

Plaintiffs point to the Recovery Audit Program, which was "fully implemented" in 2010, <u>AHA II</u>, 812 F.3d at 186, as the "primary culprit in creating and sustaining" the backlog. <u>See</u> Opp. at 5. Congress required the Secretary to set up the Program to identify under- and overpayments and recoup the latter. <u>See</u> 42 U.S.C. § 1395ddd(h)(1). To do so, the Secretary contracts with Recovery Audit Contractors (RACs), who are private entities that "audit providerfavorable MAC decisions in 'post-payment' review." <u>AHA I</u>, 76 F. Supp. 3d at 47 (citing 42 U.SC. § 1395ddd(f)(7)(A)). RACs are paid on a contingent basis — they "receive a cut of any

3

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 4 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 121 of 180

improper payments they recover" — "and can challenge claims going back as far as three years." <u>Id.</u> (citing 42 U.S.C. § 1395ddd(h)(1); <u>Statement of Work for the Medicare Fee-for-Service</u> <u>Recovery Audit Program</u> 9-10, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111racfinsow.pdf). Because a RAC's decision to deny payment of a reimbursement claim is "appealable through the same administrative process as initial denials, the RAC program has contributed to a drastic increase in the number of administrative appeals." <u>AHA II</u>, 812 F.3d at 187.

The Secretary agrees that the RAC Program is a contributor to the backlog, but also points to other sources: an increase in Medicare beneficiaries; a growing practice among some providers to appeal virtually every claim denial through ALJ review; and a significant rise in the number of appeals filed by Medicaid state agencies. <u>See Mot., Exh. A (Declaration of Ellen Murray), ¶¶ 10-13.</u>

Frustrated by the long delays, Plaintiffs — the American Hospital Association, Baxter Regional Medical Center, Covenant Health, and Rutland Regional Medical Center — filed suit in May 2014. They asked the Court to grant mandamus relief to compel the Secretary to adjudicate their pending administrative appeals in compliance with the statutory deadlines, as well as to comply with the statutory deadlines in administering the appeals process for <u>all</u> hospitals. <u>See</u> ECF No. 1 (Complaint) at 21-22. Plaintiffs then filed a motion for summary judgment, <u>see</u> ECF No. 8, and the Secretary moved to dismiss for lack of jurisdiction. <u>See</u> ECF No. 12.

The Court concluded that the jurisdictional and merits inquiries at issue merged and thus resolved the parties' motions together. <u>AHA I</u>, 76 F. Supp. 3d at 50. It analyzed six factors to determine whether the agency's delay was "so egregious' as to warrant relief," <u>id.</u> (quoting

4

<u>Telecomm. Research & Action Ctr. v. FCC</u>, 750 F.2d 70, 79 (D.C. Cir. 1984)), and concluded that because of "HHS's budgetary constraints, its competing priorities, and its incipient efforts to resolve the issue," as well as Congress's awareness of the problem, mandamus was not warranted. <u>Id.</u> at 56. It thus denied Plaintiffs' motion for summary judgment and granted the Secretary's motion to dismiss for lack of jurisdiction. <u>Id.</u>

Plaintiffs appealed, and the D.C. Circuit reversed and remanded with instructions for further proceedings. The Court of Appeals explained that the jurisdictional and merits inquiries are distinct and should be approached separately. <u>See AHA II</u>, 812 F.3d at 190. It then addressed only the former, concluded that "the threshold requirements for mandamus jurisdiction are met," and reversed this Court's dismissal for lack of jurisdiction. <u>Id.</u> at 192. The Court of Appeals further directed this Court, on remand, to "determine whether 'compelling equitable grounds' now exist to issue a writ of mandamus," <u>id.</u>, and identified factors weighing in favor of and against mandamus. <u>See id.</u> at 192-93.

On remand, this Court held a status hearing at which the Secretary submitted that a stay of proceedings would be appropriate. The Court requested briefing, and the Secretary has now moved to stay this action until September 30, 2017, the close of the next full appropriations cycle.

II. Legal Standard

"Cases may be stayed for any number of reasons. Parallel criminal prosecutions may be ongoing; dispositive appellate decisions may be pending; or the parties may otherwise desire some respite." <u>Liff v. Office of the Inspector General for the U.S. Dep't of Labor</u>, No. 14-1662, 2016 WL 4506970, at *2 (D.D.C. Aug. 26, 2016). "To accommodate these ups and downs of litigation," <u>id.</u>, the Court possesses a "power to stay proceedings [that] is incidental to the power

5

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 6 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 123 of 180

inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants. How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an even balance." <u>Air Line Pilots Ass'n v. Miller</u>, 523 U.S. 866, 879 n.6 (1998) (quoting <u>Landis v. N. Am. Co.</u>, 299 U.S. 248, 254-55 (1936)).

III. Analysis

Whatever this Court originally thought of the merits of this case, it must, of course, follow the Court of Appeals' direction on remand. In its opinion, that court set out several considerations weighing for and against mandamus, each of which this Court addresses in the subsections that follow. <u>See</u> Parts III.A, B, *infra*. Weighing those considerations, as well as acknowledging the fact that the backlog had worsened since this Court's 2014 decision, the Court of Appeals hypothesized that this Court, on remand, "might find it appropriate to issue a writ of mandamus ordering the Secretary to cure the systemic failure to comply with the deadlines." <u>AHA II</u>, 812 F.3d at 193. The Court of Appeals nonetheless cautioned that "if the district court determines on remand that Congress and the Secretary are making significant progress toward a solution, it might conclude that issuing the writ is premature" and "consider such action as ordering the agency to submit status reports." <u>Id.</u> If, however, "the political branches have failed to make meaningful progress within a reasonable period of time — say, the close of the next full appropriations cycle, ... the clarity of the statutory duty likely will require issuance of the writ." <u>Id.</u>

As a threshold matter, it is important to note that the question immediately before this Court is whether to grant the Secretary's Motion for Stay, not whether to grant mandamus relief. Similar to the issuance of mandamus, however, which requires a balance of the equities, <u>see id.</u>

6

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 7 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 124 of 180

at 191, deciding whether a stay is appropriate requires the Court to assess the parties' asserted interests, weigh the equities, and exercise its judgment. <u>See Air Line Pilots Ass'n</u>, 523 U.S. at 879 n.6. The stay and mandamus inquiries thus are overlapping. The Court, consequently, structures its analysis of the Secretary's Motion for Stay around the Court of Appeals' factors for and against mandamus and the critical consideration of whether the legislative and executive branches are making "significant progress toward a solution." <u>AHA II</u>, 812 F.3d at 193.

A. Factors Against Mandamus

As the Court of Appeals observed, "Perhaps counseling most heavily against mandamus is the writ's extraordinary and intrusive nature, which risks infringing on the authority and discretion of the executive branch." <u>Id.</u> at 192. Granting the writ in this case would almost surely require the Secretary to significantly alter the agency's priorities and operations, particularly as to the RAC Program. The Court is mindful of the agency's "comparative institutional advantage" in this domain and of the practical challenges that would flow from denying the stay and granting the writ. <u>In re Barr Labs, Inc.</u>, 930 F.2d 72, 74 (D.C. Cir. 1991); <u>see also AHA I</u>, 76 F. Supp. 3d at 51, 53-54.

Likewise, the Court must consider "the Secretary's good faith efforts to reduce the delays within the constraints she faces." <u>AHA II</u>, 812 F.3d at 192. The Secretary repeatedly has assured the Court that resolving the ALJ backlog is "a matter of the highest priority," Mot. at 2; Reply at 1, and has suggested the agency submit status reports every six months during the stay to enable the Court and Plaintiffs to monitor the political branches' progress in reducing the backlog. <u>See</u> Mot. at 10. Importantly, the Secretary appears to have devoted considerable effort to designing and implementing various administrative initiatives to target the backlog, as

7

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 8 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 125 of 180

documented in the declaration of Ellen Murray, Assistant Secretary for Financial Resources and HHS's Chief Financial Officer. See Mot., Exh. A.

Echoing a point the Court made in its prior Opinion, the Court of Appeals also cited as a factor against mandamus "Congress's awareness of and attention to the situation." <u>AHA II</u>, 812 F.3d at 192 (citing 76 F. Supp. 3d at 56). Though still true, the force of Congress's knowledge and ability to act as a reason to deny mandamus diminishes with the passage of time absent meaningful legislative action, particularly as the backlog and delays have worsened.

Finally, the availability of escalation as a remedy counsels against the conclusion that the delays are so egregious as to warrant mandamus relief. <u>Id.</u> at 192. As the Court of Appeals observed, however, escalation "may offer less than full relief." <u>Id.</u> ALJ review is an appellant's first opportunity for a full evidentiary hearing, during which the provider may provide oral testimony and "engage with ALJs and respond to questions in real time." <u>AHA I</u>, 76 F. Supp. 3d at 48. If a provider escalates past the QIC and ALJ, the DAB almost certainly will decide the appeal based only on the MAC record, for "although the DAB <u>may</u> conduct additional proceedings," <u>id.</u> (citing 42 C.F.R. § 405.1108(d)(2)), it will not do so "unless there is an extraordinary question of law/policy/fact." Id. (citation omitted).

B. Factors for Mandamus

On the other side of the ledger are "several significant factors" favoring mandamus. <u>AHA II</u>, 812 F.3d at 193. Notably, the delays have resulted in a "real impact on 'human health and welfare." <u>Id.</u> (quoting <u>TRAC</u>, 750 F.2d at 80). The problem, as this Court earlier explained, is that "[h]ospitals are deeply out of pocket due to denied claims." <u>AHA I</u>, 76 F. Supp. 3d at 52. In fact, Amicus Curiae The Fund for Access to Inpatient Rehabilitation reports that the problem has worsened. <u>See</u> Amicus Opp. at 14. Using statistics not available at the time

8

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 9 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 126 of 180

of its previous brief to this Court, Amicus offers a bleaker picture in connection with this Motion. In March 2015, 249 rehabilitation hospitals — 21.5% of the rehabilitation hospitals that participate in Medicare — together had pending appeals worth \$135 million. <u>Id.</u> at 4-5. Rehabilitation hospitals, moreover, win 80% of their reimbursement claims on appeal. <u>Id.</u> at 5. That figure is even higher — 87% — when the win rate is calculated using the value, rather than number, of the claims, <u>id.</u>, suggesting the vast majority of that \$135 million rightfully belongs with the hospitals. But as long as the claims are tied up in the appeals process, they cannot access those funds. Because of the consequent financial burden, some providers are "forced to reduce costs, eliminate jobs, forgo services, and substantially scale back," all of which affects the quality and quantity of patient care. <u>AHA I</u>, 76 F. Supp. 3d at 52; <u>see also</u> Amicus Opp. at 13-14, 16-17. These problems likely will worsen in the coming years because, as discussed below, the backlog is projected to grow considerably absent legislative intervention. <u>See</u> Projections Chart.

In addition, the "substantial discretion" granted to the Secretary by Congress "to implement [the Recovery Audit Program] and determine its scope" — including to curtail it as necessary to meet the statutory deadlines — favors granting the writ, as "congressionally imposed mandates and prohibitions trump discretionary decisions." <u>AHA II</u>, 812 F.3d at 193 (citing 42 U.S.C. § 1395ddd(h)).

C. Progress Toward a Solution

Considering only the above arguments, given the extraordinary nature of the writ and the Court's reluctance to insert itself into the management of a complicated agency process, the Court might be inclined to grant the Secretary's Motion for Stay. Yet there is one more consideration critical to the Court's ultimate decision: whether the administrative and legislative

9

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 10 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 127 of 180

fixes offered in the Secretary's briefing constitute progress sufficient to warrant pausing this litigation until September 30, 2017. Unfortunately, the Court must conclude that they do not.

The Secretary discusses two categories of interventions intended to combat the backlog: (1) administrative actions with and without impact projections — *i.e.*, estimates of the effect on the backlog; and (2) legislation to reform the appeals process and provide the agency with additional funding. The Court looks at each.

1. Administrative Fixes

The numerous administrative actions for which the Secretary has impact projections can be grouped into four buckets. First, efforts to promote settlements: The Centers for Medicare and Medicaid Services (CMS) within HHS, which oversees the first two steps in the appeals process — redetermination by the MAC and reconsideration by the QIC — recently settled approximately 260,000 inpatient-hospital claims currently awaiting ALJ review. <u>See</u> Murray Decl., ¶ 19(a). And staff at OMHA — the office that oversees ALJ review – is working to facilitate settlement conferences between CMS and appellants with a threshold number of claims and/or amounts at issue pending before OMHA. <u>Id.</u>, ¶ 19(e). The Secretary projects that those settlement-conference facilitations will reduce the number of appeals currently pending at OMHA by 27,000 by the end of FY2020. <u>Id.</u>

Second, changes to the administrative-appeals process: An appellant now may waive its right to an oral hearing before an ALJ and instead have its appeal adjudicated on the record by an OMHA senior attorney advisor and then reviewed by an ALJ on the papers. Id., ¶ 19(g). Appellants with 250 or more claims pending at OMHA may elect to have OMHA adjudicate their claims using statistical sampling and extrapolation. Id., ¶ 19(f). OMHA also has received permission to reemploy retired ALJs on a temporary and intermittent basis to conduct hearings

10

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 11 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 128 of 180

and issue decisions part-time. <u>Id.</u>, ¶ 19(h). Together, those interventions are projected to enable OMHA to process an additional 56,000 appeals by the end of FY2020. <u>Id.</u>, ¶ 19(f)-(h). The Secretary, furthermore, has offered suppliers of diabetic-testing and oxygen equipment in certain jurisdictions the opportunity to discuss their claims with the QIC at the reconsideration level, submit additional supporting documentation, and receive feedback and information on CMS policies and requirements. <u>Id.</u>, ¶ 19(d). That initiative is projected to reduce by 13,000 the number of appeals that otherwise would have reached OMHA by FY2020. <u>Id.</u>, ¶ 19(d)(ii). More significantly, based on the information the QIC obtains from those discussions, it will reopen certain reconsideration decisions pending at OMHA, which will resolve more than 202,000 appeals currently pending at OMHA and, by FY2020, reduce the number of appeals that reach OMHA by 63,000. <u>Id.</u>

Third, front-end limitations on provider activity: In certain jurisdictions, providers and suppliers now must obtain authorization from a MAC before providing particular items or services. Id., ¶ 19(c). Prior authorization is projected to reduce by 269,000 the number of appeals that otherwise would have reached OMHA by the end of FY2020. Id.

Fourth, and finally, changes to the Recovery Audit Program: The Secretary has introduced three modifications to RAC contracts. Before referring a claim for recoupment, RACs must offer providers the opportunity to discuss the basis of the claim and submit additional information to substantiate it; RACs may only conduct a certain number of reviews under a given topic unless they get approval from CMS for further reviews; and RACs will be paid only after their decisions are upheld by a QIC in a reconsideration decision or the timeframe to file an appeal at step two expires. Id., ¶ 19(b). Together, the three contract modifications are

11

projected to reduce by 22,000 the number of appeals that reach OMHA by the end of FY2020. Id.

In addition to the administrative actions with projected impacts, HHS plans to attack the backlog with several actions for which it cannot currently estimate numerical impact, including expanding access to electronic case-adjudication processing and web-based appeal-management systems; beefing up oversight efforts to increase consistency and reduce erroneous denials; training ALJs and staff on Medicare coverage law, policy, and administrative-appeal procedures; reorganizing and updating existing field offices and opening new ones; assigning appellants with at least 200 appealed reconsiderations to the same ALJ; and improving communication between the various actors involved in the appeals process. Id., \P 21. HHS has also implemented initiatives to reduce the current and projected backlog at the DAB, as some of the actions just described will increase the number of appeals it receives. The DAB-focused initiatives involve hiring paralegals to help process cases, improving case management, and processing appeals electronically. Id., \P 24. In late June 2016, the Secretary issued a notice of proposed rulemaking that, if adopted, would codify many of the proposed administrative fixes in regulation. See Reply, Exh. A.

Let us pause here. The previous five paragraphs are packed with impressive-sounding action items and numbers appending multiple zeros. Summing up, HHS asserts that these administrative measures now underway for which it can project impact numbers will result in 50% fewer backlogged OMHA appeals in FY2020 than would exist absent the interventions. <u>See Murray Decl.</u>, ¶ 20. Sounds like "significant progress toward a solution," doesn't it? Alas, no. As is often the case, the devil is in the details.

12

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 13 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 130 of 180

Even assuming each one of the Secretary's administrative fixes for which HHS can project impact numbers is implemented according to plan, the OMHA backlog will still <u>grow</u> every year between FY2016 and FY2020 — from 757,090 to 1,003,444 appeals. <u>See</u> Projections Chart. Admittedly, that is less bad than if the Secretary does nothing. Absent any intervention, the OMHA backlog at the end of FY2020 will be over 1,900,000. <u>Id.</u> But "significant progress toward a solution" cannot simply mean that things get worse more slowly than they would otherwise. It has to mean real movement towards statutory compliance. The process must improve. By the Secretary's own numbers, the proffered administrative fixes do not clear that bar.

The scope of the initiatives involving the RAC Program give the Court particular pause. At the end of April 2016, there were around 300,000 RAC-related appeals pending ALJ review, which constituted a sizable portion — 31% — of all pending OMHA appeals. See id., ¶ 2; Projections Chart. Yet the only RAC-related action the Secretary reports to be undertaking or planning to undertake consists of three modifications to RAC contracts that will reduce the number of appeals that reach OMHA by FY2020 by just 22,000. See Murray Decl., ¶ 19(b). Twenty-two thousand is only about 7% of the <u>current</u> RAC-related OMHA backlog; it almost surely will be an even smaller percentage of the RAC-related OMHA backlog in FY2020. The Secretary's failure to offer a more robust response to the high volume of appeals generated by the RAC Program — a program over which she has "substantial discretion," <u>AHA II</u>, 812 F.3d at 193 — is concerning. And that is so even without entertaining the argument from Plaintiffs and Amicus that there are reasons to doubt HHS's estimates regarding the efficacy of its proposed modifications to the RAC contracts. <u>See</u> Opp. at 10; Amicus Opp. at 11-12.

13

2. Legislative Fixes

Administrative reforms are not the only arrows the Secretary has in her quiver. She also points to the improvements proposed by her sister branch — Congress. According to the Secretary, these legislative fixes will happen via two vehicles — the President's FY2017 Budget and the Audit & Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015 (AFIRM Act). If passed, they would increase OMHA and DAB appropriations by \$1.3 billion over ten years and permit HHS to use RAC Program recoveries to supplement annual OMHA and DAB appropriations. See Murray Decl., $\P 22(b)$. With that additional funding, OMHA would be able to dramatically expand ALJ review, on-the-record adjudications, and settlement-conference facilitations. Id., $\P 22(b)$, (h), (i).

The Secretary also focuses on the AFIRM Act's policy reforms, which include letting OMHA use less expensive Medicare Magistrates instead of ALJs to adjudicate cases with low amounts in controversy; giving the Secretary the authority to require prior authorization for nonemergency items or services; instituting a filing fee for appeals, refundable to those appellants who receive a fully favorable determination; permitting the Secretary to adjudicate appeals using sample and extrapolation techniques and consolidate related appeals; requiring an adjudicator to remand an appealed claim to step one when a party submits new documentary evidence at or beyond step two; and allowing OMHA to issue decisions without a hearing if there are no material facts in dispute and the ALJ determines that binding authority controls the outcome. Id., ¶ 22(a), (c)-(g).

Combining the administrative measures and the legislative fixes would reduce the number of pending OMHA cases to 50,000 by FY2020 and totally eliminate the backlog of pending OMHA cases older than 90 days by FY2021. <u>See</u> Projections Chart. Plaintiffs scoff at

14

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 15 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 132 of 180

the notion that this Congress should be expected to deliver on the fixes the Secretary says it will, and certainly not within the period of time requested for the stay, which includes the upcoming elections, a lame-duck congressional session, and the new President's first eight months in office, when he or she will be focused on his or her most critical legislative priorities. <u>See</u> Opp. at 12.

The Secretary rejoins that dismissing Congress' potential to act is premature because the Court of Appeals "contemplated that Congress would be afforded some time to respond to [its] ruling." Reply at 15. But it has been seven months since the Court of Appeals issued its decision, and Congress has taken no action. The Chairmen of the Senate and House Budget Committees have refused to hold hearings on the President's FY2017 budget. See Amicus Opp. at 6 (citing Ryan Murphy & William Allison, Joint Announcement from House and Senate Budget Committees on OMB Hearing, U.S. House of Representatives Comm. on the Budget (Feb. 4, 2016), http://budget.house.gov/news/documentsingle.aspx?DocumentID=394136). Finally, as the Secretary acknowledges, Congress did not fund the "robust increase in budget authority designated for increased adjudication capacity at OMHA" included in the President's FY2016 budget. See Reply at 16. That Congress refused to do so when it had ample knowledge of the backlog supports the conclusion that it is unlikely to approve an increase for FY2017. The Secretary gives no reason to believe things will be different this year. In addition, it has been 21 months since the AFIRM Act was reported by the Senate Finance Committee to the full Senate on December 8, 2015. See S. Rep. No. 114-177 (2015). No debate or vote has been scheduled, and the Secretary offers no evidence that any legislative action is imminent, that the bill has support in the House of Representatives, or that the President would sign it. See Amicus Opp. at 8.

15

Case 1:14-cv-00851-JEB Document 38 Filed 09/19/16 Page 16 of 16 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 133 of 180

While it is not the Court's role to comment on the priorities of a co-equal branch of government, it must draw the conclusion that Congress is unlikely to play the role of the cavalry here, riding to the rescue of the Secretary's besieged program.

* * *

In sum, the Court cannot conclude that the Secretary's current proposals will result in meaningful progress to reduce the backlog and comply with the statutory deadlines. Although the Court remains loath to intervene in the legislative and executive branches' efforts — or lack thereof, as it may be — to respond to the problem, its "ultimate obligation is to enforce the law as Congress has written it." <u>AHA II</u>, 812 F.3d at 193. The balance of interests drives the conclusion that there are equitable grounds for mandamus, and the Court will not issue a stay and further delay the proceedings.

The Court, however, does not possess a magic wand that, when waved, will eliminate the backlog. Plaintiffs' suggestion that the Court simply order HHS to resolve each of the pending appeals by the statutorily prescribed deadlines is extremely wishful thinking. <u>See</u> Opp. at 2. The Court will thus ask the parties to appear for a status conference to discuss how next to proceed.

IV. Conclusion

For the foregoing reasons, the Court will deny Defendant's Motion for Stay. A separate Order so stating will issue this day.

<u>/s/ James E. Boasberg</u> JAMES E. BOASBERG United States District Judge

Date: September 19, 2016

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Civil Action No. 14-CV-851-JEB

Defendant.

[PROPOSED] ORDER

Upon consideration of Plaintiffs' Motion for Summary Judgment and Memorandum of

Points and Authorities in Support, and the opposition and reply thereto, it is hereby

ORDERED that Plaintiffs' Motion for Summary Judgment is GRANTED; and it is

further

ORDERED that judgment BE and hereby IS ENTERED in favor of Plaintiffs; and it is

further

DECLARED that delays in adjudicating Medicare appeals by Defendant Secretary of

Health and Human Services (HHS) violate the Medicare Act, 42 U.S.C. § 1395ff; and it is

further

ORDERED that HHS must comply with the statutory obligations in the Medicare Act in administering the appeals process for all hospitals by:

(1) submitting a proposal to the Court within thirty days of the date of this Order for(a) offering reasonable settlements to broad groups of Medicare providers; (b) delayingrepayment of disputed Medicare claims, and tolling the accrual of interest on those claims for all

Case 1:14-cv-00851-JEB Document 39-1 Filed 10/14/16 Page 2 of 2 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 135 of 180

periods of time for which an appeal is pending beyond the statutory maximums; and (c) imposing financial penalties on Recovery Audit Contractors that achieve poor outcomes at the Administrative Law Judge (ALJ) level. Plaintiffs may submit comments on Defendant's proposal within twenty-one days after its filing, and the Court may schedule further proceedings or take such other steps as may be needed to resolve this issue;

(2) submitting status reports every sixty days, until compliance with statutory deadlines resumes, providing (a) updated figures for the current and projected appeals backlog, and (b) a description of any significant changes that will affect the backlog;

(3) eliminating the backlog of appeals pending at the ALJ level by January 1, 2021; and

(4) after elimination of the backlog, conducting and concluding each hearing and decision pending at the ALJ level within ninety days, as required by 42 U.S.C. § 1395ff(d)(1)(A); and it is further

ORDERED that HHS shall pay all costs and reasonable attorney's fees to Plaintiffs pursuant to 28 U.S.C. § 2412.

Entered this _____ day of _____, 2016.

The Honorable James E. Boasberg United States District Judge

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, Civil Action No. 14-cv-00851 (JEB)

Defendant.

DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant Sylvia M. Burwell, in her official capacity as Secretary of Health and

Human Services, by and through undersigned counsel, hereby moves for summary

judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. In support of this

motion, Defendant submits the accompanying Supplemental Declaration of Ellen

Murray, Assistant Secretary for Financial Resources and Chief Financial Officer of

Health and Human Services. A proposed order is also attached.

Respectfully submitted this 7th day of November, 2016.

BENJAMIN C. MIZER Principal Deputy Assistant Attorney General CHANNING D. PHILLIPS United States Attorney JOEL McELVAIN Assistant Director, Federal Programs Branch

<u>/s/ Caroline Lewis Wolverton</u> CAROLINE LEWIS WOLVERTON Senior Trial Counsel U.S. Department of Justice Civil Division, Federal Programs Branch

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Attorneys for Defendant

EXHIBIT 1

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official) capacity as SECRETARY OF HEALTH AND) HUMAN SERVICES,)

Civil Action No. 14-cv-00851 (JEB)

Defendant.

SUPPLEMENTAL DECLARATION OF ELLEN MURRAY

I, Ellen Murray, declare as follows:

1. I am the Assistant Secretary for Financial Resources and Chief Financial Officer of the Department of Health and Human Services (HHS or Department). I have held this position since February 2010. Among my duties, I provide advice and guidance to the Secretary on all aspects of budget, financial management, grants and acquisition management, and provide for the direction and implementation of these activities across the Department. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties. This declaration supplements my prior declaration in this case dated May 25, 2016 (May declaration), which was submitted as an exhibit to Defendant's Motion for Stay. Attached as Exhibit 1 is a true and correct copy of that May 25, 2016 declaration.

Current Statistics and Projections

2. In the May declaration, based on the projected impact of both administrative and legislative actions, HHS expected the number of pending OMHA cases to fall to just 50,000 by the end of FY 2020, and the number of pending OMHA cases over 90 days old to be eliminated completely by FY 2021. Now, based on updated data and the projected impact of both types of actions, HHS expects the number of pending OMHA cases over 90 days old to be eliminated completely by the end of FY 2019 – two years earlier than previously projected. Attached as Exhibit 2 is a true and correct copy of an updated table showing data and projections as of September 30, 2016 as to the number of pending OMHA cases from the end of FY 2014 to the end of FY 2021 under different scenarios. The table illustrates anticipated changes in the number of pending cases based on the projected impact of the current administrative actions for which data is available and the projected impact of the proposed legislative actions as of September 30, 2016.

3. In the May declaration, we projected that there would be 757,090 appeals pending at OMHA at the end of FY 2016 after the impact of administrative initiatives were taken into account. We now estimate that there were 658,307 appeals pending at the end of FY 2016, which is a decrease of 13% from our previous estimate and a nearly 26% reduction in the number of pending appeals from the beginning of FY 2016 (886,418 appeals). In the May declaration, we projected that there would be 807,576 appeals pending at the end of FY 2017 after the impact of administrative initiatives were taken into account. We now estimate that there will be 560,663 appeals pending at the end of FY 2017, which is a decrease of nearly 31% from our previous estimate and a nearly 37% reduction in the number of pending appeals from the beginning of FY 2016 (886,418 appeals).

4. This significant drop in appeals pending at OMHA is mainly attributable to (a) more appeals being resolved through the CMS Hospital Settlements, *see* Ex. 1 ¶ 19.a, than projected; (b) more appeals being resolved through OMHA Settlement Conference Facilitations, *see* Ex. 1, ¶ 19.e, than projected; (c) lower appeal receipts to OMHA than projected; (d) additional projected appeals that may be resolved through the reopening of CMS Hospital Settlements, *see infra* ¶ 12; (e) data reconciliation of pending appeals to identify appeals that were duplicative in the data; and (f) additional projected appeals that may be resolved through settlement with State Medicaid Agencies, *see infra* ¶ 15-16.

5. HHS continues to explore additional administrative initiatives that can further reduce the appeals pending at OMHA and the number of new appeal receipts to OMHA. The focus of these efforts to develop new administrative initiatives is to identify one-time initiatives that would remove a large group of pending appeals at OMHA, similar to the other one-time initiatives currently underway.

Current Composition of the Backlog

6. While more than 700 providers and suppliers, State Medicaid Agencies, and beneficiaries currently have appeals pending at OMHA, the top ten appellants comprise more than 40% of all pending appeals at OMHA, and the top 100 appellants comprise nearly 55% of all pending appeals at OMHA. The single largest appellant, a durable medical equipment (DME) supplier, alone has filed more than 24% of all pending appeals at OMHA. This provider also has an error rate estimated at over 24%, which discourages our settling of these claims through nontraditional methods due to program integrity concerns. Comparatively, the acute care hospital with the largest number of appeals pending at OMHA is the 14th largest appellant and comprises

just 0.4% of total appeals pending. The administrative initiatives that HHS has undertaken have focused on groups of appeals of similar or homogenous claim types or issues, including DME claims, and have made progress in reducing the number of pending appeals at OMHA. The impact of these initiatives is illustrated in Exhibit 2.

7. The current breakdown of the pending appeals at OMHA as of September 30,2016 is as follows:

- a. 46%: Durable Medical Equipment, Prosthetics, Orthotics and Supplies Supplier appeals
- b. 23%: Acute care hospital appeals
- c. 14%: Home health and hospice claim appeals
- d. 6%: Outpatient therapy claim appeals
- e. 3%: Practitioner service appeals
- f. 2%: Ambulance service appeals
- g. 6%: Service categories that account for less than 2% of pending appeals

8. Many DME denials result from documentation issues related to medical supplies, which the suppliers appeal with the objective of introducing new evidence at the ALJ level. These also tend to be high volume suppliers that make it a routine practice to appeal denials. As described in the May declaration, ¶ 19.c, CMS has extended the use of prior authorization for some DME items, to the extent permissible under law and cost effectiveness given the additional resources required for prior authorization reviews. In addition, CMS has initiated a demonstration project to engage suppliers at the QIC reconsideration level to discuss documentation deficiencies and resolve matters for new claims being processed and the

supplier's appeals pending at the ALJ level of appeal. A summary of the demonstration is included in the May declaration, \P 19.d.

9. Appeals generated from the denial of claims through the Department's statutorily mandated Recovery Audit Contractor (RAC) program have decreased drastically from FY 2013, both in terms of incoming appeals and appeals currently pending before OMHA. In terms of appeals received by OMHA, the numbers have changed as follows¹:

a. FY 2013: 193,105 RAC-related appeals (50.3% of total OMHA receipts)

b. FY 2014: 273,407 RAC-related appeals (53.8% of total OMHA receipts)

c. FY 2015: 31,624 RAC-related appeals (14.1% of total OMHA receipts)

d. FY 2016: 15,761 RAC-related appeals (9.5% of total OMHA receipts)

10. As of September 30, 2016 (the end of FY 2016), OMHA has 154,592 RAC-

related appeals pending, down from a high of 437,524 RAC-related appeals pending on September 30, 2015 (the end of FY 2015). Up to 95,000 of these appeals could be resolved through the reopening of the Hospital Appeals Settlement Program, *see infra* ¶ 12. Attached is Exhibit 3, which shows the drop in the proportion of RAC appeals received at OMHA since FY 2013. That percentage continues to drop.

11. The reduction in RAC-related appeals at OMHA is due to several factors. RAC activity decreased temporarily while CMS was negotiating a new Statement of Work (SOW) with the RACs, but several other changes took place that are expected to make lasting and

¹ Note that due to system-generated data associated with the CMS Hospital Appeals Settlement Program, OMHA appeals that were received in FY 2014 but were not entered into the case tracking system in 2014 became associated with FY 2015 and FY 2016, which is when the settlements for those appeals were finalized and processed. As a result, an adjustment has been made to reflect that 16,305 RAC-associated appeals in FY 2015 and 17,918 RA-associated appeals in FY 2016 were received in FY 2014. All of these appeals have been resolved in the CMS Hospital Appeals Settlement Program.

continuing reductions to RAC-related appeal receipts. Notably, patient status reviews, i.e., reviews focusing on whether medically necessary services should have been provided on an inpatient basis or on an outpatient basis, previously accounted for a substantial portion of RAC appeals. CMS has instituted a new process for reviewing patient status claims, utilizing contractors under the Quality Improvement Organization program. Additionally, CMS implemented revised Additional Documentation Request limits that became effective in January 2016. Under these new request limits, the total number of inpatient hospital claims that are being reviewed by RACs, which had previously accounted for the majority of RAC appeals at OMHA, has been substantially reduced.

New Initiatives to Reduce the Backlog

12. <u>Reopening of Hospital Settlement Offer for Inpatient Status Claims</u>: On

September 28, 2016, CMS announced that it would provide eligible providers who failed to avail themselves of the original settlement offer made in September 2014 a renewed opportunity to settle their patient status claims currently under appeal using the Hospital Appeals Settlement process. On November 3, 2016, CMS further announced that it would make available an administrative agreement to eligible hospitals willing to withdraw their pending appeals for a settlement rate of 66% of the net allowable amount for those claims. The settlement percentage is slightly reduced from the 68% provided in the original Hospital Appeals Settlement to account for administrative costs to the Department to continue the appeals process for cases of appellants who chose not to avail themselves of the original settlement. For the original Hospital Appeals Settlement, the Department determined 68% was an appropriate settlement percentage based on its knowledge of the specific types of claims at issue and the associated value of the services

performed. HHS examined the denied amounts, the tendency of hospitals to appeal decisions, and the vulnerability that hospitals and CMS face throughout the appeals process. Additionally, because the services themselves were not determined to be medically unnecessary but were rather billed in the incorrect setting based on the documented record, CMS initially allowed these appellants to re-bill under Part B for the allowable Part B services if they lost their Part A appeal. This settlement option was an extension of that rebilling option to make it more efficient for appellants to resolve their appeals. The original Hospital Appeals Settlement for inpatient status claims removed an estimated 288,726 appeals from the OMHA docket. Assuming that appellants accept the opportunity, we estimate that an additional 95,000 appeals will be removed from the appeals pending at OMHA through the reopened settlement offer for inpatient status claims.

13. The Hospital Appeals Settlement is based on a unique set of circumstances that does not apply to other appeals in the backlog. These settlements involve a large homogenous universe of claims denied for the same reason, which can be resolved on a global, rather than on a case-by-case, basis. Specifically, the settlements only involve appeals of patient status claims, which, as noted above, *see supra* ¶ 11, are determinations that otherwise medically necessary services should have been furnished on an outpatient basis, rather than on an inpatient basis. In these cases, some payment was due for services; the issue was whether services would be paid as inpatient or outpatient services, which are paid at different rates and include coverage of different services. Appeals eligible for the settlement did not involve medically unnecessary services, but rather necessary services where the record did not support the inpatient admission that was billed by the provider. This is in contrast to the majority of appeals that involve a denial

because an item or service is not a covered Medicare benefit or was determined to be not reasonable and necessary.

Additional OMHA Settlement Conference Facilitations (SCF): As explained in 14. the May declaration. OMHA staff who have been trained in mediation techniques are facilitating settlement conferences between CMS and appellants to discuss administratively settling appeals. SCFs allow CMS to consider individualized factors, such as (1) the type of item or service at issue, (2) the governing policy regarding the item or service at issue, (3) the cost to the Department for adjudicating the appeals at issue, (4) a sample of the provider's/supplier's claims, and (5) the provider's/supplier's historical overturn rate on appeal. As a result, SCFs allow CMS to meet its Medicare Trust Fund obligations as set forth in the May declaration, ¶ 19.e. As of May 2016, only providers and suppliers that had at least 20 claims, or \$10,000, at issue in appeals pending before OMHA for most Part B appeals, or that had at least 50 claims and \$20,000 at issue in appeals pending before OMHA for most Part A appeals could qualify for a SCF. Based on the success of this initiative, with 9,088 appeals resolved as of September 30, 2016, and continued appellant interest, OMHA is adding 11 trained facilitators before the end of the calendar year, and additional expansions of the SCF program are planned to offer the opportunity to additional Part A appellants.

15. <u>Proposed Solutions for Addressing State Medicaid Agency Appeals</u>: Annually, approximately 14,000 new receipts at OMHA are State Medicaid Agency appeals. Medicare and Medicaid have different coverage requirements and processes for determining which program covers which service in the case of individuals who receive both Medicare and Medicaid benefits. Some State Medicaid Agencies pursue Medicare payment in almost every case where the State Medicaid Agency has paid for services for these Medicare-Medicaid beneficiaries.

These States also appeal virtually every Medicare claim denial, which has contributed significantly to the backlog.

16. In order to address the State Medicaid Agency appeals in the backlog, OMHA and CMS are working to expand the existing SCF project to facilitate the settlement of State Medicaid Agency appeals pending at OMHA and the DAB. This initiative will largely address claims for home health and skilled nursing facility services. Currently, CMS is engaged in active discussions with OMHA and certain State Medicaid Agencies regarding a Memorandum of Understanding (MOU) between CMS and the State Medicaid Agencies for participation in the SCF project. If CMS and the State Medicaid Agencies are able to reach settlement agreements to resolve the pending appeals, we estimate that it will reduce the appeals backlog in early calendar year 2017 by at least 55,000 appeals at OMHA.

17. <u>Recovery Audit Initiatives</u>: CMS pays RACs on a contingency fee basis when their claim review results in an overpayment collection, or an underpayment returned to the provider. CMS does not compensate RACs for the costs of reviewing every claim to identify those overpayments or underpayments. If a RAC determination is overturned on appeal, the RAC loses any payment that it may have previously earned from the collection that occurred because of the claim denial. This means that in the event that no overpayment is collected or the overpayment is returned, the RAC does not earn (or keep) any payment for the time spent reviewing the claim, nor does it receive any associated overhead costs for its operations.

18. In the new RAC SOW, which took effect on October 31, 2016, CMS included three additional financial incentives for RACs to make accurate claim determinations. *First*, CMS requires RACs to maintain an overturn rate of less than 10% at the first level of appeal (excluding claims where the provider submits new evidence to the appeal adjudicator or corrects)

the claims). Under the SOW, RACs will earn a 0.1% contingency fee increase for each percentage point below 10% that they maintain their overturn rates. For example, a RAC with a base contingency fee rate of 8% and a 9% appeal overturn rate would receive a 0.1% contingency fee increase, for a total contingency fee of 8.1%.

19. Second, CMS requires the RACs to maintain an accuracy rate of at least 95%, as determined by an independent validation contractor, which reviews random, monthly samples of RAC improper payment decisions to determine the accuracy of those determinations. Under the SOW, RACs will earn a 0.2% contingency fee increase for each percentage point above 95% that they maintain their accuracy rates. For example, a RAC with a base contingency fee rate of 8% and a 96% accuracy score would receive a 0.2% contingency fee increase, for a total contingency fee of 8.2%.

20. Additionally, failure by a RAC to maintain an overturn rate of less than 10% at the first level of appeal or to maintain an accuracy rate of 95% as determined by the independent validation contractor will result in CMS taking necessary action, including, but not limited to, progressively reducing the additional documentation requests (ADRs) that the RAC can issue to providers, requiring the RAC to prepare a Corrective Action Plan, deciding to not exercise the next option period of the contract, and/or modifying or terminating the contract.

21. *Third*, under the new SOW, CMS withholds the RAC's contingency fee payment until after a reconsideration decision has been issued or after the time frame to file an appeal at the second level of appeal has expired.

22. These three new additional financial measures coupled with the measures laid out in my May declaration that were in place before the new SOW took effect, *see* Ex. 1 ¶ 19.b (describing discussion period initiative and limits on the number of RAC reviews), are in HHS's

judgment sufficient to encourage accurate decisions by RACs. We estimate that these RAC SOW changes will reduce appeals to OMHA by 26,000 appeals through the end of FY 2021.

23. CMS has also temporarily reduced the look-back review period, i.e., the period from the date of service that RACs are permitted to review an initial determination to pay a claim, for patient status reviews. This reduction gives providers the opportunity to rebill for medically necessary Part B inpatient services, instead of having to file an appeal. Typically, RACs are allowed to look back up to three years from the date a claim was paid. For patient status reviews, in cases where the provider submits its claim within three months of the date of service, RACs now can only review these claims within six months of the date of service on the claim. In compliance with an order of this Court, CMS is prepared to keep this policy in place until OMHA is adjudicating appeals within 90 days. CMS is also prepared to reduce the look-back review period to one year for all other claims subject to RAC review. Alternatively, a possible remedy could include an instruction to CMS not to approve RAC reviews for patient status until OMHA is adjudicating appeals within 90 days.

24. Current RAC accuracy rates, as determined by an independent validation contractor, are as follows:

- a. FY 2014: All RACs have at least a 91% accuracy rate, with an average of over 96%
- b. FY 2015: All RACs have at least a 95% accuracy rate, with an average of over 98%
- c. FY 2016: All RACs have at least a 91% accuracy rate, with an average of over 96%

25. The first two levels of appeals (redetermination and reconsideration) do not merely "rubber-stamp" RAC decisions such that providers must take their appeals to the third level to receive a fair review. In FY 2015, at the first level of appeal, there were 84,533 redetermination decisions and dismissals involving RAC determinations, and 48,102 of those decisions were favorable to the provider, for an overturn rate of 57%. At the second level of appeal, for FY 2015, there were 56,793 reconsideration decisions and dismissals involving RAC determinations, and 9,908 of those decisions were favorable to the provider, for an overturn rate of 17%. At the third level of appeal, of the appeals that were not settled, for FY 2015, there were 15,563 ALJ decisions and dismissals involving RAC determinations, and 6,704 of those decisions were favorable or partially favorable to the provider, for an overturn rate of 43%. While in many of the overturned RAC decisions providers presented documentation that was missing or corrected technical errors after the RAC made its determination, the data show that redeterminations and reconsiderations provide for meaningful review of RAC determinations.

26. Documentation requirements in Medicare billing regulations are included to ensure that Medicare coverage and payment requirements are being met. Ignoring them in RAC reviews would increase the risk that the Medicare Trust Funds are being used to pay for services that are not covered or payable as billed. In addition, documentation issues occur in only a small percentage of appeals and so eliminating them from RAC reviews would not be an effective means of reducing the backlog. Additionally, preventing RACs from undertaking reviews of whether a service provided was reasonable and necessary would increase the risk that the Medicare Trust Funds are paying for services that are not covered under Medicare, endangering the availability of the Medicare Trust Funds for future generations.

Suspension of Recoupment and Interest Accrual Would Increase, Not Decrease, the Backlog and Undermine the Medicare Trust Funds.

27. The Department has a fiduciary responsibility to protect the Medicare Trust Funds. In fulfillment of this duty, the Department takes seriously efforts to combat fraud, abuse, and improper payments to help protect the Medicare Trust Funds for current and future generations. This includes aggressively pursuing outstanding Medicare overpayments. Suspension of recoupment and accrual of interest would undermine those efforts and would operate to *increase*, not decrease, appeals pending in the backlog.

28. Suspension of recoupment and accrual of interest is only applicable to claims that were denied after they were already paid. A significant number of appeals in the backlog were denied before they were paid by Medicare. Therefore, suspension of recoupment and accrual of interest would not offer relief to a significant number of appellants.

29. If recoupment and accrual of interest were suspended, every provider and supplier would have an incentive to appeal every claim denied as an overpayment and to continue to pursue appeals through every level of appeal because there would be no downside in doing so; there are no filing fees in the administrative appeals process, and the amount in controversy required for an ALJ hearing (currently \$150) is relatively low. Thus, providers and suppliers who ultimately lose their appeal effectively would receive an interest-free loan from the government for the duration of the appeals process, which, would only grow longer as more providers use the appeals process to delay recoupments and accrual of interest. This would make the backlog at OMHA substantially worse.

30. Recoupment of a determined Medicare overpayment and accrual of interest incentivize providers to make a serious evaluation of the merit of their claims in deciding whether to file an appeal and whether to continue a filed appeal. Interest begins to accrue at the

determination of overpayment, and recoupment begins after an adverse reconsideration decision, which constitutes the third adverse determination on a Medicare claim. Once providers and suppliers receive an adverse reconsideration decision, many do not appeal to OMHA, and some subsequently withdraw an OMHA appeal after filing it. For example, in FY 2015, approximately 50% (204,273) of fully unfavorable reconsideration decisions, i.e., those decisions upholding the denial of payment in full with no partial payment, were not appealed to OMHA, and in that same year approximately 5% (nearly 10,000) of appeals to OMHA were later voluntarily withdrawn by the appealing party with no attempt at escalation. Suspending recoupment and the accrual of interest may endanger this attrition of appeals, which would make the backlog at OMHA significantly worse.

31. Suspending recoupment and interest accrual could have significant costs to the Medicare Trust Funds. Annually, on average, CMS collects approximately \$153 million in principal and \$15 million in interest after the second level of appeal (reconsideration). The likelihood of recovering overpayments diminishes with time because providers may file for bankruptcy, go out of business, or request a compromise from CMS.

32. Many appeals in the backlog involve potentially fraudulent claims submitted by providers and suppliers, totaling upwards of hundreds of millions of dollars per year. Based on CMS' experience, any delay in recoupment for these providers and suppliers is especially risky because there is an increased chance that they will file for bankruptcy, go out of business, or put CMS in the position of having to accept a partial payment in order to recover as much money as possible for the Medicare Trust Funds. Delay in recoupment could also encourage some providers and suppliers to submit questionable Medicare claims in the hope that they are not subject to post-payment review of those claims.

33. Under current law, if a provider or supplier receives a favorable decision from an ALJ (or the DAB), the government returns any recouped funds to the provider or supplier and pays interest on the amount recouped. Currently, the rate of interest paid on these overturned decisions is nearly 10%, which is a 500% premium over the less than 2% interest a 10-year Treasure bill is currently paying. This benefit compensates appellants for their temporary loss of access to funds.

34. If recoupment after a reconsideration decision would constitute a financial hardship for a provider or supplier, CMS may grant, upon request, an extended repayment plan up to three years, and up to five years in cases of extreme hardship. *See* 42 U.S.C. § 1395ddd(f)(1), (2); 42 C.F.R. § 401.607(c).

35. Suspension of the accrual of interest and/or recoupment is not appropriate for a demonstration project under § 402 of the Medicare statute (42 U.S.C. § 1395b-1). CMS has interpreted demonstration authority under (a)(1)(A) of this section to involve demonstrations testing a different way of paying for Medicare services, and suspension of the accrual of interest and/or recoupment do not demonstrate a different way of paying for Medicare services. Suspension of the accrual of interest and/or recoupment does not qualify under the demonstration authority provided under (a)(1)(J) of this section because it does not improve the post-payment review process or other otherwise relate to improved methods for the investigation and prosecution of fraud.

36. Suspension of the accrual of interest and/or recoupment also is not appropriate for a demonstration project under Center for Medicare and Medicaid Innovation (CMMI) demonstration authority (42 U.S.C. § 1315a) for "test[ing] innovative payment and service delivery models to reduce program expenditures." Suspension of recoupment and interest

accrual is not an innovative payment or service delivery model, nor does it demonstrate a different way of paying for Medicare services. Under CMMI demonstration authority, the Secretary shall choose models for testing from those where she has determined that there is evidence that the model addresses a (1) defined population for which there are deficits of care leading to poor clinical outcomes or (2) potentially avoidable expenditures. 42 U.S.C. § 1315a(b)(2)(A). Allowing hospitals to simply retain money that would otherwise be recouped or collected as interest does not address a defined population for which there are deficits of care leading to poor clinical outcomes. Allowing hospitals to simply retain money that would otherwise be recouped or collected as interest does not address a defined population for which there are deficits of care leading to poor clinical outcomes. Allowing hospitals to simply retain money that would otherwise be recouped or collected as interest does not address a defined population for which there are deficits of care leading to poor clinical outcomes. Allowing hospitals to simply retain money that would otherwise be recouped or collected as interest does not address potentially avoidable expenditures either.

Blanket Global Settlements to Resolve the Backlog Could Undermine the Medicare Trust Funds and Exacerbate the OMHA Backlog

37. If providers and suppliers receive a blanket global settlement not based on their individual error rates and not taking into account any concerns CMS or law enforcement have about fraudulent or abusive billing, the Medicare Trust Funds could be forced to pay out substantially more than they would had the claims been adjudicated in the normal course. If the blanket global settlement offer were voluntary and substantially under 100%, providers and suppliers would be incentivized to only settle claims that they believe would not be ultimately paid on appeal, and they would continue to appeal their stronger claims to receive higher payment. Providers and suppliers would be incentivized to only settle claims appeals in order to receive the settlement offer, which would make the backlog worse. As stated previously, CMS is committed to

offering individualized settlements to providers based on individualized information and assessments, such as through the Settlement Conference Facilitation.

38. Likewise, the possibility of receiving a default judgment would incentivize providers and suppliers to appeal every denied claim, meritorious or not, in order to get payment. This could result in HHS making Medicare payments for claims that do not meet Medicare coverage and payment requirements as determined by the individualized examination at the three previous levels of administrative review (initial determination, redetermination, and reconsideration). This could lead to substantial overpayments from the Medicare Trust Funds, which could endanger the financial integrity of those funds.

Alternative Remedies Exist to Address Pending Appeals and Incoming Appeals

39. One additional remedy to address pending appeals that CMS could implement in compliance with an order of this Court would be to offer to resolve pending appeals at OMHA by applying an individualized payment percentage to the Medicare allowable amount for pending claims. The payment percentage could be based on an individual provider's historic success rate in OMHA appeals (including both decided and dismissed appeals). For providers without a sufficient history of appeals at OMHA, CMS could extrapolate a payment percentage based on a sampling of the provider's appealed claims. Once the payment percentage was applied to the allowable amount, and the provider was paid, the appeal involving that paid claim would be dismissed from the backlog. However, to protect the Medicare Trust Funds, providers that were or are the subject of program integrity or law enforcement scrutiny should be excluded from this option.

40. To establish a more stable environment for future appeals, the potential remedy addressed in the prior paragraph should include a provision that requires a provider to agree to the use of sampling and extrapolation to resolve future appealed claims when a certain number of claims are appealed within a given time-frame. This also would save providers time and costs to address appealed claims compared to the traditional process.

41. To address providers that are experiencing a financial hardship as a result of delays in obtaining an ALJ hearing, the Court could fashion a remedy ordering OMHA to prioritize the pending appeals of providers that currently qualify for an extended repayment plan for recoupment due to financial hardship under existing authorities. If the Court imposes this remedy, appeals involving both pre-payment and post-payment denials of qualifying providers should be prioritized. Under such a remedy, the appeals should be prioritized before the appeals of other providers and suppliers, but after the appeals of Medicare beneficiaries and Part C and Part D plan enrollees, the prioritization of which above non-beneficiary/enrollee appellants is subject to a settlement agreement in *Exley v. Burwell*, No. 3:14-cv-01230 (D. Conn. Aug. 1, 2016).

Quarterly Status Reports

42. Providing reports to the court regarding the progress of the backlog is most efficient if done on a quarterly basis. Providing reports on a quarterly basis would allow natural fluctuations in statistics regarding the backlog to stabilize, as appeal receipts are not consistent. Some providers and suppliers accumulate a batch of appeals and file them all at once, and other providers and suppliers appeal on a rolling basis. In addition, the impact of the administrative initiatives is difficult to evaluate when not given sufficient time to take effect between data

collection points; quarterly reports should allow sufficient time. Requiring reports on a more frequent basis than quarterly also could divert resources from adjudicating appeals.

Time from Initial Determination to DAB Decision Absent Backlog

43. Under applicable statutory and regulatory authorities, the time from the issuance of the notice of initial denial of a claim to receipt of a decision by the DAB absent the backlog can be expected to take approximately 745 days, and even longer if extensions are granted as allowed by regulation. See 42 U.S.C. § 1395ff(a)(3)(C)(i) (120 days to file request for redetermination after receipt of initial determination); 42 C.F.R. § 405.942(a)(1) (additional 5 days for mailing); 42 U.S.C. 1395ff(a)(3)(C)(ii) (60 days to issue a redetermination); 42 U.S.C. §1395ff(b)(1)(D)(i) (180 days to file request for reconsideration); 42 C.F.R. § 405.962(a)(1) (additional 5 days for mailing); 42 U.S.C. § 1395ff(c)(1)(C)(i) (60 days to issue reconsideration decision); 42 U.S.C. § 1395ff(b)(1)(E)(ii) (time to file hearing request to be set by regulation and 42 C.F.R. § 405.1004 provides 60 days to file a request for ALJ hearing); 42 C.F.R. § 405.1002(a)(3) (additional 5 days for mailing); 42 U.S.C. § 1395ff(d)(1)(A) (90 days to issue an ALJ decision); 42 C.F.R. § 405.1102(a)(1) (60 days to file request for DAB review); 42 C.F.R. § 405.1102(a)(2) (additional 5 days for mailing); 42 U.S.C. § 1395ff(d)(2)(A) (90 days to issue a DAB decision); 42 C.F.R. § 405.1036(c)(2) (allowance for extension of DAB decision); see also 42 C.F.R. § 405.942(a) (allowance for extension for redetermination request); 42 C.F.R. § 405.960(a) (allowance for extension for redetermination decision); 42 C.F.R. § 405.962(a) (allowance for extension for reconsideration request); 42 C.F.R. § 405.970(a) (allowance for extension for reconsideration); 42 C.F.R. § 405.1014(c) (allowance for extension for hearing request); 42 C.F.R. § 405.1016(a) (allowance for extension of ALJ decision); 42 C.F.R. §

405.1102(a)(1) (allowance for extension for request for DAB review); 42 C.F.R. § 405.1100(c) (allowance for extension of DAB decision).

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

Executed on November 7, 2016 in Washington, D.C.

days for mailing); 42 (0.8.C. 1395fffa)(6)(C)(fi) (60 days to issues a redetermination; 42 (U.S.C. § 1395ff(b)(1)(D)(f) (180 days to file request for reconsideration); 42 (C.F.R. § 405.952(a)(1)
(additional 5 days for mailing); 42 (U.S.C. § 1395ff(c)(1)(C)(f) (60 days to issue reconsideration)
decision; 42 U.S.C. § 1355ff(b)(C)(f)(f) (fine to file hearing request to be set by regulation and decision; 42 U.S.C. § 1395ff(c)(1)(C)(f) (60 days to issue reconsideration)
42 C.F.R. § 405,1004 provides 60 days to file a request for ALJ hearing); 42 C.F.R. §
405, (002(a)(f) (additional 5 days for mailing); 42 U.S.C. § 1395ff(d)(1)(A) (90 days to issue an ALL decision); 42 C.F.R. § 405,1102(a)(1) (60 days to file request for DAB review); 42 C.F.R. §
405, (102(a)(f) (additional 5 days for mailing); 42 U.S.C. § 1395ff(d)(1)(A) (90 days to issue an ALL decision); 42 C.F.R. § 405,1102(a)(1) (60 days to file request for DAB review); 42 C.F.R. §
405,1102(a)(2) (additional 5 days for mailing); 42 U.S.C. § 1395ff(d)(2)(A) (90 days to issue an ALL decision); 42 C.F.R. § 405,11036(a)(2) (allow ance for extension of DAB decision); 42 C.F.R. § 405,1036(a)(2) (allow ance for extension for redetermination request; 42 C.F.R. §
405,162(a)(a) (allowance for extension for redetermination decision); 42 C.F.R. § 405,90(a)
405,960(a) (allowance for extension for redetermination decision); 42 C.F.R. § 405,90(a)
406,960(a) (allowance for extension for redetermination decision); 42 C.F.R. § 405,90(a)
407,960(a) (allowance for extension for redetermination decision); 42 C.F.R. § 405,90(a)
408,960(a) (allowance for extension for redetermination decision); 42 C.F.R. § 405,90(a)

20

Exhibit 2: MEDICARE APPEALS BACKLOG - REDUCTION ACTIONS Data as of 09/30/2016

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| Projections with Impacts of
Administrative Actions and
Congressional Actions (both
legislative and budget) | | | | | | | Projections with Impact of
Taking Administrative
Actions

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 | | | | | | Projections with No Action
Taken | | | |
 | | |
| Legislative/Budget Dependent Actions Impact Total | Prior Authorization for any non-emergent Medicare Item or Service Legislative Proposal | On-the-Record Adjudication (Additional Capacity - Budget Dependent) | OMHA Settlement Conference Facilitations (Additional Capacity - Budget Dependent) | Recovery Audit Reimbursement/Pending Legislation | Legislation: Magistrates; Procedural Issues and Revised AIC | Cumulative Pending - With Current Actions Taken | Administrative Actions Impact Total

 | Settlement Conference Faciliation for State Medicaid Agencies | QIC Demonstration - Resolution of Appeals Pending at OMHA

 | Statistical Sampling (Administrative Actions under Current Authorities and Budget) | Senior ALJ Program | On-the-Record adjudication
 | OMHA Settlement Conferences | QIC Demonstration - Appeals Resolved before Reaching OMHA | QIC Demonstration - Provider Education Impact | Prior Authorization (Administrative Actions) | Recovery Audit Program Contract Modifications | CMS Hospital Settlement | Cumulative Pending - No Action Taken | Received appeals combined for efficiency | Disposition | New Receipts
 | Beginning Workload Balance | |
| - | r | | • | • | 4 | 767,422 | •

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 | ı | |
 | , | | | • | | • | 767,422 | | (87,337) | 474,063
 | 380,696 | FY 2014 |
| - | • | | • | • | - | 883,975 | (44,926)

 | - | •

 | , | • | •
 | (2,443) | ' | • | , | • | (42,483) | 928,901 | • | (78,881) | 240,360
 | 767,422 | FY 2015 |
| - | | , | | , | 1 | 658,307 | (281,250)

 | 1 | (3,150)

 | 1 | (585) | (2,013)
 | (6,645) | (2,180) | (125) | (19,170) | (1,139) | (246,243) | 942,000 | (64,149) | (87,123) | 206,854
 | 886,418 | FY 2016 |
| (114,395) | (7,562) | (3,000) | (45,000) | (16,833) | (42,000) | 560,663 | (252,514)

 | (55,000) | (32,175)

 | (5,000) | |
 | | | | | | | 850,627 | • | (92,000) | 246,870
 | 695,757 | FY 2017 |
| (266,128) | (14,128) | (22,000) | (45,000) | (101,000) | (84,000) | 621,333 | (112,975)

 | - | (34,650)

 | (5,000) | (3,960) | (3,000)
 | (5,000) | (10,710) | (530) | (45,205) | (4,920) | • | 929,273 | - | (92,000) | 265,646
 | 755,627 | FY 2018 |
| (281,058) | (29,058) | (22,000) | (45,000) | (101,000) | (84,000) | 681,291 | (124,114)

 | - | (37,125)

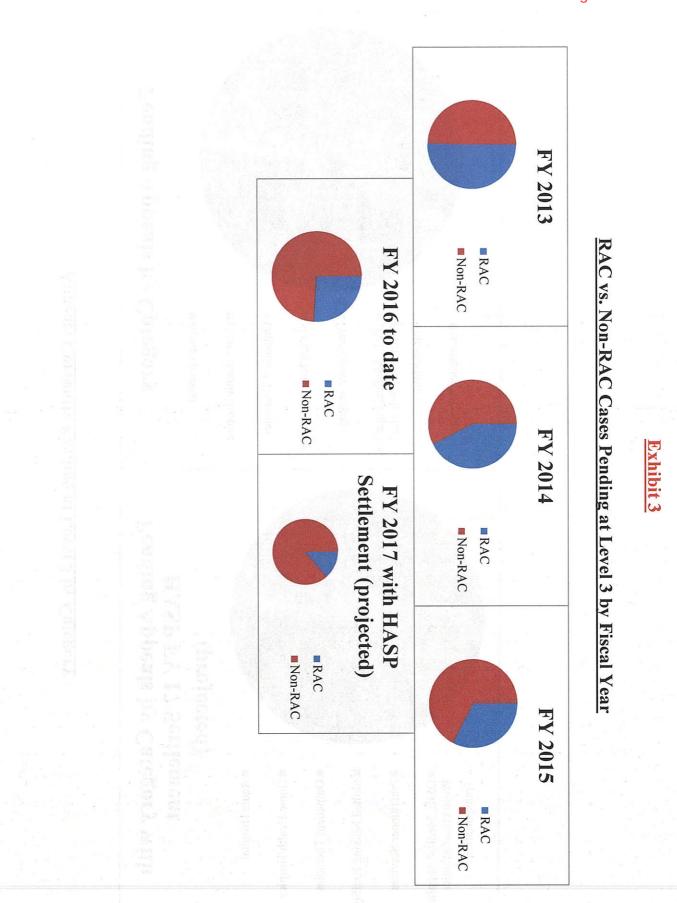
 | (5,000) | (3,960) | (3,000)
 | (5,000) | (12,225) | (681) | (51,755) | (5,368) | I | 1,113,344 | 1. | (92,000) | 276,071
 | 929,273 | FY 2019 |
| (281,910) | (29,910) | (22,000) | (45,000) | (101,000) | (84,000) | 757,329 | (116,727)

 | - | (39,600)

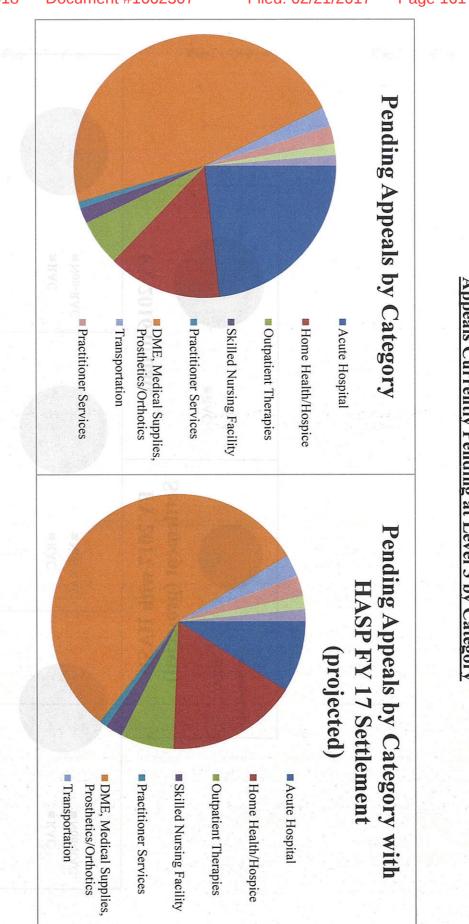
 | (5,000) | (3,960) | (3,000)
 | (5,000) | (13,740) | (840) | (39,995) | (5,591). | - | 1,306,109 | • | (92,000) | 284,765
 | 1,113,344 | FY 2020 |
| (282,758) | (30,758) | (22,000) | (45,000) | (101,000) | (84,000) | 895,978 | (62,770)

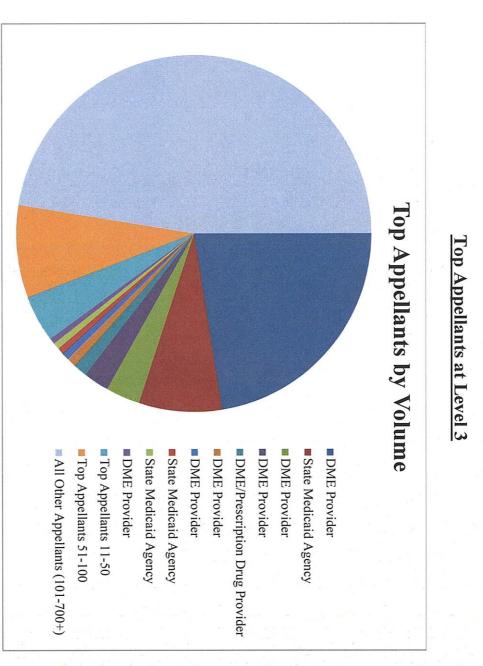
 | • | •

 | (5,000) | (3,960) | (3,000)
 | (5,000) | 0 | • | (39,995) | (5,815) | • | 1,507,529 | • | (92,000) | 293,419
 | 1,306,110 | FY 2021 |
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Appeals Currently Pending at Level 3 by Category





UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 14-851 (JEB)

<u>ORDER</u>

As set forth in the accompanying Memorandum Opinion, the Court ORDERS that:

- 1. Plaintiffs' Motion for Summary Judgment is GRANTED;
- 2. Defendant's Motion for Leave to File Reply is GRANTED;
- 3. Defendant's Cross-Motion for Summary Judgment is DENIED;
- Defendant must achieve the following reductions from the current backlog of cases pending at the ALJ level: 30% by December 31, 2017; 60% by December 31, 2018; 90% by December 31, 2019; and 100% by December 31, 2020; and
- 5. Defendant shall file status reports with the Court every 90 days.

SO ORDERED.

<u>/s/ James E. Boasberg</u> JAMES E. BOASBERG United States District Judge

Date: December 5, 2016

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 14-851 (JEB)

MEMORANDUM OPINION

Two and a half years ago, the American Hospital Association and affiliated entities asked this Court to issue a writ of mandamus to compel the Secretary of Health and Human Services to adjudicate pending Medicare-reimbursement appeals in compliance with statutorily imposed deadlines. Plaintiffs sought relief from a morass in which hundreds of thousands of appeals were languishing in a highly backlogged administrative process. Now, after a motion for summary judgment, a motion to dismiss for lack of jurisdiction, an appeal to and remand from the D.C. Circuit, and a motion to stay, the Court can finally grant Plaintiffs a remedy. The incantation of mandamus does not generate an instantaneous cure-all for complex problems, however, and so this Opinion focuses on the form the relief will take.

I. Background

Understandably frustrated by long delays in the administrative-appeal process for Medicare-reimbursement claims, Plaintiffs filed this suit in May 2014. See ECF No. 1

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Case 1:14-cv-00851-JEB Document 48 Filed 12/05/16 Page 2 of 7 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 165 of 180

(Complaint). Although sympathetic, the Court was reluctant to intervene and thus initially concluded that mandamus was not warranted and dismissed the case for lack of jurisdiction. <u>Am. Hosp. Ass'n v. Burwell (AHA I)</u>, 76 F. Supp. 3d 43, 56 (D.D.C. 2014). The D.C. Circuit reversed and remanded with instructions for further proceedings, including a direction to this Court to "determine whether 'compelling equitable grounds' now exist to issue a writ of mandamus." <u>Am. Hosp. Ass'n v. Burwell (AHA II)</u>, 812 F.3d 183, 192 (D.C. Cir. 2016).

Upon remand, the Secretary moved to stay the proceedings until September 30, 2017, the close of the next full appropriations cycle, to permit HHS to pursue various administrative and legislative efforts designed to tackle the significant appeals backlog. <u>See</u> ECF No. 30 (Motion to Stay). The Court denied that request. <u>Am. Hosp. Ass'n v. Burwell (AHA III)</u>, 2016 WL 5106997 (D.D.C. Sept. 19, 2016). In so doing, it concluded that there existed "equitable grounds for mandamus." <u>Id.</u> at *8. Recognizing, though, that it could not practicably order HHS to resolve each of the pending appeals by the statutorily prescribed deadlines, the Court asked the parties to address in briefing the specific forms mandamus relief should take. <u>See</u> Minute Order of Oct. 3, 2016. They have now done so, although HHS has also asked the Court to reconsider its prior decision to grant mandamus.

For the curious reader, a more detailed account of the administrative-appeal process for Medicare-claim reimbursements and the causes and scope of the backlog can be found in the Court's prior Opinions. <u>See AHA III</u>, 2016 WL 5106997, at *1-2; <u>AHA I</u>, 76 F. Supp. 3d at 46-48.

II. Analysis

A. Plaintiffs' Proposals

As requested by the Court, Plaintiffs devote serious thought to possible actions the Secretary could undertake to address the backlog of administrative appeals. They propose three categories of discrete interventions and, in the alternative, an overall timetable by which the Secretary must achieve reductions in the backlog. <u>See</u> ECF No. 39 (Motion) at 4-13.

As to the reforms, Plaintiffs suggest that the Secretary should: (1) offer reasonable settlements to certain broad groups of Medicare providers and suppliers; (2) for some subset of disputed Medicare claims, alleviate the financial strain on providers by deferring their duty to repay the Secretary and tolling the accrual of interest on those claims for waiting times beyond the statutory deadlines; and (3) impose financial penalties on Recovery Audit Contractors for high reversal rates by Administrative Law Judges. <u>See</u> Mot. at 4-11.

Correctly anticipating that the Court might prefer to avoid directing the particulars of the Secretary's backlog-reduction efforts, however, Plaintiffs alternatively propose that it simply require the Secretary to meet certain numeric reduction targets through 2020, leaving to her discretion the means by which such targets are to be achieved. <u>Id.</u> at 12-13. Plaintiffs' proffered timetable is as follows:

- 30% reduction from the current backlog of cases pending at the ALJ level by December 31, 2017;
- 60% reduction from the current backlog of cases pending at the ALJ level by December 31, 2018;
- 90% reduction from the current backlog of cases pending at the ALJ level by December 31, 2019;
- Elimination of the backlog of cases pending at the ALJ level by December 31, 2020.
- On January 1, 2021, [granting of] default judgment in favor of all claimants whose appeals have been pending at the ALJ level without a hearing for more than one calendar year.

<u>Id.</u> at 12. As a reminder, ALJ review is the third of four levels in the administrative-appeal process set out in the Medicare Act and is the step at which the backlog and delays are especially significant. <u>See AHA III</u>, 2016 WL 5106997, at *1-2.

B. Defendant's Response

The Secretary counters that all of Plaintiffs' proposed remedies are inappropriate. <u>See</u> ECF No. 41 (Opposition) at 11. But first, she devotes nearly seven pages of briefing to repeating the same plea that animated her previous stay request: she is hard at work, progress is in sight, and mandamus should not issue. <u>Id.</u> at 1-7. Recounting various backlog-reduction efforts undertaken by HHS since moving for a stay in spring 2016, Defendant contends that the good faith and impact of those efforts shift the balance of factors against mandamus. <u>Id.</u>

As directed by the Court of Appeals, this Court analyzed the factors counseling in favor of and against mandamus in its prior Opinion. <u>See AHA III</u>, 2016 WL 5106997, at *3-5. The Secretary's latest brief does not provide enough evidence of progress to tilt the scales. According to a declaration from Ellen Murray, HHS's Assistant Secretary for Financial Resources and Chief Financial Officer, the estimated impact of some of the administrative actions that HHS outlined in the last round of briefing is much greater than the agency previously thought, and HHS has expanded the scope of some of those interventions based on promising results thus far. <u>See</u> ECF No. 41-1 (Declaration of Ellen Murray), ¶ 2-22. Although the Court is glad to learn that the backlog-reduction projections are better than earlier reported, they are still unacceptably high. The Secretary does not point to any categorically new administrative actions and, critically, continues to promise the elimination of the backlog only "with legislative action" — a significant caveat. <u>See</u> Opp. at 6; <u>AHA III</u>, 2016 WL 5106997, at *7-8 (explaining that the Court "must draw the conclusion that Congress is unlikely to play the role of the cavalry

here"). The Secretary's renewed arguments notwithstanding, equitable grounds for mandamus remain.

C. <u>Resolution</u>

Defendant next questions the legality and propriety of Plaintiffs' three proposed initiatives and offers a set of her own. See Opp. at 7-23. The Court need not dive into the parties' debate over those competing reforms, however. It continues to believe that it should intrude as little as possible on the Secretary's specific decisionmaking processes and operations, and it thus concludes that Plaintiffs' proposed timetable with deadlines for set backlog-reduction targets is the preferable approach. See AHA III, 2016 WL 5106997, at *4 (noting the "agency's 'comparative institutional advantage' in this domain'') (quoting In re Barr Labs, Inc., 930 F.2d 72, 74 (D.C. Cir. 1991)); AHA II, 812 F.3d at 192 (flagging the risk of "infringing on the authority and discretion of the executive branch''). The Court appreciates that Plaintiffs could have chosen to demand immediate relief; instead, they have commendably offered a thoughtful and reasonable four-year plan for this complex problem.

Defendant nonetheless argues that imposing such a timetable would require her to "make payment on Medicare claims regardless of the merit of those claims," which "would squarely conflict with the Medicare statute." Opp. at 22-23 (citing 42 U.S.C. §§ 1395f, 1395g(a), 1395y(a)(1)(A)). But the timetable does not so require. It simply demands that the Secretary figure out how to undertake "proper claim substantiation" within a reasonable timeframe. <u>Id.</u> at 22. The Secretary's protest, moreover, elides the fact that the statutory prohibition on improper payments is not the only legal constraint on HHS's claims-adjudication process. The agency is also bound by statutorily mandated deadlines, of which it is in flagrant violation as to hundreds of thousands of appeals. <u>AHA II</u>, 812 F.3d at 190-92; Murray Decl., Exh. 1. Satisfying the

statutory demands for both accuracy and timeliness will no doubt prove challenging, but such is the task at hand.

Turning to logistics, the Secretary does not otherwise dispute the specific dates and reduction percentages in Plaintiffs' proposed timetable. The Court therefore adopts the end-of-calendar-year deadlines and the mandatory-percentage reductions listed above — *i.e.*, 30% reduction from the current backlog of cases pending at the ALJ level by December 31, 2017; 60% by December 31, 2018; 90% by December 31, 2019; and 100% by December 31, 2020.

Defendant does take issue, however, with the last bullet point in Plaintiffs' timetable: the suggestion that, as of January 1, 2021, default judgment be entered in favor of all claimants whose appeals have been pending at the ALJ level without a hearing for more than one calendar year. See Mot. at 12; Opp. at 22-23. Requiring default judgment in all such pending appeals if the benchmarks are not met, the Secretary contends, would "create perverse incentives for providers and suppliers to appeal non-meritorious claims." Opp. at 22. That is, "[a]ny provider could pursue any claim with the expectation that the end result would be payment, no matter how little merit in the claim." Id. at 23. That result, in turn, "could endanger the Medicare Trust Funds." Id.

The Court agrees that this prospect raises some concern; as a result, it will not automatically enter default judgments in all qualifying appeals on January 1, 2021. Instead, if the Secretary fails to meet the above deadlines, Plaintiffs may move for default judgment or to otherwise enforce the writ of mandamus. <u>Cf.</u> Fed. R. Civ. P. 55(d) ("A default judgment may be entered against the United States, its officers, or its agencies only if the claimant establishes a claim or right to relief by evidence that satisfies the court.").

Case 1:14-cv-00851-JEB Document 48 Filed 12/05/16 Page 7 of 7 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 170 of 180

Finally, Plaintiffs ask that the Court order the Secretary to file regular status reports. <u>See</u> Mot. at 13. The Secretary believes quarterly reports — every 90 days — would be appropriate, <u>see</u> Opp. at 23, and Plaintiffs do not presently object, despite having initially requested reports every 60 days. <u>Compare</u> Mot. at 13, <u>with</u> ECF No. 43 (Reply) at 12. The Court will thus adopt the Secretary's timeline. The reports should communicate HHS's progress in reducing the backlog and should include updated figures for the current and projected backlog, as well as a description of any significant administrative and legislative actions that will affect the backlog.

III. Conclusion

For the foregoing reasons, the Court will grant Plaintiffs' Motion for Summary Judgment and deny Defendant's Cross-Motion for Summary Judgment. Although the Court will administratively terminate the case, it will retain jurisdiction in order to review the required status reports and rule on any challenges to unmet deadlines. A separate Order so stating will issue this day.

> <u>/s/ James E. Boasberg</u> JAMES E. BOASBERG United States District Judge

Date: December 5, 2016

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Civil Action No. 14-cv-00851 (JEB)

Defendant.

SUPPLEMENTAL DECLARATION OF ELLEN MURRAY

I, Ellen Murray, declare as follows:

1. I am the Assistant Secretary for Financial Resources and Chief Financial Officer of the Department of Health and Human Services (HHS or Department). I have held this position since February 2010. Among my duties, I provide advice and guidance to the Secretary on all aspects of budget, financial management, grants and acquisition management, and provide for the direction and implementation of these activities across the Department. The statements made in this declaration are based on my personal knowledge, information contained in agency files, and information furnished to me in the course of my official duties. This declaration supplements my prior declarations in this case dated May 25, 2016 (May Decl.) and November 7, 2016 (November Decl.), which were submitted as an exhibit to Defendant's Motion for Summary Judgment.

2. As of December 5, 2016, there were 657,955 cases that had been pending before the Department's Office of Medicare Hearings and Appeals (OMHA). In its Order of the same date, this Court instructed the Department to reduce this backlog by 30% by the end of 2017; by 60% by the end of 2018; by 90% by the end of 2019; and by 100% by the end of 2020. For the reasons explained in my prior declarations and further explained below, the Department cannot reduce the backlog on the schedule that the Court has required without violating its statutory duty to protect the Medicare Trust Funds.

3. My November declaration recited that, based on the projected impact of both administrative and legislative actions, HHS expected the number of cases that have been pending before OMHA for more than 90 days to be eliminated completely by the end of FY 2019. A critical part of this November projection was the projected impact of legislative actions, which would have provided the Department additional funding and new authorities. November Decl. ¶ 2 and Ex. 2 thereto. The 114th Congress adjourned without taking any legislative actions to address the backlog of Medicare appeals. OMHA's adjudication capacity, therefore, is fixed at present levels.

4. Absent substantial new resources and authorities from Congress, the Department has no means to, and therefore cannot, meet the reduction targets required by the Court's December 5, 2016 order and simultaneously satisfy its fiduciary duty to the Medicare Trust Funds to pay only for claims that satisfy coverage requirements as set forth by statute. The only way for the Department to potentially meet such reduction targets without legislative action would be to settle claims for the full value or nearly the full value of each appeal without regard to its merit. This measure would result in the payment of non-meritorious and sometimes fraudulent claims, and, even still, might not resolve OMHA's backlog, as it would also encourage appellants to flood the appeals system with every denied claim – regardless of merit – with the hope that it would eventually also be paid, which would make the backlog at OMHA even worse. *See* November Decl. ¶ 37-38; *see also id.* at ¶ 32. This situation would put the

Department even further behind in meeting the statutory timeframe to adjudicate appeals and force the Department to violate its responsibility to preserve and safeguard the Medicare Trust Funds. *See id.* at ¶¶ 37-38.

5. As previously explained, the Department has a vital fiduciary responsibility to preserve and safeguard the Medicare Trust Funds by paying only meritorious claims. This responsibility includes paying only legitimate claims and ensuring the Medicare Trust Funds only pay for services and administrative expenses provided for by the Medicare statute. November Decl. ¶¶ 27, 38; May Decl. ¶¶ 5, 7.

6. The liability to the Medicare Trust Funds in settling claims in the manner and proportion suggested by the Court's order would be significant. As of December 5, 2016, there were 657,955 appeals pending at OMHA with total billed amounts-in-controversy of approximately \$6.6 billion. While the actual amounts paid may be lower because providers and suppliers generally bill Medicare at higher amounts than what Medicare fee schedules and agreements allow for payment, the impact of these payments on the Medicare Trust Funds would still be significant.

7. Further, the claims pending at OMHA have already been rejected at three levels of review. Based on the FY 2016 Administrative Law Judge (ALJ) reversal rate of 28%, it can reasonably be assumed at that least 72% of these claims lack merit or are procedurally flawed and should not be paid. *See* May Decl. ¶ 21(c). The ALJ reversal rate continues to decrease as administrative initiatives remove pending claims that would otherwise merit and receive full or partial payment before an ALJ adjudicates the claim. The remaining claims are, therefore, more likely to be non-meritorious and have their denial upheld on ALJ review.

Case 1:14-cv-00851-JEB Document 49-1 Filed 12/15/16 Page 5 of 5 USCA Case #17-5018 Document #1662307 Filed: 02/21/2017 Page 174 of 180

8. Thus, the court order effectively requires the Secretary to violate one of her most critical fiduciary and statutory duties – safeguarding and preserving the Medicare Trust Funds – by paying vast sums of money to settle meritless claims that do not meet statutory and regulatory requirements for payment and inviting even more appeals that would only exacerbate the existing backlog at OMHA and the Departmental Appeals Board.

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

Executed on December 15, 2016 in Washington, D.C.

Ellen Murray

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 14-851 (JEB)

<u>ORDER</u>

Early last month, the Court granted summary judgment in favor of Plaintiffs and ordered the Secretary of Health and Human Services to reduce the Medicare-appeals backlog by certain numeric targets set through the end of 2020. <u>Am. Hosp. Ass'n v. Burwell (AHA IV)</u>, 2016 WL 7076983, at *3-4 (D.D.C. Dec. 5, 2016). The Secretary now brings a Motion to Reconsider under Federal Rule of Civil Procedure 59(e), arguing that reconsideration is necessary to correct a clear error and prevent a manifest injustice. <u>See</u> ECF No. 49 at 1. The Court will deny the Motion.

A Rule 59(e) motion is analyzed under a "stringent" standard. <u>See Ciralsky v. CIA</u>, 355 F.3d 661, 673 (D.C. Cir. 2004) (quoting <u>Firestone v. Firestone</u>, 76 F.3d 1205, 1208 (D.C. Cir. 1996) (*per curiam*)). Such a motion "is discretionary and need not be granted unless the district court finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." <u>Firestone</u>, 76 F.3d at

1208 (quoting <u>Nat'l Tr. v. Dep't of State</u>, 834 F. Supp. 453, 455 (D.D.C. 1993)); <u>see also</u> 11
Charles Alan Wright, Arthur R. Miller, *et al.*, <u>Federal Practice & Procedure</u> § 2810.1 (3d ed.
2016). Rule 59(e), moreover, "is not a vehicle to present a new legal theory that was available prior to judgment," <u>Patton Boggs LLP v. Chevron Corp.</u>, 683 F.3d 397, 403 (D.C. Cir. 2012), or to reargue previously raised theories. <u>Piper v. U.S. Dep't of Justice</u>, 312 F. Supp. 2d 17, 21 (D.D.C. 2004).

The Secretary contends that reconsideration is warranted here because the Court's decision to order scheduled reductions in the appeals backlog will force her to pay pending claims without regard to their merit, which the Medicare statute does not permit. See Mot. at 2 (citing 42 U.S.C. §§ 1395f, 1395g(a), 1395y(a)(1)(A)). But Defendant's argument that she cannot comply with both the reduction targets and her statutory obligation to protect the Medicare Trust Funds is not new; it was twice urged in prior briefing. See ECF No. 41 (Defendant's Motion for Summary Judgment) at 22-23; ECF No. 45-1 (Reply in Support of Defendant's Motion for Summary Judgment) at 8-9.

The Court is not unsympathetic to Defendant's plight, nor does it take lightly the decision to intervene in an executive agency's efforts to respond to a complex problem. <u>See Am. Hosp.</u> <u>Ass'n v. Burwell (AHA I)</u>, 76 F. Supp. 3d 43, 55-56 (D.D.C. 2014), rev'd Am. Hosp. Ass'n v. <u>Burwell (AHA II)</u>, 812 F.3d 183, 192 (D.C. Cir. 2016); <u>Am. Hosp. Ass'n v. Burwell (AHA III)</u>, 2016 WL 5106997, at *8 (D.D.C. Sept. 19, 2016). This Court must follow the instructions of the D.C. Circuit, however, and here the standard it set out, <u>see AHA II</u>, 812 F.3d at 192-93, led this Court to conclude that equitable grounds existed for mandamus and that the reductions timetable was the most appropriate form of such relief.

As the Secretary argues nothing she did not raise in previous filings and has not met the

exacting Rule 59(e) standard, the Court ORDERS that Defendant's Motion is DENIED.

IT IS SO ORDERED.

/s/ James E. Boasberg

JAMES E. BOASBERG United States District Judge

Date: January 4, 2017

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs,

v.

NORRIS W. COCHRAN, in his official capacity as ACTING SECRETARY OF HEALTH AND HUMAN SERVICES, Civil Action No. 14-cv-00851 (JEB)

Defendant.

NOTICE OF APPEAL

Notice is hereby given this 30th day of January, 2017, that the Defendant, Norris W. Cochran, in his official capacity as Acting Secretary of Health and Human Services,¹ hereby appeals to the United States Court of Appeals for the District of Columbia Circuit from the Order (ECF No. 47) and Memorandum Opinion (ECF No. 48) of this Court, entered on the 5th day of December, 2016, granting the Plaintiffs' Motion for Summary Judgment, denying the Defendant's Cross-Motion for Summary Judgment, and ordering the Defendant to take the actions described in paragraphs 4 and 5 of the Order, as well as from all other opinions, orders, and rulings in this action, including, but not limited to the Order (ECF No. 52) of this Court, entered on the 4th day of January, 2017, denying the Defendant's Motion for Reconsideration.

Respectfully submitted,

¹ Pursuant to Fed. R. Civ. P. 25(d), Acting Secretary Cochran is substituted in his official capacity as the defendant in this action.

CHAD A. READLER Acting Assistant Attorney General

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<u>/s/ Caroline Lewis Wolverton</u> CAROLINE LEWIS WOLVERTON Senior Trial Counsel, Federal Programs Branch D.C. Bar No. 496-433 U.S. Department of Justice Civil Division P.O. Box 883 Washington, D.C. 20001 Tel. (202) 514-0265 Fax (202) 616-8470 caroline.lewis-wolverton@usdoj.gov

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Attorneys for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2017, I electronically filed the foregoing joint appendix with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Joshua Salzman

Joshua M. Salzman