

No. 18-540

In the Supreme Court of the United States

LESLIE RUTLEDGE, in her official capacity as
Arkansas Attorney General,
Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

**On Writ of Certiorari to the
United States Court of Appeals
for the Eighth Circuit**

**JOINT APPENDIX
VOLUME I**

LESLIE RUTLEDGE Arkansas Attorney General	SETH P. WAXMAN <i>Counsel of Record</i>
NICHOLAS J. BRONNI Solicitor General <i>Counsel of Record</i>	WILMER CUTLER PICKERING HALE AND DORR LLP 1875 Pennsylvania Ave., NW Washington, DC 20006 (202) 663-6000 seth.waxman@wilmerhale.com
VINCENT M. WAGNER Deputy Solicitor General	
ASHER STEINBERG	
DYLAN L. JACOBS Assistant Solicitors General	<i>Counsel for Respondent</i>
SHAWN J. JOHNSON Senior Assistant Attorney General	
OFFICE OF THE ARKANSAS ATTORNEY GENERAL 323 Center St., Ste. 200 Little Rock, AR 72201 (501) 682-6302 nicholas.bronni@ arkansasag.gov <i>Counsel for Petitioner</i>	

**PETITION FOR CERTIORARI FILED OCTOBER 22, 2018
CERTIORARI GRANTED JANUARY 10, 2020**

TABLE OF CONTENTS

	Page
<u>Volume I</u>	
District court docket entries (No. 4:15-cv-510)...	1
Court of appeals docket entries (No. 17-1609) ...	31
Court of appeals docket entries (No. 17-1629).....	48
Complaint (Dist. Ct. Dkt. No. 1)	63
Excerpts of testimony given during the hearing on Motion for Preliminary Injunction (Dist. Ct. Dkt. No. 44).....	91
Answer to Complaint by Leslie Rutledge (Dist. Ct. Dkt. No. 48).....	111
Declaration of Melanie Kracke (Dist. Ct. Dkt. No. 75-3, Ex. 3)	123
Declaration of Amy Bricker (Dist. Ct. Dkt. No. 75-3, Ex. 4)	133
Declaration of David A. Hyman (Dist. Ct. Dkt. No. 75-3, Ex. 6)	140
Expert Report of John Jones (Dist. Ct. Dkt. No. 75-3, Ex. 12).....	174
Excerpts of Deposition Transcript of John Jones (Dist. Ct. Dkt. No. 77-2)	201
Expert Witness Report of Donna West-Strum (Dist. Ct. Dkt. No. 77-3)	210
Declaration of Kristy Reed (Dist. Ct. Dkt. No. 77-4)	259
Declaration of Robert Geyer (Dist. Ct. Dkt. No. 77-10)	265

TABLE OF CONTENTS—Continued

	Page
Excerpts of Deposition Transcript of Donna West-Strum (Dist. Ct. Dkt. No. 77-16)	269
Plaintiff’s Response to Statement of Purportedly Material Facts in Support of the State’s Motion for Summary Judgment (Dist. Ct. Dkt. No. 85-1)	301
State’s Response to PCMA’s Local Rule 56.1 Statement of Undisputed Material Facts (Dist. Ct. Dkt. No. 89).....	341

Volume II (Under Seal)

USScript Pharmacy Benefit Management Services Agreement (Dist. Ct. Dkt. No. 75-3, Ex. 5).....	359
OptumRx Pharmacy Network Agreement (Dist. Ct. Dkt. No. 75-3, Ex. 15)	379
Excerpt of OptumRx 2016 provider manual (Dist. Ct. Dkt. No. 75-3, Ex. 17).....	430

U.S. DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
(CENTRAL DIVISION)

Civil Docket For Case #: 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

v.

RUTLEDGE

DOCKET ENTRIES

DATE	#	PROCEEDINGS
08/13/2015	1	COMPLAINT for Declaratory, Injunctive, and other Relief against Leslie Rutledge, filed by Pharmaceutical Care Management Association. Fee of \$ 400 paid; Receipt Number LIT052754. Summons issued. (Attachments: # 1 Civil Cover Sheet) (kdr) (Entered: 08/13/2015)
08/13/2015	2	MOTION for Preliminary Injunction by Pharmaceutical Care Management Association. (kdr) (Entered: 08/13/2015)
08/13/2015	3	MEMORANDUM IN SUPPORT of 2 Motion for Preliminary Injunction and Expedited Briefing Schedule and Hearing filed by Pharmaceutical Care Management Association.

DATE	#	PROCEEDINGS
		(Attachments: # 1 Exhibits 1-5) (ljb) (Entered: 08/14/2015)
08/13/2015	4	Corporate Disclosure Statement (Rule 7.1) by Pharmaceutical Care Management Association identifying Other Affiliate Aetna Pharmacy Management, Other Affiliate Catamaran Corp, Other Affiliate Cigna Pharmacy Management, Other Affiliate CVS Health Corp, Other Affiliate Express Scripts, Other Affiliate Humana Pharmacy Solutions, Other Affiliate LDI, Other Affiliate Med-Impact Healthcare System, Other Affiliate Optum Rx, Other Affiliate Prime Therapeutics, Other Affiliate USScript for Pharmaceutical Care Management Association. (ljb) (Entered: 08/14/2015)
08/13/2015	5	MOTION for Leave to Appear pro hac vice by Dean Richlin filed by Pharmaceutical Care Management Association. Fee \$100 paid, Receipt #LIT052755. (ljb) (Entered: 08/14/2015)
08/13/2015	6	MOTION for Leave to Appear pro hac vice by Andrew M London filed by Pharmaceutical Care Management Association. Fee \$100 paid, Receipt #LIT052756. (ljb) (Entered: 08/14/2015)

DATE	#	PROCEEDINGS
08/13/2015	7	MOTION for Leave to Appear pro hac vice by Kristyn Marie DeFilipp filed by Pharmaceutical Care Management Association. Fee \$100 paid, Receipt #LIT052757. (ljb) (Entered: 08/14/2015)
08/17/2015	8	ORDER granting 5 , 6 , and 7 motions to proceed pro hac vice filed by Dean Richlin, Andrew London, and Kristyn DeFilipp. Richlin, London, and DeFilipp are admitted pro hac vice because they meet the requirements of Local rule 83.5. Accordingly, they are directed to register with CM/ECF in the Western District of Arkansas by 5:00 p.m., Wednesday, August 19, 2015. Signed by Chief Judge Brian S. Miller on 8/17/2015. (ljb) (Entered: 08/17/2015)
08/17/2015	9	AMENDED ORDER granting 5 , 6 , and 7 motions to proceed pro hac vice filed by Dean Richlin, Andrew London, and Kristyn DeFilipp. Richlin, London, and DeFilipp are admitted pro hac vice because they meet the requirements of Local Rule 83.5. Accordingly, they are directed to register with CM/ECF in the Eastern District of Arkansas by 5:00 p.m., Friday, August 21, 2015. Signed by Chief Judge Brian S. Miller on 8/17/2015. (ljb) (Entered: 08/17/2015)

DATE	#	PROCEEDINGS
08/21/2015	10	NOTICE of Appearance by Shawn J. Johnson on behalf of Leslie Rutledge (Johnson, Shawn) (Entered: 08/21/2015)
08/21/2015	11	MOTION for Extension of Time to File Response/Reply as to 2 MOTION for Preliminary Injunction, MOTION for Extension of Time to File Answer re 1 Complaint () by Leslie Rutledge (Johnson, Shawn) (Entered: 08/21/2015)
08/24/2015	12	ORDER granting 11 motion for extension of time. Defendant is directed to file her responses on or before September 22, 2015. Signed by Chief Judge Brian S. Miller on 08/24/2015. (rhm) (Entered: 08/24/2015)
08/24/2015	13	NOTICE of Appearance by Dean Richlin on behalf of Pharmaceutical Care Management Association (Richlin, Dean) (Entered: 08/24/2015)
08/24/2015	14	NOTICE of Appearance by Kristyn Marie DeFilipp on behalf of Pharmaceutical Care Management Association (DeFilipp, Kristyn) (Entered: 08/24/2015)
08/24/2015	15	NOTICE of Appearance by Andrew W. London on behalf of Pharmaceutical Care Management Association

DATE	#	PROCEEDINGS
		(London, Andrew) (Entered: 08/24/2015)
08/25/2015	16	INITIAL SCHEDULING ORDER: Rule 26(f) Conference to occur by 10/29/2015. Rule 26(f) Report due by 11/12/2015. Proposed Bench Trial set for sometime during the week of 12/5/2016 09:30 AM in Little Rock Courtroom #2D before Chief Judge Brian S. Miller. Signed at the Direction of the Court on 8/25/15. (bmt) (Entered: 08/25/2015)
09/22/2015	17	MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM by Leslie Rutledge (Attachments: # 1 Exhibit A - Arkansas Act 900 of 2015, # 2 Exhibit B - Arkansas Act 1194 of 2013)(Johnson, Shawn) (Entered: 09/22/2015)
09/22/2015	18	BRIEF IN SUPPORT re 17 Motion to Dismiss for Failure to State a Claim filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 09/22/2015)
09/22/2015	19	RESPONSE in Opposition re 2 MOTION for Preliminary Injunction filed by Leslie Rutledge. (Attachments: # 1 Exhibit A - Kristy Reed Declaration (including Attachs. 1-4), # 2 Exhibit B - Robert Geyer Declaration (including Attachs. 1-2), # 3 Exhibit C - Arkansas Act 1194 of 2013, # 4 Exhibit D - October 2013

DATE	#	PROCEEDINGS
		Correspondence from Attorney General to PBMs, # 5 Exhibit E - Arkansas Act 900 of 2015, # 6 Exhibit F - July 3, 2015 Correspondence from Attorney General to PBMs, # 7 Exhibit G - Express Scripts Addendum dated June 15, 2015 (under seal), # 8 Exhibit H - Humana Addendum dated September 2015 (under seal))(Johnson, Shawn) (Entered: 09/22/2015)
09/22/2015	20	BRIEF IN SUPPORT re 19 Response in Opposition to Motion, filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 09/22/2015)
09/22/2015	21	MOTION to Seal Document 19 Response in Opposition to Motion, <i>Exhibits G and H</i> by Leslie Rutledge (Johnson, Shawn) (Entered: 09/22/2015)
09/22/2015	22	BRIEF IN SUPPORT re 21 Motion to Seal Document filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 09/22/2015)
09/29/2015	23	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Order granting 21 motion to seal document. Signed by Chief Judge Brian S. Miller on 9/29/2015. (bnk) (Entered: 09/29/2015)
09/30/2015	24	SEALED EXHIBITS. (kdr) (Entered: 09/30/2015)

DATE	#	PROCEEDINGS
10/05/2015	25	MOTION for Leave to File <i>Reply Memorandum</i> by Pharmaceutical Care Management Association (Attachments: # 1 Document Reply Memorandum)(London, Andrew) (Entered: 10/05/2015)
10/06/2015	26	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Order granting 25 motion for leave to file. Plaintiff is directed to file its reply within 3 days after the entry of this order. Signed by Chief Judge Brian S. Miller on 10/6/2015. (bnk) (Entered: 10/06/2015)
10/06/2015	27	REPLY to Response to Motion re 2 MOTION for Preliminary Injunction filed by Pharmaceutical Care Management Association. (London, Andrew) (Entered: 10/06/2015)
10/08/2015	28	MOTION for Extension of Time to File Response/Reply as to 17 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM by Pharmaceutical Care Management Association (Pruitt, Lyn) (Entered: 10/08/2015)
10/13/2015	29	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) ORDER granting unopposed 28 motion for extension of time to file response re 17 motion to dismiss up to and including 10/13/15. Signed by Chief Judge Brian S.

DATE	#	PROCEEDINGS
		Miller on 10/13/15. (bmt) (Entered: 10/13/2015)
10/13/2015	30	RESPONSE in Opposition re 17 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by Pharmaceutical Care Management Association. (DeFilipp, Kristyn) (Entered: 10/13/2015)
10/16/2015	31	ORDER denying 2 Pharmaceutical Care Management Association's motion for preliminary injunction Motion for Preliminary Injunction. A hearing is scheduled for Friday, 10/23/2015, at 10:30 at the Richard Sheppard Arnold United States Courthouse, Room 2D. Parties should be prepared to present witnesses. Signed by Chief Judge Brian S. Miller on 10/16/2015. (kdr) (Entered: 10/16/2015)
10/16/2015	32	NOTICE of Hearing: Preliminary Injunction Hearing is rescheduled for Wednesday, November 4, 2015 at 10:30 AM in Little Rock Courtroom #2D before Chief Judge Brian S. Miller. (NOTE: previously set for 10/23/15)(bmt) (Entered: 10/16/2015)
10/20/2015	33	REPLY to Response to Motion re 17 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 10/20/2015)

DATE	#	PROCEEDINGS
10/22/2015	34	MOTION for Leave to Appear pro hac vice by Catherine Deneke filed by Pharmaceutical Care Management Association. Fee \$100 received. Receipt #LIT053773. (met) (Entered: 10/22/2015)
10/23/2015	35	ORDER granting 34 Catherine Deneke's motion to appear pro hac vice; and directing Deneke to register with CM/ECF in the Eastern District of Arkansas by 5:00 p.m., Monday, 10/26/2015. Signed by Chief Judge Brian S. Miller on 10/23/2015. (kdr) (Entered: 10/23/2015)
10/23/2015	36	ORDER authorizing Dean Richlin, Kristyn Bunce DeFilipp, Andrew London, Catherine Deneke, Barbara Levy, Stephanie Kanwit, Lyn Pruitt, David Hyman, Brian McCarthy, Amy Bricker, and Melanie Kracke to bring electronic devices into the Richard Sheppard Arnold Courthouse in Little Rock beginning Wednesday, 11/4/2015, and each day thereafter until the hearing on the motion for preliminary injunction is completed. Signed by Chief Judge Brian S. Miller on 10/23/2015. (kdr) (Entered: 10/23/2015)
10/28/2015	37	NOTICE of Appearance by Catherine Deneke on behalf of Pharmaceutical Care Management Association

DATE	#	PROCEEDINGS
		(Deneke, Catherine) (Entered: 10/28/2015)
10/28/2015	38	NOTICE of Appearance by Sarah R. Tacker on behalf of All Defendants (Tacker, Sarah) (Entered: 10/28/2015)
11/02/2015	39	ORDER authorizing Leah Stoecker, Christopher A. Smith, and Mary Zilinski to bring electronic devices into the Little Rock Courthouse beginning Wednesday, 11/4/2015, and each day thereafter until the hearing on the motion for preliminary injunction is completed. Signed by Chief Judge Brian S. Miller on 11/2/2015. (kdr) (Entered: 11/02/2015)
11/02/2015	40	ORDER authorizing Dwight Davis and John Trainor-Namir to bring electronic devices into the Little Rock Courthouse beginning Wednesday, 11/4/2015, and each day thereafter until the hearing on the motion for preliminary injunction is completed. Signed by Chief Judge Brian S. Miller on 11/2/2015. (kdr) (Entered: 11/02/2015)
11/04/2015	41	PRELIMINARY INJUNCTION HEARING held before Chief Judge Brian S. Miller on 11/4/2015. Case called. Parties present. Dean Richlin, Catherine Deneke and Lyn Pruitt on behalf of plaintiff. Shawn Johnson and Sarah Tacker on behalf of

DATE	#	PROCEEDINGS
		defendant. Nature of proceedings stated on the record. Openings statements made. Plaintiff's proof began and concluded. Defendant's proof began and completed. For reasons stated on the record, ruling on motion for preliminary injunction will be issued at a later date. COURT ADJOURNED. Copies of exhibits retained by the court. (Court Reporter Judy Ammons.) (Attachments: # 1 Defendant's exhibit and witness list, # 2 Plaintiff's exhibit and witness list) (bmt) (Entered: 11/05/2015)
11/10/2015	42	RESTRICTED TRANSCRIPT of hearing held on November 4, 2015. (plm) (Entered: 11/10/2015)
11/12/2015	43	Joint MOTION to Continue <i>Deadline in Initial Scheduling Order for Filing FRCP 26(f) Report</i> by Pharmaceutical Care Management Association (Deneke, Catherine) (Entered: 11/12/2015)
11/13/2015	44	TRANSCRIPT of Hearing on Motion for Preliminary Injunction Proceedings held on November 4, 2015, before Judge Brian S. Miller. Court Reporter Judith A. Ammons. Transcript may be viewed only at the public terminals in the Clerk's office. Copies of transcript are only available through the Official Court Reporter before the deadline for

DATE	#	PROCEEDINGS
		Release of Transcript Restriction. After that date it may be obtained through PACER. DEADLINES: Notice of Intent to Request Redaction due 11/23/2015. Redaction Request due 12/4/2015. Redacted Transcript Deadline set for 12/14/2015. Release of Transcript Restriction set for 2/11/2016. (plm) (Entered: 11/13/2015)
11/16/2015	45	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) ORDER granting joint 43 motion to modify initial scheduling order 16 . The parties will up to two weeks after the court's decision is issued on plaintiff's motion for preliminary injunction for conferring and filing a report pursuant to FRCP 26(f). Signed by Chief Judge Brian S. Miller on 11/16/15. (bmt) (Entered: 11/16/2015)
11/25/2015	46	ORDER denying 17 Defendant's Motion to Dismiss for Failure to State a Claim. Signed by Chief Judge Brian S. Miller on 11/25/15. (tjb) (Entered: 11/25/2015)
11/25/2015	47	ORDER denying 2 Plaintiff's MOTION for Preliminary Injunction. Signed by Chief Judge Brian S. Miller on 11/25/15. (tjb) (Entered: 11/25/2015)

DATE	#	PROCEEDINGS
12/09/2015	48	ANSWER to 1 Complaint with Jury Demand by Leslie Rutledge. (Johnson, Shawn) (Entered: 12/09/2015)
12/09/2015	49	REPORT of Rule 26(f) Planning Meeting by Pharmaceutical Care Management Association. (London, Andrew) (Entered: 12/09/2015)
12/10/2015	50	FINAL SCHEDULING ORDER: Jury Trial set for sometime during the week of 12/5/2016 09:30 AM in Little Rock Courtroom #2D before Chief Judge Brian S. Miller. Discovery due by 7/13/2016. All motions, except motions in limine are due by 8/8/2016. Pretrial Disclosure Sheet due by 11/4/2016. Status Report due by 8/8/2016. Signed at the Direction of the Court on 12/10/15. (bmt) (Entered: 12/10/2015)
01/27/2016	51	MOTION for Partial Summary Judgment by Pharmaceutical Care Management Association (Attachments: # 1 Document Memorandum in Support of Motion, # 2 Document Statement of Undisputed Material Facts, # 3 Appendix Appendix)(London, Andrew) (Entered: 01/27/2016)
02/09/2016	52	MOTION for Extension of Time to File Response/Reply as to 51 MOTION for Partial Summary Judgment <i>Pursuant to Fed. R. Civ. P.</i>

DATE	#	PROCEEDINGS
		<i>56(d)</i> by Leslie Rutledge (Attachments: # 1 Exhibit A - Defendants First Interrogatories and First Requests for Production of Documents, # 2 Exhibit B - Declaration of Shawn J. Johnson) (Johnson, Shawn) (Entered: 02/09/2016)
02/26/2016	53	RESPONSE in Opposition re 52 MOTION for Extension of Time to File Response/Reply as to 51 MOTION for Partial Summary Judgment Pursuant to <i>Fed. R. Civ. P 56(d)</i> filed by Pharmaceutical Care Management Association. (Attachments: # 1 Appendix Appendix) (London, Andrew) (Entered: 02/26/2016)
03/07/2016	54	ORDER denying, without prejudice, 51 Plaintiff's motion for partial summary judgment because defendant has satisfactorily shown that it needs to conduct more discovery; and granting 52 Defendant's request to deny plaintiff's motion for summary judgment for the same reasons. Signed by Chief Judge Brian S. Miller on 3/7/2016. (kdr) (Entered: 03/07/2016)
05/25/2016	55	AGREED PROTECTIVE ORDER. Signed by Chief Judge Brian S. Miller on 5/25/2016. (Attachments: # 1 Exhibit A)(kdr) (Entered: 05/25/2016)

DATE	#	PROCEEDINGS
05/25/2016	56	First MOTION to Compel <i>Discovery</i> by Leslie Rutledge (Attachments: # 1 Exhibit A - Chart containing PCMA's written discovery responses and objections, # 2 Exhibit B - Correspondence from Shawn Johnson to Dean Richlin dated May 3, 2016, # 3 Exhibit C - Letter from Dean Richlin to Shawn Johnson dated May 11, 2016)(Johnson, Shawn) (Entered: 05/25/2016)
05/25/2016	57	BRIEF IN SUPPORT re 56 Motion to Compel, filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 05/25/2016)
06/13/2016	58	First MOTION for Extension of Time to File Response/Reply as to 56 First MOTION to Compel <i>Discovery</i> by Pharmaceutical Care Management Association (DeFilipp, Kristyn) (Entered: 06/13/2016)
06/14/2016	59	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Order granting 58 unopposed motion for extension of time to file a response to 56 first motion to compel <i>discovery</i> . Signed by Chief Judge Brian S. Miller on 6/14/16. (bnk) (Entered: 06/14/2016)
06/17/2016	60	RESPONSE in Opposition re 56 First MOTION to Compel <i>Discovery</i>

DATE	#	PROCEEDINGS
		filed by Pharmaceutical Care Management Association. (Attachments: # 1 Affidavit of Kristyn DeFilipp, # 2 Exhibit 1 to Affidavit of Kristyn DeFilipp, # 3 Exhibit 2 to Affidavit of Kristyn DeFilipp)(DeFilipp, Kristyn) (Entered: 06/17/2016)
06/22/2016	61	REPLY to Response to Motion re 56 First MOTION to Compel <i>Discovery</i> filed by Leslie Rutledge. (Attachments: # 1 Exhibit A - PCMA Web Page Listing Board of Directors) (Johnson, Shawn) (Entered: 06/22/2016)
06/23/2016	62	MOTION to Withdraw as Attorney by Pharmaceutical Care Management Association (Deneke, Catherine) (Entered: 06/23/2016)
06/24/2016	63	MOTION for Leave to File <i>Surreply</i> by Pharmaceutical Care Management Association (Attachments: # 1 Exhibit Surreply, # 2 Appendix Appendix A)(London, Andrew) (Entered: 06/24/2016)
06/24/2016	64	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) ORDER granting 63 motion for leave to file surreply in opposition to motion to compel discovery. Plaintiff is directed to file its surreply forthwith. Signed by Chief

DATE	#	PROCEEDINGS
		Judge Brian S. Miller on 6/24/16. (bmt) (Entered: 06/24/2016)
06/24/2016	65	REPLY to Response to Motion re 56 First MOTION to Compel <i>Discovery Surreply</i> filed by Pharmaceutical Care Management Association. (Attachments: # 1 Appendix A) (London, Andrew) (Entered: 06/24/2016)
06/24/2016	66	ORDER granting 62 Catherine Deneke's motion to withdraw as counsel and directing the clerk to immediately terminate Deneke as counsel of record. Signed by Chief Judge Brian S. Miller on 6/24/2016. (kdr) (Entered: 06/24/2016)
06/24/2016	67	ORDER denying 56 Defendant's Motion to Compel Discovery. Signed by Chief Judge Brian S. Miller on 6/24/2016. (kdr) (Entered: 06/24/2016)
07/07/2016	68	NOTICE by All Defendants of <i>Deposition of John Jones</i> (Johnson, Shawn) (Additional attachment(s) added on 7/7/2016: # 1 Main Document - Correct) (thd). (Entered: 07/07/2016)
07/07/2016	69	NOTICE OF DOCKET CORRECTION re: 68 Notice to Take Deposition. CORRECTION: The signed document was added as an attachment to docket entry 68 , based on the attached correspondence. (thd) (Entered: 07/07/2016)

DATE	#	PROCEEDINGS
07/08/2016	70	Joint MOTION for Extension of Time to Complete Discovery <i>and File Motions</i> by Pharmaceutical Care Management Association (London, Andrew) (Entered: 07/08/2016)
07/11/2016	71	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) ORDER granting joint 70 motion for extension of time to complete discovery and file dispositive motions. The discovery deadline is extended up to and including 7/20/16. The dispositive motions deadline is extended up to and including 8/15/16. Signed by Chief Judge Brian S. Miller on 7/11/16. (bmt) (Entered: 07/11/2016)
08/08/2016	72	STATUS REPORT by Pharmaceutical Care Management Association. (DeFilipp, Kristyn) (Entered: 08/08/2016)
08/12/2016	73	MOTION for Leave to File <i>Under Seal Exhibits to Local Rule 56.1 Statement of Undisputed Material Facts</i> by Pharmaceutical Care Management Association (DeFilipp, Kristyn) (Entered: 08/12/2016)
08/12/2016	74	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Order granting 73 motion for leave to file confidential exhibits under seal. Signed by Chief

DATE	#	PROCEEDINGS
		Judge Brian S. Miller on 8/12/2016. (bnk) (Entered: 08/12/2016)
08/15/2016	75	MOTION for Summary Judgment by Pharmaceutical Care Management Association (Attachments: # 1 Document Memorandum in Support of Motion, # 2 Document Statement of Undisputed Material Facts, # 3 Appendix Exhibits to Statement of Undisputed Material Facts) (DeFilipp, Kristyn) (Entered: 08/15/2016)
08/15/2016	76	SEALED Document (jap) (Entered: 08/15/2016)
08/15/2016	77	MOTION for Summary Judgment by Leslie Rutledge (Attachments: # 1 Exhibit A - Act 900, # 2 Exhibit B - Deposition of John Jones, # 3 Exhibit C - Declaration of Donna West-Strum, # 4 Exhibit D - Declaration of Kristy Reed, # 5 Exhibit E - Declaration of Susan Hayes, # 6 Exhibit F - 11/4/15 Preliminary Injunction Hearing Excerpts, # 7 Exhibit G - Deposition of Susan Hayes, # 8 Exhibit H - Filed Under Seal, # 9 Exhibit I - Filed Under Seal, # 10 Exhibit J - Declaration of Bob Geyer, # 11 Exhibit K - Filed Under Seal, # 12 Exhibit L - Act 1194 of 2013, # 13 Exhibit M - Consumer Complaints Samples, # 14 Exhibit N - State's Oct. 2013 Correspondence, # 15 Exhibit O - Walmart

DATE	#	PROCEEDINGS
		Earnings Call dated 8-18-15, # 16 Exhibit P - Deposition of Donna West-Strum, # 17 Exhibit Q - Filed Under Seal)(Johnson, Shawn) (Entered: 08/15/2016)
08/15/2016	78	BRIEF IN SUPPORT re 77 Motion for Summary Judgment,,, filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 08/15/2016)
08/15/2016	79	STATEMENT OF FACTS (Local Rule 56.1) re 77 Motion for Summary Judgment,,, filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 08/15/2016)
08/15/2016	80	MOTION to Seal <i>Exhibits H, I, K and Q</i> by Leslie Rutledge (Johnson, Shawn) (Entered: 08/15/2016)
08/16/2016	81	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Order granting 80 motion to seal exhibits H, I, K, and Q. Signed by Chief Judge Brian S. Miller on 8/16/2016. (bnk) (Entered: 08/16/2016)
08/22/2016	82	First MOTION for Extension of Time to File Response/Reply as to 77 MOTION for Summary Judgment , 75 MOTION for Summary Judgment by Pharmaceutical Care Management Association (DeFilipp, Kristyn) (Entered: 08/22/2016)

DATE	#	PROCEEDINGS
08/22/2016	83	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Order granting 82 joint motion for extension of time to file Response to cross-motions for summary judgment on or before 9/9/2016. Signed by Chief Judge Brian S. Miller on 8/22/2016. (bnk) (Entered: 08/22/2016)
09/09/2016	84	MOTION to Seal Document <i>Response to Defendant's Statement of Material Facts</i> by Pharmaceutical Care Management Association (London, Andrew) (Entered: 09/09/2016)
09/09/2016	85	RESPONSE in Opposition re 77 MOTION for Summary Judgment filed by Pharmaceutical Care Management Association. (Attachments: # 1 Document Response to Statement of Material Facts, # 2 Exhibit Hearing Testimony of Amy Bricker) (London, Andrew) (Entered: 09/09/2016)
09/09/2016	86	SEALED DOCUMENT. (sew) (Entered: 09/09/2016)
09/09/2016	87	RESPONSE in Opposition re 75 MOTION for Summary Judgment filed by All Defendants. (Attachments: # 1 Exhibit, # 2 Exhibit) (Johnson, Shawn) (Entered: 09/09/2016)

DATE	#	PROCEEDINGS
09/09/2016	88	BRIEF IN SUPPORT re 75 Motion for Summary Judgment, filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 09/09/2016)
09/09/2016	89	STATEMENT OF FACTS (Local Rule 56.1) re 75 Motion for Summary Judgment, <i>Response to PCMA's Statement of Material Facts</i> filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 09/09/2016)
09/12/2016	90	ORDER granting 84 Plaintiff PCMA's motion to file its response under seal. PCMA may file its response to 79 defendant Leslie Rutledge's statement of material facts under seal. Signed by Chief Judge Brian S. Miller on 9/12/2016. (kdr) (Entered: 09/12/2016)
09/16/2016	91	REPLY to Response to Motion re 75 MOTION for Summary Judgment filed by Pharmaceutical Care Management Association. (London, Andrew) (Entered: 09/16/2016)
09/19/2016	92	REPLY to Response to Motion re 77 MOTION for Summary Judgment filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 09/19/2016)
09/20/2016	93	NOTICE OF HEARING ON MOTIONS re 75 77 motions for summary judgment: Motion Hearing set for 11/4/2016 at 10:30 AM in Little Rock Courtroom #2D before Chief

DATE	#	PROCEEDINGS
		Judge Brian S. Miller. (bmt) (Entered: 09/20/2016)
10/07/2016	94	Joint MOTION to Extend Time <i>and Amend Scheduling Order</i> by Pharmaceutical Care Management Association (DeFilipp, Kristyn) (Entered: 10/07/2016)
10/11/2016	95	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) ORDER granting joint 94 motion to amend scheduling order and extend deadlines. An amended final scheduling order will issue. Signed by Chief Judge Brian S. Miller on 10/11/16. (bmt) (Entered: 10/11/2016)
10/11/2016	96	FIRST AMENDED FINAL SCHEDULING ORDER: Jury Trial reset for sometime during the week of 3/27/2017 09:30 AM in Little Rock Courtroom #2D before Chief Judge Brian S. Miller. Motions in limine are due by 3/17/2017. Pretrial Disclosure Sheet due by 2/24/2017. Signed at the Direction of the Court on 10/11/16. (bmt) (Entered: 10/11/2016)
11/04/2016	97	(This is a TEXT ENTRY ONLY. There is no pdf document associated with this entry.) Minute Entry for proceedings held before Chief Judge Brian S. Miller: Motion Hearing held on 11/4/2016 re 77 MOTION for

DATE	#	PROCEEDINGS
11/14/2016	98	<p>Summary Judgment filed by Leslie Rutledge, 75 MOTION for Summary Judgment filed by Pharmaceutical Care Management Association. D. Richland and L. Pruitt pltf counsel, S. Johnson and S. Tacker deft counsel. (Court Reporter Judith A. Ammons.) (plm) (Entered: 11/04/2016)</p> <p>TRANSCRIPT of Hearing on Motions for Summary Judgment held on 11/4/2016, before Judge Brian S. Miller. Court Reporter - Judith A. Ammons. Transcript may be viewed only at the public terminals in the Clerk's office. Copies of transcript are only available through the Official Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. DEADLINES: Notice of Intent to Request Redaction due 11/25/2016. Redaction Request due 12/5/2016. Redacted Transcript Deadline set for 12/15/2016. Release of Transcript Restriction set for 2/13/2017. (mcz) (Entered: 11/14/2016)</p>
01/12/2017	99	<p>RESPONSE in Support re 75 MOTION for Summary Judgment <i>Notice of Supplemental Authority</i> filed by Pharmaceutical Care Management Association. (Attachments:</p>

DATE	#	PROCEEDINGS
		# 1 Exhibit A)(DeFilipp, Kristyn) (Entered: 01/12/2017)
01/26/2017	100	REPLY to Response to Motion re MOTION for Summary Judgment <i>and Notice of Supplemental Authority (Doc. 99)</i> filed by Leslie Rutledge. (Johnson, Shawn) (Entered: 01/26/2017)
01/27/2017	101	ADDENDUM filed by Pharmaceutical Care Management Association to 99 Response in Support of Motion. (Attachments: # 1 Exhibit A - Petition for Rehearing En Banc) (DeFilipp, Kristyn) (Entered: 01/27/2017)
02/16/2017	102	ADDENDUM filed by Pharmaceutical Care Management Association to 99 Response in Support of Motion. <i>for Summary Judgment</i> (Attachments: # 1 Exhibit Order of the U.S. Court of Appeals for the Eighth Circuit in PCMA v. Gerhart) (London, Andrew) (Entered: 02/16/2017)
02/17/2017	103	Joint MOTION to Extend Time <i>for Trial Date</i> by Pharmaceutical Care Management Association (London, Andrew) (Entered: 02/17/2017)
02/24/2017	104	Joint MOTION for Extension of Time to File <i>Pre-Trial Disclosure</i>

DATE	#	PROCEEDINGS
		<i>Sheet</i> by Pharmaceutical Care Management Association (London, Andrew) (Entered: 02/24/2017)
02/24/2017	105	PRETRIAL DISCLOSURE SHEET by Pharmaceutical Care Management Association. (London, Andrew) (Entered: 02/24/2017)
02/24/2017	106	PRETRIAL DISCLOSURE SHEET by Leslie Rutledge. (Johnson, Shawn) (Entered: 02/24/2017)
03/01/2017	107	ORDER granting 75 PCMA's motion for summary judgment on PCMA's ERISA claim because act 900 is invalid as applied to PBMs in their administration and management of ERISA plans; granting 77 the government's motion for summary judgment on all other claims; and denying as moot 103 104 the joint motion to extend time, and dismissing this case, with prejudice. Signed by Chief Judge Brian S. Miller on 3/1/2017. (kdr) (Entered: 03/01/2017)
03/01/2017	108	JUDGMENT : Pursuant to the order entered on this day, this case is dismissed with prejudice. Signed by Chief Judge Brian S. Miller on 3/1/2017. (kdr) (Entered: 03/01/2017)
03/20/2017	109	NOTICE OF APPEAL as to 107 Order on Motion for Summary Judgment,,,, Order on Motion to Extend Time,, Order on Motion for Extension

DATE	#	PROCEEDINGS
		of Time to File, by Pharmaceutical Care Management Association. (London, Andrew) (Entered: 03/20/2017)
03/20/2017	110	NOTIFICATION OF APPEAL and NOA SUPPLEMENT as to 109 Notice of Appeal filed by Pharmaceutical Care Management Association re: 107 Order and 108 Judgment. NOTIFICATION TO COUNSEL: REQUEST FOR TRANSCRIPTS SHOULD BE FILED WITH THE DISTRICT COURT CLERK. (mcz) (Entered: 03/20/2017)
03/22/2017	111	NOTICE OF CROSS APPEAL as to 108 Judgment, 107 Order on Motion for Summary Judgment,,,, Order on Motion to Extend Time,, Order on Motion for Extension of Time to File, by Leslie Rutledge. (Johnson, Shawn) (Entered: 03/22/2017)
03/22/2017	112	USCA Docketing Letter and Briefing Schedule as to 109 Notice of Appeal filed by Pharmaceutical Care Management Association. USCA Case Number 17-1609 Transcript due by 5/1/2017. (mcz) (Entered: 03/22/2017)
03/22/2017	113	NOTIFICATION OF APPEAL and NOA SUPPLEMENT as to 111 Notice of Cross Appeal filed by Leslie Rutledge re: 107 Order and 108 Judgment. NOTIFICATION TO

DATE	#	PROCEEDINGS
		COUNSEL: REQUEST FOR TRANSCRIPTS SHOULD BE FILED WITH THE DISTRICT COURT CLERK. (mcz) (Entered: 03/22/2017)
03/24/2017	114	USCA Docketing Letter and Briefing Schedule as to 111 Notice of Cross Appeal filed by Leslie Rutledge. USCA Case Number 17-1629. Transcript due by 5/3/2017, if necessary. (mcz) (Entered: 03/24/2017)
03/28/2017	115	USCA Appeal Fees received. \$505 receipt #LIT061133 re 111 <i>Notice of Cross Appeal</i> filed by Leslie Rutledge. (sew) (Entered: 03/28/2017)
04/10/2017	116	ORDER of USCA as to 109 Notice of Appeal filed by Pharmaceutical Care Management Association: The appellant has failed to pay to the Clerk of the United States District Court the requisite docketing fees. Appellant is directed to show cause, within 14 days of the date of this order, why this appeal should not be dismissed for failure to prosecute. (mcz) (Entered: 04/10/2017)
04/11/2017	117	USCA Appeal Fees received \$505.00 receipt number LIT061385 re 109 Notice of Appeal filed by Pharmaceutical Care Management Association. (alm) (Entered: 04/11/2017)
04/12/2017	118	ORDER of USCA as to 109 Notice of Appeal filed by Pharmaceutical Care

DATE	#	PROCEEDINGS
		Management Association: We have been notified by the District Court that the docket fee has been paid. The show cause order is hereby set aside. (mcz) (Entered: 04/12/2017)
05/01/2017	119	Transmitted Record on Appeal to US Court of Appeals re 109 Notice of Appeal filed by Pharmaceutical Care Management Association and 111 Notice of Cross Appeal filed by Leslie Rutledge: Transcript of 11/4/2015 Hearing (Docket entry 44), and Transcript of 11/4/2016 Hearing (Docket entry 98). (mcz) (Entered: 05/01/2017)
06/08/2018	120	OPINION of USCA as to 109 Notice of Appeal filed by Pharmaceutical Care Management Association and 111 Notice of Cross Appeal filed by Leslie Rutledge. (mcz) (Entered: 06/08/2018)
06/08/2018	121	USCA JUDGMENT as to 109 Notice of Appeal filed by Pharmaceutical Care Management Association, and 111 Notice of Cross Appeal, filed by Leslie Rutledge: The judgment of the district court in this cause is affirmed in part, reversed in part, and remanded to the district court for proceedings consistent with the opinion of this court. (mez) (Entered: 06/08/2018)

DATE	#	PROCEEDINGS
07/10/2018	122	JUDGMENT: pursuant to 120 USCA Opinion, judgment is entered for plaintiff Pharmaceutical Care Management Association, and this case is dismissed with prejudice. Signed by Chief Judge Brian S. Miller on 7/10/2018. (mcz) (Entered: 07/10/2018)
07/10/2018	123	MANDATE of USCA in accordance with the opinion and judgment of 06/08/2018, as to 109 Notice of Appeal and 111 Notice of Cross Appeal. (mcz) (Entered: 07/10/2018)
10/29/2018	124	Letter from Clerk, USCA: Letter from Clerk, USCA: The Petition for Writ of Certiorari has been filed in USCA Case Number 17-1609. (cmn) (Entered: 10/29/2018)
01/16/2020	125	Letter from Clerk, USCA: The Petition for Writ of Certiorari has been granted by the United States Supreme Court in USCA Case Number 17-1609. (ajt) (Entered: 10/16/2020)

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Court of Appeals Docket #: 17-1609

PHARMACEUTICAL CARE MANAGEMENT

v.

LESLIE RUTLIDGE

DOCKET ENTRIES

DATE	PROCEEDINGS
03/22/2017	Civil case docketed. [4514791] [17-1609] (CMH) [Entered: 03/22/2017 09:16 AM]
03/22/2017	Originating court document filed consisting of notice of appeal, docket entries, Order and Judgment both dated 3/1/2017. [4514797] [17-1609] (CMH) [Entered: 03/22/2017 09:21 AM]
5/22/2000	<p>BRIEFING SCHEDULE SET AS FOLLOWS:</p> <p>Transcript due on or before 05/01/2017. Appendix due 05/11/2017. BRIEF APPELLANT, Pharmaceutical Care Management Association due 05/11/2017</p> <p>Appellee brief is due 30 days from the date the court issues the Notice of Docket Activity filing the brief of appellant.</p> <p>Appellant reply brief is due 14 days from the date the court issues the Notice of</p>

DATE	PROCEEDINGS
	Docket Activity filing the appellee brief. [4514801] [17-1609] (CMH) [Entered: 03/22/2017 09:23 AM]
03/24/2017	CROSS APPEAL [4515922] BRIEFING SCHEDULE SET AS FOLLOWS: Transcript due on or before 05/03/2017. BRIEF APPELLANT, Pharmaceutical Care Management Association due 05/15/2017. Appendix due 05/15/2017. Appellee/cross Appellant brief due 30 days from the date the court issues the Notice of Docket Activity filing the appellant's brief. [4515922] [17-1609, 17-1629] (CMH) [Entered: 03/24/2017 10:58 AM]
03/28/2017	CORPORATE disclosure statement filed by Appellant Pharmaceutical Care Management Association in 17-1609, Appellee Pharmaceutical Care Management Association in 17-1629. - FOR CAL [4517452] [17-1609, 17-1629] (AML) [Entered: 03/28/2017 09:10 PM]
03/28/2017	APPEARANCE filed by Dean Richlin for Appellant Pharmaceutical Care Management Association w/service 03/28/2017 [4517453] [17-1609] (AML) [Entered: 03/28/2017 09:16 PM]
03/28/2017	APPEARANCE filed by Kristyn DeFilipp for Appellant Pharmaceutical Care Management Association w/service 03/28/2017 [4517454] [17-1609] (AML) [Entered: 03/28/2017 09:18 PM]

DATE	PROCEEDINGS
03/28/2017	APPEARANCE filed by Andrew London for Appellant Pharmaceutical Care Management Association w/service 03/28/2017 [4517455] [17-1609] (AML) [Entered: 03/28/2017 09:20 PM]
03/28/2017	APPEARANCE filed by Lyn Pruitt for Appellant Pharmaceutical Care Management Association w/service 03/28/2017 [4517456] [17-1609] (AML) [Entered: 03/28/2017 09:22 PM]
04/06/2017	APPEARANCE filed by Shawn J. Johnson for Appellee Leslie Rutledge w/service 04/06/2017 [4521288] [17-1609] (SJJ) [Entered: 04/06/2017 04:19 PM]
04/07/2017	Certificate of transcript filed by Appellant Pharmaceutical Care Management Association in 17-1609, Appellee Pharmaceutical Care Management Association in 17-1629. No Transcript[4521539] [17-1609, 171629] (AML) [Entered: 04/07/2017 01:05 PM]
04/07/2017	METHOD of appendix preparation filed by Appellant Pharmaceutical Care Management Association in 17-1609, Appellee Pharmaceutical Care Management Association in 17-1629 - Separate Appendix - w/service 04/07/2017 [4521541] [17-1609, 17-1629] (AML) [Entered: 04/07/2017 01:07 PM]
04/07/2017	Certificate of transcript filed by Appellant Leslie Rutledge in 17-1629. No Transcript [4521738] [17-1629, 17-1609] (SJJ) [Entered: 04/07/2017 04:18 PM]

DATE	PROCEEDINGS
04/10/2017	CLERK ORDER: APPELLANT has failed to pay to the Clerk of the District Court the requisite docketing fees. APPELLANT is directed to show cause within 14 days why this appeal should not be dismissed for failure to prosecute. Response of Pharmaceutical Care Management Association due 04/24/2017 [4521835] [17-1609] (CMH) [Entered: 04/10/2017 08:59 AM]
04/11/2017	Originating court document filed consisting of district court document - paid docketing fee receipt filed by Pharmaceutical Care Management. [4523449] [17-1609] (CMH) [Entered: 04/12/2017 11:51 AM]
04/12/2017	CLERK ORDER: Appellant has paid the \$505 appellate filing and docketing fee to the District Court; therefore the show cause order of April 10, 2017 is hereby dissolved. [4523461] [17-1609] (CMH) [Entered: 04/12/2017 11:58 AM]
05/09/2017	RECORD FILED - HEARING TRANSCRIPT, 1 volumes, Location STL, Comments: Hearing on Motion for Preliminary Injunction [Copy do not return to the District Court at end of case], Source Location: USDC / EALR, Dt. of Proceeding/Hearing: 11/04/2015, No. of Pgs.: 267, Court Reporter: Ammons, Judith A. [4534354] [17-1609, 17-1629] (STL) [Entered: 05/09/2017 01:17 PM]

DATE	PROCEEDINGS
05/09/2017	RECORD FILED - HEARING TRANSCRIPT, 1 volumes, Location STL, Comments: Hearing on Motions for Summary Judgment [Copy do not return to the District Court at end of case], Source Location: USDC / EALR, Dt. of Proceeding/Hearing: 11/04/2016, No. of Pgs.: 83, Court Reporter: Ammons, Judith A. [4534355] [17-1609, 17-1629] (STL) [Entered: 05/09/2017 01:19 PM]
05/15/2017	APPELLANT brief of Pharmaceutical Care Management Association in 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4536384] [17-1609, 17-1629] (AML) [Entered: 05/15/2017 06:04 PM]
05/15/2017	Addendum of APPELLANT submitted for review by Pharmaceutical Care Management Association in 17-1609 [4536385] [17-1609, 17-1629] (AML) [Entered: 05/15/2017 06:14 PM]
05/16/2017	ADDENDUM of APPELLANT FILED by Appellant Pharmaceutical Care Management Association in 17-1609 , w/service 05/15/2017 [4536579] [17-1609, 17-1629] (YML) [Entered: 05/16/2017 11:01 AM]

DATE	PROCEEDINGS
05/16/2017	Brief deficiency notice sent to counsel, Attorney Mr. Andrew M. London for Appellant Pharmaceutical Care Management Association in 17-1609. [4536587] [17-1609, 17-1629] (YML) [Entered: 05/16/2017 11:10 AM]
05/16/2017	APPELLANT brief of Pharmaceutical Care Management Association in 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4536923] [17-1609, 17-1629] (AML) [Entered: 05/16/2017 04:30 PM]
05/16/2017	<p>BRIEF FILED - APPELLANT BRIEF filed by Pharmaceutical Care Management Association in 17-1609. w/service 05/16/2017 , Length: 10,321 words</p> <p>10 COPIES OF PAPER BRIEFS FROM Pharmaceutical Care Management Association due 05/22/2017 WITH certificate of service for paper briefs.</p> <p>Second brief of aplee/cr. aplnt due on 06/15/2017. [4536937] [17-1609, 17-1629] (YML) [Entered: 05/16/2017 04:48 PM]</p>
05/18/2017	Paper copies Appellant/Petitioner Brief, [4536937-2] filed by Pharmaceutical Care Management Association in 17-1609 10

DATE	PROCEEDINGS
	paper copies received. w/Addendum attached [4537969] [17-1609, 17-1629] (YML) [Entered: 05/18/2017 04:34 PM]
05/18/2017	MOTION to seal entire appendix, filed by Appellant/Cross-Appellee Pharmaceutical Care Management Association in 17-1609, 17-1629 w/service 05/18/2017. [4537991] [17-1609, 17-1629]--[Edited 06/20/2017 by YML]***COC UPDATED* (YML) [Entered: 05/18/2017 05:07 PM]
05/18/2017	CLERK ORDER:Granting <u>[4537991-2]</u> motion to seal filed by Appellant/Cross-Appellee Pharmaceutical Care Management Association. The Court is hereby sealing the following: Appellant/Cross-Appellee's Appendix [4537993] [17-1609, 17-1629] (YML) [Entered: 05/18/2017 05:10 PM]
05/18/2017	RECORD FILED - SEALED APPENDIX, 1 volumes, Location STI, Comments: 3 Copies [4537995] [17-1609, 17-1629] (YML) [Entered: 05/18/2017 05:15 PM]
06/15/2017	APPELLEE brief of Leslie Rutledge in 17-1609, 17-1629 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4547616] [17-1609, 17-1629] (SJJ) [Entered: 06/15/2017 11:31 AM]

DATE	PROCEEDINGS
06/15/2017	Addendum of APPELLEE submitted for review by Leslie Rutledge in 17-1609, 17-1629 [4547620] [171609, 17-1629] (SJJ) [Entered: 06/15/2017 11:33 AM]
06/15/2017	ADDENDUM of APPELLEE/CROSS-APPELLANT FILED by Appellee/Cross-Appellant Leslie Rutledge in 17-1609,17-1629 , w/service 06/15/2017 [4547701] [17-1609, 17-1629] (YML) [Entered: 06/15/2017 01:30 PM]
06/15/2017	BRIEF FILED - BRIEF APPELLEE/CROSS APPELLANT filed by Leslie Rutledge in 17-1609, 17-1629. w/service 06/15/2017 , Length: 14,685 words 10 COPIES OF PAPER BRIEFS FROM Leslie Rutledge due 06120/2017 WITH certificate of service for paper briefs. Third brief of Pharmaceutical Care Management Association brief due on 07/17/2017. [4547702] [17-1609, 17-1629] (YML) [Entered: 06/15/2017 01:34 PM]
06/20/2017	MOTION to seal portion of appendix, filed by Appellee Leslie Rutledge in 17-1609, Appellant Leslie Rutledge in 17-1629 w/service 06/19/2017. [4548922] [17-1609, 17-1629]--[Edited 06/20/2017 by YML]***COC added*** (YML) [Entered: 06/20/2017 11:13 AM]

DATE	PROCEEDINGS
06/20/2017	CLERK ORDER:Granting [4548922-2] motion to seal filed by Appellee/Cross-Appellant Leslie Rutledge. The Court is hereby sealing the following: Appellee/Cross-Appellant's Appendix [4549024] [17-1609, 17-1629] (YML) [Entered: 06/20/2017 01:27 PM]
06/20/2017	RECORD FILED - SEALED APPENDIX, 2 volumes, Location STL, Comments: 3 Copies (Appellee/Cross-Appellant's) [4549063] [17-1609, 17-1629] (YML) [Entered: 06/20/2017 02:13 PM]
06/20/2017	Paper copies Second Brief, [4547702-2] filed by Leslie Rutledge in 17-1609, 17-1629 10 paper copies received. w/Addendum attached [4549066] [17-1609, 17-1629] (YML) [Entered: 06/20/2017 02:14 PM]
06/21/2017	AMICUS brief of Arkansas Pharmacists Association and National Community Pharmacists Association submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. [4549348] [17-1609, 17-1629] (RTS) [Entered: 06/21/2017 08:47 AM]
06/21/2017	BRIEF FILED - AMICUS BRIEF filed by Arkansas Pharmacists Association and National Community Pharmacists Association in 17-1609, 17-1629 w/service 06/21/2017 , Length: 7,646 words 10 COPIES OF PAPER BRIEFS FROM

DATE	PROCEEDINGS
	Arkansas Pharmacists Association and National Community Pharmacists Association due 06/26/2017 WITH certificate of service for paper briefs [4549500] [17-1609, 17-1629] (YML) [Entered: 06/21/2017 11:02 AM]
06/21/2017	APPEARANCE filed by Robert T. Smith for Amici on Behalf of Appellee(s) Arkansas Pharmacists Association and National Community Pharmacists Association w/service 06/21/2017 [4549575] [17-1609] (RTS) [Entered: 06/21/2017 12:05 PM]
06/21/2017	APPEARANCE filed by Howard R. Rubin for Amici on Behalf of Appellee(s) Arkansas Pharmacists Association and National Community Pharmacists Association w/service 06/21/2017 [4549579] [17-1609] (RTS) [Entered: 06/21/2017 12:06 PM]
06/21/2017	APPEARANCE filed by Daniel E. Lipton for Amici on Behalf of Appellee(s) Arkansas Pharmacists Association and National Community Pharmacists Association w/service 06/21/2017 [4549584] [17-1609] (RTS) [Entered: 06/21/2017 12:08 PM]
06/22/2017	Paper copies Amicus Brief, [4549500-2] filed by Arkansas Pharmacists Association and National Community Pharmacists Association in 17-1609, 17-1629 10 paper copies received. [4550136] [17-1609, 17-1629] (YML) [Entered: 06/22/2017 02:55 PM]

DATE	PROCEEDINGS
07/17/2017	REPLY brief of Pharmaceutical Care Management Association in 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login-to CM/ECF and then open the document link in your Notice of Docket Activity. [4558040] [17-1609, 17-1629] (AML) [Entered: 07/17/2017 05:49 PM]
07/18/2017	<p>BRIEF FILED - REPLY APPELLANT/CROSS APPELLEE filed by Pharmaceutical Care Management Association in 17-1609, 17-1629, w/service 07/17/2017 , Length: 12,766 words</p> <p>10 COPIES OF PAPER BRIEFS FROM Pharmaceutical Care Management Association due 07/24/2017 WITH certificate of service for paper briefs</p> <p>. appellee Leslie Rutledge reply brief due on 08/01/2017 [4558420] [17-1609, 17-1629] (YML) [Entered: 07/18/2017 02:45 PM]</p>
07/20/2017	<p>Paper copies Third Brief, [4558420-2] filed by Pharmaceutical Care Management Association in 17-1609, 17-1629 10 paper copies received.</p> <p>[4559490] [17-1609, 17-1629] (YML) [Entered: 07/20/2017 03:48 PM]</p>
07/20/2017	MOTION for extension of time to file brief until 08/15/2017, filed by Attorney Mr. Shawn J. Johnson for Appellant Leslie

DATE	PROCEEDINGS
	Rutledge in 17-1629 w/service 07/20/2017, [4559573] [17-1629, 17-1609] (SJJ) [Entered: 07/20/2017 05:27 PM]
07/21/2017	CLERK ORDER:Granting [4559573-2] motion for extension of time to file brief filed by Mr. Shawn J. Johnson. brief of Leslie Rutledge due on 08/15/2017 [4559771] [17-1609, 17-1629] (YML) [Entered: 07/21/2017 12:05 PM]
07/25/2017	Please note that this case has been screened for oral argument. The exact date of your oral argument has not been determined at this time. You will be receiving a calendar approximately 4 weeks before the scheduled argument date. Please review the current and future argument dates immediately to determine if you have any conflicts. <u>Click Here to View Published Argument Calendars and Future Court Session Dates and Locations</u> If you do have conflicts with any of the argument dates, please inform this court by sending a letter using the ECF docketing event 'Correspondence to Court', 'Letter filed' 'regarding availability for oral argument'. Your compliance with this policy will minimize the need for motions to continue or reschedule oral argument. The court also encourages you to notify the clerk if conflicts with these dates develop

DATE	PROCEEDINGS
	in the future. The clerk's office takes conflict dates into consideration in scheduling oral arguments but cannot guarantee that every request will be honored. [4560556] [17-1609, 17-1629] (BWB) [Entered: 07/25/2017 08:12 AM]
07/26/2017	LETTER from Appellant Pharmaceutical Care Management Association in 17-1609 regarding availability for oral argument. w/service 07/26/2017 [4561421] [17-1609, 17-1629] (AML) [Entered: 07/26/2017 01:28 PM]
07/31/2017	LETTER from Appellee Leslie Rutledge in 17-1609, Appellant Leslie Rutledge in 17-1629 regarding availability for oral argument. w/service 07/31/2017 [4563192] [17-1609, 17-1629] (SJJ) [Entered: 07/31/2017 04:48 PM]
08/15/2017	REPLY brief of Leslie Rutledge in 17-1629, 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4568503] [17-1629, 17-1609] (SJJ) [Entered: 08/15/2017 11:14 AM]
08/15/2017	BRIEF FILED - REPLY APPELLEE/CR APPELLANT BRIEF filed by Leslie Rutledge in 17-1609, 17-1629 w/service 08/15/2017 , Length: 4,734 words

DATE	PROCEEDINGS
	<p>10 COPIES OF PAPER BRIEFS FROM Leslie Rutledge due 08/21/2017 WITH certificate of service for paper briefs</p> <p>[4568825] [17-1609, 17-1629] (YML) [Entered: 08/15/2017 04:53 PM]</p>
08/18/2017	<p>28(j) citation filed by Appellant/Cross-Appellees Pharmaceutical Care Management Association in 17-1609, 17-1629 w/service 08/18/2017 - FOR CAL [4570016] [17-1609, 17-1629]--[Edited 08/25/2017 by YML] (AML) [Entered: 08/18/2017 08:18 AM]</p>
08/18/2017	<p>Paper copies Fourth brief, <u>[4568825-2]</u> filed by Leslie Rutledge in 17-1609, 17-1629 10 paper copies received.</p> <p>[4570506] [17-1609, 17-1629] (YML) [Entered: 08/18/2017 04:26 PM]</p>
08/25/2017	<p>Response of Appellee/Cross-Appellant Leslie Rutledge in 17-1609, 17-1629 to 28(j) citation, filed by Pharmaceutical Care Management Association in 17-1609, 17-1629 <u>[4570016-2]</u>, <u>[4570016-3]</u>. w/service 08/25/2017 - FOR CAL [4572775] [17-1629, 17-1609]--[Edited 08/25/2017 by YML] (SJJ) [Entered: 08/25/2017 03:24 PM]</p>
12/07/2017	<p>SET FOR ARGUMENT - CASE PLACED ON CALENDAR - <i>for Argument in St. Louis on Tuesday, January 09, 2018.</i> To be heard before Judges James B. Loken, C. Arlen Beam and Jane Kelly in Division III. The courtroom deputy</p>

DATE	PROCEEDINGS
	<p>will be Yvette Lisenby. All attorneys presenting oral argument must complete a Response Form. Click Here to Complete the Oral Argument Response Form. Click Here for the Complete Calendar</p> <p>PLEASE REVIEW THE ENTIRE CALENDAR CAREFULLY, PARTICULARLY THE COUNSEL NOTICE PAGE <i>if you are appointed counsel under the Criminal Justice Act and require airline transportation to oral argument, the court will issue a travel authorization the next business day.</i> [4608444] [17-1609, 17-1629] (TAB) [Entered: 12/07/2017 03:13 PM]</p>
12/07/2017	<p>ARGUMENT RESPONSE/APPEARANCE FORM filed by Mr. Shawn J. Johnson for Leslie Rutledge in 17-1609, 17-1629 for argument in January, at the U.S. Courthouse in St. Louis, Missouri. [4608513] [17-1609, 17-1629] (SJJ) [Entered: 12/07/2017 04:02 PM]</p>
12/07/2017	<p>ARGUMENT RESPONSE/APPEARANCE FORM filed by Mr. Dean Richlin for Pharmaceutical Care Management Association in 17-1609, 17-1629 for argument in January, at the U.S. Courthouse in St. Louis, Missouri. [4608521] [17-1609, 17-1629] (AML) [Entered: 12/07/2017 04:13 PM]</p>
01/09/2018	<p>ARGUED & SUBMITTED in St. Louis to Judges James B. Loken, C. Arlen Beam,</p>

DATE	PROCEEDINGS
	Jane Kelly on 01/09/2018 Mr. Dean Richlin for Appellant/Cross-Appellee Pharmaceutical Care Management Association and Mr. Shawn J. Johnson for Appellee/Cross-Appellant Leslie Rutledge in 17-1609, 17-1629. No Rebuttal. RECORDED. Click Here To Listen to Oral Argument [4618227] [17-1609, 17-1629] (YML) [Entered: 01/09/2018 12:48 PM]
06/08/2018	OPINION FILED - THE COURT: James B. Loken, C. Arlen Beam and Jane Kelly AUTHORING JUDGE:C. Arlen Beam (PUBLISHED) [4670689] [17-1609, 17-1629] (YML) [Entered: 06/08/2018 09:43 AM]
06/08/2018	JUDGMENT FILED - The judgment of the originating court is AFFIRMED in part, REVERSED in part and REMANDED in accordance with the opinion. JAMES B. LOKEN, C. ARLEN BEAM and JANE KELLY Hrg Jan 2018 [4670719] [17-1609, 17-1629] (YML) [Entered: 06/08/2018 10:01 AM]
06/22/2018	MOTION to Clarify the Opinion, filed by Attorney Mr. Andrew M. London for Appellant Pharmaceutical Care Management Association in 17-1609 w/service 06/22/2018. [4675483] [17-1609, 17-1629] (AML) [Entered: 06/22/2018 03:42 PM]
06/26/2018	JUDGE ORDER: [4675483-2] Denying motion to clarify the opinion filed by Mr. Andrew M. London. Hrg Jan 2018

DATE	PROCEEDINGS
	[4676235] [17-1609, 17-1629] (JMM) [Entered: 06/26/2018 11:08 AM]
07/10/2018	MANDATE ISSUED. [4680591] [17-1629, 17-1609] (YML) [Entered: 07/10/2018 11:34 AM]
08/03/2018	Supreme Court Letter extending time to file cert petition until 10/08/2018. [4690603] [17-1609] (YML) [Entered: 08/06/2018 03:52 PM]
10/10/2018	Supreme Court Letter extending time to file cert petition until 10/22/2018. [4713843] [17-1609, 17-1629] (YML) [Entered: 10/10/2018 11:15 AM]
10/24/2018	U.S. Supreme Court Notice of cert filed in the Supreme Court on 10/24/2018, case No. 18-540 [4720327] [17-1609]–[Edited to remove filing from associated case 01/16/2020 by AMT] (YML) [Entered: 10/29/2018 03:39 PM]
01/10/2020	SUPREME COURT order filed granting cert petition. Order filed on 01/10/2020 in case No.18-540. [4872080] [17-1609] (AMT) [Entered: 01/16/2020 02:06 PM]

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Court of Appeals Docket #: 17-1629

PHARMACEUTICAL CARE MANAGEMENT

v.

LESLIE RUTLEDGE

DOCKET ENTRIES

DATE	PROCEEDINGS
03/24/2017	Civil case docketed. [4515881] [17-1629] (CMH) [Entered: 03/24/2017 10:11 AM]
03/24/2017	Originating court document filed consisting of notice of appeal, docket entries, Order and Judgment both dated 3/1/2017. [4515913] [17-1629] (CMH) [Entered: 03/24/2017 10:48 AM]
03/24/2017	CROSS APPEAL [4515922] BRIEFING SCHEDULE SET AS FOLLOWS: Transcript due on or before 05/03/2017. BRIEF APPELLANT, Pharmaceutical Care Management Association due 05/15/2017. Appendix due 05/15/2017. Appellee/cross Appellant brief due 30 days from the date the court issues the Notice of Docket Activity filing the appellant's brief. [4515922] [17-1609, 17-1629] (CMH) [Entered: 03/24/2017 10:58 AM]

DATE	PROCEEDINGS
03/28/2017	CORPORATE disclosure statement filed by Appellant Pharmaceutical Care Management Association in 17-1609, Appellee Pharmaceutical Care Management Association in 17-1629. - FOR CAL [4517452] [17-1609, 17-1629] (AML) [Entered: 03/28/2017 09:10 PM]
03/28/2017	Originating court document filed consisting of district court document of receipt for appellate docketing fee paid by Appellant Leslie Rutledge. [4517499] [17-1629] (CMH) [Entered: 03/29/2017 08:19 AM]
03/28/2017	UPDATED fee status - [Case Number 17-1629: paid - cs] [4517502] [17-1629] (CMH) [Entered: 03/29/2017 08:21 AM]
03/29/2017	APPEARANCE filed by Shawn J. Johnson for Appellant Leslie Rutledge w/service 03/29/2017 [4518020] [17-1629] (SJJ) [Entered: 03/29/2017 05:46 PM]
03/30/2017	APPEARANCE filed by Dean Richlin for Appellee Pharmaceutical Care Management Association w/service 03/30/2017 [4518390] [17-1629] (AML) [Entered: 03/30/2017 02:26 PM]
03/30/2017	APPEARANCE filed by Kristyn DeFilipp for Appellee Pharmaceutical Care Management Association w/service 03/30/2017 [4518396] [17-1629] (AML) [Entered: 03/30/2017 02:28 PM]
03/30/2017	APPEARANCE filed by Andrew London for Appellee Pharmaceutical Care Management Association w/service 03/30/2017

DATE	PROCEEDINGS
	[4518410] [17-1629] (AML) [Entered: 03/30/2017 02:34 PM]
03/30/2017	APPEARANCE filed by Lyn Pruitt for Appellee Pharmaceutical Care Management Association w/service 03/30/2017 [4518417] [17-1629] (AML) [Entered: 03/30/2017 02:35 PM]
04/07/2017	Certificate of transcript filed by Appellant Pharmaceutical Care Management Association in 17-1609, Appellee Pharmaceutical Care Management Association in 17-1629. No Transcript[4521539] [17-1609, 17-1629] (AML) [Entered: 04/07/2017 01:05 PM]
04/07/2017	METHOD of appendix preparation filed by Appellant Pharmaceutical Care Management Association in 17-1609, Appellee Pharmaceutical Care Management Association in 17-1629 - Separate Appendix - w/service 04/07/2017 [4521541] [17-1609, 17-1629] (AML) [Entered: 04/07/2017 01:07 PM]
04/07/2017	METHOD of appendix preparation filed by Appellant Leslie Rutledge in 17-1629 - Separate Appendix w/service 04/07/2017 [4521734] [17-1629, 17-1609] (SJJ) [Entered: 04/07/2017 04:16 PM]
04/07/2017	Certificate of transcript filed by Appellant Leslie Rutledge in 17-1629. No Transcript[4521738] [17-1629, 171609] (SJJ) [Entered: 04/07/2017 04:18 PM]

DATE	PROCEEDINGS
05/09/2017	RECORD FILED - HEARING TRANSCRIPT, 1 volumes, Location STL, Comments: Hearing on Motion for Preliminary Injunction [Copy do not return to the District Court at end of case], Source Location: USDC / EALR, Dt. of Proceeding/Hearing: 11/04/2015, No. of Pgs.: 267, Court Reporter: Ammons, Judith A. [4534354] [17-1609, 17-1629] (STL) [Entered: 05/09/2017 01:17 PM]
05/09/2017	RECORD FILED - HEARING TRANSCRIPT, 1 volumes, Location STL, Comments: Hearing on Motions for Summary Judgment [Copy do not return to the District Court at end of case], Source Location: USDC / EALR, Dt, of Proceeding/Hearing: 11/04/2016, No. of Pgs.: 83, Court Reporter: Ammons, Judith A. [4534355] [17-1609, 17-1629] (STL) [Entered: 05/09/2017 01:19 PM]
05/15/2017	APPELLANT brief of Pharmaceutical Care Management Association in 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4536384] [17-1609, 17-1629] (AML) [Entered: 05/15/2017 06:04 PM]

DATE	PROCEEDINGS
05/15/2017	Addendum of APPELLANT submitted for review by Pharmaceutical Care Management Association in 17-1609 [4536385] [17-1609, 17-1629] (AML) [Entered: 05/15/2017 06:14 PM]
05/16/2017	ADDENDUM of APPELLANT FILED by Appellant Pharmaceutical Care Management Association in 17-1609 , w/service 05/15/2017 [4536579] [17-1609, 17-1629] (YML) [Entered: 05/16/2017 11:01 AM]
05/16/2017	Brief deficiency notice sent to counsel, Attorney Mr. Andrew M. London for Appellant Pharmaceutical Care Management Association in 17-1609. [4536587] [17-1609, 17-1629] (YML) [Entered: 05/16/2017 11:10 AM]
05/16/2017	APPELLANT brief of Pharmaceutical Care Management Association in 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4536923] [17-1609, 17-1629] (AML) [Entered: 05/16/2017 04:30 PM]
05/16/2017	BRIEF FILED - APPELLANT BRIEF filed by Pharmaceutical Care Management Association in 17-1609. w/service 05/16/2017 , Length: 10,321 words

DATE	PROCEEDINGS
	<p>10 COPIES OF PAPER BRIEFS FROM Pharmaceutical Care Management Association due 05/22/2017 WITH certificate of service for paper briefs</p>
	<p>. Second brief of aplee/cr. apint due on 06/15/2017. [4536937] [17-1609, 17-1629] (YML) [Entered: 05/16/2017 04:48 PM]</p>
05/18/2017	<p>Paper copies Appellant/Petitioner Brief, [4536937-2] filed by Pharmaceutical Care Management Association in 17-1609 10 paper copies received. w/Addendum attached [4537969] [17-1609, 17-1629] (YML) [Entered: 05/18/2017 04:34 PM]</p>
05/18/2017	<p>MOTION to seal entire appendix, filed by Appellant/Cross-Appellee Pharmaceutical Care Management Association in 17-1609, 17-1629 w/service 05/18/2017. [4537991] [17-1609, 17-1629]--[Edited 06/20/2017 by YML]***COC UPDATED* (YML) [Entered: 05/18/2017 05:07 PM]</p>
05/18/2017	<p>CLERK ORDER:Granting [4537991-2] motion to seal filed by Appellant/Cross-Appellee Pharmaceutical Care Management Association. The Court is hereby sealing the following: Appellant/Cross-Appellee's Appendix [4537993] [17-1609, 17-1629] (YML) [Entered: 05/18/2017 05:10 PM]</p>
05/18/2017	<p>RECORD FILED - SEALED APPENDIX, 1 volumes, Location STI, Comments: 3</p>

DATE	PROCEEDINGS
	Copies [4537995] [17-1609, 17-1629] (YML) [Entered: 05/18/2017 05:15 PM]
06/15/2017	APPELLEE brief of Leslie Rutledge in 17-1609, 17-1629 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4547616] [17-1609, 17-1629] (SJJ) [Entered: 06/15/2017 11:31 AM]
06/15/2017	Addendum of APPELLEE submitted for review by Leslie Rutledge in 17-1609, 17-1629 [4547620] [17-1609, 17-1629] (SJJ) [Entered: 06/15/2017 11:33 AM]
06/15/2017	ADDENDUM of APPELLEE/CROSS-APPELLANT FILED by Appellee/Cross-Appellant Leslie Rutledge in 17-1609,17-1629 , w/service 06/15/2017 [4547701] [17-1609, 17-1629] (YML) [Entered: 06/15/2017 01:30 PM]
06/15/2017	BRIEF FILED - BRIEF APPELLEE/CROSS APPELLANT filed by Leslie Rutledge in 17-1609, 17-1629. w/service 06/15/2017 , Length: 14,685 words 10 COPIES OF PAPER BRIEFS FROM Leslie Rutledge due 06/20/2017 WITH certificate of service for paper briefs
	. Third brief of Pharmaceutical Care Management Association brief due on

DATE	PROCEEDINGS
	07/17/2017. [4547702] [17-1609, 17-1629] (YML) [Entered: 06/15/2017 01:34 PM]
06/20/2017	MOTION to seal portion of appendix, filed by Appellee Leslie Rutledge in 17-1609, Appellant Leslie Rutledge in 17-1629 w/service 06/19/2017. [4548922] [17-1609, 17-1629]--[Edited 06/20/2017 by YML]***COC added*** (YML) [Entered: 06/20/2017 11:13 AM]
06/20/2017	CLERK ORDER:Granting <u>[4548922-2]</u> motion to seal filed by Appellee/Cross-Appellant Leslie Rutledge. The Court is hereby sealing the following: Appellee/Cross-Appellant's Appendix [4549024] [17-1609, 171629] (YML) [Entered: 06/20/2017 01:27 PM]
06/20/2017	RECORD FILED - SEALED APPENDIX, 2 volumes, Location STL, Comments: 3 Copies (Appellee/Cross-Appellant's) [4549063] [17-1609, 17-1629] (YML) [Entered: 06/20/2017 02:13 PM]
06/20/2017	Paper copies Second Brief, <u>[4547702-2]</u> filed by Leslie Rutledge in 17-1609, 17-1629 10 paper copies received. w/Addendum attached [4549066] [17-1609, 17-1629] (YML) [Entered: 06/20/2017 02:14 PM]
06/21/2017	AMICUS brief of Arkansas Pharmacists Association and National Community Pharmacists Association submitted for review. The time for filing the subsequent brief (if

DATE	PROCEEDINGS
	any) does not begin to run until the brief has been approved and filed . [4549348] [17-1609, 17-1629] (RTS) [Entered: 06/21/2017 08:47 AM]
06/21/2017	BRIEF FILED - AMICUS BRIEF filed by Arkansas Pharmacists Association and National Community Pharmacists Association in 17-1609, 17-1629 w/service 06/21/2017 , Length: 7,646 words 10 COPIES OF PAPER BRIEFS FROM Arkansas Pharmacists Association and National Community Pharmacists Association due 06/26/2017 WITH certificate of service for paper briefs [4549500] [17-1609, 17-1629] (YML) [Entered: 06/21/2017 11:02 AM]
06/22/2017	Paper copies Amicus Brief, [4549500-2] filed by Arkansas Pharmacists Association and National Community Pharmacists Association in 17-1609, 17-1629 10 paper copies received. [4550136] [17-1609, 17-1629] (YML) [Entered: 06/22/2017 02:55 PM]
07/17/2017	REPLY brief of Pharmaceutical Care Management Association in 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4558040] [17-1609, 17-1629] (AML) [Entered: 07/17/2017 05:49 PM]

DATE	PROCEEDINGS
07/18/2017	BRIEF FILED - REPLY APPELLANT/ CROSS APPELLEE filed by Pharmaceutical Care Management Association in 17-1609, 17-1629, w/service 07/17/2017 , Length: 12,766 words 10 COPIES OF PAPER BRIEFS FROM Pharmaceutical Care Management Association due 07/24/2017 WITH certificate of service for paper briefs . appellee Leslie Rutledge reply brief due on 08/01/2017 [4558420] [17-1609, 17-1629] (YML) [Entered: 07/18/2017 02:45 PM]
07/20/2017	MOTION for extension of time to file brief until 08/15/2017, filed by Attorney Mr. Shawn J. Johnson for Appellant Leslie Rutledge in 17-1629 w/service 07/20/2017. [4559573] [17-1629, 17-1609] (SJJ) [Entered: 07/20/2017 05:27 PM]
07/21/2017	CLERK ORDER:Granting [4559573-2] motion for extension of time to file brief filed by Mr. Shawn J. Johnson. brief of Leslie Rutledge due on 08/15/2017 [4559771] [17-1609, 17-1629] (YML) [Entered: 07/21/2017 12:05 PM]
07/25/2017	Please note that this case has been screened for oral argument. The exact date of your oral argument has not been determined at this time. You will be receiving a calendar approximately 4 weeks before the scheduled argument date. Please review the current and future

DATE	PROCEEDINGS
	<p>argument dates immediately to determine if you have any conflicts.</p> <p><u>Click Here to View Published Argument Calendars and Future Court Session Dates and Locations</u></p> <p>If you do have conflicts with any of the argument dates, please inform this court by sending a letter using the ECF docketing event 'Correspondence to Court', 'Letter filed' 'regarding availability for oral argument'. Your compliance with this policy will minimize the need for motions to continue or reschedule oral argument. The court also encourages you to notify the clerk if conflicts with these dates develop in the future. The clerk's office takes conflict dates into consideration in scheduling oral arguments but cannot guarantee that every request will be honored. [4560556] [17-1609, 17-1629] (BWB) [Entered: 07/25/2017 08:12 AM]</p>
07/26/2017	LETTER from Appellant Pharmaceutical Care Management Association in 17-1609 regarding availability for oral argument. w/service 07/26/2017 [4561421] [17-1609, 17-1629] (AML) [Entered: 07/26/2017 01:28 PM]
07/31/2017	LETTER from Appellee Leslie Rutledge in 17-1609, Appellant Leslie Rutledge in 17-1629 regarding availability for oral argument. w/service 07/31/2017 [4563192]

DATE	PROCEEDINGS
	[17-1609, 17-1629] (SJJ) [Entered: 07/31/2017 04:48 PM]
08/15/2017	REPLY brief of Leslie Rutledge in 17-1629, 17-1609 submitted for review. The time for filing the subsequent brief (if any) does not begin to run until the brief has been approved and filed. To open/view this brief, you must first login to CM/ECF and then open the document link in your Notice of Docket Activity. [4568503] [17-1629, 17-1609] (SJJ) [Entered: 08/16/2017 11:14 AM]
08/15/2017	BRIEF FILED - REPLY APPELLEE/CR APPELLANT BRIEF filed by Leslie Rutledge in 17-1609, 17-1629 w/service 08/15/2017 , Length: 4,734 words
	10 COPIES OF PAPER BRIEFS FROM Leslie Rutledge due 08/21/2017 WITH certificate of service for paper briefs
	[4568825] [17-1609, 17-1629] (YML) [Entered: 08/15/2017 04:53 PM]
08/18/2017	28(j) citation filed by Appellant/Cross-Appellees Pharmaceutical Care Management Association in 17-1609, 17-1629 w/service 08/18/2017 - FOR CAL [4570016] [17-1609, 17-1629]--[Edited 08/25/2017 by YML] (AML) [Entered: 08/18/2017 08:18 AM]
08/18/2017	Paper copies Fourth brief, [4568825-2] filed by Leslie Rutledge in 17-1609, 17-1629 10 paper copies received.

DATE	PROCEEDINGS
	[4570506] [17-1609, 17-1629] (YML) [Entered: 08/18/2017 04:26 PM]
08/25/2017	Response of Appellee/Cross-Appellant Leslie Rutledge in 17-1609, 17-1629 to 28(j) citation, filed by Pharmaceutical Care Management Association in 17-1609, 17-1629 [4570016-2] , [4570016-3] . w/service 08/25/2017 - FOR CAL [4572775] [17-1629, 17-1609]--[Edited 08/25/2017 by YML] (SJJ) [Entered: 08/25/2017 03:24 PM]
12/07/2017	<p>SET FOR ARGUMENT - CASE PLACED ON CALENDAR - <i>for Argument in St. Louis on Tuesday, January 09, 2018.</i> To be heard before Judges James B. Loken, C. Arlen Beam and Jane Kelly in Division III. The courtroom deputy will be Yvette Lisenby. All attorneys presenting oral argument must complete a Response Form. click Here to Complete the Oral Argument Response Form. Click Here for the Complete Calendar</p> <p>PLEASE REVIEW THE ENTIRE CALENDAR CAREFULLY, PARTICULARLY THE COUNSEL NOTICE PAGE. <i>If you are appointed counsel under the Criminal Justice Act and require airline transportation to oral argument, the court will issue a travel authorization the next business day.</i> [4608444] [17-1609, 17-1629] (TAB) [Entered: 12/07/2017 03:13 PM]</p>

DATE	PROCEEDINGS
12/07/2017	ARGUMENT RESPONSE/APPEARANCE FORM filed by Mr. Shawn J. Johnson for Leslie Rutledge in 17-1609, 17-1629 for argument in January, at the U.S. Courthouse in St. Louis, Missouri. [4608513] [17-1609, 17-1629] (SJJ) [Entered: 12/07/2017 04:02 PM]
12/07/2017	ARGUMENT RESPONSE/APPEARANCE FORM filed by Mr. Dean Richlin for Pharmaceutical Care Management Association in 17-1609, 17-1629 for argument in January, at the U.S. Courthouse in St. Louis, Missouri. [4608521] [17-1609, 17-1629] (AML) [Entered: 12/07/2017 04:13 PM]
01/09/2018	ARGUED & SUBMITTED in St. Louis to Judges James B. Loken, C. Arlen Beam, Jane Kelly on 01/09/2018 Mr. Dean Richlin for Appellant/Cross-Appellee Pharmaceutical Care Management Association and Mr. Shawn J. Johnson for Appellee/Cross-Appellant Leslie Rutledge in 17-1609, 17-1629. No Rebuttal. RECORDED. <u>Click Here To Listen to Oral Argument</u> [4618227] [17-1609, 17-1629] (YML) [Entered: 01/09/2018 12:48 PM]
06/08/2018	OPINION FILED - THE COURT: James B. Loken, C. Arlen Beam and Jane Kelly g AUTHORIZING JUDGE:C. Arlen Beam (PUBLISHED) [4670689] [17-1609, 17-1629] (YML) [Entered: 06/08/2018 09:43 AM]

DATE	PROCEEDINGS
06/08/2018	JUDGMENT FILED - The judgment of the originating court is AFFIRMED in part, REVERSED in part and REMANDED in accordance with the opinion. JAMES B. LOKEN, C. ARLEN BEAM and JANE KELLY Hrg Jan 2018 [4670719] [17-1609, 17-1629] (YML) [Entered: 06/08/2018 10:01 AM]
06/22/2018	MOTION to Clarify the Opinion, filed by Attorney Mr. Andrew M. London for Appellant Pharmaceutical Care Management Association in 17-1609 w/service 06/22/2018. [4675483] [17-1609, 17-1629] (AML) [Entered: 06/22/2018 03:42 PM]
06/26/2018	JUDGE ORDER: <u>[4675483-2]</u> Denying motion to clarify the opinion filed by Mr. Andrew M. London. Hrg Jan 2018 [4676235] [17-1609, 17-1629] (JMM) [Entered: 06/26/2018 11:08 AM]
07/10/2018	MANDATE ISSUED. [4680591] [17-1629, 17-1609] (YML) [Entered: 07/10/2018 11:34 AM]
10/10/2018	Supreme Court Letter extending time to file cert petition until 10/22/2018. [4713843] [17-1609, 17-1629] (YML) [Entered: 10/10/2018 11:15 AM]

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

[Filed Aug. 13, 2015]

Civil Action No. 4:15cv510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity
as Attorney General of Arkansas,
Defendants.

This case assigned to District Judge Miller
and to Magistrate Judge Deere

COMPLAINT FOR DECLARATORY,
INJUNCTIVE, AND OTHER RELIEF

Plaintiff Pharmaceutical Care Management Association (“PCMA”), on behalf of its members, for its complaint against Leslie Rutledge (“Rutledge”) in her official capacity as Attorney General of Arkansas, asserts as follows:

INTRODUCTION

1. On April 2, 2015, Arkansas Senate Bill 688 was signed into law as Act 900 of the Arkansas General Assembly’s 90th General Session. Act 900 amends the state’s existing Maximum Allowable Cost (“MAC”) law, Arkansas Code § 17-92-507, to impose additional requirements on the pharmacy benefit managers (“PBMs”) that develop, maintain and use maximum

allowable cost or “MAC” lists for generic drugs. Act 900 will go into effect on July 22, 2015, 91 days after the April 22, 2015 sine die adjournment of the 90th General Assembly.

2. Act 900 mandates that pharmacies be reimbursed for the generic pharmaceuticals they dispense at or above the cost invoiced by wholesalers or manufacturers, regardless of whether the pharmacies could have acquired the drugs for less, and regardless of whether the pharmacies receive rebates or discounts not reflected on the wholesaler’s or manufacturer’s invoice. In essence, Act 900 guarantees Arkansas pharmacies a profit on every MAC script filled. In so doing, the act will cause higher prices for prescription drugs and thereby cause significant and substantial harm to consumers, senior citizens, health plan payers including employee benefit plans, employers and insurers, and pharmacy benefit managers (“PBMs”).

3. In addition, as the PBMs do not know the acquisition cost of the pharmaceuticals dispensed by the different pharmacies in Arkansas, the statute sets a trigger point for PBM compliance using information to which PBMs have no access.

4. This lawsuit seeks a declaration that 1) Act 900 imposes an excessive burden on interstate commerce in violation of the Dormant Commerce Clause of the United States Constitution; 2) Act 900 substantially impairs existing contracts between PCMA’s members and their customers, health insurance carriers and employers, and between PCMA’s members and pharmacies, in violation of the Contract Clauses of the United States Constitution and the Constitution of the State of Arkansas; 3) Act 900 imposes obligations on PBMs but fails to provide fair notice of when their actions are likely to become unlawful and thereby

violates the Due Process Clauses of the United States Constitution and the Constitution of the State of Arkansas; 4) to the extent that Act 900 affects the prices paid for pharmaceuticals by consumers insured through their employers, the act “relate[s] to” employee benefit plans and is thereby pre-empted by the Employee Retirement Income Security Act (“ERISA”) of 1974, 29 U.S.C. §1001, et seq.; and 5) to the extent that Act 900 affects the prices paid for pharmaceuticals by consumers insured through a Medicare Part D Plan, and to the extent that Act 900 purports to permit the disruption of a PBM’s contracted pharmacy network for a Part D plan sponsor, the act is a state law “with respect to” a Part D Plan and is thereby pre-empted by the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”), Pub. L. No. 108-173 § 232, 117 Stat. 2066, 2208 (Dec. 8, 2003). The Court should enjoin the Defendant from enforcing Act 900.

JURISDICTION AND VENUE

5. This Court has subject matter, jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this case raises questions arising under both federal law and the Constitution of the United States. The Court also has jurisdiction over claims seeking relief under the Arkansas Constitution pursuant to 28 U.S.C. § 1367, because the state claims are so closely related to the federal claims as to form part of the same case or controversy.

6. This Court has personal jurisdiction over Defendant because Defendant resides within the Eastern District of Arkansas.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because most of the events giving rise to these claims occurred in this district and the Defendant resides within the State of Arkansas.

THE PARTIES

8. PCMA is the national trade association representing PBMs with a principal place of business in Washington, D.C. Its PBM member companies administer prescription drug benefit plans for more than 236 million Americans covered by ERISA and non-ERISA (including Medicare Part D) health plans. The ERISA-covered health plans include both insured and self-funded plans sponsored by employers and labor unions. The non-ERISA covered health plans include plans sponsored by state and local governments that contract directly for PBM services, as well as plans sold in the individual health insurance market. None of the PBMs which are members of PCMA are incorporated in the state of Arkansas or have their principal places of business in the state of Arkansas.

9. PCMA brings this lawsuit on behalf of its members, which include PBMs that administer prescription drug benefits on behalf of their customers including health plans and their participants, individual consumers and their families, who reside or purchase pharmaceuticals in Arkansas and, as such, are affected by Act 900.

10. PCMA is a non-profit 501(c)(6) corporation duly organized under the laws of the State of Delaware. PCMA is a national trade association whose members include the following PBMS: Aetna Pharmacy Management; Catamaran Corporation; Cigna Pharmacy Management; CVS Health Corporation; Express Scripts; Human Pharmacy Solutions; LDI;

MedImpact Healthcare System; Optum Rx; Prime Therapeutics; and USScript (collectively, the “Members”). PCMA’s purposes include advancing the common interest of the Members, including in litigation. The claims in this Complaint serve the Members’ common interests. PCMA accordingly has Article III standing to sue on behalf of the Members under the doctrine of associational standing. Neither the claims asserted, nor the relief requested, requires the participation of individual Members in this lawsuit.

11. The injury to the Members will commence immediately upon Act 900’s effective date on July 22, 2015. Defendant Rutledge’s office already has indicated to PCMA’s members that it will begin enforcement of Act 900 on that date, including retroactive enforcement for pharmacy claims dating back two years. Such injury to the Members would make out a justiciable case had the Members themselves brought suit.

12. In addition, in order to comply with Act 900, PCMA members will be forced to immediately revise their business practices, including their pricing methodologies, the frequency with which they update them, and their appeals procedures in contravention of their existing Pharmacy Contracts.

13. PCMA members will also immediately be caused harm by provisions of Act 900 that allow pharmacists to refuse to fill prescriptions, as this could result in a breach of some of PCMA’s members’ customer contracts, and could cause some of PCMA’s members to become out of compliance with regulations promulgated by the federal Medicare agency.

14. Act 900 injures PBMs and their customers in various ways, including the following: (1) PBMs will be

forced to abandon their market-driven MAC methodology and adopt a new methodology whereby they reimburse pharmacies for their purported “acquisition cost.” This greatly diminishes the value of the MAC methodology to the PBM business model. The effects will be felt in PBMs’ nationwide business, because their customer contracts are not limited to employees in any particular state, including Arkansas; (2) PBMs will suffer substantial impairments to their contracts with pharmacies and with customers; and (3) PBMs are subject to a considerable risk of sanctions, including civil damages, criminal prosecution and the loss of their license to practice in Arkansas, because they do not have access to information that is critical for their compliance with the Act.

15. Defendant Leslie Rutledge is the Attorney General of the State of Arkansas. The Attorney General is a resident of Little Rock, Arkansas, and is being sued solely in her official capacity.

16. Defendant, and those subject to Defendant’s supervision, direction, and/or control, are responsible for the enforcement of Act 900, including the specific ERISA and Medicare preempted and unconstitutional provisions at issue here.

FACTS

A. The Prescription Drug Market and PBMs’ Role

17. Many Arkansas residents receive their prescription drug benefits through health plans, including self-funded and insured ERISA-governed employee health benefit plans, health plans offered by non-profit hospital or medical services corporations, health insurers, and health maintenance organizations, as well as health plans sponsored by unions, federal and

state government plans, and other benefit plans (collectively “health plans”).

18. Health plans contract with PBMs to administer and manage their prescription drug benefits and, in particular, to employ particular methods to keep the cost of prescription drugs down.

19. One of a PBM’s most critical tools to contain prescription drug costs is its proprietary MAC methodology and MAC list(s). PBMs each develop and administer their own unique and confidential MAC list(s), which are used to set reimbursement rates for pharmacies filling prescriptions for generic drugs. PBMs also use MAC lists to guarantee pricing terms to their customers, the health plans and self-insured employers.

20. PBMs enter into contracts with both chain and independent retail pharmacies (“Pharmacy Contracts”), in every state, including Arkansas. The Pharmacy Contracts operate to create pharmacy networks.

21. These networks are crucial to PBM contracts with their customer health plans (“Customer Contracts”), because they allow PBMs to guarantee that its customers’ members, individual consumers and their families, will receive adequate service, including accessibility at the level required by the Centers for Medicare and Medicaid Services (“CMS”) for Part D participants.

22. The retail pharmacies in a PBM’s network fill the prescriptions of health plan participants with drugs they have purchased on their own directly from wholesalers or manufacturers. When a consumer goes to a pharmacy to fill a prescription, the pharmacy will check with the PBM to confirm the applicable plan design for the health plan member in order to deter-

mine coverage and copayment information. After the prescription is filled, the PBM reimburses the pharmacy at a contractually-agreed negotiated rate minus the co-pay collected by the pharmacy from the plan participant.

B. PBMs' Use of MAC Pricing

23. The methodology for establishing these contracted prices for brand-name drugs (*i.e.*, those still under patent protection) differ from those for generic drugs (*i.e.*, those where the patent has expired and therapeutically equivalent versions are produced by any number of competing manufacturers). This lawsuit involves contracted prices for generic drugs. About 80 percent of prescriptions in the U.S. are dispensed as generic drugs. The considerable savings brought by dispensing generics over brand name pharmaceuticals is key to containing drug costs and maximizing savings to health plans and plan participants.

24. One of the most common methodologies used by PBMs in paying pharmacies for dispensing generic prescription drugs is MAC methodology. Almost four-fifths of private employer prescription drug plans (and 45 state Medicaid programs, including Arkansas Medicaid, as well as Medicare Part D plans) use MAC as a cost management tool. In a recent report, the Office of Inspector General of the U. S. Department of Health and Human Services described the “significant value MAC programs have in containing Medicaid drug costs.”¹

¹ Office of Inspector General, Medicaid Drug Pricing in State Maximum Allowable Cost Programs (August 29, 2013), p.21, available at <https://oig.hhs.gov/oei/reports/oei-03-I 1-00640.asp>.

25. MACs specify the allowable reimbursement by a PBM for a particular strength and dosage of a generic drug that is available from multiple manufacturers but sold at different prices. The use of MAC lists is critical due to the lack of price standardization for identical products from different manufacturers.

26. PBMs and their client health plans use MAC pricing to control the cost of drugs paid by or on behalf of their plan participants by establishing a consistent and reasonable price regardless of the manufacturer. By placing a ceiling on what the PBM will pay the pharmacies under their agreements, MAC pricing motivates and incentivizes pharmacies to seek and purchase generic drugs at the lowest available prices in the marketplace. Based on the extensive and continuous study of market dynamics, PBMs use MAC lists to balance fairly compensating pharmacies, so they continue to be incentivized to dispense generic products, with providing a cost-effect benefit to their health plan customers.

27. Each PBM develops and maintains multiple of its own confidential MAC pricing lists derived from its proprietary methodologies. Within each PBM, MAC lists may differ by health plan customer. These variations may range from the number of drugs on the list to the maximum allowable cost for each drug. PBMs do not typically maintain lists that are specific to the state in which the prescriptions will be filled. Indeed, many of the PBMs' customers offer prescription drug coverage to beneficiaries throughout the country, and while each of those customers may have several MAC lists associated with its contract, those lists are typically distinguished by what type of health plan the beneficiary is enrolled in, not what state they reside or work in.

28. MAC list development is a time-consuming, resource-extensive investment for each PBM. In order to develop a MAC list, the PBM must first determine which drugs to include on the list. This determination, which may be made on a client-to-client basis, is based upon numerous factors, including whether drugs are approved by the FDA or listed in the FDA's Orange Book, whether the drugs have therapeutic equivalents and how many, whether there are multiple generic versions, and the number of manufacturers supplying the drugs. The number of drugs on a MAC list can range from the hundreds to the thousands.

29. Then, for each drug that is chosen for the list, the PBM must determine the appropriate reimbursement for the drugs. MAC pricing is calculated based on multiple factors aggregated to derive what pharmacies pay, on average, for generic drugs. These factors include published Average Wholesale Prices ("AWP"), MAC lists that are made public from state Medicaid systems, the PBMs' market intelligence based on the prices its in-house mail-order pharmacies are able to negotiate, and subscription-only price compendiums that are provided at a cost to those PBMs that enroll. From those resources, each PBM develops its own pricing benchmarks and explicit formulas used to create its own unique MAC prices and MAC lists of standard reimbursements for generic drugs.

30. The PBMs' pricing methodologies and customer-specific MAC lists are unique to each PBM, and are not generally known or readily ascertainable in the PBM industry. The PBM industry is fiercely competitive. As one of their most valuable tools in providing cost-effective solutions to their customers, PBMs consider both their MAC lists and MAC pricing method-

ologies to be proprietary trade secrets, and protect them as such.

C. Act 900

31. The bill that became Act 900, which amends prior law, was filed on March 2, 2015 and passed by the Arkansas Senate on March 25, 2015 and then by the House on March 26, 2015. The legislative record reflects no reference to or study by a legislative committee regarding the potential consequences of the proposed law's provisions.

32. Act 900 became law on April 2, 2015, one month after it was originally filed. It will become effective on July 22, 2015, 91 days after the April 22, 2015 *sine die* adjournment of the 90th General Assembly.

33. Act 900 makes five significant changes to prior law:

- a. It defines "pharmacy acquisition cost" as "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice." Ark. Code § 17-92-507(a)(6).
- b. It requires PBMs to update their MAC lists within seven days from "an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in" Arkansas. Ark. Code § 17-92-507(c)(2).
- c. It requires PBMs to provide an administrative appeal procedure to allow pharmacies to challenge MAC lists (prospectively) and reimbursements (retrospectively) as being below

the “pharmacy acquisition cost.” Ark. Code § 17-92-507(c)(4)(A)(i).

- d. It requires PBMs to permit the challenging pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the cost on the relevant MAC list where the drug is not available “below the pharmacy acquisition cost from the pharmaceutical wholesaler *from whom* the pharmacy or pharmacist purchases the majority of prescription drugs for resale.” Ark. Code § 17-92-507(c)(4)(C)(iii).
- e. It provides that a “pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a *Maximum Allowable Cost List*, *a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.* (Italics in the original). Ark. Code § 17-92-507(e).

34. Violation of any provision of Act 900 constitutes a deceptive and unconscionable trade practice subject to Arkansas’ consumer protection law (Ark. Code § 4-88-101 et seq.), which subjects the violator to both civil and criminal penalties, including loss of licensure. § 17-92-507(g); § 4-88-103, 4-88-113.

35. Act 900 also states that the law does not apply to a MAC list maintained by the Arkansas Medicaid Program or the Employee Benefits Division of the Department of Finance and Administration, provided those programs do not employ a PBM to administer their prescription drug benefits. Ark. Code § 17-92-507(f).

36. In a letter dated July 10, 2015 and sent to many PBMs doing business in Arkansas, Defendant Rutledge's office stated that it interpreted Act 900 to mean "that it is a deceptive trade practice for a PBM to reimburse a pharmacist in an amount below the acquisition cost," even if that pharmacist had not yet appealed a reimbursement.

37. Act 900 does not state that its provisions should be applied retrospectively or retroactively. However, in its July 10, 2015 letter, the Attorney General's Office indicates that it intends to enforce the law retroactively, stating that it "has received numerous 'negative reimbursement' complaints from various Arkansas pharmacies over the past two years," and that its intent is to "forward these [outstanding] complaints to you again and request that you reverse and reprocess such claims in compliance with the law and in order to alleviate the negative claims or 'negative reimbursements' identified by those complaints."

D. Act 900 Harms Arkansas Consumers

38. Act 900's provisions requiring that pharmacists receive at least their acquisition cost for every prescription filled come at a great cost to PBMs, health plans, and, ultimately, Arkansas prescription drug consumers – including senior citizens.

39. Contrary to the definition of "pharmacy acquisition cost" imposed by the law, the actual cost to a pharmacy for any given prescription drug is *not* simply the price listed on the invoice received from a wholesaler, because that price does not reflect price concessions including bulk discounts and rebates.

40. Payers have historically experienced considerable difficulty in determining the "true"

market price for dispensed pharmaceuticals. This is why PBMs and other market participants have employed various strategies to determine the price they will pay when a prescribed pharmaceutical is dispensed. These strategies, which have evolved over the past several decades, have resulted in the widespread adoption of MAC lists.

41. This widespread adoption of MAC lists has had significant positive effects on pharmaceutical markets. MACs encourage pharmacies to dispense the generic version of applicable pharmaceuticals. In addition, MACs heighten the competition between generic manufacturers. MACs also ensure that pharmacies are not being overpaid for the services they provide. These three factors combine to reduce pharmaceutical costs overall. In addition, the use of MAC lists streamlines the prescription drug reimbursement process, which improves overall system performance.

42. Act 900 will cause both immediate and long term effects. In the short-term, Act 900 will force multi-state employers to modify their employee benefit plans for Arkansas-based employees. More specifically, employers will have to modify their contracts with insurers/PBMs, to ensure their Arkansas-based employees receive benefits that comply with Act 900, including Arkansas-specific MAC lists; Arkansas-specific MAC pricing; and an Arkansas-specific appeals process. Although a number of other states have enacted legislation regulating PBMs, no other state includes a “guaranteed profits” provision like Act 900. Thus, employers with Arkansas-based employees (and the insurers and PBMs that provide services to them) will have to create an Arkansas-specific employee benefit plan incorporating these disparate elements.

43. Employers based outside of Arkansas (and the PBMs that serve them) will need to similarly address the likelihood that employees and their covered dependents either live in Arkansas or travel to Arkansas at some point in time, and seek to have a prescription filled within that state. Employers could therefore either take steps to ensure plan compliance with Arkansas-specific provisions, or can ignore the requirements of Act 900 and assume the risk that their employees and covered dependents will not be able to have their prescriptions filled while in Arkansas.

44. In addition, Act 900 takes away the pharmacies' incentive to seek out the lowest price possible for a generic drug, because it promises pharmacies that they will be reimbursed for any acquisition cost they expend, rather than the MAC, which reflects average acquisition cost. Without an incentive for pharmacies to seek out the lowest price possible for a drug, wholesalers will have less incentive to compete. As a result, prescription drug prices will increase.

45. PBMs know that they will need to handle increased appeals from pharmacies that have not recovered their acquisition cost, they will respond by setting higher MACs, which will result in guaranteed profits for pharmacies that purchase the drug for less than the MAC.

46. The increased drug costs caused by Act 900 will be born directly by PBMs and indirectly by the insurers, employers and consumers in Arkansas. For example, those insurers and employers that bear the costs of prescription drug reimbursement through "pass-through" contracts will see an immediate increase in the prices paid under their PBM contracts.

47. Consumers of prescription drugs will bear some of the costs of Act 900 as well. If their prescription benefit plan has a percentage co-payment/co-insurance for pharmaceuticals, an increase in the cost of the pharmaceutical (whether attributable to a successful appeal of a MAC, or increased MACs because of the incentives created by Act 900) will result in a direct increase in the cost borne by the employee, since the co-payment is computed based on the actual cost of the dispensed drug. If the benefit plan is structured as a high-deductible plan, any increase in the cost of the pharmaceutical will similarly result in a direct increase in the cost borne by the employee, at least as long as the deductible has not been exceeded.

48. There will also be lagged effects of Act 900. The combination of increased pharmaceutical spending and increased administrative costs will cause employers and employee benefit plans (and the insurers that provide services to them) to look for savings elsewhere, including changes in plan design – such as modifications in covered benefits and the mix of co-payments and deductibles that apply to those benefits. Act 900 will also create pressure to develop new pricing models for handling generic drugs that may not be subject to a MAC – and new pricing models may trigger further changes in plan design.

E. Act 900 Harms PBMs

49. Act 900 places significant restrictions on PBMs and their ability to provide their services to those clients with covered lives in Arkansas. First, PBMs have no way of knowing when their obligation to update their MAC lists based on pharmaceutical wholesaler invoice pricing will be triggered because PBMs do not have visibility into the acquisition costs

of individual pharmacies for specific drugs with specific wholesalers.

50. Second, the law requires PBMs to reimburse pharmacies for their acquisition costs or higher. The Attorney General has notified PBMs that it intends to enforce Act 900 to require PBMs to reimburse pharmacies for their acquisition costs or higher even before a pharmacy has filed an appeal. PBMs have no ability to do this for the same reason that they are unable to update their MAC lists based on pharmacy acquisition cost: they have no visibility into what price any particular pharmacy has negotiated with any particular wholesaler.

51. Third, even if PBMs are able to comply, the law requires that they grant any pharmacy reimbursement or MAC appeal in which a pharmacy can show that the MAC/reimbursement is lower than its acquisition cost as listed on its wholesaler invoice. This will harm the PBMs because it essentially renders MAC lists as they were previously developed valueless in Arkansas.

52. Fourth, the law is in direct conflict with Pharmacy Contracts and Customer Contracts. Under Act 900, PBMs are unable to avail themselves of the bargained-for terms of their Pharmacy Contracts, including those terms related to pricing, guaranteed dispensing, and appeals. As a result, PBMs will themselves fail to meet guarantees in their Customer Contracts and will be subject to penalties as a result.

53. Fifth, PBMs will also see an increase in administrative costs under Act 900. First, even if PBMs were to gain access to individual wholesaler information, they would be forced to compile this data and calculate any changes on a near-constant basis in order to

comply with the MAC list update provision. Second, the amendments to the administrative appeal process mean that PBMs face the constant uncertainty of an increased volume of reimbursement appeals with no statute of limitations. Third, in order to properly consider whether the appeals have merit, in every appeal the PBM would need to collect and analyze data from each appealing pharmacy regarding their wholesale purchasing processes in order to determine whether they purchase the majority of their drugs from a particular wholesaler. Even assuming that those pharmacies are able and willing to provide such information, which the PBMs have no way of accessing on their own, this presents a large burden to the PBMs in processing all of this information. Fourth, in the event that an appeal is successful, the burden is on the PBM to ensure that all “similarly situated” pharmacies receive the benefit of the change to the MAC. Because this information is not publicly available, the PBMs have no means of ensuring that similarly situated pharmacies are treated similarly, unless all of those pharmacies agree to submit such information during the appeals process. All of these additional tasks add up to an enormous financial burden on PBMs.

CLAIMS FOR RELIEF

COUNT ONE

(ERISA PREEMPTION)

54. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 53 as if fully set forth herein.

55. ERISA is a comprehensive federal statute that regulates employee benefit plans with the purpose of

providing for the uniform national treatment of employee benefit plans.

56. ERISA § 514 – ERISA’s express preemption provision – provides that ERISA preempts state laws related to an employee benefit plan.

57. Act 900 “relate[s] to” an employee benefit plan due to: (1) the requirements imposed on on those PBMs that are serving individuals “living or working in Arkansas;” (2) the direct economic effect that it imposes on ERISA plans; and (3) the changes that it imposes on the structure of the plans.

58. Furthermore, Act 900 is not saved from preemption by ERISA’s savings clause, 29 U.S.C. § 1144(b)(2)(A), which saves from preemption a state law that “regulates insurance, banking or securities” because it is not directed towards entities engaged in insurance but rather is expressly directed at PBMs, which do not engage in insurance-related activity.

59. Plaintiff has no adequate remedy at law available against Defendants for the injuries and irreparable harm its members will imminently suffer when Act 900 takes effect on July 22, 2015.

COUNT TWO

(MEDICARE PREEMPTION)

60. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 59 as if fully set forth herein.

61. Medicare Part D expressly preempts any state law “with respect to” a Medicare Part D plan. Social Security Act §§ 1860D-12(g) and 1856(b)(3). The standard for determining whether Part D preempts a law is a three part test. A statute is preempted if (1) the federal government established “standards” in the

Medicare Part D program; (2) the state law is one “with respect to” these standards; and (3), the state law does not govern licensure or solvency.

62. The federal government and the Centers for Medicare and Medicaid Services have established a standard that concerns pharmacy drug pricing. For example, the Medicare statute mandates that beneficiaries have access to “negotiated prices,” which are defined by accompanying regulations as “prices for covered Part D drugs that (1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) include any dispensing fees.” 42 C.F.R. § 423.100; *see also* 42 U.S.C. § 1395w-102(d)(1)(A) (mandating access to negotiated pricing) and (d)(1)(B)(defining term).

63. The Medicare statute and Medicare regulations also establish strict standards with regard to pharmacy access for Part D enrollees. 42 U.S.C. § 1395w-104(h)(1)(C)(i) and 42 C.F.R. § 423.120(a)(1).

64. Act 900 is a law “with respect to” a Part D plan. To the extent that a state law purports to regulate the prices that a pharmacy can charge or receive for a drug that is a covered Part D drug, it is a state law with respect to a Part D standard. And, to the extent that a state law purports to permit a Part D in-network pharmacy to refuse to dispense a covered Part D drug to a Medicare beneficiary, it is a state law with respect to a Part D standard.

65. Act 900 is not a law regulating licensure or solvency. Therefore, it is preempted by the Medicare Part D and Medicare Advantage statutes.

66. Plaintiff has no adequate remedy at law available against Defendants for the injuries and irreparable harm its members will imminently suffer when Act 900 takes effect on July 22, 2015.

COUNT THREE

(DORMANT COMMERCE CLAUSE,
§§ 17-92-507(C)(4)(A)(I)(B); 17-92-
507(C)(4)(A)(11)(C); 17-92-507(C)(4)(C)(1)(C);
17-92-507(C)(4)(C)(II)-(III); 17-92-507(E))

67. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 66 as if fully set forth herein.

68. The dormant Commerce Clause of the United States Constitution limits the extent to which States can regulate interstate commerce. U.S. Const. art I, § 8, el. 3.

69. Act 900 violates the dormant Commerce Clause by imposing an undue burden on interstate commerce. The PBM and prescription drug market is an interstate market. For example, PCMA's member PBMs are all incorporated in and have headquarters outside of Arkansas, but all provide pharmacy benefit management services to plan beneficiaries within Arkansas. Many of the health plans that contract with PBMs to provide services to Arkansas beneficiaries are located outside of Arkansas, and many of those plans serve beneficiaries both inside and outside of Arkansas within the same plan. The prescription drugs that are sold in pharmacies located inside Arkansas are primarily manufactured outside of

the state and shipped into the state by out-of-state wholesalers. Many of the pharmacies that are purportedly protected by Act 900 are part of national or international chains with outlets and headquarters outside of Arkansas. Even some of the independent pharmacies engage out-of-state and/or national pharmacy services administrative organizations (“PSAOs”) to contract with managed care organizations and PBMs on behalf of their members.

70. Act 900 will harm this national prescription drug market. The act’s requirements that collectively operate to force PBMs to set MAC pricing to match pharmacy acquisition cost, as defined by the statute, will reduce competition among pharmaceutical wholesalers and pharmacies, which will result in increased prescription drug prices for health plans and their members, including some members that work outside of Arkansas but fill prescriptions in Arkansas.

71. PBMs do not have the ability to avoid doing business in Arkansas due to the national nature of the PBM business and member mobility.

72. The local benefits of Act 900 will be minimal, if there are any at all. In fact, Act 900 ultimately will harm Arkansas consumers by driving up prescription drug costs.

73. Defendants’ imminent enforcement of Act 900 is under color of state law and violates the rights, privileges and immunities of Plaintiff under the dormant Commerce Clause, and therefore is actionable under 42 U.S.C. § 1983.

74. Plaintiffs’ members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a

result of the deprivations of their federal rights, privileges and immunities caused by Act 900.

COUNT FOUR

(FEDERAL CONTRACTS CLAUSE,
§§ 17-92-507(C)(4)(A)(I)(B); 17-92-
507(C)(4)(A)(II)(C); I7-92-507(C)(4)(C)(I)(C);
17-92-507(C)(4)(C)(II)-(III); I 7-92-507(E))

75. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 74 as if fully set forth herein.

76. The Contracts Clause prohibits states from passing any law impairing the obligations of contracts. U.S. Const. art. I, §10, cl. 1 (“No state shall. . . pass any. . . law impairing the obligation of contracts”).

77. Act 900 significantly impairs both Pharmacy Contracts and Customer Contracts, including the terms relating to pricing, guaranteed dispensing, and reimbursement appeals.

78. Act 900 does not serve a significant and legitimate public purpose. The law was drafted with the sole purpose of changing contract rights between PBMs and pharmacies in order to benefit pharmacies. Further, Act 900 is harmful to the societal interest of maintaining affordable prescription drug prices and increasing access to prescription drugs.

79. The purposes of Act 900 do not warrant contractual adjustments.

80. Plaintiffs’ members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their federal rights, privileges and immunities caused by Act 900.

COUNT FIVE(CONTRACTS CLAUSE,
ARKANSAS CONSTITUTION)

81. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 80 as if fully set forth herein.

82. The Arkansas Constitution prohibits the impairment of contracts. Ark. Const., art. II §17 (“No . . . law impairing the obligation of contracts shall ever be passed”).

83. Act 900 significantly impairs both Pharmacy Contracts and Customer Contracts, including the terms relating to pricing, guaranteed dispensing, and reimbursement appeals.

84. Act 900 does not serve a significant and legitimate public purpose. The law was drafted with the sole purpose of changing contract rights between PBMs and pharmacies in order to benefit pharmacies. Further, Act 900 is harmful to the societal interest of maintaining affordable prescription drug prices and increasing access to prescription drugs.

85. The purposes of Act 900 do not warrant contractual adjustments.

86. Plaintiffs’ members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their state constitutional rights, privileges and immunities caused by Act 900.

COUNT SIX(FEDERAL DUE PROCESS CLAUSE,
§ 17-92-507(C)(2))

87. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein.

88. The Due Process Clause of the Fourteenth Amendment of the United States Constitution, provides that no state shall “deprive any person of life, liberty or property, without due process of law.” U.S. Const. amend. XIV, § 1. The Due Process Clause requires laws that regulate persons or entities to give fair notice of the conduct that is forbidden or required.

89. Act 900 violates the Due Process Clause because the regulated parties (PBMs) have no way of gaining information that will allow them to know *when* it would be required to satisfy its legal obligation to update its MAC list, or *how* to satisfy its legal obligation of reimbursing pharmacies for their acquisition cost before an appeal. A PBM is not privy to information regarding pharmacy acquisition cost, unless a pharmacy or a wholesaler chooses to share such information with the PBM.

90. The penalties for failing to comply with any provision of Act 900, including Section 17-92-507(c)(2), include liability for an unfair and deceptive trade practice, including loss of licensure to practice pharmacy in Arkansas. Therefore, if a PBM were to remain non-compliant due to its lack of notice of when its legal obligations have occurred, it could be deprived of the ability to conduct business in the state.

91. Plaintiffs’ members have no adequate remedy at law available against Defendants for the injuries

and irreparable harm they will imminently suffer as a result of the deprivations of their federal rights, privileges and immunities caused by Act 900.

COUNT SEVEN

(ARKANSAS DUE PROCESS CLAUSE)

92. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 91 as if fully set forth herein.

93. The Due Process Clause of the Constitution of the State of Arkansas provides that “No person shall. . . be deprived of life, liberty, or property, without due process of law.” Ark. Const., art. II, §8.

94. Plaintiffs’ members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their state constitutional rights, privileges and immunities caused by Act 900.

REQUEST FOR RELIEF

WHEREFORE, PCMA respectfully prays that this Court:

(1) declare that Act 900 is preempted by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001 *et seq.*;

(2) declare that Act 900 is preempted by the Medicare Part D statute, 42 U.S.C. §§ 1395w-12(g) and 1395w-26(b)(3);

(3) declare that Arkansas Code §§ 17-92-507(c)(4)(A)(i)(b); 17-92-507(c)(4)(C)(i)(c); 17-92-507(c)(4)(C)(ii)-(iii); and 17-92-507(e) violate the Commerce Clause of the United States Constitution because they excessively burden interstate commerce

(4) declare that Arkansas Code § 17-92-507(c)(2) violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution because it fails to provide adequate notice;

(5) declare that Arkansas Code § 17-92-507(c)(2) violates the Due Process Clause of the Constitution of the State of Arkansas because it fails to provide adequate notice;

(6) declare that Arkansas Code §§ 17-92-507(c)(4)(A)(i)(b); 17-92-507(c)(4)(A)(ii)(c); 17-92-507(c)(4)(C)(i)(e); 17-92-507(c)(4)(C)(ii)-(iii); 17-92-507(e) violate the Contracts Clause of the United States Constitution because they substantially impair PBMs' contracts with pharmacies and customers,

(7) declare that Arkansas Code §§ 17-92-507(c)(4)(A)(i)(b); 17-92-507(c)(4)(A)(ii)(c); 17-92-507(c)(4)(C)(i)(c); 17-92-507(c)(4)(C)(ii)-(iii); 17-92-507(e) violate the Contracts Clause of the Constitution of the State of Arkansas because they substantially impair PBMs' contracts with pharmacies and customers

(8) enter a permanent injunction enjoining Defendants and their agents from taking any action under or to enforce Act 900;

(9) enter, after hearing, a preliminary injunction, pending final resolution of this action, enjoining Defendants and their agents from taking any action under or to enforce Act 900;

(10) award Plaintiff its reasonable attorneys; fees and costs; and

(11) grant Plaintiff such additional or different relief as it deems just and proper.

Respectfully submitted,
Pharmaceutical Care
Management Association, Inc.

/s/ Lyn P. Pruitt

Lyn P. Pruitt, Ark. Bar No. 84121
Mitchell, Williams, Selig,
Gates & Woodyard, P.L.L.C.
425 West Capitol Avenue, Suite 1800
Little Rock, Arkansas 72201
Phone: (501) 688-8869
Facsimile: (501) 918-7869
Email: lpruitt@mwlaw.com

Dean Richlin
(*pro hac vice* application pending)
Kristyn DeFilipp
(*pro hac vice* application pending)
Andrew London
(*pro hoc vice* application pending)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000

*Attorneys for Pharmaceutical Care
Management Association, Inc.*

Dated: August 13, 2015

[1] IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

No. 4:15CV00510 BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff,

v.

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS
ATTORNEY GENERAL OF ARKANSAS,

Defendant.

November 4, 2015
Little Rock, Arkansas
10:33 a.m.

TRANSCRIPT OF HEARING ON MOTION FOR
PRELIMINARY INJUNCTION BEFORE THE
HONORABLE BRIAN S. MILLER, UNITED
STATES DISTRICT JUDGE

[Excerpts of Testimony of Amy Bricker]

APPEARANCES:

On Behalf of the Plaintiff:

MS. LYN PEEPLES PRUITT, Attorney at Law
Mitchell, Williams, Selig, Gates & Woodyard, PLLC
425 West Capitol Avenue, Suite 1800
Little Rock, Arkansas 72201

MR. DEAN RICHLIN, Attorney at Law
MS. CATHERINE DENEKE, Attorney at Law
Foley Hoag LLP
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210-2600

On Behalf of the Defendant:

MR. SHAWN J. JOHNSON, Attorney at Law
MS. SARAH R. TACKER, Attorney at Law
Arkansas Attorney General's Office
323 Center Street, Suite 200
Little Rock, Arkansas 72201-2610

Proceedings reported by machine stenography and displayed in realtime; transcript prepared utilizing computer-aided transcription.

Judith A. Ammons, RPR, CRR, CCR
United States Court Reporter

* * *

[118] Q. And before you held that position, what was your title?

A. Vice president of pricing, supply chain economics.

Q. And how long had you held that position before you changed titles?

A. Approximately 18 months.

Q. Okay. And how long with Express Scripts?

A. Five and a half years.

Q. What kind of company is Express Scripts?

A. They are a pharmacy benefits manager.

Q. And we've already heard some testimony this morning about what PBMs do. They have clients or customers, is that correct?

A. Yes, we do.

Q. And who are they?

A. Our plan sponsors vary in type. They could be health plans. They could be commercial employers. They could be labor union clients. They could be Medicaid agencies or Medicare plan sponsors.

Q. And for these clients, you do a variety of things, is that right?

A. I do.

Q. And one of the things that Express Scripts does is to create pharmacy networks, correct?

A. Yes.

Q. And do you have some role or responsibility in creating pharmacy networks?

* * *

[122] A. No. It's very important to note that rebates are paid by brand pharmaceuticals, by brand pharmaceutical manufacturers, for placement of their product on formulary. I think in prior testimony it wasn't clear that these were only offered for brands. And with respect to the discussion today, we're speaking of generic pharmaceuticals, and we are not receiving rebates on generics.

Q. So to the extent there's any spread between rebates received by Express Scripts and the reimbursements paid to pharmacies, that's completely irrelevant on the topic of generics, is that correct?

A. Yes. So rebates, again, are negotiated by Express Scripts with pharmaceutical manufacturers. And, in turn, Express Scripts is negotiating with our plan sponsors for what, if any, amount Express Scripts

retains of those rebates. So that's one part of the equation. The other is in pharmacy reimbursement. So Express Scripts negotiates with plan sponsors on what they will pay for brand as well as generic pharmaceuticals in our network. And, in turn, Express Scripts is negotiating with our network pharmacies on what we will pay for brands as well as generics.

Q. Thank you. And you mentioned the rebates on brands and the relationships with your clients or customers. At least to the best of your knowledge, are those rebates received by Express Scripts from pharmaceutical manufacturers known to the [123] clients or customers of Express Scripts?

A. So our clients and our customers – it depends on each of them. The contracts are different and unique. And so do they know that rebates are received? Yes. The amount that they receive is negotiated by them with Express Scripts.

Q. And by the way, do all clients and customers negotiate on their own behalf with Express Scripts?

A. No. Actually, the far majority utilize a consultant to negotiate on their behalf.

Q. So a consultant with specialized knowledge about how to deal with pharmacy benefit managers, correct?

A. Yes.

Q. Now, could you describe what it is – well, I think you already did.

I'm not sure I asked you this question. What does Express Scripts do? I mean, it's a PBM, but what does a PBM do?

A. Fundamentally, a couple of things. So we touched on negotiating with pharmaceutical manufac-

turers in exchange for rebate and for formulary placement. Secondly, negotiating with retail pharmacies to create a network of pharmacies that a plan sponsor could utilize. Also, they're offering potentially mail-order services or specialty pharmacy services for plan sponsors to use if they so choose. They are also offering a wealth of clinical or drug utilization management programs, so ensuring appropriate utilization of medications, ensuring that [124] the right prescription is dispensed, given that as a pharmacy benefits manager we're able to see all of the claims that are being dispensed for a particular patient, and then alerting retail pharmacies of potential interactions.

Q. So the role of Express Scripts is far greater than simply making sure that the pharmacist gets paid for a script that's dispensed, is that correct?

A. Absolutely. Our mission is to make pharmaceuticals safer and more affordable for our clients and members.

Q. Thank you. Now, there's been some discussion about confidentiality. The agreements between Express Scripts and its clients, those are confidential?

A. They are.

Q. Why?

A. Because it's a competitive market. You know, Professor Hyman touched on the number of PBMs that are in the marketplace. It's highly competitive. And so it's confidential in nature because I don't want my competitors knowing that relationship and vice versa.

Q. So when you would obtain an account from a client or customer, do you often have to go through some kind of process in order to win that account?

A. Absolutely. Typically issue an RFP, or a request for proposal. They are seeking bids from Express Scripts as well as our competitors. They provide a wealth of data by which we [125] might put forward an offer. And typically then they are evaluating which is the best PBM to partner with.

Q. And we've also heard that the contracts between PBMs and pharmacies are confidential, is that right?

A. That's correct.

Q. And why are those agreements confidential?

A. For the same reason. It's a two-way confidentiality. It's important that when pharmacies are negotiating with Express Scripts, they are not sharing those contracts with their peers, that those are, you know, two-party negotiations between Express Scripts and that entity. And so to devalue that would, in essence, you know, result in collusion or, you know, disadvantaging Express Scripts.

Q. And is there some competition among PBMs to win a pharmacy into its network?

A. Oh, certainly. You know, I'm only as – with respect to retail networks, I'm only as valuable as the number of retail pharmacies that are in my network. So it's important that I'm offering rates and terms and conditions that those pharmacies will agree to and, again, having a stable network in which to offer my clients.

Q. Now, let's turn for a moment to maximum allowable cost, MAC. You have some – or have had some responsibility for MAC at Express Scripts, is that right?

A. Yes.

* * *

[128] a confidential negotiation between them and their wholesaler – I have to attempt to survey the market and attempt to set pricing so that it's incenting the pharmacies in the network to buy the best price, but also ensuring that they can continue to stay in my network.

It does not serve me to have pharmacies drop out of my network, and it does not serve me to run them out of business. So I have to – it's a delicate balance that I have to achieve. My clients hire me to set pricing that is competitive, keeping their costs in mind, but I also have to ensure I have a viable network.

Q. And there was also a suggestion that it's – that a business decision is involved in setting MAC. Is this a manual decision by somebody with a green eye shade and a pencil in terms of setting the MAC price?

A. I'm not sure I understand the question.

Q. Well, does the company use some kind of algorithm in order to set the price?

A. Yes. It's confidential and proprietary. It's a trade secret of Express Scripts. It's what allows me to remain competitive. I don't share my pricing with my competitors, and vice versa, they don't with me. So it's important that while there are specific benchmarks or data points that are available to me in arriving at the endpoint, the actual formula or algorithm is not shared.

* * *

[131] Q. They are national as well?

A. Yes.

Q. And there are a handful of very large wholesalers in the country?

A. There are about three or four dominant players, but there are a number of wholesalers that distribute product.

Q. Now, I want you to turn your attention to paragraph 11 of your declaration. And, there again, to paraphrase, it says, "MAC pricing is not tied to pharmacy acquisition cost. Moreover, Express Scripts does not have access to the acquisition cost." Why is that?

A. It's a private contract entered into between the pharmacy and wholesaler. It's confidential in nature. I don't have access to that information.

Q. When the pharmacy seeks reimbursement from Express Scripts, it conveys information to you in order to get that reimbursement, correct?

A. During the processing of a transaction, is that what you're referring to?

Q. Yes, it is.

A. Yes. So at the point of sale when a patient is at the pharmacy counter, the pharmacist is entering specific data into the computer system that is instantly relayed to Express Scripts. And, in turn, we're responding on a number of factors. So we're identifying: Is this patient eligible? Is [132] this patient covered by Express Scripts? Is the drug covered by the plan sponsor? Is the dose appropriate? A wealth of information is received and then returned back to the pharmacy and as well as financial information.

Q. So in terms of the information that the pharmacist sends to you, is there financial information in that transmittal?

A. Yes. So NCPDP, which is the standard that all pharmacies and PBMs operate under, require certain data elements to be shared. Those transactions are standardized. And one of those elements is the pharmacy's usual and customary price or the price that they would charge without insurance, their cash price.

Q. And that's not the same as the acquisition cost?

A. No, it is not. It's not related at all. It's a markup of some sort.

Q. So nowhere in that data that gets transmitted to Express Scripts is the information as to what the pharmacist acquired the script for?

A. No. And, again, because that's confidential in nature, I don't actually want to know their cost as part of that, which actually then is the issue with Act 900.

Q. Now, you mentioned that when Express Scripts gets this transmittal from the pharmacist, there is a variety of functions that it performs to determine that the individual at the counter is eligible for the prescription, eligible for the [133] drug. These are all things that the pharmacist doesn't have to do, is that right?

A. That's correct.

Q. Now, in looking at Act 900, and we've talked about this this morning, you're aware that it defines the pharmacy acquisition cost as the billing invoice, correct?

A. That's correct.

Q. And is there, from Express Scripts' perspective, any concern about that definition?

A. Yes. As stated previously, invoice price is not the net cost paid by pharmacies. There are purchase discounts and rebates that are available at a future date as negotiated between them and their wholesaler.

Q. Now, there was some discussion this morning about – withdraw that. Let me go someplace else.

I'd like to direct your attention now to – let me ask you this question. Is there any information available to you that tells you that MAC produces a profit for Arkansas pharmacies across the pharmacies' entire market basket of sales?

A. I think I understand your question. So what I can share with you is that the number of appeals that Express Scripts has received over the past year is inconsequential in the number of claims that were processed.

Q. Let me ask you a couple of questions about that. I think in your affidavit you indicate the number of – number of [134] claims that Express Scripts received. And I'm referring to paragraph 5. How many claims for reimbursement in 2014 did Express Scripts receive?

A. 5.7 million.

Q. 5.7 million?

A. Yes.

Q. Across your Arkansas business?

A. Yes.

Q. And how many appeals did you receive in 2014 which would have been under the prior act, 1194?

A. 2014, we received 1100 appeals, or 0.02 percent of all claims processed.

Q. Now, Mr. Johnson indicated that the Attorney General's Office received 150 complaints under the prior act. And under his suggestion of practice at the Attorney General's Office, they presume that for every one complaint there's five other potential complaints. So let's do the math there. 150 times five is 750?

A. That's correct.

Q. If we assume that there's no overlap between your 1100 and the 750, we have 1800 complaints, does that change your view that the number of negative reimbursements brought to your attention is insignificant?

A. It's very nominal with respect to the total number of claims that are processed and reimbursed to pharmacies.

* * *

[141] Q. Yes, and the fact that it effectively negates the use of a MAC?

A. To speak to the reverse – impact of reversing and rebilling, as mentioned previously, the concern lies in the impact to the member out-of-pocket or copay. The benefit that's created by plan sponsors, in essence, is structured in a way, most cases, to incent members to have some skin in the game with respect to the price of pharmaceuticals.

Q. You're talking now about individuals who are members of a benefit plan, correct?

A. Yes, and who have a benefit that is a percent copay would be directly impacted because, at point of sale, the original time of dispense, that transaction I mentioned previously, we're basing the member copay on that transaction realtime. And the pharmacy is then messaged how much money to collect from the

patient at the counter realtime. And then if they were to appeal that claim and the appeal is granted, then they are reversing and reprocessing, the member out-of-pocket absolutely will be impacted.

Q. All right. And what about the – is there any impact to the plan sponsor, your client?

A. Yes. So, again, to the extent that the appeal is granted and the pharmacy reprocesses, there is a direct increase in cost to the plan sponsor for that claim.

Q. Now, some of your contracts are pass-through contracts, [142] correct?

A. Yes.

Q. And so in those instances, if you, as the PBM, are paying a higher price for reimbursement, that's going to fall ultimately to the plan sponsor, correct?

A. Yes. By definition, what is paid to the pharmacy is billed to the client.

Q. There was some discussion about locked-in pricing. And I believe there was testimony that for those kinds of contracts, there's no effect on the plan sponsor until the end of the contract term, is that correct, under your experience at Express Scripts?

A. You know, it's hard for me to say – we don't enter into agreements where there's some capitated arrangement with our plan sponsors, so I'm not familiar with those arrangements.

Q. There are certain arrangements where you provide some pricing protection, is that right?

A. Yes. We have guarantees in contract with our clients. That's what we're bidding, essentially, to win their business.

Q. Are those guarantees absolute?

A. I'm not sure –

Q. Well, are there any circumstances under which, despite those guarantees, costs may be shifted to plan sponsors because of an increase in pharmaceutical pricing?

A. Absolutely. Those guarantees are based off of AWP.

* * *

[145] Q. And you don't have a window into the – when there might be a 10 percent increase in a particular script across 60 percent of wholesalers?

A. It's not knowable.

Q. All right. As part of your job, are you generally familiar with state regulations that pertain to prescription drug pricing?

A. Generally, yes.

Q. Are you familiar with any other state law or regulation that does what Act 900 does?

A. There is no other state law that is in place today.

Q. And are there implications for your business due to the fact that this is a unique statute?

A. Operationally, it's quite difficult to operationalize. As I mentioned, we don't have MAC lists by state. We are serving the market at a national level to determine what is an appropriate reimbursement for a given product. And so to, you know, treat Arkansas differently than the other states is operationally burdensome. And then how Act 900 outlines what should

be received upon appeal, all of this is quite manual in nature.

Q. Now, I believe you mentioned at the beginning of your testimony that Express Scripts did issue an addendum to its contracts with pharmacists in Arkansas as a result of Act 900, is that correct?

* * *

[160] Q. Wouldn't you agree that Act 900 is concerned about this very issue on transparency, accountability, and knowing the answers to these questions about what drugs really cost?

A. I couldn't say what Act 900 is – you know, what the intent was necessarily, only the implications to me in an attempt to manage pharmacy network spend.

Q. Doesn't it seem strange to you that a business like the PBMs in general and perhaps ESI – I'm not asking you to speak on behalf of your employer – but doesn't it seem strange that a business would not want to know what the real cost is that a pharmacist is incurring as it's determining on the other side of the equation what it wants to pay?

A. Mr. Johnson, we contract with 70,000 pharmacies in America. And if you're asking do I want to know what each and every pharmacy has negotiated with each and every wholesaler for every single NDC, I would have no way of gathering that information.

Q. But the Act 900 and Act 1194 of 2013 set up a regime for that, didn't they?

A. No. I don't follow your question. I don't agree that Act 900 then would allow me to know the true cost of every drug that's dispensed.

Q. They set up an appeal process, didn't they?

A. Act 900 provides for an appeal process, yes.

Q. And so did Act 1194?

[161] A. It did.

Q. And ESI is okay with the appeals, right?

A. Yes. We actually negotiated this very bill, 11 – Act 1194 with the pharmacy association in Arkansas. We understood that there needed to be a fair appeals process, and we endorsed Act 1194.

Q. And so ESI is continually receiving appeals from pharmacists and PSAOs on their behalf?

A. Yes. As I testified previously, it's a very small fraction of the overall claims that are processed, but, yes, we receive appeals.

Q. But at the same time, you also – ESI is also willing to punish pharmacists and PSAOs for appealing too much, isn't it?

A. No. I don't know what you mean by "punish."

Q. They'll kick them out of the network, won't they?

A. No.

Q. Are you familiar with a communication that Express Scripts made to PPOK, which is a PSAO, about two weeks ago?

A. I am.

Q. And you're aware that ESI removed –

MR. RICHLIN: Sorry. If there's an exhibit or a document, it would be nice to see it.

THE COURT: Show him –

MR. RICHLIN: Thank you, Your Honor.

(Off the record.)

[171] usual and customary.

Q. And sometimes the usual and customary could potentially be better than what the PBM has, right?

A. Than what we've negotiated with the pharmacy?

Q. Right.

A. Yes.

Q. And so there's a benefit in a pharmacist sometimes being able to do that?

A. To offer prices that are lower than what I've contracted with them?

Q. Yes.

A. Sure. That would be a business decision of the pharmacy.

Q. But they are not allowed to do it under your contracts?

A. No. They are.

Q. They are allowed to turn away customers?

A. I'm sorry, Mr. Johnson. I'm lost. I thought you said something about usual and customary.

Q. Within your contracts, in the ESI and pharmacy contracts –

A. Yes.

Q. – can a pharmacist turn away a consumer at the till?

A. No.

Q. And sometimes the usual and customary, we've established, is better and the pharmacist can do that?

A. I understand your question. So all of our contracts look

* * *

[174] A. Our contracts, typically, when we're offering a new contract, there will be a phone number. They have access to the team that is responsible for negotiating contracts. And they bring forward concerns, or if they are wanting to negotiate one aspect of the contract or another, they phone someone at Express Scripts to do that.

Q. And ESI rarely would change a contract that it has pretty much established with a PSAO in benefit of an independent pharmacist, wouldn't it?

A. I disagree. We negotiate our contracts regularly.

Q. So you go in and you change the contracts for that independent pharmacy even though the PSAO has already put it in place?

A. I misunderstood your question. No. The PSAO has been assigned or selected by an individual pharmacy in this case to negotiate on their behalf. And so the contract that would be negotiated or on the table for negotiation would be that that's held between the PSAO and Express Scripts.

Q. So an independent pharmacist who doesn't have a PSAO, they are not going to have any power here, right?

A. Oh, no. I disagree. So we have 50-some in Arkansas that aren't affiliated with a PSAO. And those that are positioned in the more rural communities, they absolutely have, you know, amazing leverage. We

need them. We want them in our network. I have access standards that I'm held to with my client base. [175] I can't opt not to do business with them. So they have tremendous leverage in negotiation.

Q. You would agree that just – that doesn't make sense?

A. I'm sorry?

Q. If a local independent pharmacist wants to negotiate with one of the world's largest – in fact, the largest pharmacy benefits manager, what incentive really does ESI have to work with them?

A. I'm required in contract with clients to meet a certain access. If there are pharmacies that are in business in rural communities, I'm responsible for having them in network. There's access standards that we have to meet in order to continue to do business. So not just from a client perspective, but also in the Medicare space – I'm not sure if you're familiar with the CMS standards that are set. If there are pharmacies in rural communities, you know, we have to have them in network. And so they have tremendous leverage, even with the world's largest PBM, to negotiate favorable terms and conditions.

Q. And so with respect to appeals, if they get an appeal denied and appeal it with you, do you listen to them?

A. I listen to them all.

Q. Do you reject their appeal, or do you grant it?

A. It depends on the circumstances.

Q. If your MAC cost is below theirs, you reject it, right?

[176] A. If my MAC price is set below what they can acquire?

Q. Yes.

A. No, not unilaterally, of course not.

Q. I thought that was what this whole issue behind the General Assembly's actions here were. If that pharmacist is taking a negative reimbursement, and you claim that you've negotiated with them with this great contract, and they appeal with you a negative reimbursement, you're saying you grant it?

A. In some cases, sure.

Q. Even though your MAC is higher?

A. It's on a case-by-case basis, Mr. Johnson.

Q. Excuse me. I misspoke. Even though your MAC is lower?

A. It's on a case-by-case basis. So, you know, we're using the number of appeals to gauge: Is the pricing right? Is the pricing not right? So it really is on a case-by-case basis. Before Act 900, that's how – and in every other state in the country, that's how we're operating.

Q. How many staff at ESI are dedicated to negotiating with independent pharmacies?

A. Oh, probably five.

Q. For the country?

A. Yes.

Q. And there's 700 in Arkansas?

A. 700 independent – no, 700 in total.

Q. In total. How many independents?

[177] A. Roughly 400.

Q. And multiplied across the country, you have five people who negotiate with all of these pharmacies and provide them terms that they want?

A. So it's important to step back a moment. So 25,000 independent pharmacies in America. 20,000 are represented by PSAOs. So they've elected some other entity to negotiate on their behalf. So true independent unaffiliated, about 5,000 in the country.

Q. And those five people are also working with the PSAOs in negotiating as well?

A. Yes.

Q. It's a lot of contracts, isn't it?

A. It is a tremendous amount.

MR. JOHNSON: Your Honor, I pass the witness.

THE COURT: Redirect?

MR. RICHLIN: No questions, Your Honor.

THE COURT: You can stand down.

Let's do this. Let's take ten minutes, and come back at 4:30, and we'll begin with the next.

(Recess from 4:19 p.m. until 4:33 p.m.)

THE COURT: All right. Call your next witness.

MS. DENEKE: Melanie Kracke, Your Honor.

THE COURT: All right. Raise your right hand so we can get you sworn in.

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
LITTLE ROCK DIVISION

No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity
as Attorney General of Arkansas

Defendant.

ANSWER

Comes now Arkansas Attorney General Leslie Rutledge, by and through counsel, and for her Answer to Plaintiff's Complaint, states the following:

1. Deny that Act 900 of 2015 was passed by the Arkansas General Assembly and signed into law by the Governor only to regulate pharmacy benefits managers ("PBM") as Act 900 was passed in order to protect the public health of Arkansas citizens. Admit that Act 900 of 2015 went into effect on July 22, 2015. To the extent that Paragraph 1 contains additional allegations, those allegations are denied.
2. Deny the allegations contained in Paragraph 2.
3. Deny the allegations contained in Paragraph 3.
4. Paragraph 4 contains allegations that summarize Plaintiff's legal claims. As such, there are no factual averments that merit a response. Accordingly, to the extent that Paragraph 4 may be construed to

contain allegations against Defendant, those allegations are denied.

5. Admit that the Court has subject matter jurisdiction over the official-capacity claims for prospective injunctive relief, but deny any liability as to same. The remaining allegations contained in Paragraph 5 are denied.

6. Admit the allegations contained in Paragraph 6.

7. Admit the allegations contained in Paragraph 7.

8. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 8, and therefore, those allegations are denied.

9. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 9, and therefore, those allegations are denied.

10. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 10, and therefore, those allegations are denied.

11. Deny the allegations contained in Paragraph 11.

12. Deny the allegations contained in Paragraph 12.

13. Deny the allegations contained in Paragraph 13.

14. Deny the allegations contained in Paragraph 14.

15. Admit the allegations contained in Paragraph 15, but deny any liability of the Attorney General or the State of Arkansas in this matter.

16. Admit that the Attorney General has authority to enforce the Arkansas Deceptive Trade Practices Act

(Ark. Code Ann. § 4-88-101, *et seq.*), but deny the remaining allegations of Paragraph 16.

17. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 17, and therefore, those allegations are denied.

18. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 18, and therefore, those allegations are denied.

19. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 19, and therefore, those allegations are denied.

20. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 20, and therefore, those allegations are denied.

21. Deny the allegations contained in Paragraph 21.

22. Admit that retail pharmacies are reimbursed by pharmacy benefits managers on drugs dispensed from drug supplies obtained by the retail pharmacies from wholesalers. Deny the remaining allegations contained in Paragraph 22.

23. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 23, and therefore, those allegations are denied.

24. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 24, and therefore, those allegations are denied.

25. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 25, and therefore, those allegations are denied.

26. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 26, and therefore, those allegations are denied.

27. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 27, and therefore, those allegations are denied.

28. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 28, and therefore, those allegations are denied.

29. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 29, and therefore, those allegations are denied.

30. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 30, and therefore, those allegations are denied.

31. Admit that Senate Bill 688 was passed by both houses of the Arkansas General Assembly and became Act 900 of 2015. Deny that members of the General Assembly did not study or consider SB 688's potential consequences or provisions. To the extent that Paragraph 31 contains additional allegations, those allegations are denied.

32. Admit the allegations contained in Paragraph 32.

33. Admit that the language of Act 900 of 2015 (as codified in Ark. Code Ann. § 17-92-507) speaks for itself. Deny that the five listed changes at Paragraph 33(a) thru (e) constitutes an exhaustive list of Act 900's alterations to existing law, especially in view of the fact that Plaintiff omits from the list a provision from Act 900 that prohibits PBMs from reimbursing "a pharmacy or pharmacist in this state an amount less than the amount that the [PBM] reimburses a [PBM] affiliate for providing the same pharmacist services." Ark. Code Ann. § 17-92-507(d)(1). To the extent that Paragraph 33 contains additional allegations, those allegations are denied.

34. Admit that a violation of Act 900 of 2015 constitutes a violation of the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, *et seq.* Deny the remaining allegations contained in Paragraph 34.

35. Admit that the language Act 900 of 2015 speaks for itself. To the extent that Paragraph 35 contains additional allegations, those allegations are denied.

36. Admit that the Attorney General's Office composed a letter in July 2015 to PBMs explaining the provisions of Act 900 of 2015 and that the contents of the letter speak for itself. To the extent that Paragraph 36 contains additional allegations, those allegations are denied.

37. Admit that the Attorney General's Office composed a letter in July 2015 to PBMs explaining the provisions of Act 900 of 2015 and that the contents of the letter speak for itself. Deny the Plaintiff's assertion that the Attorney General's July 2015 correspondence expressed any retroactive application of Act 900.

To the extent that Paragraph 37 contains additional allegations, those allegations are denied.

38. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 38, and therefore, those allegations are denied.

39. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 39, and therefore, those allegations are denied.

40. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 40, and therefore, those allegations are denied.

41. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 41, and therefore, those allegations are denied.

42. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 42, and therefore, those allegations are denied.

43. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 43, and therefore, those allegations are denied.

44. Deny the allegations contained in Paragraph 44.

45. Deny the allegations contained in Paragraph 45.

46. Deny the allegations contained in Paragraph 46.

47. Defendant is without sufficient information with which to admit or deny the allegations contained

in Paragraph 47, and therefore, those allegations are denied.

48. Defendant is without sufficient information with which to admit or deny the allegations contained in Paragraph 48, and therefore, those allegations are denied.

49. Deny the allegations contained in Paragraph 49.

50. Deny the allegations contained in Paragraph 50.

51. Admit that Act 900 of 2015 requires a PBM to grant an appeal when acquisition cost of a drug exceeds the MAC reimbursement for that drug, but deny the remaining allegations of Paragraph 51.

52. Deny the allegations contained in Paragraph 52.

53. Deny the allegations contained in Paragraph 53.

54. To the extent that Paragraph 54 contains factual allegations, those allegations are denied.

55. Admit that the provisions of the ERISA law speak for themselves. Any other allegations contained in Paragraph 55 are denied.

56. Admit that the provisions of the ERISA law speak for themselves. Any other allegations contained in Paragraph 56 are denied.

57. Deny that Act 900 of 2015 “relates to” and employee benefit plan. To the extent that Paragraph 57 contains additional allegations, those allegations are denied.

58. Deny the allegations contained in Paragraph 58.

59. Deny the allegations contained in Paragraph 59.

60. To the extent that Paragraph 60 contains factual allegations, those allegations are denied.

61. Admit that the provisions of the Medicare Modernization Act and cases interpreting it speak for themselves. To the extent that Paragraph 61 contains factual allegations, those allegations are denied.

62. Admit that the provisions of the Medicare Modernization Act and cases interpreting it speak for themselves. To the extent that Paragraph 62 contains factual allegations, those allegations are denied.

63. Admit that the provisions of the Medicare Modernization Act and cases interpreting it speak for themselves. To the extent that Paragraph 63 contains factual allegations, those allegations are denied.

64. Deny the allegations contained in Paragraph 64.

65. Deny the allegations contained in Paragraph 65.

66. Deny the allegations contained in Paragraph 66.

67. To the extent that Paragraph 67 contains factual allegations, those allegations are denied.

68. Admit that the United States Constitution and the cases interpreting it speak for themselves. To the extent that Paragraph 68 contains additional factual allegations, those allegations are denied.

69. Deny the allegations contained in Paragraph 69.

70. Deny the allegations contained in Paragraph 70.

71. Deny the allegations contained in Paragraph 71.

72. Deny the allegations contained in Paragraph 72.

73. Deny the allegations contained in Paragraph 73.

74. Deny the allegations contained in Paragraph 74.

75. To the extent that Paragraph 75 contains factual allegations, those allegations are denied.

76. Admit that the United States Constitution and the cases interpreting it speak for themselves. To the extent that Paragraph 76 contains additional factual allegations, those allegations are denied.

77. Deny the allegations contained in Paragraph 77.

78. Deny the allegations contained in Paragraph 78.

79. Deny that Act 900 of 2015 constitutes a “contract adjustment” to PBM relationships with health plans. Deny the remaining allegations of Paragraph 79.

80. Deny the allegations contained in Paragraph 80.

81. To the extent that Paragraph 81 contains factual allegations, those allegations are denied.

82. Admit that the Arkansas Constitution and the cases interpreting it speak for themselves. To the extent that Paragraph 82 contains additional factual allegations, those allegations are denied.

83. Deny the allegations contained in Paragraph 83.

84. Deny the allegations contained in Paragraph 84.

85. Deny that Act 900 of 2015 constitutes a “contract adjustment” to PBM relationships with health plans. Deny the remaining allegations of Paragraph 85.

86. Deny the allegations contained in Paragraph 86.

87. To the extent that Paragraph 87 contains factual allegations, those allegations are denied.

88. Admit that the United States Constitution and the cases interpreting it speak for themselves. To the extent that Paragraph 88 contains additional factual allegations, those allegations are denied.

89. Deny the allegations contained in Paragraph 89.

90. Deny the allegations contained in Paragraph 90.

91. Deny the allegations contained in Paragraph 91.

92. To the extent that Paragraph 92 contains factual allegations, those allegations are denied.

93. Admit that the Arkansas Constitution and the cases interpreting it speak for themselves. To the extent that Paragraph 93 contains additional factual allegations, those allegations are denied.

94. Deny the allegations contained in Paragraph 94.

95. Defendant denies each and every allegation that is not specifically admitted in this Answer.

96. Defendant specifically denies that Plaintiff is entitled to any relief whatsoever.

- a. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 is preempted by the ERISA;
- b. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 is preempted by the Medicare Modernization Act;
- c. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 violates the Commerce Clause of the United States Constitution;
- d. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;

- e. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 violates the Due Process Clause of the Arkansas Constitution;
- f. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 violates the Contracts Clause of the United States Constitution;
- g. Defendant specifically denies that Plaintiff is entitled to a declaration that Act 900 of 2015 violates the Contracts Clause of the Arkansas Constitution;
- h. Defendant specifically denies that Plaintiff is entitled to a permanent injunction prohibiting the State of Arkansas from enforcing Act 900 of 2015;
- i. Defendant specifically denies that Plaintiff is entitled to a preliminary injunction prohibiting the State of Arkansas from enforcing Act 900 of 2015;
- j. Defendant specifically denies that Plaintiff should be awarded attorney fees and costs;
- k. Defendant specifically denies that Plaintiff is entitled to any other form of relief.

DEFENSES

Aside from the averments pled by Defendant above, Defendant additionally pleads the following:

1. The Court lacks subject matter jurisdiction over any official-capacity claims for any relief other than prospective injunctive relief.
2. Plaintiff has failed to state a claim for relief.

3. To the extent that any official-capacity claims are construed in Plaintiff's Complaint, Defendant is entitled to sovereign immunity.

4. To the extent that any individual-capacity claims are construed to exist in Plaintiff's Complaint, Defendant is entitled to qualified immunity.

5. Plaintiff's claims are barred by the equitable defenses of waiver, laches, and estoppel.

6. Defendant specifically assert and reserve the right to file an amended answer or other appropriate pleadings and to allege any additional affirmative defenses that might be available to her after she has had further opportunity to investigate the allegations set forth in Plaintiff's Complaint.

JURY DEMAND

1. Defendant demands a trial by jury.

WHEREFORE, the Attorney General prays that Plaintiff's Complaint is dismissed and for all other just and proper relief to which she is entitled.

Respectfully submitted,

Leslie Rutledge
Attorney General

By: /s/ Shawn Johnson

Arkansas Bar No. 2004181
Assistant Attorney General
Attorney for Defendant
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Telephone: (501) 682-1178
Facsimile: (501) 682-8118
shawn.johnson@arkansasag.gov

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity as
Attorney General of the State of Arkansas
Defendant.

DECLARATION OF MELANIE KRACKE

I, Melanie Kracke, am over 18 years of age and hereby declare as follows:

1. I am the Manager of Pharmacy Network Pricing for Prime Therapeutics LLC (“Prime”). Prime is a member of the Pharmaceutical Care Management Association (“PCMA”), and I submit this declaration in support of PCMA’s motion for preliminary injunction. Except as otherwise indicated, all facts set forth in this declaration are based of my personal know-ledge. If I were called upon as a witness, I could and would competently testify to the facts set forth below on that basis.
2. My duties include managing Prime’s drug pricing analysts that develop MAC pricing used in our contracts with pharmacies and customers.
3. Prime is a pharmacy benefits manager (“PBM”), As a PBM, Prime administers prescription drug benefit plans on behalf of plan sponsors (i.e., insurance plans and self-insured employers) across the United States. It provides plan sponsors with core pharmacy benefit

management services, including creation, administration and maintenance of networks of pharmacy providers; formulary management; clinical services such as disease management programs; assistance in benefit plan design and administration; negotiations with pharmaceutical manufacturers for discounts on drugs; plan member customer service; specialty pharmacy and mail service pharmacy operation.

Prime's Customer Contracts

4. Prime's PBM customers are not individual consumers, but rather are the plans, employers, government entities, insurance companies, managed care organizations such as health maintenance organizations ("HMOs"), and third-party administrators with which customers contract. Those customers include Medicare Part D plans and ERISA plans, as well as plans offered on health care exchanges. Some of Prime's customers are subject to Act 900, while others are not. Although Prime's customers are insurers, Prime is not itself engaged in any insurance related functions, most notably bearing risk.

5. Securing customer contracts is extremely competitive. Typically, customer contracts are won through a competitive bidding process in which Prime and other PBMs submit bids in response to requests for proposals to a prospective customer. Prime has no access to the contents of its competitors' bids while developing its bids. The PBMs compete on both financial and service terms.

6. Prime's customer contracts are transparent regarding pricing. For example, the majority of Prime's customer contracts are "pass-through," meaning that the price that a pharmacy is reimbursed for

any particular prescription is the same price that the plan is charged.

7. Customer contracts include various guarantees related to pricing and service. Many of these contracts contain escalating guarantees that require improved performance over time. Pricing guarantees can be term-by-term or in the aggregate, and rely substantially on the assumption that the MAC program that Prime has negotiated with pharmacies will be used. Prime uses pharmacy networks to ensure adequate pharmacy access, coverage and price for its customers. Prime offers its customers access to a network of pharmacies, with which the PBM has negotiated particular service levels and prices. Prime requires pharmacies within its networks to fill prescriptions when the members of a customer's plan attempt to fill them.

8. Prime's pharmacy networks meet all Medicare Part D accessibility requirements.

9. Prime's customer contracts are individually negotiated and do not employ a standard set of terms and conditions. The termination and expiration provisions of each contract vary from customer to customer. Some contracts include automatic renewal provisions, while others require extensive renegotiation at the end of the contract's term. Customer contract terms vary, but most range from one year to several years. All of Prime's customer contracts are highly confidential.

MAC pricing

10. Maximum Allowable Cost or MAC pricing governs the pricing of generic drugs covered by a plan sponsor's drug benefit. "MAC lists" are lists of drug products that are priced using MAC. Most of Prime's

MAC lists address more than a thousand unique products.

11. MAC list development and pricing is highly sensitive and confidential. Prime has numerous employees working full-time on its MAC team. That team relies upon material from a number of sources, including wholesalers and data published by CMS for public programs such as Medicaid.

12. Prime does not have access to list prices used by wholesalers to sell drugs to any particular pharmacy unless the pharmacy provides that information. Even though Prime receives some information from wholesalers, it has no way of knowing whether the prices on its wholesaler list are the same prices offered to any particular pharmacy, because pricing terms between pharmacies and wholesalers depend on the contract between those parties, to which Prime is not a party and has no access. Pharmacies contracting with Prime are under no obligation to share their acquisition cost except to submit a MAC appeal.

13. Prime treats its MAC information as highly confidential. Within the company, access to the MAC information is on a need-to-know basis. Pharmacy contracts allow pharmacies to access MAC prices on a drug-by-drug basis only through a Prime secure website. Pharmacy contracts include confidentiality provisions that provide that reimbursement information, including MAC, is highly confidential.

14. Even more sensitive is the methodology that Prime uses to create the MAC pricing. No external person can access it – not the pharmacy, and not the client for which the MAC list is created. Only Prime employees who are members of the MAC team have access to the MAC calculation models.

15. Prime currently maintains multiple MAC lists. Each customer typically uses one of the lists, and some are tailored to specific clients.

16. The same MAC list applies whether a customer's members live in Arkansas and work there, live in Arkansas and work elsewhere, live elsewhere and work in Arkansas, or live and work outside of Arkansas.

17. MAC information is updated frequently as a result of market forces.

Pharmacy Contracts

18. Prime contracts with pharmacies to ensure that its customers can access prescription drugs at those pharmacies. In exchange for the larger volume of prescription drug sales that comes from joining Prime's pharmacy network, pharmacies agree to certain service standards set by Prime.

19. Pharmacies contracting with Prime must go through a credentialing process. Pharmacies can enroll as a chain, true independent pharmacy, or independent pharmacy affiliated with a pharmacy-services administrative organization ("PSAO").

20. Pharmacy contracts provide the means by which Prime reimburses its pharmacies. For generic drugs, reimbursement is set by whatever MAC list applies to the customer or by a contracted non-MAC generic discount the pharmacy agrees to in the contract.

21. Prime has an interest in pharmacies doing well and staying in business.

22. Prime's pharmacy contracts provide for an appeals process in which a pharmacy submits its invoice to initiate further review of the drug price. This

process is another step in Prime's ongoing work to ensure its MAC lists reflect overall current market conditions.

Effects of Act 900

23. Under Act 900, Prime will have to grant any pharmacy reimbursement or MAC appeal in which the pharmacy can show that the MAC/reimbursement is lower than its acquisition cost as listed on its wholesaler invoice.

24. In other states that have passed laws regulating MAC, Prime has seen a massive increase in appeals across its commercial business and an even greater increase in appeals across its Medicare business in those states. Prime anticipates that Act 900 will cause an even larger increase in appeals because it guarantees that appealing pharmacies will be able to reverse and re-bill for a payment of their acquisition costs or higher.

25. On or about June 14, 2015, Prime received a letter from Arkansas' Attorney General. A true and accurate copy of that letter is attached as Exhibit I to this Declaration.

26. Prime made pricing guarantees to its own customers. The guaranteed pharmacy acquisition cost provisions of Act 900 likely will result in Prime falling short of some of those guarantees and paying extra contractual fees and penalties as a result. Prime estimates that its cost of doing business in Arkansas will increase as a result of these penalties.

27. Act 900 allows a pharmacy to refuse to fill a prescription if it will not receive a reimbursement for at least its acquisition cost for that prescription. This provision will prevent Prime from meeting service-

related guarantees to its customers. Prime made guarantees that customers' members would be able to fill their prescriptions at certain pharmacies. Those guarantees were made in reliance on Prime's contracts with pharmacies, which provide that pharmacies may not discriminate against persons to whom they are providing pharmacy services, and that they may not refuse services to eligible persons on the basis of how much they will be reimbursed.

28. This provision also exposes Prime to potential grievances that could be filed by Medicare Part D members against Prime.

29. Finally, Act 900 requires PBMs to update their MAC lists "on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state."

30. Prime has no way of knowing when its obligation to update its MAC list is triggered under this provision. Prime does not know and has no means of learning which pharmaceutical wholesalers doing business in Arkansas have increased pharmacy acquisition costs or by how much.

31. The only knowledge Prime would have regarding wholesaler pricing in Arkansas is via information provided by an Arkansas pharmacy, and it has no means of determining what number of wholesalers constitute "60% or more of the pharmaceutical wholesalers in the state." And, even if it could access empirical data about which wholesalers did business in Arkansas, it could not determine when those wholesalers were raising pharmacy acquisition cost.

32. Because Prime has no reliable way of conforming to the MAC update provisions of Act 900, it is exposed to significant uncertainty about its ability to operate in the Arkansas market. This will affect not only Prime's ability to provide services to Arkansas residents and employees, but also its ability to provide services in other states. This is because Prime's contracts with its customers are not constructed on a state-by-state basis, and many contracts cover lives both in and outside of Arkansas. Inability to do business in Arkansas would therefore likely have a negative effect on the business of those plans outside of the state.

33. In addition, Act 900 will affect Prime's ability to serve its customers whose members work outside of Arkansas but, because they reside or travel in Arkansas, seek to fill a prescription at a pharmacy in Arkansas. Because the members served by Prime's customers are mobile, and those who are employed outside of Arkansas may fill a prescription in Arkansas, Prime must account for the new Arkansas requirements in contracting its services for every employer nationwide.

34. For example, an employer that operates exclusively out of Memphis, Tennessee and does not conduct any business in the State of Arkansas would have to adjust its employee benefit plan for any employees that choose to live across the state line in Arkansas. This employer, operating exclusively in Tennessee, would not be able to access the full negotiated benefits of MAC pricing because its employees crossed state lines to fill their prescriptions.

35. In another example, a pharmacist could refuse to provide services to a traveler from out of state trying to fill a prescription in Arkansas, because the trav-

eler's benefit plan includes a MAC list that would reimburse the pharmacy at less than the pharmacy acquisition cost (i.e. a reimbursement a rate that is permissible in 49 other states). The only way for Prime to avoid this would be to conform all MAC lists nationwide to the Arkansas requirements, or to provide every member in the country a different MAC list when they fill prescriptions in the State of Arkansas.

36. Prime is also concerned about the financial impact that Act 900 will have on its customers and their members. Act 900's new requirements essentially force Prime to pay higher prices for generic drugs. In the short term, all of these costs will be passed along to Prime's customers under their contracts. For those customers' members who have co-insurance or still have a deductible to satisfy, those increased costs will be felt immediately at the pharmacy counter, because they have to pay a percentage of whatever the drug costs.

37. In the long term, Prime expects that the generic price increases driven by Act 900 will cause customers to raise their premium prices for health plans subject to Act 900, compared to health plans not subject to the law

38. The changes that Prime must make to its practices in the State of Arkansas to comply with the new requirements of Act 900 will result in both increased costs and drastically increased administrative and operational burdens.

39. Act 900 requires retroactive payment generally as a remedy to a claims appeal, and increases the potential number of claims appeals by giving the pharmacies the option to appeal each and every claim for which they are not paid at least their acquisition cost.

40. These appeals will impose a significant administrative burden on Prime. For every appeal that it denies, Prime will have to provide the pharmacy with a National Drug Code (“NDC”) number and the name of a national or regional pharmaceutical wholesaler operating in Arkansas that currently has the drug in stock at price below MAC. Prime has no way of obtaining the information, especially on an accurate and timely basis, regarding which wholesalers have which drugs in stock at which prices. It is Prime’s experience that wholesalers will not reliably or routinely share such information for Prime’s purpose, because sharing such information might disadvantage the wholesaler. In addition, if the NDC number for the drug provided by Prime is not available at or below pharmacy acquisition cost from the pharmaceutical wholesaler from which the pharmacy or pharmacist purchases the majority of prescription drugs, then Prime needs to adjust the MAC to be above the challenging pharmacy’s acquisition cost. This will require Prime to conduct significant inquiry into the purchasing activity of every pharmacy that brings an unsuccessful appeal in order to determine that the majority of that pharmacy’s prescription drugs are purchased from said wholesaler. It might also require Prime to adjust the price on Prime’s MAC list that is used by multiple pharmacies across the country, instead of just for the appealing pharmacy, since Prime does not have pharmacy specific MAC list pricing.

41. Prime supports PCMA bringing this action on its behalf.

I declare under penalty of perjury that the foregoing is true and correct. Executed on July 20, 2015.

/s/ Melanie Kracke
NAME

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity as
Attorney General of the State of Arkansas,

Defendant.

DECLARATION OF AMY BRICKER

I, Amy Bricker, am over 18 years of age and hereby declare as follows:

1. I am the Vice President of Pricing, Supply Chain Economics for Express Scripts, Inc. (“Express Scripts”). Express Scripts is a member of Pharmaceutical Care Management Association (“PCMA”), and I submit this declaration in support of PCMA’s motion for preliminary injunction. Except as otherwise indicated, all facts set forth in this declaration are based on my personal knowledge. If I were called upon as a witness, I could and would competently testify to the facts set forth below on that basis.

2. My duties include oversight of Express Script’s retail pharmacy pricing, including MAC pricing. I also have a general understanding of Express Scripts’ client contracts.

3. Express Scripts is a pharmacy benefits manager (“PBM”). As a PBM, Express Scripts administers prescription drug benefit plans on behalf of plan sponsors (i.e., insurance plans and self-insured employers) across the United States. Express Scripts provides

plan sponsors with core pharmacy benefit management services, including but not limited to the creation, administration and maintenance of networks of pharmacy providers.

Express Scripts' Customer Contracts

4. Express Script's PBM customers are not individual consumers, but rather are the plans, employers, government entities, insurance companies, managed care organizations such as health maintenance organizations ("HMOs"), and third-party administrators with whom Express Scripts contracts. Those customers include Medicare Part D plans and ERISA plans.

5. Express Scripts provides pharmacy benefit management services to thousands of members in Arkansas. In 2014, approximately 5.7 million retail claims were processed in the state of Arkansas.

6. Express Scripts' customer contracts are individually negotiated and can include a variety of terms and conditions. The termination and expiration provisions of each contract vary from customer to customer. The terms and conditions of Express Scripts' client contracts are confidential in nature.

7. Customer contracts include various guarantees related to pricing and services, including pricing guarantees relating to generic drugs. Customer contract terms vary, but most range from one year to five years or more.

MAC pricing

8. Maximum Allowable Cost or MAC pricing is a contractually agreed upon reimbursement mechanism applied to generic drugs reimbursed by Express Scripts. "MAC lists" are a list of drug products and

their respective pricing. MAC lists can address thousands of unique products.

9. MAC is critical to Express Scripts' ability to provide its customers with the low prices for generic drugs and to encourage pharmacy providers to seek out the most competitive acquisition pricing from their wholesalers for their drugs.

10. MAC list development is highly sensitive and confidential, and uses numerous resources, Express Scripts employs dozens of people on its MAC team. That team relies upon material from a number of confidential data sources when determining MAC pricing.

11. MAC pricing is not tied to pharmacy acquisition cost. Moreover, Express Scripts does not have access to the acquisition cost of any particular pharmacy because acquisition cost is based on the individual pharmacies contractual relationship with its wholesalers and suppliers. Express Scripts is not a part of those transactions.

12. In addition, acquisition cost is not necessarily the same as what is listed on a pharmacy's invoice from a wholesaler. Wholesaler list prices routinely exceed the actual acquisition costs incurred by pharmacies in obtaining those drugs due to various discounts, including rebates and post purchase discounts,

13. Because Express Scripts does not have access to the acquisition costs for every network pharmacy, pharmacies contracting with Express Scripts may make a higher profit margin on some drugs and less on others. Rarely, a drug may be priced lower than the pharmacies actual acquisition cost but, on balance, the pharmacy makes up the difference on other claims and remains profitable considering the pharmacy's entire "market basket."

14. Express Scripts treats its MAC lists as highly confidential and proprietary. Within the company, access to the list is on a need-to-know basis. Pharmacy contracts allow pharmacies to access static copies of MAC lists on a confidential basis.

15. Even more sensitive is the methodology that Express Scripts uses to create the MAC lists. Express Scripts limits access to the methodology,

16. Normally, a MAC list does not take into account whether a client's beneficiaries live in Arkansas and work there, live in Arkansas and work elsewhere, live elsewhere and work in Arkansas, or live and work outside of Arkansas.

17. MAC lists are updated as often as daily as a result of market dynamics.

Pharmacy Contracts

18. Express Scripts contracts with pharmacies to ensure that its clients' members can easily access prescription drugs at network pharmacies. In exchange for the larger volume of prescription drug sales that comes from joining Express Scripts' network, pharmacies agree to pricing terms and service standards.

19. Pharmacy contracts provide the means by which Express Scripts reimburses its pharmacies. For generic drugs, pharmacies generally contractually agree to be reimbursed using MAC.

20. Pharmacy claims processing generally happens in real time at the point of sale. Pharmacies are messaged member out-of-pocket or copayment amounts and what the pharmacy will receive as payment for the dispensed medication, in addition to other clinical and informational messaging.

21. Express Scripts' pharmacy contracts provide for an appeals process in which pharmacies can request the review of a specific MAC price for a particular transaction. The MAC appeal process has been in place since prior to the enactment of Act 1194 of the 2013 Regular Session.

22. The pharmacy contracts also include requirements relating to service. For example, pharmacies are not permitted to deny access to a member. Instead, pharmacies are contractually required to dispense drugs to members and direct any issues or concerns to Express Scripts. This is included in the contract to ensure members are not put in the middle of contractual disputes.

Effects of Act 900

23. Under Act 900, Express Scripts will have to grant any pharmacy reimbursement or MAC appeal where the pharmacy can show that the reimbursement it received is lower than its acquisition cost as listed on its wholesaler invoice.

24. As a result, of that appeals process, Express Scripts loses the contractual ability to apply MAC in a predictable way and incentivize pharmacies to seek the most competitive wholesalers and suppliers. Act 900 supersedes the contractually agreed upon terms and imposes its own pricing terms based only on pharmacy acquisition cost.

25. Express Scripts made pricing guarantees to its own customers based on its pharmacy contracts. By guaranteeing profit to pharmacies on all generic prescriptions, Act 900 will result in Express Scripts being unable to accurately predict and forecast generic pricing.

26. The vast majority of prescription drugs dispensed in the United States, including in Arkansas, are generics subject to MAC pricing. As a result, Express Scripts estimates that Act 900's requirements will cause a significant monetary impact to Express Scripts, its clients, and their members. Act 900 allows a pharmacy to refuse to fill a prescription if it will not receive a reimbursement for at least its acquisition cost for that prescription. This provision harms the beneficiaries of Express Scripts' customers' plans, which could have significant impact on the plans' customer satisfaction and, relatedly, on the customers' satisfaction with Express Scripts' services. It could also prevent Express Scripts from meeting service-related guarantees to its customers.

27. Act 900 requires PBMs to update their MAC lists "on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesaler doing business in the state."

28. Express Scripts has no way of knowing when this obligation is triggered because Express Scripts does not have visibility into the acquisition costs of individual pharmacies for specific drugs with specific wholesalers.

29. In addition, Act 900 will affect Express Scripts' clients located outside the state of Arkansas because their members may travel to Arkansas and fill a prescription or live in a bordering community.

30. Express Scripts is also concerned about the financial impact that Act 900 will have on its clients and their members. Act 900's new requirements essentially force Express Scripts to pay higher prices

for generic drugs. This will lead to higher prescription drug costs for health plans and eventually higher out of pocket or premium costs for members of health plans subject to Act 900, compared to health plans not subject to that law.

31. The changes that Express Scripts must make to its practices in the State of Arkansas, result in both increased costs and drastically increased administrative and operational burdens.

32. Act 900 requires retroactive payment generally as a remedy to a claims appeal and extends the time limit that pharmacies have for filing MAC appeal. In practice, because pharmacies may bring their appeals at least seven business days after the claim is originally made, such awards of retroactive payment will occur long after the sale is made at the pharmacy counter and long after the customer has paid her copay or her deductible has been calculated. Express Scripts thus must incur significant administrative and operational burdens to alter a multi-party transaction weeks, months, or even years after that transaction has occurred.

33. Express Scripts anticipates that it will have to retain one or two additional full-time equivalent employees solely to manage the Arkansas-specific MAC lists that are necessary as a result of Act 900.

34. Express Scripts supports PCMA in filing the instant action on its behalf.

I declare under penalty of perjury that the foregoing is true and correct. Executed on July 20, 2015.

/s/Amy Bricker
NAME

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity as
ATTORNEY GENERAL OF THE STATE OF ARKANSAS;

Defendants.

DECLARATION OF PROFESSOR
DAVID A. HYMAN

I, David A. Hyman, am over 18 years of age and hereby declare as follows:

1. I make this declaration based upon my own personal knowledge, except where stated to be on information and belief, and with respect to any such statements, I believe them to be true. If called upon to testify, I could competently testify to such facts.

I. Expertise and Scope

2. I am a chaired professor of law and professor of medicine at the University of Illinois. Most of my academic scholarship is on the regulation of health care financing and delivery, with a particular focus on competition law and policy. A copy of my c.v. is attached as Exhibit A. My c.v. includes all publications that I have authored from January 1, 2004 to the present.

3. During 2001-2004, I served as Special Counsel at the Federal Trade Commission (“FTC”), where I was project leader and principal author of the report jointly issued by the FTC and Department of Justice (“DOJ”),

“Improving Health Care: A Dose of Competition” (2004). The report built on twenty-seven days of hearings held throughout 2003, and a two-day workshop held in 2002. While at the FTC, I worked on a number of other projects as well, including advocacy letters directed at bills being considered in Rhode Island and California that related to PBMs and pharmaceutical pricing.

4. I was previously retained as an expert by PCMA in connection with litigation in Iowa involving the regulation of MAC pricing. I was also retained as an expert by counsel for the states of Alaska, Idaho, and Kentucky, in litigation in each of those states involving pharmaceutical pricing. A list of the relevant courts, case names, and docket numbers of those matters is attached as Exhibit B. I have also been retained as an expert in various other matters involving health law & policy.

5. I have been asked to address certain aspects of the U.S. pharmaceutical market structure; the role of pharmacy benefit managers (“PBMs”) in that market; the use of maximum allowable cost (“MAC”) provisions by PBMs and other public and private payers; and the likely impact of Arkansas Senate Bill 688, which became Act 900, on employers, employee benefit plans, and PBMs. The statements expressed in this declaration are based on relevant material that I have reviewed, a list of which is attached hereto as Exhibit C, as well as my education, training, experience, and research. My understanding is that I will be compensated at a rate of \$500 per hour for my work in this matter.

II. Background on Pharmaceutical Markets

6. Prescription pharmaceuticals come in two principal types: branded and generic. Both must be approved by the Food and Drug Administration (“FDA”) in order to be sold in the United States. Branded pharmaceuticals are typically subject to patent protection. The FDA lists approved pharmaceuticals, their generic equivalents, and all associated patents in what is commonly known as the “Orange Book.”¹ Generics must be shown to be bioequivalent to the branded drug to appear in the Orange Book.

7. The Hatch-Waxman Act (Hatch-Waxman) creates a framework encouraging generic entry.² Among other provisions, Hatch-Waxman provides a 180-day period of market exclusivity for the generic drug manufacturer that files the first request for approval (i.e., an Abbreviated New Drug Approval (“ANDA”)) with the FDA.³ For many generic drugs, this means that during

¹ The technical name for the “Orange Book” is “Approved Drug Products with Therapeutic Equivalence Evaluations.” The Orange Book gets its name from the color of the cover page when it was published in hard copy in October, 1980. FDA personnel chose the color because of the proximity of publication to Halloween. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>

² The Hatch-Waxman Act’s is also known as the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417.

³ To secure this marketing exclusivity, the generic drug company must also file what is known as a “paragraph IV certification,” which constitutes notice that the generic drug company believes the patent listed in the Orange Book is invalid, or will not be infringed by the generic drug. The generic drug company may also file a Paragraph I certification (no relevant patent is listed in the Orange Book); a Paragraph II certification (the listed

the six months after the first generic enters, there is a duopoly. After that period, other generics can enter the market, as long as the manufacturer obtains FDA approval by demonstrating bio-equivalence. Hatch-Waxman has substantially increased the availability of generic alternatives, resulting in lower drug prices.⁴ Currently, generics account for approximately 85% of filled prescriptions nationwide.

8. In general, the more generics that are available, the lower the price at which the drug can be purchased by pharmacies. However, pricing is volatile, and various supply-side and demand-side factors can affect pricing.⁵ That said, for any given pharmaceutical, the price per dispensed unit will be lower – usually

patent has expired); or a Paragraph III certification (the listed patent will expire before the requested approval).

⁴ GAO, Drug Pricing: Research on Savings From Generic Drug Use, GAO 12-371R, Jan. 31, 2012, available at <http://www.gao.gov/assets/590/588064.pdf>

⁵ Of late, there has been a significant run-up in the cost of some generic drugs. These pricing increases appear to have multiple causes. See Jonathan D. Alpern, William M. Stauffer, and Aaron S. Kesselheim, *High-Cost Generic Drugs – Implications for Patients and Policymakers*, 371 *New Engl. J. Med.* 1859 (2014) (“Numerous factors may cause price increases for non-patent-protected drugs, including drug shortages, supply disruptions, and consolidations within the generic-drug industry.”)

The issue of consolidation within the generic drug industry has attracted increased attention; eight consumer groups recently sent a letter to the Federal Trade Commission requesting that it block a proposed merger between two major generic manufacturers because of concerns the merger would lead to increased prices. See *US. Consumer Groups oppose Teva bid for generic drug rival Mylan*, July 14, 2015, at <http://www.reuters.com/article/2015/07/14/us-mylan-m-a-teva-pharm-ind-idUSKCN0PO25U20150714>

substantially lower – once generic versions become available.

9. Pharmaceutical manufacturers do not sell their products directly to patients. Instead, their products are sold to wholesalers (e.g., Amerisource Bergen, Cardinal, and McKesson), who sell in turn to pharmacies. There are also direct sales between manufacturers and chain pharmacies, where the wholesaler either plays no role, or only provides warehousing and shipping services. Pharmacy services administrative organizations (“PSAOs”) provide a number of services to independent pharmacies, including arranging for direct sales between manufacturers and individual pharmacies.⁶ PSAs make it possible for independent pharmacies to compete with chain pharmacies on a more equal footing.

10. Medicare, Medicaid, insurers, and PBMs all play important roles in the market for pharmaceuticals. Medicare has historically accounted for a very modest share of pharmaceutical purchasing. Medicare Part B (which handles drugs that are dispensed directly by physicians) does not involve PBMs. However, as discussed in greater detail below, there are similarities in the evolution of Medicare’s payment system for these pharmaceuticals to those we observe for Medicaid, insurers, and PBMs. The adoption of Medicare Part D substantially increased Medicare’s share of prescription drug spending. Medicare Part D purchasing is generally structured around the insurer and PBM model that I describe in the balance of this

⁶ Government Accountability Office, Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations, GAO 13-176, Jan. 2013, available at www.gao.gov/assets/660/651631.pdf

declaration, so the same analysis applies to Medicare Part D as to insurers and PBMs.

11. When pharmacies dispense pharmaceuticals to individual Medicaid beneficiaries, they seek reimbursement from the state Medicaid agency. Similarly, when pharmacies dispense pharmaceuticals to insured individuals, they seek reimbursement from either a PBM (if the insurer or employer has contracted with the PBM to handle prescription drug coverage) or the insurer directly. Thus, when pharmacies dispense prescription pharmaceuticals, they are paid either solely by the consumer; solely by a payer; or by both (in the event the individual's insurance coverage requires them to make a co-payment at the point of purchase).

12. PBMs play an important role in structuring the market for the administration of prescription drug benefits. Among other things, PBMs process and pay prescription drug claims; create networks of pharmacies at which prescriptions will be filled for a specified price; operate mail order pharmacies; assist physicians with e-prescribing; design pharmaceutical benefits, create formularies; and negotiate for discounts or rebates. Insurers and employers that offer a prescription drug benefit must either handle such tasks themselves; contract with a PBM to have them done as a third-party administrator; or do without. Because PBMs aggregate the purchasing power of individual insurers/employers, they are often able to obtain better terms from wholesalers, drug manufacturers, and pharmacies than would be possible if the insurers/employers sought to handle these matters themselves.

13. Contracting for PBM services is complex. Among other items, contracts must specify whether arrangement is a "pass through" or a "lock-in" contract.

When the contract is priced on a pass-through basis, the PBM bears no responsibility for cost-over-runs relative to the original bid/contract. Instead, the costs are simply passed on to the employee benefit plan, along with the costs of administering the pharmaceutical benefit. Conversely, when the contract is priced on a lock-in basis, the PBM assumes the costs associated with over-runs relative to the original bid or contract. Contracts must also specify whether the PBM retains any rebates/discounts it secures, or must pass them through to the insurer/employer.

14. Public and private payers have experienced considerable difficulty in determining the “true” market price for dispensed pharmaceuticals, and have developed various strategies to determine the price they will pay when a prescribed pharmaceutical is dispensed. Medicaid provides a useful case study, because many of the techniques that are currently used by PBMs/insurers were developed and originally deployed by state Medicaid programs. States that participate in the Medicaid program must submit a plan to the federal government for approval. The plan must “provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.”⁷

⁷ 42 U.S.C. § 1396a(a)(30)(A) (“Section 30(A)”).

15. When states include prescription drug coverage in their Medicaid program, they must also comply with state and federal regulations that limit the amount that can be paid. The specifics evolved over time, but generally involved paying the lesser of the estimated acquisition cost (EAC) plus a reasonable dispensing fee, or the providers' usual and customary charges to the general public. The EAC was typically determined based on published prices – initially the Average Wholesale Price (“AWP”), and subsequently (at least in some states) the Wholesale Acquisition Cost (“WAC”). Pharmaceutical manufacturers set AWP and WACs for each of their products, for each dosage and number of dispensed units.

16. At one time, the AWP reflected the price at which pharmacists acquired drugs from wholesalers. But it quickly became apparent that there was considerable divergence between the AWP and pharmacies' true acquisition cost, particularly as generic drugs became more prevalent. Once it was clear that AWP did not reflect acquisition cost, it was necessary to modify Medicaid's reimbursement formula, to ensure the amounts being paid more closely reflected reality (i.e., the pharmacists' actual acquisition cost).⁸

17. In 1987, the federal government responded by requiring states to implement an aggregate Federal Upper Limit (“FUL”) on specific drugs.⁹ A FUL applies if there are at least two generic competitors to a branded drug, as determined through an administra-

⁸ In addition, pharmacies were typically paid a standard dispensing fee, which did not vary based on the acquisition cost. Thus, pharmacies were reimbursed for the costs they incurred in obtaining the prescription drug, plus a dispensing fee.

⁹ 42 C.F.R. sec. 447.301 et seq.

tive process. The FUL was determined mechanically, by multiplying 1.5 by the published price for the least costly therapeutic equivalent drug.¹⁰ Pursuant to the FUL, the dispensing pharmacy is paid a flat amount, *irrespective of its actual acquisition cost for the drug in question*. FULs only applied to a limited number of pharmaceuticals, and the required administrative process meant the list of FUL drugs was not updated on a timely basis. Plus, the published information in the pricing compendia used to set the FULs often overstated the prices that were actually available in the marketplace. These factors led many to believe that additional strategies were required to ensure state Medicaid programs were not overpaying for pharmaceuticals.

18. States responded to these dynamics with two strategies: adopting MAC programs, and modifying their existing payment formulas for drugs that were not covered by a MAC or FUL. MAC programs were similar to FULs, but they applied to a far broader array of drugs, and set lower reimbursement levels

¹⁰ The Patient Protection and Affordable Care Act (“PPACA”) modified the formula for calculating a FUL. Instead of being based on $(1.5 * \text{the published price for acquiring the drug})$, the FUL, will be based on $(1.75 * \text{the average manufacturer price (“AMP”)})$. The federal government is still in the process of implementing this change. See Medicaid.gov, Federal Upper Limits, http://www.medicaid.gov/medicaid-chip-program-information/by_topics/benefits/prescription-drugs/federal-upper-limits.html. For an estimate of the impact of these changes, see Office of Inspector General, *Analyzing Changes to Medicaid Federal Upper Limit Amounts* (Oct. 2012), available at <http://oig.hhs.gov/oei/reports/oei-03-11-00650.pdf>.

than the FULs.¹¹ As of January 2012, 45 states (including Arkansas) used MACs in their Medicaid programs for certain drugs for which generic equivalents were available.¹² State Medicaid programs calculated their MACs based on pharmacies' average acquisition cost for a given pharmaceutical product. Once again, pharmacies were paid the amount specified in the MAC, *irrespective of their actual acquisition cost for the drug in question.*

19. States also modified their existing payment formulas for drugs not covered by a FIR or MAC. These changes initially took the form of subtracting a fixed percentage from the AWP, although some states switched to a formula based on WAC plus a fixed percentage.¹³ More recently, some states have moved to an approach based on the average actual acquisition cost ("AAC"). The AAC, which is also referred to as the "ingredient cost," is computed based on a survey of the invoices sent by wholesalers and manufacturers to pharmacies that purchase the drugs in question. These invoices are obtained directly from the pharmacies. By aggregating this invoice-derived pricing information, state Medicaid programs arrive at an AAC

¹¹ Richard G. Abramson et al, *Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs*, 25 Health Care Financing Review 25 (2004).

¹² Office of Inspector General, *Medicaid Drug Pricing in Suite Maximum Allowable Cost Programs* (August 29, 2013), available at <https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp>. Arkansas also uses "Generic Upper Limit" and "Capped Upper Limit" to describe its MACs.

¹³ Arkansas' Medicaid program has long relied on an AWP-based payment system. Apart from drugs covered by a FUL or MAC, Arkansas Medicaid pays AWP less 20% for generics, and AWP less 14% for branded drugs.

that provides a reasonable estimate of the average actual ingredient cost.

20. MAC programs, whether implemented by public or private payers, had at least five distinct effects on pharmaceutical markets. First, MACs encourage pharmacies to dispense the generic version of applicable pharmaceuticals. Second, MACs heighten competition among generic manufacturers. Third, MACs ensure that pharmacies are not being overpaid for the services they provide. Fourth, MACs lowered costs. Finally, MACs made prescription drug reimbursement more efficient. I briefly address each effect in turn.

a. Drug Mix

When pharmacies are only paid the amount specified in the MAC, they have a substantially increased incentive to acquire and dispense generic drugs.¹⁴ This means that a MAC will increase the share of generic drugs that are dispensed, compared to a pure cost-based reimbursement system. In the absence of a MAC, the pharmacy's incentive is quite different, since it will be paid based on a list price that often bears little resemblance to the actual acquisition cost. Thus, absent a MAC, a pharmacy that dispenses a higher-priced generic will actually be paid more – increasing the cost of providing prescription drug benefits, without providing any commensurate benefits.

¹⁴ OIG, *supra* note 12, at 5 (“Because pharmacy reimbursement is based on a single MAC price (regardless of whether a generic or brand version of a drug is dispensed), the program creates a financial incentive to substitute lower-cost generic equivalents for their brand-name counterparts.”)

b. Heightened Competition

When pharmacies only receive the amount specified in the MAC, they have an increased incentive to “shop for the best deal,” and find generic drugs at the lowest possible price (since they get to keep the difference between the acquisition price and the MAC). This heightens price competition among generic drug manufacturers and drug wholesalers, both of whom will understand that offering lower-priced generics will help drive more sales.

Absent a MAC, pharmacies do not have an incentive to buy the lowest-cost generic, since their reimbursement will be based on the list price (which, as noted above, often bears little relationship to the acquisition cost). Under those circumstances, pharmacies will seek to maximize the difference between the list price and their actual cost, rather than simply buying the lowest-cost generic.

c. Prevent Overpayment of Pharmacies

Cost-based reimbursement can lead to various forms of gaming – which result in excess payments to pharmacies. MACs help prevent this behavior, and ensure that the requisite services are obtained at a level much closer to the true costs.

d. Lower Costs

When we combine the first three effects with the lower price at which generics are dispensed, MACs cause pharmaceutical costs to be lower than they would be otherwise.¹⁵ This avoids the wasting of scarce funds.

¹⁵ *Id.* at 21 (“Our findings demonstrate the significant value MAC programs have in containing Medicaid drug costs.”)

e. Enhanced Market Efficiency

Finally, as noted above, each drug manufacturer has its own unique list price for every dosage and variation of each drug that they sell. These list prices vary widely, and bear little relationship to pharmacies' actual acquisition cost. A MAC cuts through the forest of individual list prices, and specifies the reimbursement that will be paid, regardless of the list price and the actual acquisition cost. Payers need not inquire into the specifics of individual transactions, and instead will simply pay the standardized amount. By eliminating the need to conduct individualized assessments of each pharmacy's acquisition costs, MACs help lower transaction costs and structure the market more efficiently. Although this effect does not rise to the level of "order out of chaos," it is nonetheless a real improvement in system performance.

21. Insurers and PBMs copied and modified the programs pioneered by state Medicaid programs, and MAC lists have been a well-established part of the pharmaceutical market landscape for more than two decades. Each insurer or PBM decides which drugs to include on their MAC list, and the level of payment associated with each covered drug. PBMs often maintain multiple MAC lists, each tied to the requirements of a particular employee benefit plan or insurer. Each PBM has its own formula/methodology for setting the level of payment for each covered drug on each of the MAC lists it maintains. PBMs rely on various public and proprietary sources of pricing information (including state-level MACs and FULs) to compute the level of payment specified in each MAC list.

22. As with Medicaid, insurers and PBMs set their MACs to reflect the average acquisition cost that would be incurred, on a drug-by-drug basis, by a well-

run pharmacy. Pharmacies that choose to contract with an insurer or PBM agree to accept the terms set by the insurer or PBM – including the level of reimbursement specified in the MAC list, whatever that may happen to be. Pharmacies are free to decline to contract with an insurer or PBM for whatever reason they choose – including inadequate reimbursement, uncertainty about the level of reimbursement, or the “hassle factor” of dealing with a particular insurer or PBM.

23. In designing and implementing a MAC, the insurer or PBM must balance two competing goals: it wants to ensure a broad network of pharmacies at which prescriptions may be filled (since ease of access to covered services is one of the “products” the insurer or PBM is selling) against the cost of the covered services (since low cost is also one of the “products” the insurer or PBM is selling). If an insurer or PBM errs in one direction (i.e., overly generous payment for pharmaceuticals), it will ensure a broad network of pharmacies, but the covered services will be less affordable – meaning the insurer or PBM may not get the business for which it is bidding. Conversely, if the insurer or PBM errs in the other direction (i.e., inadequate payment for pharmaceuticals), pharmacies will decline to contract; will drop out of the insurer or PBMs’ network; or may fail to stock sufficient stocks of pharmaceuticals for which the MAC payment is too low. Employers and employees will not value a pharmacy network that is too limited along any of these dimensions – meaning the insurer or PBM may not get the business for which it is bidding.

24. When properly designed, MACs steer a middle-ground between these two extremes. By paying the average acquisition costs incurred by a well-run phar-

macy, MACs create the necessary incentive for pharmacies to purchase and dispense the lowest-priced generics that are available in the market. Of course, periodic adjustments are necessary to deal with unanticipated or extraordinary circumstances, but market forces serve to discipline over-reaching by pharmacies, PBMs, and employers/employee benefit plans.

25. If a properly designed MAC is designed to reflect the “average” acquisition cost of a well-run pharmacy, why are MAC payment levels sometimes below pharmacies’ actual acquisition costs? First, the whole point of a MAC is to pay the average cost – not the actual cost. It is in the nature of an average that some transactions will be below (and others above) the average level.¹⁶ The key is not whether some transactions are below or above the average, but whether the reimbursement level set by the MAC reflects the average acquisition cost incurred by pharmacies. An additional complication is that the average acquisition cost is set by reference to a *well-run* pharmacy. Of course, not all pharmacies are well-run – and less-well-run pharmacies are likely to have higher ingredient costs. For example, pharmacies that do not “shop around” for the best deal, or buy drugs in unit sizes that have a higher price per tablet will have acquisition costs that exceed the level set in a properly designed MAC list.¹⁷ MACs thus create a powerful incentive for less-well-run pharmacies to improve their purchasing practices – thereby increasing com-

¹⁶ The share of above-MAC and below-MAC transactions will also be affected by whether generic prices are falling or rising.

¹⁷ Of course, this is not an exhaustive list of the reasons why a particular pharmacy’s drug acquisition cost could exceed a MAC.

petition at the level of wholesalers and drug manufacturers, and lowering pharmaceutical spending.

26. Because MACs result in lower pharmaceutical spending, they help make prescription drug coverage (and health insurance that encompasses such coverage) less expensive. MACs also lower the out-of-pocket costs for insured individuals with co-payments or high deductible health plans. These price effects help broaden access to pharmaceuticals and to health insurance that includes prescription drug coverage: These price effects will also help increase patient compliance, since the out-of-pocket costs of filling a prescription will be lower.

III. Arkansas' Insurance and Pharmaceutical Marketplace

27. Arkansas has approximately 3 million residents. Arkansas residents obtain health insurance coverage through a diverse array of sources, including their place of employment, or the place of employment of a family member; federal and state programs (e.g., Medicare, Medicaid, SCHIP); and non-employment based private coverage.

28. Roughly 1.25 million residents of Arkansas have private health insurance that includes prescription drug coverage provided by a PBM. Public programs with prescription drug coverage provided by a PBM account for an additional 510 thousand residents. In total, 1.76 million Arkansas residents have prescription drug coverage provided by a PBM. The remaining population (1.2 million) either is uninsured (410 thousand); in Medicaid or other public coverage that does not rely on a commercial PBM (745 thousand); or is insured but does not have prescription drug coverage (55 thousand).

29. Arkansas has relatively few large employers, but they account for a disproportionate share of employees. Large employers are much more likely to offer health insurance to their employees, so they also account for a disproportionate share of insured employees. These large employers operate in multiple states. A partial listing of major employers that have operations in Arkansas and other states would include: Alltell, Emerson Electric, Federal Express, J.B. Hunt Transport Services, Tyson Foods, UPS, and Wal-mart.

30. PCMA has eleven members, all of which are based outside of Arkansas. I am informed that PCMA members provide services to a substantial number of Arkansas employers, including financial institutions, healthcare providers, and other business entities.

31. Nationwide, the eleven members of PCMA provide services to employers located in all fifty states, covering approximately 142,000,000 covered lives. PCMA members also provide services to individuals who do not obtain coverage through an employer. In all, PCMA members provide PBM services to 236 million covered lives nationwide.

32. Arkansas has approximately 770 pharmacies, ranging from small independent individual pharmacies, to large chains, and pharmacies located in grocery stores and other large retail outlets.¹⁸ Six chains, each with more than twenty-five locations, account for fully 42% of the pharmacies in Arkansas.¹⁹

¹⁸ These figures are based on unique pharmacy locations, as reported in the National Provider Identifier (“NPI”) Database maintained by the Centers for Medicare and Medicaid Services.

¹⁹ These six chains are Wal-Mart, Walgreens, Fred’s, Harp’s, Krogers, and Super D.

33. According to the 2010 U.S. Census, roughly 56% of the Arkansas population live in urban areas, and 44% live in rural areas.²⁰ In the U.S. as a whole, 81% of the population live in urban areas, and 19% of the population live in rural areas. Expressed in terms of counties, 15% of the 75 counties in Arkansas are urban (population > 65,000); 35% are near-urban (20,000 < population < 65,000), and the remaining 50% are rural (population < 20,000).²¹

IV. Arkansas' Regulation of PBMs

34. In 2015, Arkansas enacted Act 900. Act 900 modifies the regulatory framework imposed by an earlier PBM statute (Act 1194), by imposing several new obligations:

a. PBMs must update their MAC list within seven calendar days of an increase equal to or greater than ten percent in the “pharmacy acquisition cost” from sixty percent or more of the pharmaceutical wholesalers doing business in Arkansas,²² “Pharmacy acquisition cost” is defined by Act 900 as “the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy’s billing invoice.”²³

b. If a MAC does not exceed a pharmacy’s actual acquisition cost, the pharmacy may appeal solely on that basis – even if a less expensive

²⁰ Table 1, at <https://www.census.gov/prod/cen2010/cph-2-5.pdf>

²¹ University of Arkansas Division of Agriculture, *Rural Profile of Arkansas - 2015*, at <https://www.uaex.edu/publications/pdf/MP-531.pdf>

²² Ark. Code § 17-92-507(c)(2).

²³ Ark. Code § 17-92-507(a)(6).

alternative was available in the marketplace.²⁴ The pharmacy must be given at least seven days to file an administrative appeal.²⁵ If the appeal is granted, the PBM must modify the MAC and apply the change to all similarly situated pharmacies, and permit the challenging pharmacy to reverse and re-bill the claim in question.²⁶ If the appeal is denied, the PBM must provide the pharmacy with information about a national or regional pharmaceutical wholesaler that has the drug in stock at a price below the MAC.²⁷ But, if the drug in question is not available at a price lower than the MAC from the wholesaler where the pharmacy in question purchases the majority of its prescription drugs for resale, the PBM must adjust its MAC list, and permit the pharmacy to reverse and re-bill the claim(s) in question.²⁸

c. A pharmacy may decline to fill a prescription if the MAC is below its actual acquisition cost – even if there was a less expensive source for the same drug was available in the marketplace.²⁹

d. Finally, the provisions of Act 900 do not apply to Arkansas Medicaid program beneficiaries, or to state employees (defined in Act 900 as “the Employee Benefits Division of the

²⁴ Ark. Code § 17-92-507 (c)(4)(a)(i)(b).

²⁵ Ark. Code § 17-92-507 (c)(4)(C).

²⁶ Ark. Code § 17-92-507 (c)(4)(C)(i).

²⁷ Ark. Code § 17-92-507 (c)(4)(C)(ii).

²⁸ Ark. Code § 17-92-507 (c)(4)(C)(iii).

²⁹ Ark. Code § 17-92-507 (e).

Department of Finance and Administration).³⁰ However, if the Arkansas Medicaid Program or the Employee Benefits Division ever engage the services of a PBM to handle their MAC lists, then the balance of Act 900 will apply to them as well.³¹

V. Basic Dynamics of Act 900

35. Before considering the effects of Act 900 on employers, employee benefit plans, and PBMs, it is useful to step back and understand the basic dynamics that the statute creates. Act 900 enshrines into law a requirement for PBMs to pay pharmacies at least their invoiced acquisition costs – irrespective of whether a lower priced option was available in the marketplace. Although Act 900 is framed as cost-based reimbursement, it will effectively function for many pharmacies as a “guaranteed profits” term: no matter how much a pharmacy spends to acquire a drug, they are guaranteed they will be paid at least that amount, and likely more. And, because of rebates and discounts, invoiced prices may not reflect actual drug acquisition costs – further inflating the guaranteed profits.³²

36. The “guaranteed profit” term is implemented through the administrative appeal process in Act 900. Pharmacies are entitled to appeal any MAC payment that is below their actual acquisition cost.³³ The guaranteed profits that will result are not accidental: Act 1194 provided that a pharmacy could appeal if the

³⁰ Ark. Code § 17-92-507 (f)(1).

³¹ Ark. Code § 17-92-507 (f)(2).

³² Rebates and discounts are often tied to prompt payment, or the volume of generic drugs purchased by an individual pharmacy or a group of pharmacies.

³³ Ark. Code § 17-92-507 (c)(4)(A)(i)(b).

MAC is “below the cost at which the pharmacy *may* obtain the drug” (emphasis supplied) – but this language was stricken by Act 900, and replaced with a provision that allows a pharmacy to appeal if the MAC is “below the pharmacy acquisition cost.”³⁴ Thus, Act 900 is crystal clear that pharmacies must be paid based on their actual acquisition costs, even if the pharmacy could have obtained the pharmaceutical in question for far less. Were there any doubt on this score, the Arkansas Attorney General’s Office recently sent letters to various PBMs, instructing them that Arkansas law now confirms the AG’s:

“long-held position that the Maximum Allowable Cost Lists statute does not allow for ‘negative claims’ or ‘negative reimbursements.’ This means that it is a deceptive trade practice for a PBM to reimburse a pharmacist in an amount below the acquisition cost. It also means that following an appeal by a pharmacist reflecting higher acquisition costs than a drug’s MAC, PBMs must subsequently change the drug’s MAC listing and allow for reversal and rebilling of the claim in order to reflect the higher reimbursement.”³⁵

37. A brief example helps clarify the incentive problems that result from this approach. Assume that a drug is available from two Wholesalers: A, and B.³⁶ Wholesaler A charges \$10 if the pharmacy purchases

³⁴ *Id.*

³⁵ Letter from the Arkansas Attorney General to Prime Therapeutics dated July 10, 2015, attached as an Exhibit to Declaration from Prime Therapeutics.

³⁶ The same analysis applies to pharmaceutical manufacturers, who deal directly with large pharmacy chains.

100 tablets, and \$35 if the pharmacy purchases 500 tablets. Wholesaler B charges \$15 if the pharmacy purchases 100 tablets, and \$60 if the pharmacy purchases 500 tablets. The Table below shows the price per tablet for both wholesalers for each of the two offered unit sizes.

Price per Tablet		Wholesaler	
		A	B
Unit Size (Tablets)	100	10¢	15¢
	500	7¢	12¢

38. Absent Act 900, the PBM will set the MAC at a level that reflects the average acquisition cost of a well-run pharmacy i.e., it will set the MAC at just over 7¢ per tablet, creating a very strong incentive for the pharmacy to purchase the drug only from Wholesaler A, and to do so in lots of 500 tablets. The existence of the MAC will also intensify competition in the wholesale market (i.e., it will encourage wholesaler B to lower its prices, and encourage wholesalers A and B to narrow the pricing differences between unit sizes of 100 and 500 tablets). This will help drive down pharmaceutical spending, and lower the cost of pharmaceutical coverage.

39. However, once the “guaranteed profits” term in Act 900 takes effect, pharmacies can purchase the specified drug in whatever unit size they choose – and purchase it from either Wholesaler A or Wholesaler B, confident that they can successfully appeal if the MAC does not exceed their actual acquisition cost. PBMs know that a sizeable number of appeals are in the offing if they set the MAC below the average acquisition cost incurred by pharmacies – and those pharmacies are now free to determine their own costs. PBMs will likely respond by setting higher MACs, to avoid

incurring the costs associated with handling the appeals if they maintain a low MAC. This will result in guaranteed profits for pharmacies that purchase the drug for less than the (now inflated) MAC. The higher the MAC, the less effective it will be in constraining pharmaceutical spending and increasing competition at the wholesale level – and PBMs will still have to deal with appeals from pharmacies that have actual acquisition costs that exceed the now-inflated MAC. Act 900 ensures that many pharmacies will be paid more than their average acquisition costs – thereby guaranteeing each of them a potentially large profit on their acquisition cost, wholly apart from any dispensing fee they receive.

40. If a PBM wants to efficiently administer its pharmacy network, it must determine the “right” amount to pay. As described above, this has proven to be a challenging problem. Act 900 provides a simple answer: the PBM must pay “the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy’s billing invoice.”³⁷ One problem with this approach is that it creates a significant incentive for wholesalers and manufacturers to use off-invoice discounting, thereby reducing pricing transparency and decreasing the effectiveness of price competition. Wholesalers and manufacturers already rely on rebates and discounts to help drive sales, but Act 900 is likely to supercharge these efforts, and move them off-invoice.³⁸

³⁷ Ark. Code § 17-92-507 (a)(6).

³⁸ Government Accountability Office, *Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs*, GAO 14-68, Dec. 2013, at <http://www.gao.gov/assets/660/659833.pdf> (reviewing efforts of Medicaid to develop a national

41. The United States has already experienced the problems that can result from relying solely on invoice prices to determine acquisition cost. As briefly noted above, public and private payers had long relied on publicly reported AWP's to set the level of reimbursement for pharmacies. AWP's appeared in authoritative commercial publications, and also often appeared on the invoices that pharmacies received. But AWP's did not reflect the actual acquisition costs incurred by pharmacies – in part because they did not reflect various rebates, charge-backs, and discounts.³⁹ The result was that AWP's often dramatically overstated pharmacies' true acquisition costs. Relying on AWP's resulted in massive overpayments by public and private payers, followed by years of litigation and the recovery of billions of dollars in damages.

42. Once it became clear that AWP's did not reflect actual acquisition costs, public and private payers experimented with various payment formulas (including MACs), to address this problem. In Medicare Part B, Congress enacted legislation in 2003 requiring Medicare to replace its AWP-based payment system for drugs with one based on the Average Sales Price ("ASP"), as reported quarterly by drug manufacturers.⁴⁰ ASP is computed net of any price concessions, including volume discounts, prompt pay discounts,

benchmark for retail pharmacy acquisition costs, and noting that most rebates and discounts "occur off-invoice, or are not tied to a specific drug purchase.")

³⁹ In practice, AWP's also overstated the actual acquisition costs for generic drugs, because they were not updated on a timely basis to reflect the impact of generic entry on pricing.

⁴⁰ See Use of Average Sales Prices Payment Methodology, 42 U.S.C. 1395w-3a, available at <https://www.law.cornell.edu/uscode/text/42/1395w-3a>.

cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates.⁴¹ Congress also specified that the definition of ASP could be updated administratively, to reflect the impact of any “other price concessions. . . that would result in a reduction of the cost to the purchaser.”⁴² As this example illustrates, Congress explicitly rejected the use of a cost-based payment system for pharmaceuticals that did not take account of *all* rebates, discounts, and price concessions – whether they appeared on the face of an invoice or not. Act 900 is a significant step back down a path that Congress has decisively rejected.

43. If the goal is to determine the actual acquisition cost for a particular pharmaceutical, it is necessary to take account of all discounts and rebates associated with all pharmaceutical purchases – whether they appear on the face of a particular invoice, or are recorded and reconciled elsewhere. Because Act 900 fails to do that, it creates a virtual license for wholesalers, manufacturers, and pharmacies to collude at the expense of public and private payers. This will result in increased pharmaceutical spending and higher costs for pharmaceutical coverage.

⁴¹ *See id.* at 42 U.S.C. 1395w-3a (c)(3) (“In calculating the manufacturer’s average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r-8 of this title).”)

⁴² *See id.* (“For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.”)

VI. Impact of Act 900

44. I now turn to the specific impact of Act 900 on plan administration, interstate commerce, and competition.

Impact on plan administration.

45. *Immediate Effects.* Act 900 will force multi-state employers to modify their employee benefit plans for Arkansas-based employees. More specifically, employers will have to modify their contracts with insurers/PBMs, to ensure their Arkansas-based employees receive pharmaceutical benefits that comply with the provisions of Act 900, including Arkansas-specific MAC lists; Arkansas-specific MAC pricing; and an Arkansas-specific appeals process. Although a number of other states have enacted legislation regulating PBMs, no other state includes a “guaranteed profits” provision like Act 900. Thus, employers with Arkansas-based employees (and the insurers and PBMs that provide services to them) will have to create an Arkansas-specific employee benefit plan incorporating these disparate elements.

46. Employers with operations in any of the six states that border Arkansas (Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and Texas) must similarly address the likelihood that their employees and their covered dependents either live in Arkansas, or will travel to Arkansas at some point in time, and seek to have a prescription filled while within the state. There are two ways employers can handle this scenario:

- a. Employers with operations in the six adjoining states can take steps to ensure plan compliance with the provisions of Act 900, including Arkansas-specific MAC lists; Arkansas-specific

MAC pricing; and an Arkansas-specific appeals process. This means that these employers will have created an Arkansas-specific employee benefit plan incorporating these disparate elements, even though they do not have operations in Arkansas.

- b. Employers with operations in the six adjoining states can ignore the requirements of Act 900, and make no adjustments to their benefit plan. In so doing, these employers are assuming the risk that employees and-covered dependents will not be able to have their prescriptions filled while in Arkansas.⁴³ Insurers and PBMs that contract with these employers run the risk of breaching their service-related guarantees, and are also assuming the risk of being deemed to have committed a deceptive and unconscionable trade practice.

47. Finally, employers with operations in the remaining 43 states (i.e., not in Arkansas or the surrounding six states) must also consider the possibility that their employees and covered dependents may travel to Arkansas and seek to have a prescription filled while within the state. They face the same choices as employers with operations in the six states surrounding Arkansas. To be sure, the probability an employee or covered dependent either lives in Arkansas, or will travel to Arkansas at some point in time, and seek to have a prescription filled while within the state is likely to be materially lower for

⁴³ As noted previously, Act 900 expressly authorizes pharmacies to refuse to dispense a prescribed drug if the MAC does not equal or exceed their actual acquisition cost. *See supra* note 29, and accompanying text.

these employers than for employers that fall within the other two categories.

48. *Lagged Effects.* Act 900 will also have a variety of lagged effects. The evidence is clear that MACs result in lower pharmaceutical spending. Because Act 900 will make MACs less effective, it will result in higher payments to pharmacies – thereby increasing pharmaceutical spending.⁴⁴ There are no studies estimating the impact of Act 900, but one study estimated the impact of similar legislation. This study was performed by the Washington Health Care Authority (“WHCA”), and involved “scoring” the financial impact of proposed legislation which, like Act 900, prohibited PBMs from paying pharmacies less than their actual acquisition cost. WHCA concluded the proposed legislation would make MAC lists much less effective, and would dramatically reduce pharmacies’ incentive to acquire generic drugs at the lowest possible cost.⁴⁵ Although WHCA did not specifically quantify the fiscal impact of the proposed legislation, it determined that it would “significantly increase” costs for public employee benefits and would also have a cost-increasing impact on Medicaid.⁴⁶ Because it was only scoring the on-budget costs of the proposed legis-

⁴⁴ See OIG, *supra* note 12, at 21.

⁴⁵ See WHCA Fiscal Note, SSB – 5857, available at <http://app.leg.wa.gov/billinfo/summary.aspx?year=2015&bill=5857> (concluding that pharmacies reimbursed on the acquisition cost of pharmaceuticals “would not have as strong of an incentive to acquire generic drugs at the lowest cost available. This would effectively make the maximum allowable costs (MAC) lists less effective at controlling pharmaceutical costs.”)

⁴⁶ *Id.* (“This bill, if passed, would significantly increase the costs within the Public Employees Benefits (PEB) delivery system.”)

lation, WHCA did not attempt to determine the impact on private employers and unions – but there is no reason to think it would not have similar cost-increasing effects on those payers.

49. Act 900 will also result in increased administrative burdens (and costs), including those associated with appeals and any resulting retroactive changes to MAC levels, as well as the costs of monitoring MAC lists to ensure continuing compliance with Act 900.⁴⁷

50. Employees will bear some of the costs of Act 900 as well. If the employee benefit plan has a percentage co-payment/co-insurance for pharmaceuticals, an increase in the cost of the pharmaceutical (whether attributable to a successful appeal of a MAC, or increased MACs because of the incentives created by Act 900) will result in a direct increase in the cost borne by the employee, since the co-payment is computed based on the actual cost of the dispensed pharmaceutical. If the employee benefit plan is structured as a high-deductible plan, any increase in the cost of the pharmaceutical will similarly result in a direct increase in the cost borne by the employee, at least as

⁴⁷ It is not entirely clear whether PBMs will actually be able to comply with at least one provision in Act 900 at all – and if they are able to do so, it will require considerable administrative costs. As noted above, Act 900 requires PBMs to update their MAC list within seven calendar days of an increase equal to or greater than ten percent in the “pharmacy acquisition cost” from sixty percent or more of the pharmaceutical wholesalers doing business in Arkansas. It is my understanding that PBMs operating in this space do not know what the pharmaceutical wholesalers doing business in Arkansas are actually charging on a real-time basis – let alone whether sixty percent of the wholesalers have increased their price by ten percent or more for any particular drug.

long as the deductible has not been exceeded. Sorting out these matters will also create further administrative burdens and costs.

51. The combination of increased pharmaceutical spending and increased administrative costs will cause employers and employee benefit plans (and the insurers that provide services to them) to look for savings elsewhere, including changes in plan design – such as modifications in covered benefits and the mix of co-payments and deductibles that apply to those benefits. Act 900 will also create pressure to develop new pricing models for handling generic drugs that may not be subject to a MAC – and new pricing models may trigger further changes in plan design.

52. To summarize, the immediate and lagged effects will put pressure on employers (and the insurers and PBMs that provide services to them) to create Arkansas-specific employee benefit plans, resulting in diminished plan uniformity. There are also likely to be increased costs for employers and employees, which will be reflected in the cost and breadth of health insurance, including pharmaceutical coverage.

53. *Impact on interstate commerce.* As noted above, Act 900's restrictions on the use of MACs will increase spending on pharmaceuticals. Arkansas' in-state pharmacies will be the principal beneficiaries of this increased spending – at the expense of out-of-state employers, employees, insurers and PBMs.⁴⁸

54. The way in which Act 900 handles Medicaid and state employees provides another example of discrimination against interstate commerce. As noted

⁴⁸ Of course, in-state employers and employees will bear some of the costs as well.

above, Act 900 expressly excludes Arkansas' Medicaid program and Arkansas' Employee Benefits Division of the Department of Finance and Administration from its ambit, at least as long as these entities do not contract with a PBM to manage their pharmaceutical coverage.⁴⁹ The only thing these two groups have in common is that the costs of their health coverage are on-budget expenses – borne (either in whole or in part) by the state of Arkansas. Thus, the logic of Act 900 seems to be that it is acceptable for the state of Arkansas to pay in-state pharmacies less than their actual acquisition cost as long as the state is acting in its sovereign capacity – but if it outsources the function to a commercial PBM, in-state pharmacies should receive higher payments. The discrimination in favor of in-state concentrated interests (i.e., pharmacies) could not be more clear. Stated differently, Arkansas' legislators made it clear that they thought it was important to ensure pharmacies were paid their actual acquisition costs – right up until the moment the state of Arkansas would bear the costs of doing so.

55. I have not studied the legislative history of S.B. 688, but my research in other areas leads me to expect that Arkansas' in-state pharmacies were probably the primary backers of the legislation in question.⁵⁰ It is

⁴⁹ Ark. Code § 17-92-507 (f).

⁵⁰ See, e.g., David A. Hyman & Shirley Svorny, *If Professions are Just "Cartels by Another Name," What Should We Do About It?* 163 U. Pa. L. Rev. 101 (2014), available at <http://www.pennlawreview.com/responses/index.php?id=127> (noting dominance of provider interests in use of professional licensing to restrict competition); David A. Hyman, *Drive-Through Deliveries: Is Consumer Protection Just What the Doctor Ordered?* 78 N.C. L. Rev. 5 (1999) (noting that majority of the states that enacted prohibitions on drive-through deliveries excluded state employees and Medicaid beneficiaries from the statute).

not an accident that the costs of Act 900 are primarily borne by unorganized consumers and out-of-state business interests, while the benefits are captured by a discrete and insular minority/interest group within the state of Arkansas.

56. *Impact on Competition.* MACs intensified competition in the market for generic drugs by relying on the self-interest of pharmacies to drive prices lower. Because Act 900 provides guaranteed profits, it will make pharmacies far less concerned with such matters. Thus, Act 900 will reduce the intensity of competition experienced by wholesalers and pharmaceutical manufacturers.

VII. Other Aspects of Act 900

57. *Targeting.* Arkansas is a rural state with many small independent pharmacies. There are good reasons for the Arkansas legislature to be concerned about the extent to which Arkansas residents – particularly those in rural counties – have access to pharmacy services. But, Act 900 is poorly designed to accomplish that objective. A more targeted remedy would directly subsidize the pharmacies most in need of support – and only those pharmacies. Instead, Act 900 effectively provides guaranteed profits to all pharmacies in Arkansas whether it is an independent pharmacy located in a rural county that is the only location at which prescriptions can be filled within a fifty mile radius, or it is a pharmacy that is part of a large chain, located in an urban county, with multiple competitors within a two mile radius. Second, if the Arkansas legislature was, in fact, concerned about the problem of struggling rural pharmacies, it could have subsidized them directly, using public funds. But, when given the opportunity to do so, the Arkansas legislature declined -- and excluded Medicaid bene-

ficiaries and state employees from the ambit of Act 900. Thus, the costs of the non-targeted subsidy found in Act 900 are borne by employers, employees, and out-of-state PBMs.

58. *Disruptive Potential.* Act 900 is likely to cause significant disruptions. Perhaps the most problematic provision in this regard is that pharmacies can unilaterally refuse to fill a prescription if the MAC is below the pharmacy's acquisition cost, even if the contract between the PBM and the pharmacy expressly prohibits such opportunistic behavior. This provision has the potential to significantly disrupt the functioning of the pharmacy networks created by PBMs to service their customers – and (particularly in light of the ability of pharmacies to obtain *ex post* appeals of inadequate reimbursement) seems designed to bludgeon PBMs into building a sizeable margin of over-payment into their MAC lists – or abandoning the use of MACs entirely. Again, it is probably not an accident that Act 900 excludes Medicaid beneficiaries and state employees from this provision. Once again, this means that the costs of Act 900 are disproportionately borne by out-of-state employers and PBMs.

VIII. Summary

59. The efficiencies created by MACs will be lost or dramatically diminished if PBMs are forced to conduct an *ex post* individualized inquiry into the actual acquisition cost of every pharmacy that appeals. Unless PBMs respond by setting MACs for each drug at the level of the most expensive bio-equivalent product obtained by the least efficient pharmacy in the state, they will inevitably face at least some appeals by pharmacies that have elected to purchase the drug in question from a higher cost supplier. And, if they set a MAC significantly below this inflated level, the costs

of adjudicating the inevitable appeals has the potential to swamp the benefits of using MACs in the first instance. Thus mandating reimbursement rates based on acquisition costs, as Act 900 does, will significantly weaken (if not cripple) the effectiveness of MACs, and the efficiencies associated with their use. The predictable results will include increased pharmaceutical spending and administrative costs; changes in plan design and benefits; and impacts on interstate commerce and competition.

I declare under penalty of perjury that foregoing is true and correct.

/s/David Hyman
Professor David A. Hyman

Executed on July 20, 2015

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

Case No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity as
ATTORNEY GENERAL OF THE STATE OF ARKANSAS,

Defendant.

EXPERT REPORT OF JOHN D. JONES

Introduction/Summary of Opinions

1. I am a licensed pharmacist and attorney and have worked continuously in the area of managed care pharmacy for the past 25 years. Based on my years of industry experience with health plans, pharmacy benefit management (PBM) companies and national professional and quality organizations; including experience with customer contracting, pharmacy network contracting, and maximum allowable cost (MAC) drug list development, the following summarizes the opinions I expect to offer in this matter.

Summary of Opinions Regarding the Number of Ways That Act 900 Will Impact PBM Industry

2. PBMs use MAC pricing lists as a tool to provide health plans with a cost-effective benefit plan. MAC lists allow health plans and employers who contract with health plans to contain prescription drug costs in a market with rapidly changing drug prices, maintain

pharmacy networks adequate to provide pharmacy benefits to covered members and prevent pharmacy windfall profits at the expense of client health care benefit affordability. For all of these reasons, MAC lists are a central element to the PBM-customer contractual relationship.

3. Act 900 prevents PBMs and their customers from accessing the full negotiated benefits of MAC pricing, because it forces PBMs to reimburse pharmacies for the price listed on their wholesalers invoice. Since MAC is not calculated on a transaction-by-transaction basis, and since off-invoice pricing concessions by wholesalers, pharmacy service administrative organizations (PSAOs), and drug manufacturers are not reflected in the invoice price (but would be taken into account in calculating MAC), reimbursements under Act 900 will significantly diminish the usefulness of MAC pricing.

4. Act 900's provisions requiring PBMs to grant MAC appeals and pay the invoice price for generics (absent limited circumstances) will cause PBMs to change the way they calculate MAC and/or generic drug reimbursement. This change will increase the cost of health care for those customers with beneficiaries residing in or around Arkansas or who travel to Arkansas. This change will significantly disrupt both PBM and customer expectations for contracts.

5. The same provisions of Act 900 will also disrupt pharmacy networking contracts between pharmacies and PBMs. Network contracts set reimbursement terms relying on MAC, and also provide for reimbursement appeals and service guarantees. Act 900 will result in an Arkansas exception to national customer contracts that contemplate the uniform use and administration of MAC across the 50 states.

6. Act 900 also significantly disrupts the central purpose of the pharmacy network contracts by allowing pharmacies to decline to dispense a drug to a beneficiary if the MAC price is determined by the pharmacy to be too low.

7. Going forward, PBMs will need to adopt a completely different strategy for providing services to plans with beneficiaries in, near or traveling into Arkansas. This will be disruptive to the multi-state nature of the prescription drug business, and will affect health plans and beneficiaries located outside of Arkansas.

8. PBMs are not able to comply with Act 900 as it is written because these companies do not have access to wholesaler invoice pricing on a pharmacy-by-pharmacy basis and have no way of knowing when wholesalers increase or decrease their prices to pharmacies.

Qualifications

9. My education and experience have prepared me to speak as an expert on MAC pricing as it impacts PBM customer and network pharmacy agreements. My complete CV is attached hereto as Exhibit A, and relevant experience is described below.

Education/Early Experience as Pharmacist

10. In 1975, I earned a Bachelor of Science in Pharmacy degree from Idaho State University, located in the state where I was born and raised. In 1982, I also earned a Juris Doctor degree from the University of San Francisco.

11. During pharmacy school, I interned in Alaska and after graduation moved there to work as a pharmacist with positions in an independent community

pharmacy, a skilled nursing facility and a community hospital. I left Alaska in 1977 to live and work in California.

12. I began my pharmacy work in southern California in 1977 working at a large chain store.

13. In 1978 I moved to San Francisco and began work at the University of California San Francisco (UCSF) hospital inpatient pharmacy and later advanced into a director's role at the University's pharmacy home infusion service. I was employed by UCSF for 12 years.

Experience in Managed Care Pharmacy

14. I left UCSF to join Blue Shield of California, a health care insurer, in 1990. At the time, managed care pharmacy (an organized system designed to improve both the quality and accessibility of health care, while also containing costs) was in its infancy. My responsibilities included developing pharmacy networks, an on-line electronic prescription claims systems and a formulary (a list of drugs that may be prescribed to people covered by Blue Shield's insurance plans) to support the health plan prescription drug benefits. I advanced to director of pharmacy relations during my four years at Blue Shield and developed a competitive internal pharmacy benefits product.

Experience in Pharmacy Benefit Management

15. In 1994 I joined Prescription Solutions, a pharmacy benefit manager that was a wholly owned subsidiary of PacifiCare Health Systems. Prescription Solutions was one of the first pharmacy benefit managers. I was hired as director of industry relations. For the first approximately eleven years (1994 - 2005) that

I worked for Prescription Solutions, I was responsible for pharmacy network contracting and the pharmacy network help desk, pharmacy reimbursement and appeals, MAC development, formulary management, contracting with pharmaceutical companies and regulatory compliance.

16. As the company grew, my responsibilities became more specialized. I was promoted to Vice President in or around 2003. By 2005, I was Vice President of legal and regulatory affairs. In that role, I was part of the executive management team of the PBM.

17. In 2005 PacifiCare Health Systems (and Prescription Solutions) was acquired by UnitedHealth Group. Prescription Solutions was later rebranded as OptumRx. I remained on the executive management team after the UnitedHealth acquisition and through the rebranding to OptumRx.

18. In my time working for UnitedHealth/Optum, my role continued to evolve. Based on the combination of my PBM operational experience, and my pharmacy and law degrees, I developed strategies regarding policy, legislation, and regulation, and to advocate on the PBM's behalf with state and federal policymakers. In this role, I directed the analysis of potential impact on the PBM and its clients from state and federal legislation and health policy trends.

19. I also remained an active member of the executive team, attending monthly meetings to discuss company products and operations, the competitive nature of the PBM market, MAC pricing, and demands from its clients and prospective clients including client contracting. In these meetings, I received detailed information regarding negotiations relating to new and

existing business, as well as information regarding the use of MAC in customer and pharmacy contracts.

20. As a member of the executive team, I consulted with business stakeholders and leadership across the company as policy and or legislative/regulatory questions arose. The discussions often centered around what was needed to compete in our marketplace and what clients (and consultants who advise clients) were demanding from PBMs competing in our market. These conversations were critical to understanding both the policy positions the company needed to adopt and the products and services to develop and support to satisfy the needs of the market. My role was to provide input on company operations, customer contracting, and competition from a legal policy-oriented perspective. I also advised on the impact of current and/or potential legislation and regulation on company practices, and provided compliance advice.

21. I left OptumRx as a senior vice president and a member of the executive management team in March of 2016 after 21 years.

Other Relevant Experience:

22. California Board of Pharmacy—I was appointed to serve on California’s Board of Pharmacy for two consecutive terms first by a Republican and later by a Democrat Governor (1998-2006). I was elected by the Board as its vice president 2002-2003 and twice as its president 2003-2005. The Board of Pharmacy is a consumer protection agency of the state and my responsibility was to ensure that licensees provided professional services in the best interest of their patients and in full compliance with California laws and regulations. The Board supported consumer legislation and

promulgated and enforced regulations to meet its consumer protection goals.

23. URAC Board of Directors—I was appointed to serve on the URAC (formerly known as the Utilization Review Accreditation Commission) Board of Directors in 2008 and served as its vice chairperson from 2010 to 2012 and its chairperson from 2012 to 2014. I continue to serve as a URAC board member. URAC is an independent, not for profit health care quality accreditation organization.

24. Adjunct Faculty Instructor for Pharmacy Law and Ethics at the University of California, San Diego, Skaggs School of Pharmacy (UCSD)—I have taught pharmacy students law and ethics since 2010.

25. National Benefits Coalition on Health and URAC PBM Purchasers Guide—In 2008, I chaired a panel whose members wrote the PBM Purchasers Guide including instructions on how payers should decide payment structures with their PBMs, use of expert consultants and how PBMs contract with network pharmacies.

26. Academy of Managed Care Pharmacy (AMCP) Guide to Pharmaceutical Payment Methods—In 2007, I acted as Board of Directors liaison and panel member on an expert advisory panel creating the Guide to support national and state health care policy makers in understanding pharmaceutical payment methods. I spoke at a briefing on Capitol Hill in Washington, DC to Members of Congress and health care aides to introduce the Guide to help inform the debate on health care legislation proceeding at that time.

Terms of Engagement

27. I have been engaged by Foley Hoag on behalf of Pharmaceutical Care Management Association (“PCMA”) to provide my opinions on Act 900’s impact on PBM contracting with employers, health plan clients and network pharmacies. PCMA is compensating me for my time at \$250 per hour of study and preparation time, including the time spent drafting this report, and \$350 per hour for time spent testifying in deposition or in evidentiary proceedings in court.

Material Considered

28. In preparing this report, I have reviewed a number of documents. Specifically, I have reviewed Acts 900 and 1194, Professor Hyman’s report as an expert in this case and the pleadings to this case. I may also rely on additional information provided during discovery in this case.

29. My report and any testimony I give will address my opinions and the basis for these opinions. My report also includes all facts and data that I considered in forming these opinions although much of my opinion stems from my years of experience in the managed care industry.

PBM Contracts

Parties Involved in PBM Contracting

30. In order to understand the customer contracting process, it is important to identify and understand each of the stakeholders in this process:

31. The Customer - PBM customers range from a single employer, to a small group of health plans, to a coalition of those small groups, to a large health plan. Even though some of these types of customers may be based in a single state, in general most PBM custom-

ers require multi-state plans, because their members (health insurance beneficiaries) may live in multiple states, or can be expected to travel to different states (either for work or pleasure) and will need to access their pharmacy benefits while traveling. Further, many customers are themselves based in multiple states, with beneficiaries located in multiple states without any accommodation for travel.

32. The PBM - the PBM is engaged by the customer to provide pharmacy benefit management services, which include access to a pharmacy network, formularies, MAC price lists for generic drugs, and administrative services including claims reimbursement and appeals.

33. Customer Consultants - most PBM customers engage consultants to conduct their PBM contracting negotiations for them. These consultants range from local single-person outfits to multi-national “Big 4” consulting firms. The PBM customer will dictate its objectives and priorities to the consultant, who will negotiate using those objectives and priorities as a framework for the selection criteria and process. The consultants engaged by PBM customers are paid to help find the best fit and achieve both the best financial and performance deals for their client but the final decision almost always rests with the client. Many of the consultants have worked in the PBM industry and understand competitive pricing, benefit structure, network management and access, PBM performance capabilities and how PBMs make money.

34. Pharmacies and Pharmacy Service Administrative Organization (PSAO) - Pharmacies are implicated in the PBM-customer contracting process because a PBM’s pharmacy network is a key component of the PBM-customer contract. Objectives for the PBM

pharmacy network are typically dictated by the PBM customer, and will result in the network including pharmacies ranging from large chains to independent pharmacies. The pharmacies negotiate network contract provisions either on their own behalf, or through a PSAO. PSAOs increase leverage for independent pharmacies by using collective power, and can increase small pharmacy leverage to nearly the same level as that of a large chain.

MAC Pricing and Pharmacy Network Access Are the Central Components of PBM-Customer Contracts

35. The primary objective of PBM customers is to balance price and access. If the pharmacy network meets their access and performance needs, customers will seek the lowest price possible from their PBM vendor for that network. Most often price is the determining factor in winning a bid.

36. PBMs rely on MAC lists to provide competitive prices for generic drugs. MAC lists dictate the reimbursement that a pharmacy will receive from a PBM for a specific strength and dosage of a generic drug. Since generic drugs are offered from different manufacturers at different prices, a MAC list allows for price standardization where the market does not set a standard price.

37. MAC pricing places a ceiling on what a PBM will pay a pharmacy in its network. Therefore, it motivates pharmacies to purchase generic drugs at the lowest available prices in the marketplace and to operate efficiently.

38. MAC is intended to pay an average cost of a drug. Therefore, sometimes pharmacists will receive a reimbursement that is below their costs for a particu-

lar drug, but as a whole, a well-run pharmacy can expect to profit from MAC list reimbursements.

39. In order to determine whether a PBM offers competitive pricing, customers provide their current MAC or National Drug Code list of generic drugs to the PBM, which runs it against its own pricing database to see where pricing comes out. In addition, the PBM might analyze the prescription drug claims submitted prospective customer's beneficiaries in order to understand drug mix and the impact of a MAC list on the prospective client's pricing of current prescription utilization. Often the customer will base pricing performance guaranties on this analysis and it will become part of the contract. If the PBM fails to satisfy the pricing performance guaranties in the contract, it can be subject to penalties, up to and including the total loss of the business.

The Customer Contracting Process

40. Before describing the customer contracting process, it is important to understand that the PBM industry is extremely competitive. PBM customer contracts have fairly short terms (ranging from one to ten years, averaging about two to three years). While some contracts have evergreen renewal periods, others are structured to allow for price checks mid-term during the contract allowing for renegotiation in situations where market pricing has changed, and some simply terminate at the end of the contract term and are renegotiated. Each time a contract is up for renegotiation or re-bidding, the incumbent PBM can expect that other PBMs will attempt to compete with it on price. Most PBMs will develop whatever pricing model it would take to bring new business in the door, provided that new business has the potential for profit for the PBM. This means that PBMs are frequently

updating and fine-tuning their MAC lists in order to identify the most competitive prices that they can offer while still maintaining competitive access to pharmacies for customer beneficiaries.

41. The PBM customer contracting process is complex and demands resources and subject matter expertise across all departments of a PBM. Any given customer contract will involve input from the PBM's sales, client management, client support, networking, actuarial, and operations teams. The contracting process may have dozens to hundreds of PBM employees working on it at any given time.

42. The process starts with requests for proposals (RFP) from clients or prospective new business to which interested PBMs respond. In most situations, the customer has engaged a consultant who understands PBM business models, as described above. Although the incumbent PBM frequently has an advantage in the bidding process, many PBM customers will submit their contracts for re-bidding regardless of their intention to stay with their current PBM. This serves to provide a market-check for the current PBM and the customer, and to impose competitive pressure on the incumbent PBM. The RFPs may be created and submitted by PBM vendor selection consultants or by the organization seeking PBM services. They tend to be specific in what they require from bidders in terms of price, accreditation, pharmacy access, and how the bidders should respond.

43. The RFP submission process allows the requesting organization to compare the competitive responses using a similar response format and content. It also helps to eliminate interested bidders who are not able, or are unwilling to meet the specific terms of the requesting organization. The customer and/or

its consultant then selects a small number (typically two to three, sometimes as many as six) finalist bidders. Once the finalist bidders are selected by the requesting organization, the parties negotiate for best and final offer among bidders and a successful bidder is awarded the contract.

44. Included in the response to the RFP would be pricing and pharmacy network expectations. Typically the last year's claims data from the submitting organization is priced using the network pricing model submitted as part of the bid proposal by the PBM so the submitting organization can determine whether the network pricing is competitive or offers improved pricing to the incumbent PBM.

45. Often the process of reducing the agreement to formal documentation is begun using a model contract (either from the customer, the customer's consultant or the PBM). Often the RFP will stipulate that a successful bidder will accept a particular model contract to begin negotiations.

46. The time necessary to negotiate contracts varies in length. If the parties are motivated, it could take less than one month. Most take significantly longer. It has been my experience that client contracting can often take between 90 days and 6 months. It may also be influenced by the bidding process where a customer may require acceptance of pricing and terms and conditions of the agreement unless the exceptions are specifically agreed to in writing prior to awarding the business. Larger PBMs have hundreds to over one thousand customer contracts, each with different pricing, terms and conditions.

47. In PBM contracting, everything is subject to negotiation. This makes the process complex, time-

consuming, and yields highly customized contracts. While the PBM may strive to offer model contracts including network pricing and pharmacy reimbursement for ease of administration, client demands often require customization specific to their goals and needs.

48. One point of negotiation is the method by which the PBM will be paid. Some customers choose to negotiate “pass-through” contracts, by which the customer pays the PBM using the same MAC pricing that the PBM pays to the pharmacy network. Under these circumstances, the customer pays the PBM using negotiated administrative fees or another specifically agreed payment. Other customers elect to have guaranteed price or “lock-in” contracts, by which the customer pays the locked-in price based on the drug’s published average wholesale price (AWP) or another published pricing benchmark.

Most PBM Customer Contracts are Multi-State

49. As mentioned above, many PBM customers operate in more than one state. In addition, the prescription drug market is national and interstate. Therefore, even if the employer sponsor of a health plan operates only out of one state, various factors could require the contract to include services in other states such as: having business with locations in multiple states, being located on a border state with employees living in a different state than where they work, having retirees eligible for benefits that reside in other states or having employees and their dependents who often travel for work or pleasure or leave for college. In each case, the customer needs a national network of pharmacies to provide services to its members.

50. When bidding on and negotiating a multi-state contract, the PBM must take into account the laws of the various states which would apply to the contract. PBMs have three options to ensure compliance with any particular state law. They could (1) apply the most onerous state law nationwide; (2) create a different mode of operating for that state only; or (3) avoid doing business in a state with a particularly onerous law. In most cases, the PBM will choose the first, and adopt provisions that satisfy the most onerous state laws that would apply to the contract. In some cases, however, this is not possible due to particular state laws that are particularly unfavorable to PBMs or extremely difficult to comply with. Under those circumstances, the PBM is forced to develop an operational effort specifically addressed towards complying with those laws.

51. By necessity, regardless of whether a PBM chooses to implement state-specific operational provisions, or apply a state law nationwide, the effects of any one state law are not limited to that single state. This is because PBMs do not provide their services on a state-by-state basis, and PBM customers do not limit their beneficiaries to accessing their benefits in any particular state.

The Pharmacy Networking Process is Customer-Driven

52. Customers have variable priorities for pharmacy networks. Some want broad access, with unlimited networks. Those customers will be less able to negotiate based upon network price.

53. A customer's need for a broad-access network gives a pharmacy more leverage to negotiate with the PBM to achieve the pharmacy's profit margin targets.

If a customer wants a particular pharmacy or chain of pharmacies in a network (or if inclusion of a pharmacy is necessary to meet the network access needs of the customer), the pharmacy has significant leverage to demand a higher rate of reimbursement. This is because the PBM will not gain or keep the customer's business without that pharmacy's participation.

54. PBM-pharmacy contracts also give pharmacies the ability to terminate the contract subject to its notice provisions. PBMs will do what it takes to avoid losing a pharmacy from its network, particularly because many customer contracts require notice to the customer when significant network access changes occur. Some contracts also require advanced notice to health plan members affected by the departure of a network pharmacy. In the case of pharmacies where there is little competition in the geographical area, the PBM may be compelled to offer a special or "rural rate" or even a more generous MAC pricing list to retain that pharmacy in the network.

55. Independent pharmacies typically negotiate through pharmacy service administrative organizations (PSAOs). These organizations offer group purchasing, network contract negotiations and claims payment coordination and reconciliation to their member pharmacies. Typically the PSAO contracts on behalf of its membership as a whole, giving it greater bargaining power and the ability to satisfy PBM customer access needs.

Guaranteed Pharmacy Services and Pricing is Central to Pharmacy Networking and to Customer Contracts

56. Pharmacy services and predictable pharmacy access and network pricing are primary reasons for customers to contract with PBMs. These PBM func-

tions promised in customer contracts are among the most important contract provisions.

MAC Development

57. MAC programs are common throughout the pharmacy benefit management industry and are used by most payors including the Centers for Medicare and Medicaid Services (CMS) for Medicare and Medicaid claims payment under their Federal Upper Limit program, health plans and PBMs. The programs were created in response to the rapid fluctuations in the generic prescription drug market as well as publication of multisource drug average wholesale prices that were not reflective of actual acquisition costs by the pharmacies. Payor goals have been to reimburse near the actual acquisition price and prevent windfall profits as generic prices fluctuate.

How MAC is Developed

58. MAC pricing sources are varied and depend upon what pricing intelligence is available to the entity creating the MAC prices. PBMs typically rely on large, national wholesaler prices, direct manufacturer prices, National Average Drug Acquisition Cost prices, and actual net purchase prices by the PBM's own pharmacies. As new sources of pricing become available, new pricing schemes evolve, drug shortages occur, or market demands change, PBMs will usually adapt their MAC pricing lists accordingly.

A PBM Selects Drugs For the MAC List Based on a Number of Factors.

59. A PBM chooses drugs for its MAC list based on client-specific demands and goals. As more branded prescription drugs lost patent protection, clients saw the opportunity to for savings with the emerging

competitive generic drugs and are more closely involved in how the PBM administers its MAC pricing.

60. A particular client's benefit design may dictate how many and what type of drugs comprise the MAC list. I am aware of MAC lists of fewer than 500 drugs to lists of nearly 2000 drugs. Some clients may want to cover non-prescription generic drugs to meet their needs.

61. The number of manufacturers competing in the market is an important factor since competition tends to create price fluctuations. If there is upward or downward pressure, there is still good reason to add these products to the MAC list, however.

62. The volume of prescription claims for a particular drug also is an important factor. If there are very few claims for a particular drug, a PBM may wish to omit the drug from its MAC list since the MAC would have very little financial impact and become more of an administrative burden with little return for the effort. Also, a product that is rarely dispensed is more difficult for network pharmacies to stock and keep in date making a MAC price on the drug a problem for pharmacy inventory management.

63. When determining which NDCs to use for the MAC, the team developing the MAC list selects generic products with FDA Orange Book AB equivalency rating¹ for the drug they are adding. If new

¹ The United States Food and Drug Administration publishes Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The Orange Book contains therapeutic equivalence evaluations for generic drugs, which are indicated by two-character rating code. "AB" is the code for drugs that are therapeutically equivalent to an approved drug.

generic competitors come to market, they are added among future updates. Typically the team uses Generic Product Indicators and Brand/Generic designation fields from the MediSpan drug pricing file to identify generic products for MAC consideration.²

Factors Weighed When Developing MAC

64. Ideally, a MAC pricing list should save the customer costs on drugs while causing minimal disruption to network access. A MAC list that is set too low will destabilize the network and health plan members will not have adequate access to prescription drugs. Such a result is highly undesirable for a PBM, as it can cause a great deal of administrative work to remediate. MAC prices that routinely result in pharmacies receiving reimbursements below cost will invite a larger number of appeals and accompanying reversals and make subsequent network contracting efforts more difficult. Therefore, even absent MAC laws, PBMs are highly motivated to set MAC prices at a level that satisfies the pharmacies in its network overall.

65. If a customer wants a broad access network and the MAC is crafted to be especially spare, the customer will have to make a decision as to which is most important, network stability or savings from lower MAC reimbursement.

66. When a customer wants a lower network reimbursement and is willing to accept a limited access network for its members, the network will likely be

² The Medi-Span drug pricing file is a database provided by Wolters Kluwer which links prescription drug classification codes commonly used for payment and analysis by the federal government. Generic Product Indicators and Brand/Generic designation fields are classifications included in this database.

composed of higher volume pharmacies that are willing to trade margin on individual prescriptions for greater volume. Typically, such a network is made up of pharmacies that purchase at the best pricing available and operate at a high level of efficiency. Often large pharmacy chains have an advantage in both purchasing and efficiency and contract more aggressively for lower margin business.

Mechanisms for MAC Updates/Changes

67. PBMs make regular updates to the MAC list by reviewing changes published in the same sources they used to develop the MAC pricing list. Since pricing may change frequently, most PBMs will make changes in their MAC pricing frequently. Some PBMs update MAC prices weekly, twice weekly or even daily. PBMs decide not to make changes on drugs where the price has changed insignificantly but if significant changes have occurred, it is in their best interest to update pricing.

68. If the market price of a MAC drug falls, customers will expect the savings a pricing change may bring. If the price increases significantly, pharmacies will call to notify the PBM that their pricing changes haven't kept pace and if there isn't rapid resolution there will be appeals that must be heard and responded to. If a PBM fails to update a MAC to reflect the current price, it will be forced to handle increased customer service and/or pharmacy appeals.

69. The appeals process works as follows: When a pharmacy submits an appeal, the PBM will typically review drug pricing sources for changes. The PBM will give the appealing pharmacy an answer within a time specified by either the PBM network contract or by regulation. If the PBM agrees that the pricing changes

merit a MAC pricing adjustment, it will make that change.

70. PBMs have teams of analysts reviewing pricing changes on a routine basis. These analysts rely on sophisticated information management tools that process published pricing sources to determine when the market price for a particular drug has changed. As information management has become more sophisticated, it's less likely that a PBM will be caught off-guard by a drug's pricing changes. The PBM's monitoring processes reduce the need for pricing disputes or appeals by network pharmacies.

71. It is important for PBMs to retain flexibility in using sources of information that reflect true costs to network pharmacies. Manufacturer and wholesaler invoices are not appropriate as the sole sources of price, because those documents will not reflect off-invoice discounts, performance bonuses or other creative methods of increasing margin. Also, inefficient purchasing at a higher cost should not be rewarded by overturning a price on appeal when market intelligence suggests that the drugs are commonly available for less.

Opinions on Impact of Act 900

"Guaranteed Profits" Provision

72. Act 900 forces PBMs to adjust MAC based on "pharmacy acquisition cost", rather than market-wide data. Ark. Code § 17-92-507(c)(4)(C)(iii). Pharmacy acquisition cost is defined as "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice." Ark. Code § 17-92-507(a)(6).

73. Act 900 creates an incentive for pharmacies to appeal their reimbursements, because as long as the pharmacy can show that the MAC was below the invoiced price, no matter what other market data shows, the pharmacy will prevail on appeal. PBMs would prefer not to have network pharmacies appeal their pricing and would prefer to get the price right the first time. Therefore, Act 900 incentivizes PBMs to inflate MAC in order to avoid constant challenges under the law.

74. Act 900's requirement that MAC be set at "pharmacy acquisition cost" or higher effectively guarantees pharmacists a profit on every prescription they fill. There are two reasons that Act 900 guarantees profits. First, by guaranteeing reimbursement for "pharmacy acquisition cost," Act 900 fails to take into account commonly used off-invoice pricing concessions. Second, because Act 900 incentivizes PBMs to inflate MAC in order to avoid a high volume of appeals, MAC will now be set at a level above the highest pharmacy acquisition cost for a drug. Therefore, those pharmacists that obtained the drug at a lower price will enjoy an even larger profit margin.

75. By incentivizing an inflated MAC, Act 900 negates the usefulness of MAC altogether. MAC is a tool to keep prices down, and Act 900 will cause prices to rise. Act 900 is contrary to the purpose of MAC; instead of incentivizing pharmacies to aggressively seek the lowest prices from their business partners, it incentivizes and rewards inefficient purchasing and pharmacy operations, such as poor negotiating by the pharmacy with drug wholesalers, poor business practices resulting in unfavorable contracting terms, or poor inventory management.

76. This fundamental change to MAC pricing affects both customer and pharmacy contracts. Those contracts were negotiated by informed parties in good faith and at arms length. The financial impact on the PBM customer is significant and will result in making coverage of health care less affordable.

77. The change to MAC will disrupt PBM and customer expectations in contracts since contracts are premised on price and Act 900 makes it impossible to rely on expectations for the price of generic drugs in a changing, competitive marketplace. The use of MAC pricing in anticipating prescription drug cost trend is something that PBM customers have come to rely upon in negotiating their contracts. They plan their budgets around the cost of health care for their covered plan members and Act 900 disrupts those plans.

78. Change to MAC pricing will also disrupt pharmacy network contracts.

“No Dispense” Provision

79. Act 900 allows pharmacies to decline to dispense a drug to a beneficiary if the MAC price is determined by the pharmacy to not be high enough. This unravels the central purpose of pharmacy network contracts and PBM customer contracts and puts the Arkansas consumer in the middle of a pricing dispute.

80. The key requirement for a PBM customer contract is that the PBM has contracted to provide pharmacy benefit services to the customer’s members and the pharmacies have agreed to serve those members as long as they remain in the network. PBMs ensure that this will happen by conditioning pharmacy network membership on guaranteed service. To permit pharmacists to decide whether to participate in the PBM’s network on a script-by-script basis undermines

the expectations of PBM customers and their employees or beneficiaries and destroys the purpose of a pharmacy network.

Act 900 Impacts PBMs, Health Plans, and Beneficiaries Beyond Arkansas

81. The disruption of PBM customer and pharmacy network contracts is not limited to Arkansas. Because a majority of customers have multi-state needs, the disruption will be felt outside of Arkansas. In fact, customers who have no business link in Arkansas may also be impacted if their covered retirees choose to live in Arkansas or their members' dependents choose to attend school in Arkansas. Future contracting for plans with beneficiaries in Arkansas will now be unpredictable due to this fundamental change.

82. PBMs will be forced to either (1) adopt different/new strategies for plans with beneficiaries in Arkansas inconsistent with other contracts; (2) apply strategies compliant with Act 900 nationwide; or (3) cease doing business in Arkansas altogether. However, even if the PBM opts to adopt new, Arkansas-specific strategies, by necessity employers and insurers operating outside of Arkansas will not access the full benefits of MAC pricing because their members may cross state lines to fill prescriptions. State-specific pricing is unprecedented in the PBM industry, and would cause a significant disruption to the national nature of the PBM market. State-specific practices will also present operational challenges that are expensive and unique to Arkansas.

83. The "no dispense" provision will also have interstate effect because members of a plan may travel into Arkansas only to be denied pharmacy benefits

when the pharmacist decides they aren't getting adequate profit on an individual prescription.

Provisions Requiring PBMs to Update MAC Lists Based on Changes to "Pharmacy Acquisition Cost"

84. Act 900 requires PBMs to update their MAC lists within seven days from "an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in" Arkansas. Ark. Code § 17-92-507(c)(2).

85. PBMs are not privy to the purchasing relationship that the pharmacy has with its wholesaler. PBMs consider a number of data points in setting their MAC. Some of these include wholesale price lists. The wholesaler invoice prices may only represent a portion of that financial relationship and wholesalers may have a number of different prices depending on the status (based upon volume, performance or credit standing) of their various customers. However, PBMs do not have access to all of the price lists or purchase invoices for each pharmacy customer of all of the wholesalers doing business in Arkansas that would allow the PBM to determine whether there is a unique pricing change in that market as defined by Act 900. Typically, market forces impacting drugs subject to MAC prices do not impact only one state or region, however. Generally, PBMs look at price lists from national wholesalers (AmerisourceBergen, Cardinal Health, and McKesson). In my experience local wholesalers' price lists (of which there are thousands) are not data points on which a PBM would rely for establishing MAC prices since national wholesalers would sell in local markets at the widely published national price.

86. None of the other information to which a PBM would have reasonable access would allow it to determine when there has been an increase of ten percent or more in the pharmacy acquisition cost from sixty percent or more of the wholesalers doing business in the state. Such a determination could only be done by an ongoing survey of all wholesalers on all drugs that were priced at MAC—an activity that PBMs are not currently capable of performing.

Foreseeability of Act 900

87. PBMs did not foresee that Arkansas would require pharmacies to be reimbursed at their invoice prices. This unprecedented move was not taken into account when PBMs, their customers and the network pharmacies were contracting for business effective in 2015 and 2016.

88. In particular, PBMs did not interpret Act 1194 to set the price of drugs at pharmacy acquisition cost, and did not anticipate that Act 1194 was the first step down a path towards a law prohibiting “negative reimbursement.” Act 1194 was consistent with the other types of laws that were being passed around the country in or around 2013 that were aimed at increasing transparency of MAC pricing, and requiring PBMs to update their MAC lists on a frequent basis. Nothing about Act 1194 suggested that the Arkansas legislature would soon require PBMs to reimburse pharmacies for their invoiced costs.

Reservation of Rights

89. I reserve my rights to amend, modify, supplement and/or further support my opinions based on, inter alia, information learned during additional discovery, including without limitation obtained from documents and/or testimony that are produced or

otherwise obtained after the preparation of this report. I further reserve my rights to rebut any expert opinion proffered by the defendant in this action.

90. I declare under penalty of perjury that the foregoing is true and correct. Dated: June 24, 2016

Signature: /s/ John Jones

201

[1] UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

vs.

LESLIE RUTLEDGE, in her official capacity as
ATTORNEY GENERAL OF THE STATE OF ARKANSAS,

Defendant.

DEPOSITION OF JOHN JONES

IRVINE, CALIFORNIA
FRIDAY, JULY 15, 2016

ATKINSON-BAKER, INC.
COURT REPORTERS
(800) 288-3376
www.depo.com

REPORTED BY: DIXIE LYNCH, CSR NO. 9521
FILE NO. AA06F5D

* * *

[2] Deposition of JOHN JONES, taken on behalf of
Defendant, at 2040 Main Street, 14th Floor, Irvine,
California, commencing at 10:00 a.m., Friday, July 15,
2016, before Dixie L. Lynch, CSR No. 9521.

[3] APPEARANCES:

FOR PLAINTIFF:

FOLEY HOAG LLP
BY: KRISTYN DEFILIPP
Attorney at Law
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210-2600
(617) 832-1218
kbuncedefilipp@foleyhoag.com

FOR DEFENDANT:

OFFICES OF THE ARKANSAS
ATTORNEY GENERAL
BY: SHAWN J. JOHNSON
Senior Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
(501) 682-1178
shawn.johnson@arkansasag.gov

* * *

[5] JOHN JONES,

having been first duly sworn, was
examined and testified as follows:

EXAMINATION

BY MR. JOHNSON:

Q: Good morning, Mr. Jones. I'm Shawn Johnson, senior assistant attorney general with the Arkansas Attorney General's Office; and the Pharmaceutical Care Management Association we all refer to as the PCMA in this case has asked you to testify as an expert witness; is that right?

A: That's correct.

Q: And that's in the case of PCMA vs. Leslie Rutledge in her official capacity. Am I correct about that?

A: That's correct.

Q: The PCMA has named you an expert, as I mentioned. What have you been asked to do in this case?

A: Opine on the Act 900 in the – the legislation that was passed into law, I believe in 2015, to write an expert report as to how it might impact the PBM industry and health plans, et cetera, the clients of the PBMs, networks of the PBMs.

* * *

[70] Q: Regarding pharmacy appeals, in paragraph 64 of your report, you mentioned that MAC price – “A MAC pricing list should save the customer costs on drugs while causing minimal disruption to network access.” I wanted to ask you, in general, you had mentioned that 1 percent of all pharmacy transactions would result, in your experience, in an appeal; right?

A: Less than.

Q: Less than 1 percent.

A: Uh-huh.

Q: How many of those appeals are granted versus how many are denied?

A: It has varied over the years. And I'm not sure what the current statistics are, but I would say that probably fewer than 20 percent at the time that I was working on it resulted in a change.

We got some small pharmacies that simply didn't purchase well that, you know, upon analysis of their complaint, we found that they – you know, it was without merit. They didn't like what they were getting paid, but they should have been able to purchase it at what were paying at that time.

[71] Q: And when you say they should have been able to purchase it at that price, how can you ensure that as a PBM?

A: You can't ensure it as a PBM. But, you know, can you ensure that the pharmacy is operating efficiently? If they are operating inefficiently, do you reward their inefficient operations by increasing the price?

And, you know, typically we also looked at is it just this pharmacy that can't purchase at this price, or do we have a lot of people who are having the same problem? And if our analysis shows that they should have been able to purchase at this but for whatever reason they couldn't, other people are not having the same difficulty, you know, we would probably deny the appeal because, again, it's a – it's one pharmacy complaining, and it's not a widespread problem.

* * *

[76] Q: Would you say that in one respect appeals of under-reimbursements or negative reimbursements as we have used them in this case, that appeals are helpful to PBMs in determining whether a MAC is too low?

A: We as an industry invest in handling appeals in an efficient way, and that information goes back to the management to give them indicia of how the program is working. Low number of appeals suggests, you know, that you are where the pharmacies want to be. A high

number of appeals, you know, is also suggestive that, you know, there are issues with how you are doing the pricing. So [77] you are constantly measuring your performance.

Q: So from the PBM's perspective, is it the number of appeals that come in that a PBM determines its performance by or whether or not it grants or denies the appeals themselves?

A: I would say it's the number of appeals where they could say they are meritorious. If you are looking at them and you see a change needs to be made, it's helpful, first of all, to be responsive to those because otherwise you are going to get a lot more calls and a lot more appeals.

Q: I mean, it's like for me – and this is hypothetical – when I appeal a – with my Uber driver, my taxi driver, it's Uber. And I did this the other day. I had a bad one. And I rated him poorly, and I notified Uber about it; and Uber gave me a \$5 discount off of my ride. Why isn't that sort of a service something that a PBM would appreciate knowing that something is wrong with its MAC?

MS. DEFILIPP: Objection.

THE WITNESS: The appeals with merit help you refine your MAC price. If someone points out something that needs to be changed because you simply haven't noticed an upward or a downward trend – and, by the way, it's always upward, they don't tell you about the downward trend [78] ones – but if there was an upward trend on a drug and they legitimately can't buy it and your analysts agree with that, that, yeah, it's helpful. It's helpful for us to know.

BY MR. JOHNSON:

Q: Okay.

Your second opinion in your report that you render is in paragraph 3.

A: Okay.

Q: Act 900 – I’m paraphrasing. Act 900 prevents PBMs and their customers from accessing negotiated benefits of MAC pricing because it forces PBMs to reimburse pharmacies for the price listed on their wholesaler invoice. Have I paraphrased that correctly?

A: Yes.

Q: And what do you base that opinion on?

A: Okay. So the full negotiated benefits of MAC pricing, you’ve basically told the pharmacies, you know, look. We are going to have a MAC list, and we are going to update it on a regular basis; and here are your – here are your rights under the contract for appeal. You know, we will – we will, to a degree, you know, that we have a MAC work with you on this MAC, and Act 900 basically takes that out of the contractual side of things and says instead wholesaler invoice is going to control even though [79] the wholesaler invoice may not represent all of the pricing dynamics.

* * *

[102] Q: If there’s no oversight of the market [103] intelligence that the PBM utilizes in setting drug costs or determining what they are for MAC development, they are on the honor system to enforce them the way that they say that they do; right?

A: The PBMs, if they ended up with a price that was simply too low, you know, too low for the network, the pharmacies would basically appeal. They would push

back. They would not allow it. So when you say “the honor system,” they will look to see what they think is a reasonable cost for that – or price for that pharmacy to pay for that drug on that date, on that package, et cetera. If they are too spare, they will definitely get complaints; and they will get them quickly.

* * *

[119] Q: I suppose I don’t understand what changes Act 900 causes the market intelligence protocol to incur. It doesn’t appear to me to be any different. Is it different?

MS. DEFILIPP: Objection.

THE WITNESS: It’s different only in now you have to factor in appeals.

BY MR. JOHNSON:

Q: Which those currently exist.

A: Those – well, yes, but increased numbers of appeals.

Q: That’s an assumption; right?

A: That’s an assumption. You would have an increased number of appeals. Every appeal is expensive. That’s why you try to minimize them. You try to keep the pharmacies as happy as possible. You don’t want an increased number of appeals. But anticipating the [120] likelihood that in a bold and pharmacy community would say, “Well, let’s make some more Act 900 appeals,” that will have an impact on the regulatory burden that now the PBMs will have to engage in.

Q: And they have obtained the people who already handle those appeals, haven’t they?

A: There are a team of people who handle those appeals. You know, the resources, as anything, are just enough to get the job done. There are requirements in a number of states as far as turnaround time on appeals, the type of information; and, therefore, you can't underfund that. If you have more appeals, you have to increase the number of people working in that area.

Q: How many people would you anticipate that a company like OptumRx would have to hire in order to handle what you believe to be an increased number of appeals under Act 900?

MS. DEFILIPP: Objection.

THE WITNESS: That's a good question because, again, post-acquisition, I don't – I don't know what their plans are as far as, you know, staffing, et cetera. If I was still running the unit, which I haven't for a number of years – I have seen some PSAOs that make a business out of appeals. You know, they just ramp it up because they know now you are being governed by some turnaround time [121] requirements. You know, it might easily double or triple the number of people that have to satisfy the requirements of turnaround time and meeting the goals of the regulation.

BY MR. JOHNSON:

Q: What sort of a number does that mean? What would be a doubling of the existing staff?

A: Well, if you went from, you know, 6 to 12 to 18, you know – again, it is totally hypothetical because I don't know, you know, what the new structure looks like.

Q: When you left, you are telling me, I take it, that there were six people on the MAC team?

MS. DEFILIPP: Objection.

THE WITNESS: There were –

MS. DEFILIPP: Are you talking about appeals or the MAC team?

MR. JOHNSON: The appeals. To me they are the same.

THE WITNESS: They are different.

BY MR. JOHNSON:

Q: Okay. Tell me about that.

A: Okay. So a MAC team would have people who would do appeals but also people who would do analytics, forward-thinking analytics, you know, looking at current changes and drug pricing, et cetera.

Q: Okay. So on the appeals side, how many people [122] were there?

A: I believe that was six to eight the last I checked. I wasn't over the area, but I was at least aware of it.

* * *

Expert Witness Report of Donna West-Strum, RPh,
PhD on behalf of the Arkansas Attorney General's
Office June 23, 2016

In preparation for

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

vs

LESLIE RUTLEDGE AS
ATTORNEY GENERAL OF ARKANSAS

Table of Contents

I. Expertise and Scope	4
A. Qualifications	4
B. Assignment	4
C. Materials Considered	4
D. Executive Summary	4
II. Independent Community Pharmacy is Struggling Financially	5
A. Independent community pharmacy challenged to maintain gross margins and pay expenses	5
B. Independent community pharmacists in rural areas finding it difficult to sustain their prescription business	7
C. Chain pharmacies report the same financial challenges with respect to prescription reimbursements	7
D. Independent community pharmacies in Arkansas are closing, resulting in decreased access to prescriptions and pharmacy services for many, especially those in rural areas	8

III. Factors that Comprise the Financial Health of Community Pharmacy	9
A. Reimbursement rates must cover the acquisition cost of the drug product	9
B. Pharmacies purchase drug products at lowest price possible to improve financial health	9
IV. PBM Reimbursement Impacts the Financial Health of Independent Community Pharmacy	10
A. PBMs “force” pharmacies to accept low reimbursement rates	10
B. PBM reimbursement reduces gross margins	11
C. MAC prices are controlled by PBMs and may be set below acquisition costs for Arkansas Pharmacies	11
D. MAC prices set below pharmacy acquisition cost is not a sustainable reimbursement model for community pharmacy and therefore jeopardizes access to pharmacy care for Arkansas residents	13
E. MAC price lists must be based on fair market estimates of acquisition cost for generic drug products in Arkansas for Arkansas independent community pharmacies to remain in the pharmacy dispensing business	13
F. MAC prices should be updated to reflect manufacturer price increases	14

V. Arkansas Act 900 Is Necessary to Protect Community Pharmacy Access in	15
A. Act 900 mandates PBMs maintain updated MAC lists that reflect acquisition costs that are “widely and consistently” available to Arkansas pharmacies but does not change the PBM reimbursement strategy (i.e., MAC lists). Act 900 allows the MAC reimbursement strategy to perform in the marketplace without jeopardizing the number of community pharmacies in Arkansas and patient access to prescription drug products and pharmacy services	15
B. Without Act 900, PBMs could continue to be aggressive in their MAC pricing, which jeopardizes community pharmacies and patient access to pharmacy care	16
C. Act 900 does not require PBMs to artificially inflate generic MAC prices and does not guarantee a profit for the pharmacy	17
D. Act 900 does not change community pharmacy owners’ resolve to purchase drug products at the lowest price possible	17
E. Act 900 does not put extensive burden on PBMs	18
F. Act 900 allows pharmacists to focus on patient care, rather than reimbursement appeals	18

G. “Right to Refuse to Fill a Prescription” provision strengthens Act 900 to protect patient access to community pharmacies without negatively impacting patient care	18
VI. Act 900 Prevents the Decline of Independent Community Pharmacy in Arkansas, which is important to the public health of Arkansas	19
A. Arkansas Act 900 maintains the integrity of the MAC reimbursement model and reduces the likelihood of unsustainable losses on generic prescriptions	19
B. Scenarios demonstrating how Act 900 protects the financial health of independent community pharmacy	19
VII. Conclusions	23
VIII. Appendix A: Financial Trends of Independent Community Pharmacy	24
IX. Appendix B: Illustration of Act 900’s Impact on Pharmacy Purchasing	26
X. Appendix C: References	27
XI. Appendix D: CV	34

I. Expertise and Scope

A. Qualifications

I, Donna West-Strum, am over 18 years of age and hereby declare as follows:

1. I make this declaration upon my own personal knowledge, except where stated to be on information and belief, and with respect to any such statements, I believe them to be true. If called upon to testify, I could competently testify to such facts.

2. I am chair and professor in the Department of Pharmacy Administration and professor in the Research Institute of Pharmaceutical Sciences in the School of Pharmacy at the University of Mississippi. I completed my BS in pharmacy in 1995 and my PhD in 1999. Most of my academic scholarship is related to community pharmacy, pharmacy management, medication adherence, and pharmaceutical outcomes. I have published over 80 peer-reviewed articles and written several book chapters related to community pharmacy. A copy of my CV is attached in Appendix D. All of my publications are included.

3. I am currently licensed to practice pharmacy in Mississippi. I was licensed to practice pharmacy in Arkansas from 2000 to 2009. I have testified in front of the Arkansas Legislative Council Rules and Regulations Committee on Arkansas Medicaid reimbursement. I have also served on the Expert Panel to discuss the Economic Impact of the NSURE Initiative being considered by the FDA. I have worked as a pharmacist for three different independent pharmacies. I have consulted with pharmacies, including the Little Rock Community Mental Health Center pharmacy, about financial issues.

B. Assignment

4. I have been asked to address the financial situation of independent community pharmacy over the past 10 years and the future outlook, some of the factors comprising the financial health of an independent pharmacy, an explanation of how pharmacy benefit manager (PBM) reimbursements affect the financial aspects of an independent pharmacy, an explanation of the likely effects of Arkansas Act 900 of 2015 on the independent pharmacy business in Arkansas, and a projection of the financial effects of Act 900's provisions on the independent pharmacy business in Arkansas.

C. Materials Considered

5. This report and the opinions expressed in it are based on my analysis of the information and materials available to me as of this date as well as my education, training, experience, and research. The list of materials I used is included in Appendix C. My understanding is that I will be compensated at a rate of \$250 per hour for my work in this matter. This compensation is not contingent on the outcome of this case.

D. Executive Summary

6. Independent community pharmacies are challenged to maintain gross margins and pay expenses. Chain pharmacies report the same financial challenges. As a result of these financial challenges, independent community pharmacies are closing, resulting in decreased access to prescriptions and pharmacy services. Some of the financial challenges are a result of MAC prices being set below Arkansas pharmacies' acquisition costs. This is not a sustainable reimbursement model for community pharmacy and therefore jeopardizes access to pharmacy care for Arkansas residents. MAC price lists must be based on fair

market estimates of acquisition costs for generic drug products in Arkansas for Arkansas independent community pharmacies to remain in the pharmacy dispensing business. Arkansas Act 900 mandates PBMs maintain updated MAC lists that reflect acquisition costs that are “widely and consistently” available to Arkansas pharmacies but does not change the PBM reimbursement strategy (i.e., MAC lists). Act 900 allows the MAC reimbursement strategy to perform in the marketplace. It does not require PBMs to artificially inflate generic MAC prices and does not guarantee a profit for the pharmacy. Act 900 allows pharmacists to focus on patient care, rather than reimbursement appeals. The “right to refuse to fill a prescription” provision allows the pharmacist to care for the individual patient in a way that does not risk the financial solvency of the business. Arkansas Act 900 is an importance piece of legislation that prevents the decline of independent community pharmacy and protects access to prescriptions and pharmacy services for Arkansas citizens. It maintains the integrity of the MAC reimbursement model while reducing the likelihood of unsustainable losses on generic prescriptions for pharmacies.

II. Independent Community Pharmacy is Struggling Financially

A. Independent Community Pharmacy Is Challenged to Maintain Gross Margins and Pay Expenses

7. Independent community pharmacy has been financially challenged over the last five to ten years. Appendix A provides various Tables to show the financial trends in independent community pharmacy. Data from these Tables have been pulled from the NCPA Digest, sponsored by Cardinal Health (2008-2015) and

the NCPA-Pfizer Digest (2005-2007). The National Community Pharmacists Association, the national pharmacy association representing independent pharmacies across the country, publishes the Digest report annually. The trends observed from these data are described in this report.

8. The number of prescriptions dispensed by independent community pharmacies has decreased over the past several years. Over the last five years, average prescription volume in an independent community pharmacy decreased from 64,169 annually (205 prescriptions per day) in 2010 to 61,568 annually (197 per day) in 2014. (2011 NCPA Digest and 2015 NCPA Digest) Although more people are covered by health care insurance, several factors are contributing to the decreased prescription volume: mandatory mail order or mandatory mail order for refills, the use of financial incentives for patients to fill refills at mail order, steering patients taking specialty medications to specialty pharmacies, 90-day supply prescriptions, and implementation of preferred pharmacy networks. (2015 NCPA Digest; Pharmacy Benefit Management Institute 2015) Prescription dollar sales make up approximately 90% of total dollar sales in an independent community pharmacy, thus a decrease in prescription volume has financial implications for an independent community pharmacy.

9. Payment of prescriptions by third-party payers in the community setting is the norm. Only about 10% of prescriptions filled in independent community pharmacy are for cash-paying customers. (2015 NCPA Digest) With almost everyone having prescription drug coverage, it makes it difficult for independent community pharmacies to not accept a PBM contract, especially if a substantial number of their patients are

covered by that PBM or third-party payer. (Causey 2009) Not signing a contract could mean losing a significant number of patients/customers and their prescription sales and other sales. (Roth 2014) For example, Walgreens did not contract with Express Scripts because of a disagreement over reimbursement rates in 2012, resulting in a loss of more than 80 million prescriptions or 10 percent of all prescriptions it fills in a year. Prescription drug sales decreased 6.1 percent. “The defeat was a wake-up call for Walgreens. Being the biggest pharmacy chain with more than 8,200 stores, it was still not big enough to have the negotiation power with other players in this hundreds of billion-dollar pharmaceutical industry.” (Chen December 17, 2014)

10. Over the last few years, prescription dollar sales and total dollar sales in independent community pharmacy have decreased. Prescriptions (dollar) sales have constituted 90-92% percent of total (dollar) sales in independent community pharmacy. Some of the decreasing prescription dollar sales can be attributed to a decrease in prescription volume; however, the decrease in volume does not explain all the decrease in prescription dollar sales. Other contributing factors to a decrease in dollar prescription sales include an increase in generics which have a lower sales price compared to brand name prescriptions and a decrease in reimbursement from third-party payers for both generic and brand name prescriptions dispensed. Third-party payers have continued to offer lower reimbursements for both brand and generic prescriptions to pharmacies in an effort to reduce prescription spending. (Pharmacy Benefit Management Institute 2015) Pharmacies have been forced to accept the lower reimbursement rates in an effort to maintain prescription volume.

11. The difference between what the pharmacy is reimbursed for the drug product (e.g., MAC price list plus a dispensing fee) and the pharmacy's acquisition cost of the drug product on the wholesaler invoice is the gross margin. There must be enough gross margin dollars to pay the pharmacy's expenses (e.g., salaries, insurance, computer system, rent, utilities, supplies, pharmacy licenses, etc). If a generic drug product increases in price by the manufacturer and the pharmacy has to purchase the drug product at the increased price, but the payer does not adjust the reimbursement rate (e.g., the MAC price) for the drug product to account for a change in the marketplace, then the gross margin decreases. If this happens frequently or the MAC list price is significantly lower than what the pharmacy has to pay for the drug product, it becomes difficult for the pharmacy to pay the business expenses and continue to stay in business. In other words, these losses are unsustainable over time.

12. As gross margins shrink, community pharmacies have become more efficient. For example, over the last few years, payroll expenses as a percent of sales and in dollar amount have decreased. In order to continue to stay in business, independent community pharmacies have decreased the number of personnel working in the pharmacy. (NCPA Digest 2008, NCPA Digest 2012, NCPA Digest 2015) With low gross margins, community pharmacy owners must continue to find ways to reduce personnel and operating costs, and yet still comply with the Arkansas State Board of Pharmacy regulations for public safety.

13. Pre-tax profit dollars are necessary for pharmacists, companies, and other investors to want to own a pharmacy as well as are needed to reinvest into the pharmacy (e.g., restructure pharmacy, purchase new

computer systems/software/automation, expand patient care services, implement quality improvement programs, purchase patient safety technologies, implement security measures to prevent drug diversion, etc). Independent community pharmacy owners are making less net profit dollars before taxes today compared to five years ago. (NCPA Digest, Carroll 2015)

B. Independent Community Pharmacists in Rural Areas Finding it Difficult to Sustain their Prescription Business

14. These same financial trends are seen even when you look at subsets of pharmacies. For example, the national financial trends for independent community pharmacies in rural areas are just as alarming as when looking at the national financial trends for all independent community pharmacies. According to the 2015 NCPA Digest (data from 2014), pharmacies in populations with less than 20,000 had net operating profit before tax of \$84,850 and those in areas between 20,000 and 50,000 had \$82,577. These medians are less than the median net operating profit before tax for all pharmacies (i.e., \$88,021). (NCPA Digest 2015) Also compare these numbers to NCPA Digest numbers in 2006, where a pharmacy located in an area with a population of less than 20,000 had a median net operating profit of \$95,916. (NCPA-Pfizer Digest 2006) These trends of decreasing prescriptions, decreasing reimbursement rates, decreasing sales, decreasing payroll, and lower net profits before tax are alarming, especially in rural areas. The number of pharmacies in rural areas will decline if these trends continue. Pharmacies in rural areas usually have less prescription volume; and therefore, less opportunity for volume purchasing or other benefits related to volume. Approximately 33% of independent pharmacies serve

populations with less than 10,000 and over 70% serve a population with less than 50,000. (NCPA Digest 2015) If independent community pharmacies experience continued losses when filling generic prescriptions and have to close their pharmacies, access to prescriptions and pharmacy services in rural areas will decrease. The citizens in rural Arkansas will be the ones who are impacted negatively.

C. Chain Pharmacies Report the Same Financial Challenges with Respect to Prescription Reimbursements

15. To demonstrate the validity of these independent pharmacy trends, it is important to consider the financial trends in chain pharmacies as well. These same financial trends with respect to prescriptions are being seen in chain pharmacies. Chain pharmacies (traditional chain, mass merchandisers, and grocery chains) have different business models and may be able to respond differently to changes in the environment, including third-party payer network and reimbursement strategies. However, they have also reported shrinking margins and lower profits with respect to their prescription business. (Causey 2009) An article in Forbes stated: “Drug retailers have had to deal with thin margins for a while now, owing to a combination of factors. As generic drug prices have inflated and reimbursement rates have remained flat, pharmacy chains have posted lower profits.” (Trefis Team, August 28, 2015) Three other examples that support the claim that retail pharmacies are struggling financially include:

- Wal-Mart Stores Inc reported in August 2015 that “lower margins in its pharmacy business had emerged as a drag on profits, as it gets paid less by drug plan managers and as fewer

customers pay cash . . . ” (Layne 2015, Lowery 2015)

- Target agreed to sell its pharmacy division to CVS Health Corp as “the pharmacy business posted modestly negative results in the company’s last fiscal year, despite \$4 billion in sales.” (Bomey 2015)
- Walgreen’s continues to report a decline in reimbursement rates, lower profitability from generic drugs, and lower retail pharmacy margins. (Treflis Team October 1, 2014). “Generic drug inflation has squeezed the profitability of filling prescriptions, hurting Walgreen’s bottom line . . . Sales of generic drugs usually offer higher gross margins, yet over the past year, the prices of some common generic drugs have skyrocketed because of shortage in supply. While drug costs rise, insurance companies, prescription managers and government health care programs only reimburse a fixed contractual amount for every prescription . . . Walgreen’s prescription business has consequently suffered . . . Gross profit margin dropped to the lowest level since 2010.” (Chen, December 17, 2014)

C. Independent Community Pharmacies in Arkansas Are Closing, resulting in decreased access to prescriptions and pharmacy services for many, especially those in rural areas

16. The NCPA-Pfizer Digest reported in 2005, 13.9 percent independent community pharmacies were operating at a loss, and in 2014, 21.3 percent were operating at a loss. (NCPA Digest 2015) Nationwide, there has been a net decrease in the number of independent community pharmacies from 2009 to

2014. (NCPA Digest 2015, Talsma 2013) In Arkansas specifically, there has been a decrease in the number of retail pharmacies from 720 in 2006 to 688 in 2014. Independent pharmacies, often located in rural areas, have decreased from 452 in 2006 to 395 in 2014. With a decrease in retail pharmacies, patients in Arkansas have less access to a pharmacist and health care services. It is also interesting to note that there are fewer community pharmacies in Arkansas today, although the population in Arkansas has increased to 2,966,369 in 2014 from 2,915,918 in 2010. Ultimately, this is a patient issue because patient access to prescriptions and pharmacy care are jeopardized. If retail pharmacies continue to incur unsustainable losses, more pharmacies will close and health care in these communities will suffer. Additionally, for each pharmacy that closes, it is likely that 8 or 9 people in the local community will lose their job.

III. Factors that Comprise the Financial Health of Community Pharmacy

A. Reimbursement Rates Must Cover the Acquisition Cost of the Drug Product

17. Profitability is a key factor to ensuring pharmacies remain open. As more prescriptions are paid for by third-party payers who continue to demand lower reimbursements; pharmacy owners are challenged to find ways to increase their gross margins and remain profitable. One key aspect to maintaining gross margin is to ensure that the sales price of the drug or the reimbursed amount covers the pharmacy's acquisition cost of the drug as stated on the wholesaler invoice. Fair market value reimbursements are key to the financial health of a community pharmacy. Other considerations to maintaining gross margin include finding ways to reduce cost of goods sold (i.e., to

purchase and manage inventory optimally), finding other market niches to enter and providing services that generate revenue with higher gross margins, and reducing pilferage. (Carroll 2015)

B. Pharmacies Purchase Drug Products at Lowest Price Possible to Improve Financial Health

18. Managing inventory is important to the financial health of a pharmacy. Pharmacies need to reduce the amount of product sitting on the shelf, reduce carrying costs, and purchase products at a competitive price. Most pharmacies utilize just-in-time inventory processes and have become efficient at managing their inventory. (Bouldin et al. 2014; West-Strum 2012) Pharmacies are incentivized to purchase products at the lowest price because obtaining the lowest price from a wholesaler will improve the pharmacy's gross margin. Pharmacies do not purchase different packages with different NDC numbers or different package sizes for different patient populations. In other words, they maintain one set of inventory. Purchasing the product at the lowest price possible will allow cash customers to receive a lower price, increase the probability of receiving a higher gross margin regardless of the third-party payer (i.e., PBM, private payer, Medicaid, etc), and improve the pharmacy's cash flow.

19. It is recommended that pharmacies select a primary full-service wholesaler and then have at least one secondary wholesaler. They also purchase from other generic wholesalers. Pharmacy owners will actively look to find products at the lowest cost, especially generics. Favorable pricing and purchasing terms will also be considered. It is important to select full-service wholesalers that have fewer out-of-stock situations, who have prompt and reliable delivery (including just-

in-time delivery), value-added services such as assistance with inventory management systems, marketing and layout and design support, fair return-goods policies, and other services. (Bouldin et al. 2014; West-Strum 2012) Some pharmacy chains may operate their own distribution center or perform some of these wholesaler functions within their own organization, yet they often use a full-line wholesaler also to obtain selected products in various situations. Pharmacists order products daily to ensure continued access to products for patients. There may be times when the pharmacy has to purchase a product at a higher price because their primary wholesaler is out-of-stock, just-in-time delivery is needed for patient access, or the pharmacy needs to purchase a small bottle quantity. Pharmacies should be careful of the unfamiliar wholesaler. They may be selling “short-dated” (near expiration date) products or products that are substandard. Counterfeit medications are a real-concern, and pharmacists are warned to be careful of “deals that are too good to be true.” (Bouldin et al. 2014)

IV. PBM Reimbursement Impacts the Financial Health of Independent Community Pharmacy

A. PBMs “Force” Pharmacies to Accept Low Reimbursement Rates

20. PBMs impact the financial health of community pharmacies, both independent and chain. Examples of how they impact a community pharmacy include: additional contracting and paperwork for the pharmacy, preparing for and completing PBM audits, increased expenses to fill a prescription and adjudicate it, implementation of PBM utilization management tools like refill-too-soon/quantity limits/prior authorization that impact patient-pharmacist-physician interaction, narrowing of pharmacy networks, and directing refills

to mail order pharmacies. (Kaye 2012, Talsma 2013) It is estimated that 10-20% of a pharmacist's time is now spent completing third-party administrative functions. I will mainly focus on the reimbursement of prescription drugs and its impact on independent community pharmacy.

21. PBMs may impact the prescription volume and sales of a retail pharmacy. "When small retail pharmacies have little negotiation power, third-party payors provide a take-it-or-leave-it contract with low reimbursement rates that put the pharmacies in a catch-22, sign the contract with a low reimbursement rate or lose customers." (Causey 2009) Moreover, PBMs are selecting pharmacies which are willing to pay a "preferred network fee", or which meet some other criteria (e.g., agree to a lower reimbursement) to be in a preferred network. Beneficiaries may then be incentivized to use the preferred pharmacies.

22. Another impact of PBMs on community pharmacy is cash flow. The lag in reimbursement time from a PBM for a prescription affects the pharmacy's cash flow. Community pharmacies have not always received timely reimbursements from PBMs, making it difficult to pay the operating expenses in a timely manner. Some states have passed laws to ensure prompt payment by PBMs to pharmacies. Without prompt payment, it becomes difficult for a pharmacy to continue to operate.

B. PBM Reimbursement Reduces Gross Margins

23. As PBMs have become more aggressive in their reimbursement structures to reduce pharmaceutical spending, retail pharmacies have seen reduced gross margins and reduced profits. Studies have shown how third-party reimbursement impacts community

pharmacy profitability negatively (Carroll 2008; Reisetter et al. 2008). In a 2012 NCPA survey, over half of independent community pharmacies stated that PBM reimbursement and auditing practices were significantly affecting their ability to provide patient care and remain in business (National Community Pharmacists Association September 2012).

24. The contracts that pharmacies receive from PBMs in many respects are not negotiable, and the reimbursement rates are already established in the contract. (Causey 2009) The reimbursement for a prescription drug product comprises two elements: estimated drug ingredient cost (or estimated acquisition cost of the drug) and a dispensing fee for the pharmacy. (Pharmacy Benefit Management Institute 2015; Lee 1983) This reimbursement strategy has been based on the PBM estimating the drug ingredient cost on a fair market value. These contract reimbursement rates directly affect the dollar sales of a pharmacy and hence impact gross margin, profitability, and productivity, of the pharmacy. PBMs continue to lower their reimbursement rates, and there is more aggressive MAC erosion as PBMs have consolidated or merged. (Talsma 2013)

C. MAC Prices Are Controlled by PBMs and May Be Set Below Acquisition Costs for Arkansas Pharmacies

25. When a contract with a third-party payer is signed, there is a reimbursement formula for brands, generics, and specialty drugs. The estimated drug ingredient cost should reflect a fair, market value (i.e., a fair estimate of the current acquisition cost for Arkansas pharmacies) for the drug product. There are several methods to estimate ingredient cost, depending on brand or generic.

26. For brand name drugs, AWP is used. AWP is average wholesale price. This is a published cost, but not the acquisition cost for the pharmacy. Thus, a percent is deducted from the AWP to more accurately represent the pharmacy's acquisition cost. The AWP percentage has continually decreased over the years. According to the 2015-2016 Pharmacy Benefit Management Institute report, the median AWP discount for PBM reimbursement was 83 or 84% of AWP (or AWP-16 or 17%).

27. Generics will either be reimbursed using a MAC price list (generics on a MAC price list) or using a formula similar to the brand name drugs for non-MAC generics. Note almost all generics are reimbursed using a MAC price list. Maximum Allowable Cost (MAC) prices represent the maximum payment amounts for generic medications on the MAC price list.

28. Because MAC price lists provide consistent "pricing for generic medications made by different manufacturers they are an important source of discounted prescription drug costs for PBMs. PBMs generally consider their MAC lists to be proprietary information and it is common for PBMs to use different MAC lists within their book of business." (Pharmacy Benefit Management Institute 2015) The pharmacy-PBM contract does not disclose the methodology or terms and conditions for payment of generic drugs, other than the use of a MAC price list. It is possible that the PBM may create a MAC price for a product using a NDC listed in a national pricing compendium but no longer actively marketed or may use the price of a NDC for the product that is temporarily unavailable. (Nicholson 2016) Thus the MAC list price for a product may be based on a price by which Arkansas pharmacies do not have access to.

PBMs can adjust reimbursement rates for generics to pharmacies at any time, without notice, or delay a change in reimbursement rates. In theory, a PBM could decide to decrease reimbursement for all generics to one cent per dose, regardless of what the pharmacy's acquisition cost is and the pharmacy would be bound by contract to dispense all the generic medications at below cost.

29. The pharmacy is basically agreeing to be reimbursed for generics at whatever rate the PBM sets. Pharmacy owners have reported that usually as manufacturer/wholesaler prices would decrease, the PBM would decrease the price on the MAC list for reimbursement. Recently generic price increases have occurred in the generic marketplace, and it appears that PBMs have been much slower to increase the reimbursement price on a MAC list or not increase the MAC price at all for a product that has seen a manufacturer price increase. (Roth 2014, NCPA Survey 2015) A pharmacy may appeal the MAC price, but this is a lengthy, cumbersome process. Based on my professional pharmacist interactions and my review, often the appeal is denied, and it is difficult to dispute given the MAC price list is owned and controlled by the PBM. (NCPA Survey 2015, review of Arkansas pharmacists' complaints to Arkansas Attorney General)

30. It is difficult to negotiate with a PBM on the MAC price list since it is not transparent. According to a NCPA survey (September 2012), 96.2% of independent community pharmacies stated that a typical PBM contract has minimal or no transparency of how generic pricing is determined. Forty-nine percent of respondents said that PBMs set the reimbursement for generics below the product's acquisition cost to the pharmacy more than 10% of the time. Over 90% of

independent pharmacists agreed that PBMs reduce their MAC prices faster for products that have gone down in price rather than increasing MAC prices for products that have gone up. Likewise, the National Association of Chain Drugstores (NACDS) commented, “NACDS supports increased transparency between plans and participating neighborhood pharmacies, such as including in contracts clearly defined drug pricing methodologies, routinely updating drug pricing, and allowing pharmacies to contest changes in their reimbursement . . . Such rules would encourage pharmacy participation, meaning increased access and options for patients, ultimately leading to improved health and reduced healthcare costs.” (Nicholson 2016)

D. MAC Prices Set Below Pharmacy Acquisition Cost is Not a Sustainable Reimbursement Model for Community Pharmacy and therefore Jeopardizes Access to Pharmacy Care for Many Arkansas Residents

31. The pharmacy owner does not control its reimbursement rates for the majority of prescriptions (i.e., generics) it fills and is obligated by contract to accept the MAC reimbursement rates even though they may be lower than the pharmacy’s acquisition costs as stated on the wholesaler invoice. Being obligated to accept a reimbursement that is less than the acquisition cost for at least 10% of the prescriptions is not sustainable. Based on my review and professional interactions and experiences, pharmacies are reporting more prescriptions being sold at a loss and a greater loss per prescription each year due to decreased reimbursements from PBMs. The MAC reimbursement strategy was originally intended to pay pharmacies for their acquisition cost of the product; yet, PBMs have become aggressive at setting MAC prices lower

than pharmacy's acquisition cost to reduce spending and have not been updating their MAC price list to account for manufacturer price increases. (NCPA Survey 2015, Roth 2014, Kaye 2012, Talsma 2013, Oxford Family Pharmacy Data, Arkansas pharmacists' complaints to Arkansas Attorney General)

32. The other element to the reimbursement formula is the dispensing fee. The dispensing fee compensates the pharmacy for filling the prescription, counseling, drug utilization review, and other dispensing services. It is estimated that it costs around \$10 to dispense a prescription. (NCPA Digest 2015) The median dispensing fee paid by PBMs to pharmacies ranges from \$1.74 to \$1.92. (Pharmacy Benefit Management Institute 2015) Given the dispensing fee is less than the cost to dispense, it is critical that pharmacies receive a reimbursement for the drug product that covers the pharmacy's acquisition cost. Given the low dispensing fees, setting the MAC price at a fair market value for acquisition cost does not guarantee a profit for the pharmacy. The MAC reimbursement strategy does not include any profit component, although reasonable pharmacy profits are necessary for the pharmacy to remain in business to provide pharmacy services to patients in the future.

E. MAC Price Lists Must be based on Fair Market Estimates of Acquisition Cost for Generic Drug Products in Arkansas for Arkansas Independent Community Pharmacies to Remain in the Pharmacy Dispensing Business

33. Because the pharmacy is not controlling the acquisition cost of the product (i.e., the manufacturer/wholesaler sets the price), the product is for a medical need, and the pharmacist is not selecting the product

to be dispensed (i.e., the prescriber is normally the one making the therapeutic decision), the reimbursement model for a generic drug product must continue to be based on a fair market estimate of the acquisition cost for that product in Arkansas. The MAC price strategy was originally intended to limit the ingredient cost to the lowest price at which a generic drug product is widely and consistently available (Lee et al. 1983). Thus, the MAC price needs to be based on current acquisition cost available in Arkansas. MAC pricing was not intended to jeopardize the pharmacy's business. The health implications of having a MAC list that does not reflect the current generic marketplace would be suboptimal.

F. MAC Prices Should Be Updated to Reflect Manufacturer Price Increases

34. In 2014, 80% percent of prescriptions were dispensed as a generic in independent community pharmacy. (NCPA Digest 2015) Other sources indicate that today's generics represent about 85% of the prescription volume. In 2013, after years of declining generic prices, generic list prices from manufacturers began to increase. (Lapook 2014; Trefis Team 2015; Rosenthal 2014) The Wall Street Journal reported that generics increased in price by 37% during one quarter and that prices for certain drugs had risen over the past year by more than 1000%. (Silverman 2015) This increase in price is due to the manufacturer increasing the price of the drug. The price increases seem to be caused by a shortage of drug products, weaker competitors going out of business, only one or two suppliers for some generic drug products (less competition), FDA slow approval process for generic manufacturers, and other reasons. (Islam 2015; Engelberg et al. 2016)

35. One analysis showed that from 2013 to 2014, about half of 2,376 unique generic products had increased in “price” based on the National Average Drug Acquisition Cost (NADAC) data. (Fein August 2014) The 49% of drugs that decreased in cost had a median decrease of 6.8%, while the 50% of drugs that increased in cost had a median increase of 11.8%. Some products had significant increases, with 224 drug products increasing by more than 100%. Pharmacies have observed the increase in generic drug prices. Independent community pharmacists in a NCPA Survey (2015) indicated that in the past six months they had experienced over 100 instances of a large upswing acquisition price for a generic drug.

Top 10 Generic Drugs With the Largest Percentage Increase in NADAC per Unit, July 2013 vs. July 2014

Product	NADAC per Unit (7/4/13)	NADAC per Unit (7/2/14)	% Change in NADAC per Unit
tetracycline 500 mg capsule	\$0.05	\$8.59	17,714%
tetracycline 250 mg capsule	\$0.06	\$4.26	7,340%
captopril 25 mg tablet	\$0.02	\$0.83	4,340%
captopril 12.5 mg tablet	\$0.02	\$0.67	3,937%
captopril 50 mg tablet	\$0.03	\$1.31	3,806%
captopril 100 mg tablet	\$0.06	\$2.04	3,570%
clomipramine 75 mg capsule	\$0.42	\$8.15	1,818%
doxazosin mesylate 1 mg tab	\$0.05	\$0.62	1,169%
fluconazole 100 mg tablet	\$0.14	\$1.50	996%
doxazosin mesylate 2 mg tab	\$0.06	\$0.56	899%

NADAC = National Average Drug Acquisition Cost
 Source: Pembroke Consulting analysis of Center for Medicare & Medicaid Services data files.
 Published on Drug Channels (www.DrugChannels.net) on August 12, 2014



36. Generic drug inflation is expected to continue and impacts a retail pharmacy financially. (Fein 2014) For example, doxazosin mesylate for hypertension

increased 1,169% percent, which represented a 57 cent per dose increase (from 5 cents per dose to 62 cents per dose). If you are a retail pharmacy and have one patient that needs that drug (30 doses per month), then your acquisition cost of the drug changed from \$1.50 to \$18.60 per month for this one patient. If the patient takes the medicine for 12 months, then the pharmacy's cost to purchase the drug changed from \$18.00 to \$223.20 for the year. If the PBM does not alter the MAC price list to account for this increase and instead continues to have a MAC near 5 to 10 cents per dose, the pharmacy will lose nearly \$200 this year on this one medication for one patient. Pharmacies are filling thousands of generic prescriptions, and therefore, what seems like just a 57 cent increase in price per dose from the manufacturer can result in a significant loss to a pharmacy if not reimbursed at fair market value. Even small increases in generic prices can have significant economic consequences for a pharmacy if the reimbursement rate does not reflect the current marketplace, given 80-85% of the prescriptions filled are generic. Moreover, the pharmacy does not control the prescription mix dispensed; therefore, it is not accurate to say that the pharmacy can make it up on another prescription where the MAC may be higher than the pharmacy's acquisition cost. There are other examples where the price of a generic may have increased by hundreds of dollars. Again, if the MAC price list does not reflect this increase immediately, the pharmacy will be faced with losing hundreds of dollars for each prescription it fills of this generic medication.

V. Arkansas Act 900 Is Necessary to Protect Community Pharmacy Access in Arkansas and Does Not Negatively Impact the Marketplace

A. Arkansas Act 900 Mandates PBMs Maintain Updated MAC lists that Reflect Acquisition Costs that are “Widely and Consistently” Available to Arkansas Pharmacies but Does Not Change the PBM Reimbursement Strategy (i.e., MAC lists). Act 900 allows the MAC Reimbursement Strategy to Perform in the Marketplace without Jeopardizing the Number of Community Pharmacies in Arkansas and Patient Access to Prescription Drug Products and Pharmacy Services.

37. The use of a MAC price was originally intended to limit the ingredient cost reimbursement of the generic to the lowest price at which the generic was “widely and consistently” available. (Lee et al. 1983) Pharmacies in Arkansas have been faced with PBM MAC price lists not being designed or updated in a timely manner to reflect prices (i.e., acquisition costs) which are “widely and consistently” available in Arkansas. According to the 2015 NCPA survey, 62.3% of independent community pharmacists who responded indicated that it took the PBM more than three months to update their reimbursement rates. This mirrors the numerous pharmacists’ complaints which have been reported to the Arkansas Attorney General’s office with respect to the PBM not reimbursing enough to cover the pharmacy’s acquisition cost of the drug and the pharmacy’s inability to find/purchase the product at a price equal or lower than the MAC price. The National Association of Chain Drug Stores (NACDS) has also commented that there is a need for more information on the sources used to create the

MAC lists, price adjustments to the MAC list at least twice a month or within 3 days if the product changes in price by more than 100%, a process for the pharmacy to submit 200 claims per appeal, and the creation of MAC price lists based on NDCs of products that are in sufficient supply from national pharmaceutical wholesalers and are not obsolete or temporarily unavailable. (Nicholson 2016)

38. Arkansas Act 900 does not address all of these concerns about a MAC price list, but it is a step in the right direction. Act 900 was needed to maintain the integrity of the MAC price list reimbursement strategy. Act 900 does not create a new reimbursement strategy, but instead regulates the PBM to maintain MAC price lists that reflect current, fair market values of generic products in Arkansas (i.e., reflect wholesaler prices (or pharmacy acquisition costs from a wholesaler) which are widely and consistently available in Arkansas). PBMs will continue to use a MAC price list and can continue to encourage the dispensing of generics, heighten competition among generic manufacturers when there are multiple manufacturers, ensure pharmacies are not overpaid for the services they provide, and control costs of generics.

39. If PBMs develop aggressive MAC price lists that do not estimate the pharmacy's acquisition cost fairly, then the reimbursement model is not justifiable and community pharmacy in Arkansas is at risk. In fact, MAC reimbursement rates below the pharmacy's acquisition costs will result in some pharmacies closing, specifically in rural areas, and some patients not having access to pharmacy and other health care services. (Causey 2009) Act 900 allows the MAC reimbursement strategy to perform in the marketplace without jeopardizing the number of community

pharmacies in Arkansas and patient access to prescription drug products and pharmacy services.

B. Without Act 900, PBMs Could Continue to be Aggressive in their MAC Pricing, which Jeopardizes Community Pharmacies and Patient Access to Pharmacy Care

40. PBMs will continue to use the same reimbursement strategy (i.e., MAC price lists) but will now need to be diligent in monitoring the marketplace to ensure current MAC prices reflect wholesaler prices that are widely and consistently available to Arkansas pharmacies. Without Act 900, there is the possibility of continued MAC price erosion and the creation of MAC price lists which frequently do not cover the pharmacy's acquisition costs for generic products in Arkansas. This would likely result in pharmacies experiencing unsustainable losses and would jeopardize their ability to provide patient care. Access to retail pharmacies is important for patients with complex, chronic diseases and for patients in rural areas. Pharmacies are often the most accessible health care provider to them. Pharmacies going out of business in a rural state is a public health issue. Pharmacies in rural areas may provide medications, medication information, medication adherence programs, health care screenings, immunizations, smoking cessation services, disease management programs, and other health care services. They are a key component of access to health care. Studies have shown that patients who receive pharmacist care have better clinical and economic outcomes. (Brennan et al. 2012; Cranor et al. 2003)

C. Act 900 Does Not Require PBMs to Artificially Inflate Generic MAC Prices and Does Not Guarantee a Profit for the Pharmacy

41. Arkansas Act 900 does not guarantee a profit for the pharmacy on a prescription. It does regulate that the PBM must establish MAC prices that are based on current estimations of the acquisition cost of the product to pharmacies in Arkansas. It does not guarantee a profit for the pharmacy on a prescription, as the pharmacy must cover the ingredient cost and dispensing costs before a profit is realized. Furthermore, Act 900 does not require the MAC price to be inflated, and thus the acquisition cost and the MAC reimbursement rate could be cost neutral for the pharmacy.

42. As generic manufacturers increase prices, pharmaceutical costs increase when the product is utilized; however, squeezing gross margins from the pharmacy does not fix the problem of rising pharmaceutical costs. Act 900 prevents retail pharmacy from paying for the entire increase in generic prices from manufacturers at the expense of their business. The pharmacy has to pay the increased price so that they can ensure patients in their community have access to these drug products, which could be life-saving. If the PBMs do not increase their MAC price for this product to reflect this marketplace change, then pharmacies are paying for the manufacturer price increase. This is not sustainable. Act 900 requires the PBM to adjust MAC prices to represent fair market value even if this means increasing the MAC prices to represent increases in prices from the manufacturers. Act 900 does not state that the MAC price be inflated, but that due diligence is used to determine a price that represents the fair market value of the product in Arkansas (i.e.,

lowest price that is consistently and widely available to Arkansas pharmacies).

D. Act 900 Does Not Change Community Pharmacy Owners' Resolve to Purchase Drug Products at the Lowest Price Possible

43. Pharmacies will have to continue to be efficient and effective in purchasing and inventory management and operations, as described in a scenario in Appendix B. Act 900 will not impact the purchasing patterns of pharmacies. As previously described, they are incentivized in multiple ways to purchase products at the lowest cost, if possible. Furthermore, the pharmacy will not purchase products for "PBM patients" differently than purchasing products for their Medicaid patients, state employee patients, cash patients, or other patients not enrolled with a PBM. For the pharmacy to remain profitable, they will need to continue to find the lowest price available to ensure that the acquisition cost is below the MAC price of any payer and to avoid having to appeal a reimbursement. Pharmacies will still search for wholesalers who offer competitive pricing because of the importance of having a gross margin large enough to cover expenses. Wholesalers will continue to compete in multiple ways, including price of drugs.

E. Act 900 Does Not Put Extensive Burden on PBMs

44. Because reimbursement at lower than acquisition cost is not a sustainable model, chain and independent retail pharmacies have spent much time and effort advocating for faster updates on the Federal Upper Limits for generics. (National Community Pharmacists Association January 12, 2015; National Association of Chain Drug Stores February 26, 2015)

The Federal Upper Limits have been revised and are being updated monthly. State Medicaid programs are continually updating their MAC price lists to reflect the FULs and the NADAC data. There are sources available to find estimated acquisition costs. PBMs with access to the NADAC data and other sources of pharmaceutical data should be able to monitor their MAC price lists and update prices in a timely manner. In fact, PerformRx (a Philadelphia-based PBM) says it aims for MAC list pricing that does not provide reimbursement lower than the acquisition cost for any given claim; Excellus Blue Cross Blue Shield manages its MAC lists and bases them on realistic acquisition costs and the availability of competitive generics, even if it means changing prices often; and Navitus Health Solutions (Wisconsin-based PBM) each month reviews and updates drug items on the MAC list to reflect changes in drug acquisition costs. (Edlin 2012) These statements indicate that PBMs should be able to comply with Act 900.

F. Act 900 Allows Pharmacists to Focus on Patient Care, Rather than Reimbursement Appeals

45. Act 900 allows the pharmacists to focus more on patient care, rather than appealing claims frequently to PBMs. Appealing many generic prescriptions is not practical, it increases operating costs for the pharmacy, and it delays reimbursement which impacts cash flow.

G. “Right to Refuse to Fill a Prescription”
Provision Strengthens Act 900 to Protect
Patient Access to Community Pharmacies
Without Negatively Impacting Patient Care

46. Act 900 has a provision to allow a pharmacy to refuse to fill a prescription if the MAC price does not cover the pharmacy’s acquisition cost as listed on the wholesaler invoice. This is an indirect pressure on PBMs to comply with this legislation. This should not be interpreted as a right to refuse care to this patient. Pharmacists will find it difficult to not fill a prescription due to a reimbursement issue, because of patient care. Pharmacists also know they must remain solvent to provide patient care to their community. Whether they fill the prescription or find an alternative solution, they will provide care and ensure that the patient receives appropriate drug therapy in a timely manner. Pharmacists have taken the “Oath of a Pharmacist” where they pledge to devote to serving others, to consider the welfare of humanity and relief of suffering as their primary concern, and to assure optimal outcomes for their patients. However, this provision gives the pharmacist the ability to use their professional judgment on how to deal with a patient situation, where the pharmacy will lose money on dispensing a prescription. The pharmacist may contact the prescriber to discuss alternative therapies that may be equally beneficial to the patient but not jeopardize the financial stability of the pharmacy. Another option would be for the pharmacist to not fill the prescription but instead help the patient find a pharmacy that will fill the prescription. Another option would be to refer the patient to the mail-order pharmacy component of his/her health plan if available and appropriate. This situation is similar to a pharmacy being out-of-stock of a product. When this

situation occurs, the pharmacist will use his/her professional judgment on how to handle the situation (e.g., refer to another pharmacy, borrow the drug from another pharmacy, order the drug for tomorrow delivery if patient can wait a day, etc). Just like the out-of-stock situation, the pharmacist faced with filling a prescription at a reimbursement rate below acquisition cost will care for the patient and use his/her professional judgment on how to handle the situation. The pharmacist may even opt to give the patient 3 or 4 days worth of product as they work with the physician, PBM, or other pharmacy to find an acceptable solution. This provision provides the pharmacy owner with more autonomy over his/her business. If the frequency of filling prescriptions at a loss for a PBM or the dollar amount on a prescription is a significant loss and puts the pharmacy's business at risk, then the pharmacist should have the autonomy to make a professional judgment with respect to filling a prescription at a loss or finding another solution to help this patient while maintaining business for the good of the community.

VI. Act 900 Prevents the Decline of Independent Community Pharmacy in Arkansas, which is important to the public health in Arkansas

A. Act 900 Maintains the Integrity of the MAC Reimbursement Model and Reduces the Likelihood of Unsustainable Losses on Generic Prescriptions

47. Each pharmacy will be impacted differently, given their prescription mix, cost of goods sold, and PBM contracts. Act 900 will at least provide a reimbursement environment that ensures that MAC price lists used by PBMs are current and reflect fair value market prices in Arkansas. This maintains the

integrity of the reimbursement model and reduces the likelihood of unsustainable losses on generic prescriptions. Pharmacies will be more likely to receive a reimbursement that covers the acquisition cost of the generic drug, thus maintaining a gross margin for generic drug products. This is important to the financial sustainability of retail pharmacy, especially independent community pharmacy, and to protecting continued access to prescriptions and health care services for Arkansas citizens living in rural areas.

B. Scenarios Demonstrating How Act 900 Protects the Financial Health of Independent Community Pharmacy

48. Given MAC prices and acquisition costs of pharmacies are proprietary information, it is difficult to project the exact financial effects of Act 900 on one pharmacy store or on retail pharmacy as a whole. However, several different examples can show that without Act 900, the pharmacy's gross margin is jeopardized. With Act 900, the PBM's reimbursement is more likely to reflect the pharmacy's acquisition cost, even as generic prices increase, and thus the pharmacy will likely be able maintain a gross margin. Each example provides different estimates; however, they all show how a MAC price list that does or does not represent the fair market value of a generic product in Arkansas will impact a pharmacy. Even a lag of change in MAC prices to represent a generic price increase can have a negative financial impact on a community pharmacy.

49. Using numbers from an independent pharmacy located in a rural area (Oxford Family Pharmacy; Oxford, MS) illustrates the impact of third-party reimbursements. Adam Baskerville, pharmacist-in-charge provided me summary data for the store as it

closed its doors (i.e. went out of business) on May 17, 2016. In 2013, this pharmacy sold 8.3% of prescriptions for a loss with an average loss of \$5.56 per prescription; in 2014, 8.6% prescriptions were sold at a loss with an average loss of \$6.44; and in 2015, 12.3% of prescriptions were sold at a loss with an average loss of \$6.98 per prescription. This case demonstrates the trend of more prescriptions not being reimbursed to cover the pharmacy's acquisition costs for products as well as the decreasing reimbursements resulting in greater losses per prescriptions. Although this store was located in Mississippi, it is comparable to other small independent pharmacies in rural areas in Arkansas. Act 900 is designed to maintain the use of MAC pricing that is based on estimated acquisition costs of generic products in Arkansas. If this pharmacy had been located in Arkansas with Act 900 in effect, the pharmacy may have been able to continue to operate. The trend for 2015 may have been reversed.

50. If MAC prices are not based on acquisition costs which are widely and consistently available in Arkansas, it is likely that a pharmacy will dispense prescriptions that result in a loss to the pharmacy. The Table below shows the financial impact of a pharmacy dispensing anywhere from 5-15% of generic prescriptions at a loss. Act 900 should decrease the percent of prescriptions being filled at a loss as well as the average loss amount per prescription, since the MAC price will reflect an acquisition cost that is widely and consistently available in Arkansas. This will prevent pharmacies from experiencing thousands of dollars in loss per year, which jeopardizes their ability to stay in business.

Assume average independent pharmacy fills 49,254 generic prescriptions per year; Assume 18,716 (38%) are paid for by a PBM			
	% (N) of prescriptions where the MAC price is set below a pharmacy's acquisition cost		
Average loss per prescription	5% (936)	10% (1871)	15% (2807)
\$2	\$1,872	\$3,742	\$5,614
\$5	\$4,680	\$9,355	\$14,035
\$25	\$23,400	\$46,775	\$70,175

51. The Table below shows how a delay in increasing a MAC price for a generic after the manufacturer increases the price affects a pharmacy's revenue. Given the MAC price is meant to reflect the current market value of the product, the pharmacy is not being paid what it is owed. The PBM is delaying reimbursement to keep this money. Act 900 would help ensure that pharmacies are being paid what they are owed. From the two examples in the Table below, an increase in price on one product could mean the pharmacy is losing hundreds to thousands of dollars within a 90-day period if the MAC price list is not updated. Act 900 should help the pharmacy maintain a gross margin since the MAC price will be updated frequently to represent fair market value.

	Rx Cost per unit	MAC per unit	Rx Cost per unit after manuf. price increase	If no adjustment to MAC	If 30 days go by...and pharmacy fills 1 per day	If 60 days go by...and pharmacy fills 1 per day	If 90 days go by...and pharmacy fills 1 per day
Doxycycline	0.06	0.11	3.36	-3.25 loss per unit; 10 day supply then loss of \$32.50 per Rx	\$975	\$1,950	\$2,925
Isosorbide Mononitrate ER	0.10	0.20	0.31	-0.11 per unit; 30 day supply then loss of \$3.30 per Rx	\$99	\$198	\$297

52. Another way to demonstrate how Act 900 will impact a pharmacy is to consider the profit and loss statement. In the example below, the 2015 NCPA Digest data are presented. Scenario A shows how increases in generic acquisition costs (due to increased manufacturer prices) impact the pharmacy's cost of goods sold (COGS) and gross margin. An increase in COGS without a change in MAC reimbursement results in a significant loss to the pharmacy. Scenario B includes increased reimbursement for these products due to updated MAC lists, as required by Act 900, to reflect the current market value of generics in Arkansas. The pharmacy does not make more profit but is able to maintain their gross margin to pay expenses.

	NCPA Digest	Scenario A	Scenario B
Prescription sales	3,329,740	3,329,740	3,374,807
Other sales	272,114	272,114	272,114
Total sales	3,601,854	3,601,854	3,646,921
Prescription COGS	2,613,909	2,658,976	2,658,976
Other COGS	178,541	178,541	178,541
Total COGS	2,792,450	2,837,517	2,837,517
Gross margin	809,404	764,337	809,404
Expenses	727,993	727,993	727,993
Net profit before taxes	81,411	36,344	81,411

Scenario A Assumptions:

Assume pharmacy fills 61,568 prescriptions and 49,254 of those are generic

Assume average acquisition cost for generic prescription=\$15.50

Assume 50% of generic drug products experience an increase in manufacturer price with an average increase of 11.8%, then 50% will then have an average pharmacy acquisition cost of \$17.33, increasing cost of goods sold (COGS) by \$45,067.

Assume no changes to the MAC list to adjust for manufacturer price increases, then the pharmacy's net profit is reduced by \$45,067, making it difficult for an independent pharmacy to remain in business

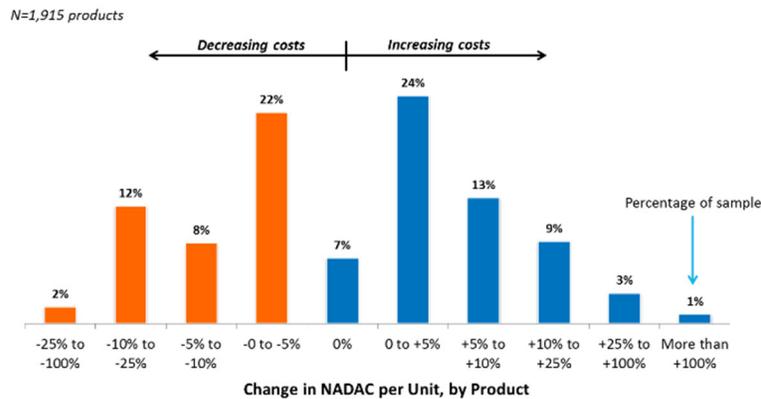
Scenario B Assumptions:

Same as Scenario A except now Act 900 is considered and the MAC price list is updated to reflect the manufacturer price increases (i.e, \$1.83 in increased acquisition cost per prescription). Reimbursement now reflects the current market value and the pharmacy avoids experiencing unsustainable losses.

53. Pembroke Consulting calculated the change in generic drug costs for one quarter in 2015, as shown in the Figure below. To illustrate the importance of PBMs to update their MAC lists promptly, I applied these increase and decrease percentages to 100 generics with an average cost of \$20. As shown in the spreadsheet below, the cost of goods sold would be \$33 (\$127-94) higher each day for the pharmacy owner who dispenses this set of 100 prescriptions. If the MAC

prices are not adjusted, this would result in the pharmacy being underpaid over \$12,000 in a one year time period (\$33*365 days). The assumption that the decreases in price will offset the increases in price is not accurate. With Act 900, PBMs will keep their MAC price lists updated and thus not short the pharmacy with respect to reimbursement.

Generic Drugs, Change in NADAC per Unit, 2015:Q2 (April 2015 vs. July 2015)



NADAC = National Average Drug Acquisition Cost
 Source: Pembroke Consulting analysis of Center for Medicare & Medicaid Services data files
 Published on Drug Channels (www.DrugChannels.net) on August 25, 2015.



Based on 100 generics	Pharmacy Cost	Price increased by %	Change in COGS	#of scripts	Change in COGS
24 products increased in price by 0-5%	\$20	5% increase	\$1	24	\$24
13 products increased by 5-10%	\$20	10% increase	\$2	13	\$26
9 products increased by 10-25%	\$20	15% increase	\$3	9	\$27
3 products increased by 25-100%	\$20	50% increase	\$10	3	\$30
1 product increased more than 100%	\$20	100% increase	\$20	1	\$20
				TOTAL	\$127
6 products have no change in price				6	
		Price decreased by %			
22 products decreased by 0-5%	\$20	5% decrease	(\$1)	22	(\$22)
8 products decreased by 5-10%	\$20	10% decrease	(\$2)	8	(\$16)
12 products decreased by 10-25%	\$20	15% decrease	(\$3)	12	(\$36)
2 products decreased by 25-100%	\$20	50% decrease	(\$10)	2	(\$20)
0 products decreased by more than 100%	\$20	100% decrease	(\$20)	0	0
				TOTAL	(\$94)

VII. Conclusions

54. Community pharmacies, specifically independent community pharmacies, are struggling financially and finding it difficult to remain in business. The closing of community pharmacies in Arkansas would significantly impact access to medications and pharmacy services for Arkansas citizens. Act 900 allows the MAC reimbursement strategy of PBMs to perform in the marketplace without jeopardizing the number of community pharmacies in Arkansas. Act 900 requires PBMs to maintain MAC prices that reflect acquisition costs that are “widely and consistently” available to Arkansas pharmacies. This will reduce the likelihood of unsustainable losses on generic prescriptions for community pharmacies, thereby protecting access to pharmaceuticals and pharmacy services for Arkansas citizens.

I declare under penalty of perjury that this report is true and correct.

/s/ Donna West Strum
Donna West Strum, RPh, PhD

June 23, 2016

VIII. Appendix A: Financial Trends of Independent Community Pharmacy

The NCPA Digest data provide a public look at the financial position of independent pharmacies. The data are collected annually and thus provide a reliable source to look at the financial trends of this segment of the market. However, with any study or data collection, there are limitations. Independent pharmacy owners volunteer to participate in the study and self-report the data. NCPA does use various techniques to look for outliers or problems with reported data. It is difficult to determine if there are statistically significant differences between the means or medians from year to year; however, the publication does allow for one to evaluate trends and how these same variables vary over time. All the data included in this Appendix are from the 2005-2015 NCPA Digest publications. It appears that independent community pharmacy is experiencing financial challenges and “fiscal pain” with respect to prescription sales.

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Annual Rx volume	61,071	61,087	61,052	62,379	64,635	64,169	62,969	62,583	62,424	61,568
Refill volume	31787 (52%)	32998 (54%)	32964 (54%)	33967 (54%)	35822 (55%)	35367 (55%)	34088 (54%)	33028 (53%)	33587 (54%)	31429 (51%)
Daily Rx volume	190	196	196	196	207	205	201	201	200	197
% Generic	56%	58%	61%	65%	69%	72%	NA	76%	78%	80%

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Cash	13%	9%	13%	12%	12%	11%	14%	12%	10%	11%
Medicaid	23%	15%	14%	15%	13%	16%	17%	18%	17%	17%
Medicare Part D	*5%dis card	24%	25%	29%	30%	30%	32%	33	34%	34%
Private	59%	52%	48%	44%	45%	43%	38%	37%	39%	38%

	2007	2008	2009	2010	2011	2012	2013	2014
Rx	\$3,344,571	\$3,619,354	\$3,756,265	\$3,698,748	\$3,532,300	\$3,507,284	\$3,589,648	\$3,349,740
Total	\$3,604,413	\$3,880,802	\$4,026,097	\$4,022,455	\$3,532,300	\$3,854,158	\$3,892,702	\$3,621,854

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Rx Sales	\$3,210,239	\$3,429,664	\$3,344,571	\$3,619,354	\$3,756,265	\$3,698,748	\$3,532,300	\$3,507,284	\$3,589,648	\$3,349,740
Rx COGS	\$2,481,749	\$2,486,506	\$2,605,742	\$2,800,434	\$2,878,661	\$2,836,108	\$2,754,835	\$2,737,994	\$2,748,221	\$2,613,909
Gross margin dollars for prescriptions	\$728,490	\$781,963	\$738,829	\$818,920	\$877,604	\$862,640	\$777,465	\$769,290	\$841,427	\$735,831

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
# of FTEs	12.8	13.4	11.3	10.5	10.7	10.6	10.3	9.9	9.8	9.9
Payroll expense as percent of sales	13.4%	13.6%	13.4%	13.5%	14.4%	14.5%	13.4%	13.7%	13.4%	13.0%
	\$467,071	\$466,434	\$493,510	\$525,791	\$569,210	\$582,301	\$513,419	\$528,020	\$521,622	\$470,841

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Cost of dispensing	\$10.53	\$10.63	\$10.89	\$11.01	\$11.97	\$12.44	\$12.19	\$11.96	\$11.17	\$10.98

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Median net profit before tax	\$102,566	\$68,180	\$89,000	\$89,210	\$94,640	\$92,340	\$91,110	\$95,845	\$88,683	\$88,021

	2009	2010	2011	2012	2013	2014
# of independents nationwide	23,117	23,064	23,106	23,029	22,814	22,478

YEAR	Types of Pharmacies in Arkansas				
	Total Retail Pharmacies	Independent	Chain	Supermarket	Mass Merchandiser
2014	688	395	78	54	161
2013	708	402	69	69	168
2012	690	426	64	67	133
2011	710	427	60	65	158
2010	706	425	59	64	158
2009	706	425	59	64	158
2008	711	427	53	77	154
2007	712	442	46	77	147
2006	720	452	43	77	148

IX. Appendix B: Illustration of Act 900's Impact on Pharmacy Purchasing

Given the scenario below, there are several scenarios that could occur.

Bottle Size	Wholesaler A	Wholesaler B
100	10 cents per unit	15 cents per unit
500	7 cents per unit	12 cents per unit

This scenario seems simple, but in reality there is much more to consider when evaluating how Act 900 will impact competition among pharmacies and wholesalers. First it is important to know if Wholesaler A and Wholesaler B sell product in Arkansas. If Wholesaler A is a small regional wholesaler in the northeast then a MAC price based on Wholesaler A's price is not realistic for an Arkansas pharmacy. Does Wholesaler A have the product in stock or is it listed for this price but not available (on backorder)? A MAC price based on Wholesaler A's price which is not available to pharmacies in Arkansas is not realistic. Act 900 prevents the PBM from establishing a MAC price that is based on a "wholesaler price" that may not even be available to Arkansas pharmacies.

If Wholesaler A conducts business in Arkansas and has product available then the PBM can use Wholesaler A to inform their MAC price list. Considering this wholesaler and other marketplace information, a MAC price for this product may be set below Wholesaler B's price. The PBM would then be able to show the Arkansas pharmacy where they can obtain the product for a price equal to or below the MAC. Pharmacies who purchase product from Wholesaler B can then either pressure Wholesaler B to review its pricing or can change wholesalers. Even if the MAC price was set at a price equal to Wholesaler B's price, pharmacists would continue to seek wholesalers with overall lower prices in order to optimize gross margins. Competition between wholesalers would continue.

X. Appendix C: References

1. Bomey N. (2015, June 15) 5 Reasons why Target sold Pharmacy Biz to CVS. USA Today. Retrieved

from <http://www.usatoday.com/story/money/2015/06/15/target-cvs-pharmacy-sale/71248932/>

2. Bouldin AS, Holmes ER, Garner D, et al. (2014) Purchasing and Inventory Management. In Pharmacy Management, Leadership, Marketing and Finance. 2nd edition (editors: Chisholm-Burns, Vaillancourt A, Shepherd M). Jones and Bartlett. Burlington, MA.

3. Brennan T.A., Dollear T.J., Hu M, et al. 2012) An Integrated Pharmacy-Based Program Improved Medication Prescription And Adherence Rates in Diabetes Patients. Health Affairs 31, no 1: 120-129.

4. Carroll, N. V. (2008). Estimating the impact of Medicare Part D on the profitability of independent community pharmacies. Journal of Managed Care Pharmacy, 14(8), 768-779.

5. Carroll, N. (2015, July 13). How do retail pharmacies make money? Pharmacy Business and Economics. Retrieved from <https://wp.vcu.edu/nvcarroll/2015/07/13/how-do-retail-pharmacies-make-money/>

6. Causey, L. (2009, June). Nuts and Bolts of Pharmacy Reimbursement: Why It Should Matter To You. Health Law Perspectives. Retrieved from [https://www.law.uh.edu/healthlaw/perspectives/2009/\(LC\)Pharmacy.pdf](https://www.law.uh.edu/healthlaw/perspectives/2009/(LC)Pharmacy.pdf)

7. Chen C. (2014, December 17) Walgreen combats shrinking margins with size. Covering Companies. Retrieved from <http://coveringcompanies.2014.journalism.cuny.edu/2014/12/17/walgreen-combats-shrinking-margins-size/>

8. Cranor C.W., Bunting B.A., Christensen D.B. (2003) The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy.

Diabetes Care Program. *J Am Pharm Assoc.* 2003;43:173–84.

9. Edlin M. (2012, March 01). Plans scramble to optimize shifting generic drug costs. *Managed Healthcare Executive*. Retrieved from <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/content/plans-scramble-optimize-shifting-generic-drug-costs>

10. Engelberg, A., Avorn, J., & Kesselheim, A. (2016, February 23). Addressing Generic Drug Unaffordability And Shortages By Globalizing The Market For Old Drugs. *Health Affairs Blog*. Retrieved from <http://healthaffairs.org/blog/2016/02/23/addressing-generic-drug-unaffordability-and-shortages-by-globalizing-the-market-for-old-drugs/>

11. Fein, A. (2014, August 12). Retail Generic Drug Inflation Reaches New Heights. *Drug Channels Institute*. Retrieved from <http://www.drugchannels.net/2014/08/retail-generic-drug-inflation-reaches.html>

12. Islam I. (2015, August 31). Rising Cost Of Drugs: Where Do We Go From Here? *Health Affairs Blog*. Retrieved from <http://healthaffairs.org/blog/2015/08/31/rising-cost-of-drugs-where-do-we-go-from-here/>

13. Kaye, A. (2012, June 03). How PBMs Affect the Future of Community Pharmacy. *RxEconsult*. Retrieved from <http://www.rxeconsult.com/healthcare-articles/How-PBMs-Affect-the-Future-of-Community-Pharmacy-161/>

14. Lapook, J. (2014, November 14). Why some generic drug prices are skyrocketing. *CBS Interactive Inc*. Retrieved from <http://www.cbsnews.com/news/generic-drug-prices-skyrocketing/>

15. Layne, N. (2016, August 18). Wal-Mart's drug problem: Pharmacy business drags on profit. *Rueters*.

Retrieved from <http://www.reuters.com/article/us-walmart-stores-results-pharmacy-idUSKCN0QO01V20150819>

16. Lee AJ, Hefner D, Dobson A et al. (1983). Evaluation of the Maximum Allowable Cost Program. *Health Care Financing Review*. 1983; 4(3): 71-82.

17. Lowery, M. (2015, August 21). Wal-Mart: Pharmacies weighing down corporate profits. *Drug Topics*. Retrieved from <http://drugtopics.modernmedicine.com/drug-topics/news/walmart-pharmacies-weighing-down-corporate-profits?page=full>

18. National Association of Chain Drug Stores. (2015, February 26). "Examining the FY 2016 HHS Budget". A Statement of the National Association of Chain Drug Stores for the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health. Retrieved from http://www.nacds.org/pdfs/pr/2015/EC_HHS_Subcommittee_Budget_Testimony.pdf

19. National Community Pharmacists Association. (2012, September) Survey of Community Pharmacies Impact of Pharmacy Benefit Manager (PBM) Contracting and Auditing Practices on Patient Care. Retrieved from <http://www.ncpanet.org/pdf/leg/sep12/pbmsurvey0912final.pdf>

20. National Community Pharmacists Association. (2015, January 12). NCPA Backs Generic Drug Payment Legislation. Retrieved from <http://www.ncpanet.org/newsroom/news-releases/2015/01/12/ncpa-backs-generic-drug-payment-legislation>

21. NCPA Survey. (April 2015). Summary Report. National Community Pharmacists Association. Alexandria, VA.

22. 2015 NCPA Financials Digest, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

23. 2014 NCPA Financials Digest, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

24. 2013 NCPA Financials Digest, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

25. 2012 NCPA Digest: Financial Benchmarks, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

26. 2011 NCPA Digest: Financial Benchmarks, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

27. 2010 NCPA Digest: Financial Benchmarks, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

28. 2009 NCPA Digest, National Community Pharmacists Association, Alexandria, VA.

29. 2008 NCPA Digest: Financial Benchmarks, Sponsored by Cardinal Health. National Community Pharmacists Association, Alexandria, VA.

30. 2007 NCPA-Pfizer Digest, National Community Pharmacists Association, Alexandria, VA.

31. 2006 NCPA-Pfizer Digest, National Community Pharmacists Association, Alexandria, VA.

32. 2005 NCPA-Pfizer Digest, National Community Pharmacists Association, Alexandria, VA.

33. Nicholson KN. (2016, January 22). NACDS Comments on the Health Carrier Prescription Drug

Benefit Management Model Act. National Association of Chain Drug Stores. Retrieved from http://www.naic.org/documents/committees_b_regulatory_framework_related_nacds_comments_1-22-16.pdf

34. Pharmacy Benefit Management Institute. (2015) 2015-2016 Prescription Drug Benefit Cost and Plan Design Report. Pharmacy Benefit Management Institute. Plano, Texas.

35. Reisetter, B. C., Dunson, D. H., Kolassa, E. M., & Schwab, P. (2008). Effect of Medicare Part D reimbursement on community pharmacy profitability. Centers for Pharmaceutical Marketing and Management Policy Report. University of Mississippi School of Pharmacy. Retrieved from <http://www.drake.edu/deltarx/articles/other/effectofmedicarepartdreimbursementoncommunitypharmacyprofitability/>

36. Rosenthal, E. (2014, July 08). Rapid Price Increases for Some Generic Drugs Catch Users by Surprise. The New York Times Company. Retrieved from http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?_r=0

37. Roth, B. (2014, October 03). Why Some Large Retail Pharmacy Chains Are Struggling With Reimbursement And Generic Price Inflation. Retrieved from <http://consultbfg.com/large-retail-pharmacy-chains-struggling-reimbursement-generic-inflation/>

38. Silverman, E. (2015, April 14). Feds to Probe Impact of Generic Drug Price Increases on Medicaid. The Wall Street Journal. Retrieved from <http://blogs.wsj.com/pharmalot/2015/04/14/feds-to-probe-impact-of-price-increases-of-generic-drugs-on-medicaid/>

39. Talsma, J. (2013). The PBM squeeze. Drug Topics. Retrieved from <http://drugtopics.modernmedicine.com/drug-topics/news/tags/mac/pbm-squeeze>

40. Trefis Team. (2015, February 27). Why Are Generic Drug Prices Shooting Up? Retrieved from <http://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/#7e7e52d6377e>

41. Trefis Team. (2015, August 28). Can Pharmacy Retailers Finally Stop Worrying About Generic Price Inflation? Forbes/Investing. Retrieved from <http://www.forbes.com/sites/greatspeculations/2015/08/28/can-pharmacy-retailers-finally-stop-worrying-about-generic-price-inflation/#1192f1c43d3e>

42. Treflis Team (2014, October 1) Walgreen Reports Strong Topline Growth but Pharmacy Margin Pressure Remains. Forbes/Investing. Retrieved from <http://www.forbes.com/sites/greatspeculations/2014/10/01/walgreen-reports-strong-topline-growth-but-pharmacy-margin-pressure-remains/#5323ee05779d>

43. West-Strum D. "Chapter 23: Purchasing and Inventory Management," Pharmacy Management, 3rd Edition (Desselle, Zgarrick, Alston-editors), McGraw-Hill, New York: NY: 2012, 427-445.

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
LITTLE ROCK DIVISION

No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity
as Attorney General of Arkansas,
Defendant.

DECLARATION OF KRISTY REED

1. I, Kristy Reed, am over the age of eighteen (18) years and competent to testify in the state and federal courts located in the State of Arkansas.

2. I am currently the owner of Super V Drugs, which is located at 1000 East Matthews Avenue, Jonesboro, Arkansas 72401. The town of Jonesboro has a population of approximately 70,000 people.

3. Super V Drugs is a local, family-owned, independent pharmacy that has been in business since 1979. I have been a practicing pharmacist since 1993 and took over the business from father.

4. Attached hereto are true and correct copies of consumer complaints that I submitted to the Office of the Arkansas Attorney General in 2014 and 2015. I submitted these consumer complaints as anticipated by Act 1194 of 2013 and the Attorney General's prac-

tice of receiving complaints from Arkansas consumers. These consumer complaints represent evidence of negative reimbursements from pharmacy benefits managers (“PBM”).

5. The State of Arkansas passed a maximum allowable cost list regulation in 2013 that required PBMs to include alternate national drug code numbers if denying a drug reimbursement based upon existence of a cheaper wholesale price.

6. I submitted at least several consumer complaints explaining non-compliance with the 2013 requirements. Four of these complaints are summarized in the following paragraphs.

7. On July 7, 2015, I submitted a consumer complaint against OptumRx regarding a March 18, 2015 prescription for Tropicium Chloride ER 60mg that I filled. (Attach. 1 at 3.) I had purchased the dispensed portion of the drug for \$161.50. (Attach. 1 at 2-3.) OptumRx (a PBM) reimbursed me \$132.12 on the transaction, which resulted in a net loss of \$29.38. (Attach. 1 at 3.) I appealed the negative reimbursement, and, on April 8, 2015, OptumRx denied the appeal stating, “MAC in alignment with market reimbursement.” (Attach. 1 at 4.) OptumRx did not provide an alternate NDC number for the drug.

8. On July 7, 2015, I submitted a separate consumer complaint against Humana regarding a February 4, 2015 prescription for Hydrocodone/APAP 5-325mg that I filled. (Attach. 2 at 1.) I had purchased the dispensed portion of the drug for \$20.99, however, Humana (a PBM) reimbursed me only \$13.60 on the transaction, which resulted in a net loss of \$7.39. (Attach. 2 at 3.) I appealed the negative reimbursement, and, on March 12, 2015, Humana denied the

appeal stating, “[t]his is on our MAC list and is available for less than we are reimbursing per unit. Please make sure you are buying the cheapest on the market. There will be no action taken at this time.” (Attach. 2 at 4.) Humana did not provide an alternate NDC code to support its appeal decision. (Attach. 2 at 4.) I searched for cheaper versions of the drug, and only one source had the drug listed more cheaply, however at that source, the drug was unavailable for purchase. (Attach. 2 at 1.)

9. In another July 7, 2015 consumer complaint, I complained against Catamaran regarding a negative reimbursement. (Attach. 3 at 1.) On June 18, 2015, I had dispensed a prescription for Fluoxetine HCL 20mg Tab. (Attach. 3 at 3.) I had purchased the dispensed portion of the drug for \$75.61, yet Catamaran (a PBM) reimbursed me only \$56.31 on the transaction, which resulted in a net loss of \$19.30. (Attach. 3 at 3.) I appealed the negative reimbursement, and, on July 2, 2015, Catamaran denied the appeal stating, “[n]o change” and provided an alternate NDC number of 00378-0735-01, which was the exact same NDC that I had used in filling the prescription. (Attach. 3 at 4.) Despite the fact that Catamaran had based its denial on the same drug that I used to fill the prescription, Catamaran nonetheless reimbursed me in an amount less than my cost of acquiring the drug.

10. On February 16, 2015, I submitted a consumer complaint against Express Scripts regarding a negative reimbursement. (Attach. 4 at 1.) On November 21, 2014, I had dispensed a prescription for Cazian PAK. (Attach. 4 at 3.) I had purchased the dispensed portion of the drug for \$18.76, but Express Scripts (a PBM) reimbursed me \$16.14, which resulted in a net loss of \$2.62. (Attach. 4 at 3.) I appealed the negative

reimbursement, and, on December 11, 2014, Express Scripts denied the appeal stating, “[u]pon review, Express Scripts has determined that you are being properly reimbursed based on current market conditions. The relevant product is available at or below the current MAC price, including but not limited to [NDC No.] 00555905167.” (Attach. 4 at 4.) When I attempted to purchase the alternate NDC drug, it was not available for purchase at the price utilized by Express Scripts on the negative reimbursement.

11. Because PBMs process claims for the vast majority of all pharmacy customers, I must contract with PBMs in order to have an insured customer base and viable business. Accordingly, contracts with PBMs are not optional in my line of work. In order to provide pharmacy services to my customer base, which is primarily insured individuals, I must agree to the terms that PBMs offer in order to join their networks, and there is no room for negotiation.

12. According to my contracts with PBMs, I must dispense every prescription that is presented, and I must agree to be reimbursed according to the PBMs’ MAC pricing methodology, but I do not get to see the MAC pricing methodology.

13. In my industry, a pharmacist needs to make approximately \$10.00-\$11.00 on each prescription in order to cover the costs of remaining in business. This means that, in order to pay utilities, salaries and other costs of doing business as a small business, my pharmacy needs to net \$10.00-\$11.00 per prescription in order to break even.

14. During the work week of September 14, 2015 through September 19, 2015 (5.5 days), I have filled 57 prescriptions that resulted in negative claims totaling

approximately \$333.00. Accordingly, on average, I experience roughly ten negative reimbursements every day. This is a significant loss to my business.

15. A review of my records reflects that during the period of June 21, 2015 through September 21, 2015, I dispensed 856 prescriptions below cost (*i.e.*, resulted in negative reimbursements). The total actual loss amount for this period was \$5,708.57. This figure, however, does not take into account the cost of doing business.

16. Taking into account the fact that my business needs to obtain approximately \$10.00-\$11.00 on each prescription in order to cover expenses of doing business, my business has lost a great deal more than \$5,708.57. Rather, multiplying the 856 negative reimbursements by the \$10.00 average results in \$8,560 in lost revenue plus the actual \$5,708.57 in loss results in a three- month total of \$14,268.57.

17. The loss of revenues discussed above is a significant problem for a small business like mine. I utilize the revenues from prescriptions in order to pay utilities as well as salaries for my employees. As a corporate citizen, I ensure that my employees have the ability to grow through salary increases, health insurance coverage, as well as optional retirement accounts. I also try to allow my business to sponsor local events and activities in support of my community. The negative reimbursement issue is making it extremely difficult for me to accomplish these things on behalf of my employees and my community. They also make it difficult for me to expand my business, provide jobs to the community and to innovate.

18. Simply stated, the ability of my company to remain in business is threatened by the ongoing negative reimbursements that PBMs continue pay.

Closing my doors and moving to another industry would harm my patients and my community.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 22, 2015.

/s/ Kristy Reed, P.D.
Kristy Reed, P.D.

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
LITTLE ROCK DIVISION

No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION
Plaintiff.

v.

LESLIE RUTLEDGE, in her official capacity
as Attorney General of Arkansas,
Defendant.

DECLARATION OF ROBERT GEYER

1. I, Robert Geyer, am over the age of eighteen (18) years and competent to testify in the state and federal courts located in the State of Arkansas.
2. I am currently the owner of Medi Shop Pharmacy, which is located at 204 Highway 71 South, Mena Arkansas 71953. The town of Mena has a population of approximately 6,000 people.
3. Medi Shop is one of two independent pharmacies in the town of Mena. Mena has four licensed pharmacies (two of which include national chain stores).
4. Attached hereto are true and correct copies of consumer complaints against pharmacy benefits manager that I submitted to the Office of the Arkansas Attorney General in 2014. These consumer complaints represent evidence of negative reimbursements from pharmacy benefits managers (“PBM”).

5. The State of Arkansas passed a maximum allowable cost list regulation in 2013 that required PBMs to include alternate national drug code numbers if denying a drug reimbursement based upon existence of a cheaper wholesale price.

6. I submitted at least several consumer complaints explaining non-compliance with the 2013 requirements. Two of these complaints are summarized in the following paragraphs.

7. Complaint No. 14-03454. On July 10 and 21, 2014, I filled a prescription for Betamethasone DP 0.05% Ointment. (Attachment 1 at 5.) I had purchased these drugs for \$47.13 and \$49.95, respectively. (Attachment 1 at 3, 5.) US Script (the PBM) reimbursed me \$25.14 for each transaction, which represented a loss of \$21.99 on the July 10 fill and a loss of \$24.81 on the July 21 fill. (Attachment 1 at 5.) I appealed the July 10 negative reimbursement, and, on August 4, 2014, US Script responded by denying the appeal and stating that no adjustment would be made, but it did not provide the alternate NDC or wholesaler supporting its view of the lower MAC price. (Attachment 1 at 4.)

8. Complaint No. 14-03452. On February 20, 2014, I filled a prescription for Morphine Sulfate 15mg Extended Release. (Attachment 2 at 2.) I had purchased the dispensed portion of the drug for \$26.97. (Attachment 2 at 2-3.) US Script (the PBM) reimbursed me \$24.82 on the transaction, which represented a net loss of \$2.15. (Attachment 2 at 2.) On February 25, 2014, I appealed the negative reimbursement. (Attachment 2 at 3-4.) On March 6, 2014, US Script responded by denying the appeal and explaining that no adjustment would be made and stating, "Please inquest [*sic*] with your wholesalers to find less

expensive purchasing options. Explanation of outcome: Market conditions.” (Attachment 2 at 5.) US Script did not provide an alternate NDC code to support its lower MAC price. (Attachment 3 at 5.) On March 6, 2014, I appealed a second time. (Attachment 2 at 7-8.) In this appeal, I explained that “Arkansas state MAC legislation requires the identity of the NDC of a cheaper product available in Arkansas.” (Attachment 2 at 8.) After a telephone conference with US Script regarding the matter, I followed up with an email explaining that the alternate NDC number that US Script proposed was not any cheaper than his wholesaler price at AmerisourceBergen. (Attachment 2 at 9.) It did not change the appeal denial decision.

9. In my industry, a pharmacist needs to make approximately \$10.00-\$11.00 on each prescription in order to cover the costs of remaining in business. This means that, in order to pay utilities, salaries and other costs of doing business as a small business, my pharmacy needs to net \$10.00-\$11.00 on each prescription filled in order to break even.

10. During the past work week (5.5 days), I have filled 23 prescriptions that resulted in negative claims totaling \$53.07. Accordingly, on average, I experience roughly four negative reimbursements every day. This is significant in a small town and with a smaller customer base.

11. A review of my records reflects that during the period of June 17, 2015 through September 17, 2015, I dispensed 307 prescriptions below cost (*i.e.*, resulted in negative reimbursements). The total actual loss amount for this period was \$1,829.60. This figure, however, does not take into account the cost of doing business.

12. Taking into account the fact that my business needs to obtain approximately \$10.00-\$11.00 on each prescription in order to cover expenses of doing business, my business has lost a great deal more than \$1,829.60 in three months time. Rather, multiplying the 307 negative reimbursements by the \$10.00 average results in \$3,070 in lost revenue plus the actual \$1,829.60 in loss results in a three- month total of \$4,899.60.

13. This trend is extremely difficult to withstand, and I am concerned about remaining in business in order to provide pharmacy services to the people of Mena, Arkansas and surrounding areas.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 21, 2015.

/s/ Robert Geyer, Pharm.D.
Robert Geyer, Pharm.D.

[1] THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

Civil Action No. 2012-0066

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity as
ATTORNEY GENERAL OF THE STATE OF ARKANSAS
Defendant.

ORAL DEPOSITION OF
DONNA WEST-STRUM, RPH, PHD

Taken at the instance of the Plaintiff on
Wednesday, July 20, 2016, at the University of
Mississippi, Guyton Hall, 49 Guyton Drive,
University, Mississippi, beginning at 9:00 a.m.

(Appearances noted herein)

Reported by: Tiffany R. Seawright,
CSR Edwards Reporting, Inc.
435 Katherine Drive, Suite A
Jackson, Mississippi 39232
601-355-DEPO (3376)
800-705-DEPO (3376)

[2] APPEARANCES:

KRISTYN DEFILIPP, ESQ.
Foley Hoag, LLP
155 Seaport Boulevard
Boston, Massachusetts 02210

COUNSEL FOR PLAINTIFF

SHAWN JOHNSON, ESQ.
Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201

COUNSEL FOR DEFENDANT

* * *

[23] A. It does say that. You are correct.

Q. Okay. And then let me turn to the page before that, page 3, and in that, in the bottom of page 3, Section D, doesn't it require the PBM to change the MAC for each similarly situated pharmacy as defined by the payor that is subject to that list?

A. Yes. But that's a different scenario because that's the appeal is being upheld.

Q. Okay. And if the appeal is upheld that means the PBM didn't have a fight with the pharmacy about whether or not they could obtain the price, they just increased the MAC price; right?

A. Right.

Q. So that means if the pharmacy won the appeal the PBM also has to grant the appeal or change the price for all similarly situated pharmacies; right?

A. That's right. They would need to change their MAC price list to represent the fair market value of the product.

Q. Well, not the fair market value, the pharmacy's acquisition cost; correct?

A. It doesn't really say what it has to be, but it is going to have to be at a value where the pharmacist can purchase it at that cost. It just says if the appeal is upheld, make the change in the maximum [24] allowable cost. I don't –

Q. And that changes –

A. Well, I think –

Q. Go ahead.

A. I think the PBM can use their information sources and market intelligence and all the resources that they use currently to make a MAC list, to put a price on or put a cost on there that will cover the acquisition cost for the pharmacy. Again, this is only, you know, most MAC lists are – they already cover acquisition cost of the pharmacy. This is about though the increasing trend. And used to all MAC lists cost covered pharmacy acquisition cost and then it's continually increased. I don't know an exact number, but I would say anywhere from 5 to 15 percent is a fair estimate.

Q. Okay. So that between 5 and 15 percent are the number of prescriptions that are – the MAC – for which the MAC is set below the acquisition cost; is that correct?

A. That's correct. But not all of those are appealed.

Q. Okay. But those are the numbers, those are the percentages of prescriptions on which you would find that a pharmacist is taking a loss per prescription?

A. Yes.

[25] Q. Okay.

A. But back to if the PBM can say here is a wholesaler where you could – here is several wholesalers where you can buy it for less money, most pharmacists are going to look for that. They need to buy it at the lowest possible cost regardless of what the MAC is. Because the lower they can get their price, the more money they can make. And there is so many different MAC lists that that's their goal is to buy it at the cheapest price.

Q. So but Act 900 doesn't require them to do that, does it?

A. Doesn't require pharmacies to buy it at the lowest cost, is that what you are asking?

Q. The Act 900 doesn't require a pharmacy to change it's acquisition cost unless the PBM can provide an NDC from their primary wholesaler; correct?

A. Act 900 is not about pharmacy purchasing patterns.

Q. Okay. Now, are you aware – you testified earlier about why MAC was developed. And what's the basis of your knowledge about why MAC was developed?

A. Well, so initially it was to promote the use of generics so that it would encourage pharmacists, patients, to use generics because that was – if you set [26] a MAC price and there was still a brand name out there it was going to be more expensive and the pharmacy wasn't going to get reimbursed. Two, it increased competition between generic manufacturers. So now, if I have five generic manufacturers, four are priced low but one is priced high, I can now encourage pharmacies – wholesalers, pharmacies, patients to make sure they're buying from the generic manufacturer that has the lowest price.

Q. And it did that. What's the basis of your knowledge? How do you know this about MAC?

A. Just reading.

Q. Okay. And, in fact, MAC – so in the way that you described this increase in competition among wholesalers, MAC had the act of reducing the price of generics; correct?

A. Yes.

Q. Okay. And so you basically said there is two reasons that MAC was developed, one, was to increase the drug mix to favor generics; right?

A. Right. And I think we are past that in today's market price.

Q. Right. Because the vast majority of drugs dispensed are generic; right?

A. Right. And people are comfortable with generics.

[27] Q. Right. And then the second reason was to encourage wholesaler competition, would you agree, had the affect of reducing the cost of those generic drugs; right?

A. Yes. I'm sorry. It's really not just wholesaler competition, it's really the generic manufacturer competition.

Q. Okay. And but it also increases competition for both wholesalers and the manufacturers; right?

A. Right.

Q. And the reason why MAC was developed – when you are talking about that second reason to reduce the cost, that was because generic prices had been increasing in the years before MAC was developed; right?

A. Well, I was thinking more it just was not all generic manufacturers were coming out with as low a price. So if you had five different generic manufacturers, one might decide, you know what, I can price this a little bit higher, make a little bit more money. And so to keep wholesalers and pharmacies from buying that one which is more expensive when over here is the exact same product that's AB rated for less.

Q. Okay. And in your scenario, pharmacies would sometimes still buy that drug at that higher price; right, after the MAC?

[28] A. That's right.

Q. And that's because it didn't – there wasn't a cap to reimbursement?

A. Right. Because it would be reimbursed on using a different formula and so they would still be reimbursed for their acquisition cost. And so the idea was –

Q. Right.

A. Yeah.

Q. So in the different formula would be something that was based off of average wholesale price?

A. Yes, AWP.

Q. Okay. Right. And for purposes of the deposition we can refer to Average Wholesale Price as AWP; okay?

You just have to say okay.

A. Okay.

Q. Okay. And are you aware that studies have shown that MAC reduced the cost of drugs because it provided that incentive to shop for the best price?

A. Yes.

Q. And state governments, including Arkansas, used MAC for their prescription benefit programs; right?

A. I believe so, yes.

Q. And the federal government does too; right?

A. Yes. MAC or Federal Upper Limit.

Q. Okay. And numerous commercial plans also use MAC [29] for their reimbursement; right?

A. Right. Yes.

Q. So there must be some benefit to the payor for using MAC since all of those payors are employing the system; right?

A. Yes.

Q. Okay.

A. Yeah. I think MAC pricing is efficient. It's just if you are not paying the acquisition – if a pharmacist has to purchase the drug for a patient and is not going to get reimbursed what they paid for it, that's unsustainable over time. It would be very difficult to stay in business.

Q. Are you aware that MAC was intended to operate as an average, a reimbursement for the average fair market price of the drug?

A. That's not my – I thought it would be to represent an acquisition cost that's widely and consistently available.

Q. Okay. So assuming that that definition is correct, that it's an acquisition cost is widely and consistently available, even if there were acquisition costs

that were widely and consistently available, there might be some pharmacies that would end up paying more than that cost; right?

[30] A. Yes.

Q. Some of them might not be able to access that price for whatever reason; right?

A. Yes.

Q. Because maybe they didn't try, that would be one reason, they didn't try to get a lower price?

A. That would be a reason. But, again, pharmacies are struggling so it's – they are looking for the lowest priced drug and it's in their best interest financially to find – if they – if the MAC is 15 cents and they can buy it for 10 cents and make 5 cents, okay. But if they can buy it for 5 cents they can make 10 cents, so the goal of the pharmacy is not to just purchase drugs but really to find it at the lowest possible cost. And the trend –

Q. Well, that's assuming that all pharmacies are acting as reasonable economic actors; right? They are all looking out for their best economic interests?

A. Yes. And they –

Q. Is that your assumption?

A. Yes. Because they pretty much have to in today's environment or they won't stay in business at all.

Q. Okay. But some pharmacists might not have good credit; right, and that might change their ability to access a good price from their wholesaler?

* * *

[42] BY MS. DEFILLIP:

Q. Well, that's not what I asked. Doesn't Act 900 take away the threat of dispensing a drug and losing money?

A. I don't think it takes away the threat completely.

Q. Why not?

A. Because I have to appeal. I mean, they can deny the appeal.

Q. Wouldn't you agree that it reduces the threat of operating at a loss on a transaction?

A. It reduces the threat which I think is important to the sustainability of certainly independent pharmacies in Arkansas.

Q. Would you agree that under Act 900 a wholesaler could charge a high price on its invoice and grant off-invoice discounts to its customers?

A. Did you say "could they", is that the question?

Q. They could, couldn't they under Act 900?

A. They could. But I think market –

Q. And –

A. The competitive –

Q. The wholesaler – my question was whether or not they could?

A. They could, yes.

[43] Q. Okay. And particularly because the court reporter is trying to take down both what we are saying, I just ask that you just answer the question that I'm asking. I will usually follow up with an opportunity for you to state your reasoning behind that and if I don't I'm sure your report contains it. So just please

just answer the questions as I ask them. So if a wholesaler charges a high price on its invoice and then granted off-invoice discounts to its customers, the pharmacies, the pharmacies could appeal using that higher invoice price; right?

A. Right.

Q. It wouldn't have to disclose to the PBM the fact that it got off-invoice discounts?

A. That's not my – I don't think so.

Q. Okay. And the wholesaler would get paid the same amount no matter what; right?

A. Right.

Q. Okay. And the pharmacy would be able to retain a higher margin than if those discounts were on-invoice; right?

A. If they get the appeal awarded, is that the assumption?

Q. Yes. Assume that a pharmacy –

A. Yes.

[44] Q. So they would have a higher margin than if they had appealed using a price that included the discounts?

A. Right. Yes.

Q. Right. Okay. And so that could be a way for a wholesaler to compete for pharmacy business, couldn't it?

A. I think they are still going to compete on price and invoice price.

Q. But they could compete by offering, you know, a higher invoice price with more off-invoice discounts in addition to competing on price; right?

A. They could.

Q. So isn't there a danger that Act 900 allows for this kind of collusion between pharmacies and wholesalers?

A. I don't think so.

Q. Why not?

A. Well, I think the discounts, for the most part there is no way it's not uniform. I have no way to calculate that. The industry doesn't really have a way to calculate that currently.

Q. To calculate off-invoice discounts?

A. Right. Like, yeah. I don't –

Q. Well, doesn't MAC take into account off-invoice discounts?

[45] A. I think they do, but I don't know how they do it.

Q. You talked about other ways besides negotiating, so one way that you mentioned that a pharmacist could reduce the cost of goods sold is inventory management; right?

A. Right.

Q. And so the goal of inventory management is to minimize the investment in inventory and then while sales rise, but also making sure that the inventory is available when it's needed; right?

A. Right.

Q. Is the goal to turn over inventory as quickly as possible?

A. Well, you want to – well, you want to sell it as quickly as possible. I mean, if it's sitting there then you are carrying that cost.

Q. Right.

A. So –

Q. But wouldn't it be fair to say that a well informed pharmacy manager might try to buy more inventory at a low price if they have the sense that the prices were rising?

A. They could do that.

Q. Yeah. And in that case they might actually have more inventory than they need for the time period;

* * *

[58] Q. Okay. And so when they are looking at all that information, how would they determine whether there was an increase of 10 percent in the invoice price?

A. Well, like NADAC will tell you that there's been a percent increase in national average acquisition costs, so it wouldn't be invoice so to speak but how they define cost.

Q. Okay.

A. If you are partnering with a wholesaler, I mean, you would obviously be keeping acquisition costs so you would be able to calculate it and you could have a database that would automatically do that I would think.

Q. And would you agree that they would have to do this, like keep track in that database of every single drug on their MAC list?

A. Yes. I think they are already keeping up-to-date to some extent given that the majority of MAC price lists already cover acquisition costs of pharmacies. I think they are monitoring this.

Q. And as far as you know PBMs already look at their own purchase pricing and appeals and whatever wholesaler pricing they can get their hands on; right?

A. That's my understanding, but I have not worked for a PBM.

Q. Okay.

[59] A. That's what you would either read or hear about if you went to the Manager Care Pharmacy Meeting or something like that.

Q. Okay. Let's go to paragraph 11 of your report. In the very first sentence of that paragraph you define gross marketing as, "The difference between what the pharmacy is reimbursed for the drug product (e.g., MAC price list plus a dispensing fee) and the pharmacy's acquisition cost of the drug product on the wholesaler invoice." Right?

A. Right.

Q. But that doesn't – that doesn't take into account discounts that are non-invoice; right?

A. That will depend on how the pharmacy calculates that or what they do with that. It's usually pretty negligible. When I look at a pharmacy's P&L statement that's not a huge amount of money so.

Q. Okay. You're saying that off-invoice discounts are not a huge amount of money?

A. I think it's negligible, yes.

Q. Okay. And Act 900 doesn't take into account the dispensing fee with granting an appeal; right?

A. Right. Because Act 900 is about the acquisition cost.

Q. Most pharmacies have a primary wholesaler and a [60] secondary wholesaler at least; right?

A. Right.

Q. And they usually have a contract with at least a primary wholesaler; right?

A. Right.

Q. And that contract sets up some of their discounts, doesn't it?

A. Right.

Q. And sometimes there is a discount for exclusivity or mere exclusivity with that primary wholesaler; right?

A. Right. So volume, you are going to purchase so much volume.

Q. And sometimes an independent pharmacy might enter into a wholesaler contract through their PSAO; is that right?

A. Right.

Q. And that's where the PSAO would negotiate the bulk discounts with the wholesaler and do some aspect of the purchasing for them; right?

A. Right.

Q. Okay. And to be clear, a PSAO is a Pharmacy Services Administration Organization?

A. Right.

Q. So the wholesaler's contract provides for some sort of a reconciliation; right?

[61] A. Right.

Q. And so at the end of a month or maybe a quarter or a year, whatever time specified by that contract, the wholesaler will apply those volume discounts that you mentioned; right?

A. Right.

Q. And there might be some other discounts that get applied during that reconciliation period?

A. Right.

Q. And that reconciliation is done after invoicing; right?

A. Right.

Q. Okay. So would you agree that the wholesaler's invoice does not include all the discounts and the pricing sessions that a pharmacy might receive in purchasing a drug product from a wholesaler?

A. Right.

Q. And the invoice is issued at the time of the purchase; right?

A. Right.

Q. Would an invoice reflect a prompt payment discount?

A. I think it could. I don't know if it would or not. I think it could, but it could not. I mean, I think it could probably goes both ways. Right.

[62] Q. Okay. And just to be clear, what is a prompt payment discount?

A. Well, some – that's the fire alarm.

(Off the record.)

BY MS. DEFILIPP:

Q. So Dr. West, before we were interrupted by the fire alarm I think we were talking about prompt payment discounts.

A. Yes.

Q. So what is a prompt payment discount?

A. It's when a pharmacy pays by a specified day. So there could be prepay where they actually have you based on some average amount that usually buy prepay or it could be that you pay within 14 days of ordering. So there is some specific date and if you promptly pay then you get that discount.

Q. And is it usually like a percent off the price? Like is it a flat rate off or is it a percentage off?

A. I would say it is probably more of a percentage off, but, again, I don't know what all the different pharmacy and wholesaler arrangements are.

Q. Do most wholesalers use a prompt payment discount to your knowledge?

A. To my knowledge, yes.

Q. Okay. And so say you have the option of having a [63] prepay discount, if it's a prompt payment discount – the invoice is typically issued before a payment is made; right?

A. Right.

Q. And so that invoice, it might have the terms of prompt payment on it but it wouldn't indicate whether the discount was applied; right?

A. Right.

Q. Okay. And are you familiar with copay coupons?

A. I'm aware of them.

Q. What are they?

A. Are you talking about where like a manufacturer provides a coupon to a prescriber or patient so that they don't have to pay the copay.

Q. Is that what your understanding of what a copay coupon is?

A. Yes.

Q. Okay. And so are they ever provided to pharmacists or I suppose the payer provides them to the pharmacist?

A. I'm thinking as the pharmaceutical manufacturer providing them to the prescriber to give to the patients.

Q. And then when the patient goes to the pharmacy they pay with that coupon; right?

[64] A. Right.

Q. And so then the pharmacy has to redeem the coupon from the manufacturer; is that right?

A. That would be my understanding.

Q. Okay. And so if the pharmacy – okay. So strike that. So I think you agreed with me before the break that a wholesaler's invoice would not include all the discounts or price concessions that a pharmacist might receive; right?

A. Correct.

Q. Now, you are aware that Act 900 requires PBMs to reimburse pharmacies for the price on their invoice; right?

A. Correct.

Q. And so now knowing that that price on the invoice doesn't reflect certain discounts, does that change your opinion at all about your opinion that Act 900 forces MAC to rely on fair market pricing?

A. It doesn't. Because I think those discounts are negligible and I don't know how you would calculate or how a pharmacy even calculates all of that.

Q. What do you mean, how a pharmacy calculates all of that?

A. How you would figure up – maybe if you meet a certain volume you get a certain discount off, so does [65] that apply to everything you bought or it's going to vary per pharmacy and per its wholesaler. It's not uniform, so I don't know how to calculate that.

Q. Right. Well, one way of calculating that is for the MAC – for the PBM to take all of those discounts into account where they are making the MAC price; right?

A. Again, it wouldn't be uniform across pharmacy, so I don't think that would be – that would probably hurt your rural pharmacy that's probably not getting –

Q. It would hurt your rural pharmacy because why?

A. They wouldn't be getting the same discounts, same volume purchasing discounts that say Wal-Mart would.

Q. Are you aware that PBM will often offer rural pharmacies improved reimbursement terms for them to enter, for them to join the network?

A. I'm aware that if they need a pharmacy in the network because that's the only rural pharmacy there that, yes, sometimes they have to negotiate and it's my understanding that's mainly with brand name drugs and not generic drugs.

Q. Because but the goal of that negotiation is to ensure that overall it's worth that pharmacy's while to join the network; right?

A. Yes. So that the pharmacy will make the decision to join the network, yes.

[66] Q. Right. And the pharmacy will make that business decision based on looking at the PBM contract as a whole, not necessarily at transaction by transaction; right?

A. Right. And then but the MAC price isn't transparent, the MAC price list usually so – and it can fluctuate throughout the term of the contract – so it's very difficult to negotiate that and to know. That's sort of the part that you don't really know as a pharmacist when you sign that contract.

Q. And but MAC has been around for, you know, more than 20 years, hasn't it?

A. MAC pricing, is that what you said?

Q. Yeah.

A. Yes.

Q. Yes. So pharmacists know those things that you just said about MAC that they won't necessarily – that it might fluctuate from day-to-day and that they won't necessarily be able to pinpoint what MAC price is going to be in anticipation of dispensing a drug; right?

A. Right.

Q. Now, I want to get back to your opinion that MAC price – is it your opinion that MAC should reflect the price, the lowest price a generic drug is widely and consistently available?

[67] A. I think that would be the goal of the PBM, yes.

Q. Okay. And so you agree that if MAC follows the method by which it limits the reimbursements, the lowest price at which a generic is widely and consistently available, it would be a fair way of reimbursing pharmacists?

A. Yes.

Q. Okay. In paragraph 38 you say that Act 900 regularly – oh, go ahead and flip to that.

A. Paragraph 38?

Q. Yes.

A. Okay. I'm there.

Q. Okay. You say that Act 900, "Regulates the PBM to maintain MAC price lists that reflect current, fair market values of generic products in Arkansas." What's the basis for your opinion that Act 900 reflects current values of generic products?

MR. JOHNSON: Kristyn, is that in paragraph 38? Am I missing it?

THE WITNESS: Yeah, it's there.

MS. DEFILIPP: Yeah. It's in the fourth line down, "Maintain MAC price lists that reflect current, fair market values."

MR. JOHNSON: Okay. I'm sorry. Go ahead and re-ask your question. I apologize.

[68] MS. DEFILIPP: No. That's fine, Shawn. It's pretty dense.

THE WITNESS: Based on either things I've heard at national meetings or things I've read, it's my understanding that sometimes a MAC price will be based off of an old NDC number that's not available anymore. So that's what I was – that would not be appropriate in my opinion.

BY MS. DEFILIPP:

Q. But doesn't Act 900 actually require the PBM to reimburse the pharmacy's invoice price no matter when the pharmacy purchased the drug?

A. Yeah. But it will be pretty current because these drugs have expiration dates, so they can't purchase a drug and it sit there for five years.

Q. Well, how long is the expiration usually?

A. Usually a year.

Q. Okay. So they could purchase them and have them sit around for nine months; right?

A. Right.

Q. And the price could fluctuate pretty wildly in that nine months, couldn't it?

A. Right.

Q. But Act 900 would require PBM to reimburse for the price when the pharmacist bought it; right?

[69] A. Right.

Q. So it actually has nothing to do with current values of the prices; right?

A. Well, I guess it depends on how you define "current" so.

Q. Right. So but and actually depending on a pharmacy's inventory management practices, it could be reflecting the value of a drug from a year ago; right?

A. Right.

Q. Okay. So we talked before about your reading of Act 900 and it's not your reading that the PBM's NDC has to be available from the pharmacy's primary wholesaler; right?

A. I'm sorry. Can you repeat that?

Q. So you testified earlier when we were talking about, you know, where in the statute it said that the price had to be widely and consistently available. You said it's not true that Act 900 requires the PBM's MAC price to be based on an NDC that's available from a pharmacy's primary wholesaler; right?

A. My interpretation is that if they can find wholesalers where you can purchase it, here is the NDC and here is some wholesalers where you can purchase it for this price, that you could deny that claim, that's my interpretation.

[70] Q. Okay. I'd like you right now to assume that my interpretation that I suggested to you earlier is correct.

A. Okay.

Q. In that interpretation that the PBM has to grant the appeal unless they can provide an NDC that's available from the pharmacy's primary wholesaler?

A. Okay.

Q. So assuming that's true, does that change your opinion Act 900 takes into consideration whether the price is widely and consistently available?

A. It doesn't change my opinion completely.

Q. Does it change it a little, partially?

A. I'm thinking most of primary wholesalers are going to be one of the large national wholesalers 90 percent of the time. So –

Q. So wouldn't you agree that if the pharmacy – go ahead, Dr. West. I'm sorry. Finish your thought.

A. No. Go ahead.

Q. So wouldn't you agree that if you have a pharmacy who has a primary – you know assuming that Act 900 requires it to be the primary wholesaler?

A. Yeah.

Q. Wouldn't you agree that Act 900 will allow a pharmacy that does not purchase from a national [71] wholesaler to be reimbursed at a price that is not necessarily widely or consistently available in Arkansas?

A. If the – yes. If the PBM does not want to deny the appeal. If they have to grant it then, yes.

Q. Okay.

A. But I would think the PBM would deny the appeal.

Q. Right. But I'm assuming for purposes of this question –

A. Right.

Q. Okay. So assuming the PBM has to grant the appeal unless it can provide an NDC from the primary wholesaler, you would agree that Act 900 does not require that the price be set at something that's widely or consistently available?

A. Okay. Again, my interpretation would be that they would have to grant that appeal, but they wouldn't have to change their whole – well, you said they did. You said that was part of the law.

Q. Well, then assuming they should grant the appeal and so then your next response is they don't have to change it for anyone else?

A. Well, that's what I was going to say but you already pointed out that, that they would adjust the maximum allowable cost list. So if that's your –

[72] Q. So, yes?

A. In that interpretation, yes.

Q. Okay. We talked earlier before the break about the number of negative reimbursements or the percents of negative reimbursements as compared to the total of generics dispensed; right?

A. Right.

Q. And you testified that it was a very small number. Let me clarify the record. Sorry. You testified that the percent of reimbursements that were below acquisition costs was small; right?

A. Right.

Q. And you said you weren't sure of the number but you thought it was somewhere between 5 and 15 percent of generic – was it 5 to 15 percent of generic prescriptions?

A. No. I think it's just 5 to 15 percent of prescriptions, so they won't all be generics.

Q. Okay. And in your report you relied on a 2012 NCPA survey; right?

A. Yes.

Q. Okay. And in that survey the 51 percent of the pharmacies responding reported that their reimbursements were higher than MAC 90 percent of the time or greater; right?

[73] A. Right.

Q. And so for each of those pharmacies, for each of those prescriptions 90 percent of 51 percent of the pharmacies, those pharmacists were profiting from those prescriptions; right?

A. From the ones that were above the MAC, is that what you're talking about?

Q. Yes. Well, the ones the MAC was above acquisition cost?

A. Right. I wouldn't use the word "profiting", but I would use that they have some gross margin left to pay their expenses. I don't know if they profited.

Q. Okay. Right. And then that gross margin some of it might be used to pay the rent, for example; right? A. Right. For prescription bottles.

Q. Yeah. Okay. So you would agree that most prescriptions don't cost – you would agree that most pharmacies do not take a loss on most of their prescriptions; right?

A. Right.

Q. Okay. Now, let's assume that under Act 900 a PBM increases the MAC price in order to avoid processing more appeals. Assuming that happens, won't those pharmacies, the ones that were already not taking a loss on their reimbursements, won't they see even greater

* * *

[86] Q. Even after the Act 900?

A. Yes.

Q. And Scenario B assumes that MAC prices are updated according to when – considering Act 900; right?

A. Really that they are just updated to reflect the increase in manufacturer price, with or without Act 900.

Q. Okay. And what you say here is the same as Scenario A is that now Act 900 is considered; right?

A. Okay. So, right. So, yes. So they are updating their prices every seven days and reflecting the increase in manufacturer price.

Q. Okay. And so what is your understanding of how Act 900 makes that happen?

A. Makes what happen?

Q. So you say that Scenario B is considering Act 900 and in this scenario a PBM – the MAC list somehow is updated to perfectly reflect the increase in the cost of drugs; right?

A. Right. And, again, how they would perfectly do it, but I think they can get close to doing it because they are already doing it for most of the drugs on the MAC lists. But I think they can watch the NADAC, they can partner with wholesalers which they probably already do, they may own their own pharmacies. Sometimes it's just in the news that certain drugs have increased in [87] price. And so, again, using that market intelligence I think they can get close.

Q. Well, I think I should restate my question which is that you are listing a lot of ways that a PBM could

stay on top of a MAC price; right, or stay on top of the acquisition price; right?

A. Yeah.

Q. Okay. But how does Act 900 make that happen?

A. I don't think it makes it happen. I think it's an incentive for the PBM. I mean, it says you are supposed to update it in seven days and maybe the PBMs will figure out how to follow the law. But, I mean, you're right, it doesn't make it happen. And I didn't –

Q. Your table – sorry. Let's go to paragraph 53.

A. I'm sorry. I didn't hear the paragraph number. Sometimes it cuts out. It's okay.

Q. In paragraph 53 –

A. Okay.

Q. So this is a table – did you pull this table wholesale from the Drug Channels Institute?

A. Not the table but the graph.

Q. Okay. So did you generate the table yourself?

A. Yes.

Q. Okay. And so this table assumes that all [88] generics start at the same price, that's \$20; right?

A. Right.

Q. But that's not how it happens in reality; right?

A. Right. They are not all \$20, is that what you are saying?

Q. Right.

A. Yeah.

Q. It varies quite widely in price; right?

A. Right.

Q. Okay. Like I think you gave an example in your report of a drug that actually itself changed in price from like \$4 to \$200; right?

A. Right.

Q. And beyond just the drug change, you know, a single drug changing in price, you might have on one MAC list some drugs that are 10 cents; right, and some drugs that are like \$50; right?

A. Right.

Q. Okay. So if you take away this assumption from your chart that all the generics start at the same price, you can't really show that decreases don't offset increases; right?

A. Right. It's going to depend on each pharmacy's prescription mix.

Q. Okay. Going back to paragraph 43 in your report. [89] We've looked at this one before. The very last line of paragraph 43, you say, "Wholesalers will continue to compete in multiple ways, including price of drugs." What other ways besides prices of drugs do wholesalers compete?

A. I think service, service delivery. I mean, if I have a wholesaler that when I order drugs that it's supposed to come tomorrow and it's frequently late or half my order is incorrect, so I want to have good service, service delivery. Wholesalers will offer a variety of services to help the pharmacy manage their inventory. They may provide some software, tools, things like that.

Q. Okay. And what's the basis for your opinion that wholesalers will continue to compete in multiple ways under Act 900?

A. I think it's a very competitive market place and pharmacies are still going to be wanting to find drugs at the cheapest rate. And so the wholesaler will want that pharmacy business and will continue to compete.

Q. So you would agree that the wholesaler's incentive to compete on price comes at least in part from pharmacy pressure?

A. Sure. Pharmacists are looking for lower prices.

Q. And when they do that, that causes the [90] wholesalers to compete against one another; right?

A. Right.

Q. In paragraph 44 of your report you say that PBMs should be able to update their MAC lists in a timely manner; right?

A. Right.

Q. And I'll say I'm summarizing what you say in that paragraph.

A. Right.

Q. And this opinion is based on the fact that state Medicaid programs update their MAC prices frequently?

A. Yeah. Right.

Q. That's one of the –

A. That's one. That's one reason.

Q. Okay. And that it's also based on the fact that a few different PBMs have reported that they try to update their MAC lists to reflect acquisition costs; right?

A. Right.

Q. Would you agree that if the number of MAC lists increases, the amount of work to be done to update them would also increase?

A. I think, yes, it would. Yes.

Q. Go to paragraph 14 of your report. In the second to last sentence of that paragraph you say, "If [91] independent community pharmacies experience continued losses when filling generic prescriptions and have to close their pharmacies, access to prescriptions and pharmacy services in rural areas will decrease." What is your source for this conclusion?

A. Well, based on if the trend is that MAC prices are becoming very aggressive and so there is more negative reimbursements, then it's going to be difficult to stay in business. Because generics are the majority of the pharmacist's business. And this is rural areas where it's likely to be an independent, it's likely to have 90 percent of its business be prescription drugs. And so even on the drug that's covering the acquisition costs, the margins are very, very small. And so it makes it difficult to say I want to continue to invest or for anyone new to say I want to spend a half a million to a million dollars to open a pharmacy. And so access will decrease.

Q. Okay. You'd agree that independent pharmacies can exist in all different geographic areas; right?

A. That's right, yes.

Q. So there is – some of them are in rural areas as you've mentioned; right?

A. Correct.

Q. And some are in suburban areas?

[92] A. Yes.

Q. Right? Some are in urban areas; right?

A. Right.

Q. Okay. Are you aware of any specific pharmacies in rural Arkansas that have closed within the last five years?

A. I am not familiar with any specific pharmacies in rural Arkansas that have closed. The data that's in The Digest which comes from NCPDP would suggest that pharmacies in Arkansas, I don't know if they are in rural or not, have closed in the last five years.

Q. Do you have any data to support the conclusion that residents of rural Arkansas do not have sufficient access to their prescription medication?

A. Today?

Q. Yes. Today.

A. I do not have that data.

Q. Okay. Do you have any data that would support the conclusion that residents of rural Arkansas are at risk of not having access to their actual medication?

A. Well, I think there are definitely some areas in rural Arkansas where there is only one or two independents. And so and if they are struggling financially and they close then that would be an area – I mean, because about 90 percent of Arkansas, I think, [93] is considered underserved. So if a pharmacy closed it would be difficult.

Q. Okay. When you say 90 percent of Arkansas is considered underserved, what does “underserved” mean?

A. That's based on the HRSA definition, Health Services – I can't remember what all HRSA stands for. But they have definitions of what they consider underserved, so not very many healthcare professionals for a given area.

Q. Okay. Now, those residents of rural Arkansas, where there is only one or two independent pharmacies, they could get some of their medication from mail order pharmacies, couldn't they?

A. They could.

Q. Okay. And when you said there was only one or two independent pharmacies, do you mean in the whole area there's only one or two pharmacies and either or both of them is independent or there is only one or two independent pharmacies and there are also chains?

A. No. I mean, that would be the only pharmacies. The independents would be the only pharmacies and you might have to drive 30 or 45 minutes, maybe longer depending on where you live.

Q. Okay. Let's look at Table 9 in your report in the appendix of your report.

* * *

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
LITTLE ROCK DIVISION

No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION
Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity
as Attorney General of Arkansas

Defendant.

PLAINTIFF'S RESPONSE TO STATEMENT
OF PURPORTEDLY MATERIAL FACTS IN
SUPPORT OF THE STATE'S MOTION FOR
SUMMARY JUDGMENT

Pursuant to Local Rule 56.1(b), Plaintiff Pharmaceutical Care Management Association ("PCMA"), by and through its undersigned counsel, herein submits the following responses to Defendant Leslie Rutledge's ("State's") statement of purportedly material facts in support of State's Motion for Summary Judgment. To the extent PCMA does not dispute facts asserted by the Attorney General, PCMA does so only for purposes of this summary judgment motion.

Pharmacy Benefits Managers

1. The three largest pharmacy benefits managers ("PBM") (i.e., Express Scripts, CVS/Caremark and OptumRx) are all members

of the Pharmaceutical Care Management Association (“PCMA”), and they are all publicly traded.

Response to 1: Undisputed, but immaterial.¹

2. Together, the three largest PBMs have annual revenues in excess of \$400 billion.

Response to 2: Undisputed, but immaterial.²

3. While the initial purpose of the PBM industry was to provide pharmacists with a revenue stream that could fund repurchasing of depleted inventory, the goal of the PBM industry has shifted to saving health care payers money by reducing pharmacy costs.

Response to 3: Undisputed, but immaterial.³

4. PBMs offer health care plan customers a variety of channels from which members can purchase prescription drugs, including retail pharmacies, mail order pharmacies, and specialty drug dispensaries.

Response to 4: Undisputed.

5. Specific services offered by PBMs include: claims processing, customer and client services, report and data generation, clinical

¹ The ownership, revenues, and market-share of the members of PCMA has no bearing on any issue that the Court must decide in order to rule on the State’s Motion for Summary Judgment.

² *See supra* note 1.

³ The initial purpose of the PBM industry and the initial development of MAC has no bearing on any issue that the Court must decide in order to rule on the State’s Motion for Summary Judgment.

management, financial management, retail/mail order and specialty drug fulfillment.

Response to 5: Undisputed.

6. A health plan could handle pharmacy benefits management on their own, “but they’ve decided it’s cheaper and more cost effective for them to outsource it to someone else.”

Response to 6: This assertion is not supported by record evidence. The State has failed to quote the full sentence cited. The testimony cited in paragraph 6 states that a health plan could handle pharmacy benefits management “in theory.” See Exhibit F to the Attorney General’s Motion (AG Ex. F), PI Hearing, Hyman Test. p. 44:13-15. Moreover, the State’s own expert, Susan Hayes, testified that health plans engage PBMs “because they could not do that work themselves.” Hayes, Dep. at 55:11-12

Arkansas Pharmacy Healthcare Marketplace

7. Approximately 44% of Arkansas’s population resides in rural areas.

Response to 7: Undisputed.

8. Arkansans are heavily dependent on independent pharmacies, which comprise approximately 58% of all Arkansas pharmacies.

Response to 8: Disputed and immaterial as to whether Arkansans are “heavily dependent” on independent pharmacies.⁴ Undisputed that independent

⁴ There is no record evidence tending to show that the closure of any independent pharmacy located in a rural area eliminates

pharmacies comprise approximately 58% of all Arkansas pharmacies.

9. Pharmacies are often the most accessible health care provider for Arkansas's rural population.

Response to 9: Undisputed, but immaterial.⁵

10. Pharmacies in rural areas may provide medications, medication information, medication adherence programs, health care screenings, immunizations, smoking cessation services, disease management programs, and other health care services.

Response to 10: Undisputed, but immaterial.⁶

11. Because patients who receive pharmacist care have better clinical and economic outcomes, the prospect of pharmacies going out of business in Arkansas presents a significant threat to the public health.

Response to 11: Undisputed but immaterial that patients who receive pharmacist care have better clinical and economic outcomes.⁷ Disputed and immaterial

the access of Arkansans to pharmacists or prescription drugs. Further, there is no record evidence tending to show that Act 900 purports to address an issue - so-called negative reimbursements from the use of the reimbursement system known as Maximum Allowable Cost ("MAC") - that actually threatens the ability of independent pharmacies located in rural areas to remain in business.

⁵ See *supra* note 4.

⁶ See *supra* note 4.

⁷ "Pharmacist care" is a broad term. There is no record evidence tending to show that clinical and economic outcomes are

that the prospect of pharmacy closure presents a significant threat to public health.⁸

12. Approximately 70% to 90% of all drugs dispensed in independent pharmacies are generic drugs.

Response to 12: Undisputed, but immaterial.⁹

13. In general, there are three pharmaceutical wholesalers in the United States: McKesson, Cardinal and Amerisource Bergen.

Response to 13: This assertion is not supported by record evidence.¹⁰ Further answering, it is undisputed that there are 1,515 licensed pharmaceutical wholesalers in the State of Arkansas.¹¹

14. Two of the three constitute more than 60% of wholesale drugs purchased by pharmacists.

Response to 14: Undisputed, but immaterial.¹²

not also improved by access to chain pharmacies and/or mail order and internet pharmacies; *see also supra* note 4.

⁸ *See supra* note 4.

⁹ *See supra* note 4.

¹⁰ The Attorney General lists the three largest national wholesalers, but it is undisputed that additional national and regional wholesalers operate in the State of Arkansas. *See* AG Ex. B, Jones Dep. 14;8; Exhibit 2 to PCMA's Motion for Summary Judgment (Dkt. #75) (PCMA Ex. 2), PI Hearing Tr., Testimony of John Trainor-Namir, 203:22-204:9 (stating that there are both regional and national pharmaceutical wholesalers).

¹¹ *See* AG Ex. B, Jones Dep. 14;8.

¹² Act 900 does not rely on 60% of wholesale drugs purchased by pharmacists in the state by volume. Rather it imposes duties on PBMs based upon the prices used by 60% of wholesalers in the

15. Pharmacist relationships with wholesalers sometimes yield discounts or incentive payments from wholesalers due to prompt payment or exclusivity. These payments, however, are negligible in their amounts.

Response to 15: Undisputed that pharmacist relationships with wholesalers yield discounts or incentive payments due to prompt payment, exclusivity, or other reasons. Disputed and immaterial that the amounts are negligible.¹³

16. Because prescription drugs are available on a national basis, there are a few geographic variances.

Response to 16: Undisputed.

17. Therefore, if a drug is not available in Arkansas at a MAC price set by a PBM, then it is not available nationally at that price either.

Response to 17: Undisputed.

state. Ark. Code § 17-92 507(c)(2) (MAC list must be updated based on timing of price increase “from sixty percent (60%) or more of the pharmaceutical wholesaler[s] doing business in the state.”) Therefore, whether two out of three national wholesalers sell 60% of the drugs in the state by volume is immaterial.

¹³ The size of off-invoice discounts is disputed. *See* PCMA Ex. 12, Jones Decl., ¶71 (stating that these discounts are a means of “increasing margin”). However, the relative size of those discounts is immaterial to PCMA’s claims in this case, as it only affects the degree to which pharmacies are guaranteed profits on each and every transaction by Act 900, not the fact of those guaranteed profits. *See* PCMA Ex. 6, Hyman Decl., ¶ 40.

18. Independent community pharmacy has been financially challenged over the last five to ten years.

Response to 18: Undisputed, but immaterial.¹⁴

19. The number of prescriptions dispensed by independent community pharmacists has decreased over the past ten years. Over the last five years, volume has decreased from 61,169 annually (205 prescriptions per day) to 61,568 (197 prescriptions per day).

Response to 19: Undisputed, but immaterial.¹⁵

20. Decreases in volume are due to: (1) mail-order pharmacy mandated by PBM/health plan; (2) steering of patients to specialty pharmacy; (3) 90-day supply prescriptions, and (4) implementation of preferred pharmacy networks.

Response to 20: Undisputed, except that the record evidence cited does not support the assertion that mail-order pharmacy mandates are imposed by PBMs, which is nonetheless immaterial.

21. While a loss of prescription volume accounts for some of the significant decreases in prescription dollar sales by independent pharmacists, it does not account for them all. Rather, third-party payers have continued to offer lower reimbursements for generic prescriptions, and pharmacies have been forced to accept these lower reim-

¹⁴ See *supra* note 4.

¹⁵ See *supra* note 4.

bursements in order to maintain prescription volume.

Response to 21: Disputed but immaterial that pharmacies have been forced to accept lower reimbursements.¹⁶ Undisputed as to the remainder of no. 21. Further answered, that an increase in generics, which have a lower sales price compared to brand name drugs, also has resulted in a decrease in prescription dollar sales.¹⁷

22. In order to stay in business, independent pharmacies have decreased the number of personnel working in the pharmacy in order to accommodate for lower reimbursement revenues. The number of full-time equivalents employed by independent pharmacies has declined from 12.8 in 2005 to 9.9 in 2014.

Response to 22: Undisputed, but immaterial.¹⁸

23. Independent community pharmacy owners are making less net profit dollars before taxes today compared to five years ago.

Response to 23: Undisputed, but immaterial.¹⁹

24. Since 2006, rural pharmacies (communities fewer than 20,000) have experienced a decrease in median net profit from \$95,916 in 2006 to \$84,850 in 2015.

¹⁶ See AG Ex. P, West-Strum Dep., p. 157 (stating that pharmacies make a business decision that agreeing to be part of PBM pharmacy helps the pharmacy stay in business); see *supra* note 4.

¹⁷ AG Ex. C, West-Strum, Decl., ¶10.

¹⁸ See *supra* note 4.

¹⁹ See *supra* note 4.

Response to 24: Undisputed, but immaterial.²⁰

25. These losses are unsustainable and will ultimately lead to fewer pharmacies being available to Arkansas consumers and less access particularly in the rural areas.

Response to 25: Disputed and immaterial.²¹

26. Despite their size and ability to absorb losses, chain pharmacies are nonetheless experiencing similar problems. In the second quarter of 2015, Walmart reported to its investors that its three major factors contributing to underperformance were under-reimbursements from PBMs, shrink, and a decline in gross margin.

Response to 26: Undisputed, but immaterial.²² Further answered, in Arkansas, the number of chain pharmacies and pharmacies at mass merchandisers like Walmart has increased over the past ten years.²³

27. The percentage of pharmacies operating at a loss has increased from 13.9% in 2005 to 21.3% in 2014.

²⁰ See *supra* note 4.

²¹ See *supra* note 4.

²² There is no record evidence tending to show that Act 900 purports to address an issue - so-called negative reimbursements, from the use of the reimbursement system known as MAC - that actually threatens the ability of chain pharmacies located in rural areas to remain in business. Further, there is no record evidence tending to show that the closure of any chain pharmacies located in a rural area eliminates Arkansans' access to pharmacists or prescription drugs.

²³ AG Ex. C, West-Strum, Decl. at Appendix A.

Response to 27: There is no evidence in the record to support this assertion.²⁴

28. In Arkansas, the number of independent pharmacies has decreased from 452 in 2006 to 395 in 2014.

Response to 28: Undisputed, but immaterial.²⁵

29. With such a decrease in pharmacies, Arkansans have less access to a pharmacist and health care services.

Response to 29: There is no evidence in the record to support this assertion.²⁶

30. With gross margin being mandatory for remaining in business, one key aspect to preserving gross margin is to ensure that PBM reimbursements cover the pharmacist's acquisition costs as stated on the wholesaler invoice.

²⁴ The statistic cited to by the Attorney General is based on a nationwide survey of independent community pharmacies. All other pharmacies, including chain pharmacies and pharmacies operating at mass merchandisers, are not included in this statistic. The record contains no evidence relating to the profitability of (a) Arkansas retail pharmacies, (b) Arkansas independent pharmacies; or (c) rural pharmacies in Arkansas. *See also supra* note 4.

²⁵ *See supra* note 4. During the same period of time, the number of chain pharmacies in Arkansas has increased from 43 in 2006 to 78 in 2014 and the number of pharmacies at mass merchandisers in Arkansas has increased from 148 in 2006 to 161 in 2014. AG Ex. C, West-Strum, Decl. at Appendix A.

²⁶ *See supra* note 4.

Response to 30: Disputed and immaterial.²⁷

31. Pharmacies are always incentivized to purchase products at the lowest price because obtaining the lowest price from a wholesaler will preserve and possibly improve the pharmacy's gross margin.

Response to 31: Disputed but immaterial.²⁸

32. Pharmacies typically have a relationship with a primary, full-service wholesaler and at least one secondary wholesaler.

Response to 32: Undisputed.

33. The PBM reimbursement for a prescription drug product comprises two elements: an estimated drug ingredient cost and a dispensing fee for the pharmacy. This reimbursement strategy is based upon the PBM estimating the drug ingredient cost on a fair market value, and these reimbursement rates affect the dollar sales,

²⁷ Pharmacists can retain gross margin even while being reimbursed for some percentage of prescriptions for less than stated on wholesaler invoice because MAC is an average. *See* PCMA Ex. 6, Hyman Decl., ¶25. Thus, although some reimbursements are below the cost on the wholesale invoice, the majority of reimbursements are above the cost paid by the pharmacy. *Id.*; AG Ex. P, West-Strum Dep., 24:15. Additionally, pharmacists get off-invoice discounts, so the wholesaler invoice is not an actual cost paid by the pharmacist. *See* PCMA Ex. 6, Hyman Decl., ¶40; *see also supra* note 4.

²⁸ Studies have shown that prohibiting PBMs from paying pharmacies less than their actual acquisition cost will dramatically reduce the pharmacies' incentive to acquire generic drugs at the lowest possible cost. *See* PCMA Ex. 6, Hyman Decl., ¶48.

gross margin, profitability, and productivity of pharmacies.

Response to 33: Undisputed, but immaterial.²⁹

34. Cost of dispensing is approximately \$10 per prescription. Dispensing fees paid by PBMs, however, are less than \$10 and typically range from \$1.74 to \$1.92.

Response to 34: Disputed and immaterial.³⁰

35. Hence, ingredient cost reimbursements reflecting actual costs is critical if the pharmacy is to maintain any gross margin on its prescription drug transactions.

Response to 35: Disputed and immaterial.³¹

36. In recent years, upstream generic price increases have occurred, and PBMs have been slow to raise pharmacy reimbursements to reflect the increases, which has generated pharmacist appeals that are routinely denied by PBMs.

Response to 36: Undisputed that generic drug price increases have occurred in recent years. Disputed and immaterial that PBMs are slow to raise pharmacy reimbursements to reflect the increases.³² Disputed

²⁹ Facts regarding dispensing fees are not material to this dispute because Act 900 does not address dispensing fees.

³⁰ See *supra* note 29.

³¹ See *supra* note 27; see also *supra* note 4.

³² The record evidence, as well as the previous law in Arkansas, shows that PBMs update their MAC lists frequently. See Exhibit A, PI Hearing, Bricker Test., at 129:5 (stating that Express Scripts evaluates its MAC list on a daily basis); see also Act 1194 (requiring PBMs to update MAC lists every seven days). Even if it were the case that PBMs were slow to respond to price

and immaterial that pharmacist appeals are routinely denied by PBMs.³³

37.If MAC reimbursements do not reflect actual acquisition costs immediately for the rising cost of a specific drug, then pharmacists are faced with losing hundreds of dollars for each prescription of that drug.

Response to 37: Disputed and immaterial.³⁴

38.The experience of independent pharmacists reflects that it takes approximately three months for PBMs to update their reimbursement rates to reflect actual market conditions.

Response to 38: Inadmissible. The statement is hearsay under Federal Rule of Evidence 802 insofar as it used to assert the length of time it takes for a PBM to update their reimbursement rates.

increases, this fact is immaterial because Act 900 does not provide a discernible mechanism to require PBMs to respond more quickly, because the MAC list update provision is unconstitutionally vague. *See* PCMA's Opposition to Motion for Summary Judgment, Section V.

³³ *See* PI Hearing, Bricker Test. at 176 (stating that pharmacy appeals are dealt with on a case-by-case basis). Even if it were the case that pharmacy appeals were routinely denied, this fact is immaterial because Act 900 unconstitutionally operates to mandate particular standards for pharmacy appeals contrary to existing contractual relationships. Further, PCMA raises a facial challenge to Act 900. The rate at which appeals are granted or denied by any given PBM has no bearing on any issue the Court must decide in order to rule on the State's Motion for Summary Judgment.

³⁴ *See supra* note 27; *see also supra* note 4.

39. PBM reimbursements and auditing practices significantly affect the ability of pharmacists to provide patient care and remain in business.

Response to 39: Disputed and immaterial.³⁵

40. It is difficult for pharmacies to negotiate with PBMs on MAC price lists because the methodologies are not transparent. As a result, pharmacists experience approximately 10% of reimbursements below their cost of acquisition.

Response to 40: Undisputed but immaterial that reimbursements below cost are approximately 10% of prescriptions filled.³⁶ Disputed but immaterial that it is difficult for pharmacies to negotiate with PBMs on MAC price lists because methodologies are not transparent.³⁷

41. Dr. Bob Geyer, a pharmacist in Mena, Arkansas (approximately 6,000 population), estimates that during the three-month time frame of June 17, 2015 through September 17, 2015, he dispensed 307 prescriptions below the cost of acquisition. The total amount that his pharmacy lost due to negative reimbursements during that time period amounted to \$1,829.60.

³⁵ Act 900 does not address PBM auditing practices, and PBM auditing practices are not relevant to any of the claims or defenses in this case; *see also supra* note 4.

³⁶ *See supra* note 4.

³⁷ *See* Exhibit A, PI Hearing, Bricker Test., 137:10-14 (stating that PSAOs are able to negotiate more favorable terms on behalf of independent pharmacies); *see also supra* note 4.

Taking into account the fact that a pharmacist must make approximately \$10 on each prescription, these losses amount to \$4,899.60

Response to 41: Undisputed but immaterial.³⁸

42. Dr. Kristy Reed, a pharmacist in Jonesboro, Arkansas (approximately 70,000 population), estimates that during the three-month time frame of June 21, 2015 through September 21, 2015, she dispensed 856 prescriptions below the cost of acquisition. The total amount that her pharmacy lost due to negative reimbursement during that time period amounted to \$5,708.57. Taking into account the fact that a pharmacist must make approximately \$10 on each prescription, these losses amount to \$14,268.57.

Response to 42: Undisputed but immaterial.³⁹

43. Daily prescription volumes have increased from 190 per day in 2005 to 197 per day in 2014. And while gross margins have slightly increased, these increases have not kept up with the fact that it is more expensive to do business as a pharmacist in 2014 than it was in 2005.

Response to 43: Undisputed but immaterial.⁴⁰

44. Accordingly, pharmacists have cut the number of full-time equivalents that they

³⁸ See *supra* note 4; *supra* note 27.

³⁹ See *supra* note 4; *supra* note 27.

⁴⁰ See *supra* note 4.

hire from 12.8 in 2005 to 9.9 in 2014. While this would usually increase savings to the pharmacy, pharmacies have nonetheless reported a decrease in median net profit from \$102,566 in 2005 to \$88,021 in 2014.

Response to 44: Undisputed but immaterial.⁴¹

PBM/Health Plan Contracts

45. PBMs and health plans typically contract for an annual or three year term.

Response to 45: Undisputed.

46. Because of the market power of the three largest PBMs, many payers do not have the ability to negotiate contract terms, especially if the payer covers fewer than 5,000 lives.

Response to 46: Disputed and immaterial.⁴² The leverage of payers - the government, private insurers and employers - in contract negotiations with PBM is not at issue in this case.

47. There are two pricing mechanisms contained in the PBM/Health Plan contracts: (1) lock-in (or traditional, or spread pricing); and (2) pass-through (or transparent).

Response to 47: Undisputed.

48. Lock-in contracts include those where a PBM charges the plan sponsor one price and reimburses a pharmacy a lesser price,

⁴¹ See *supra* note 4.

⁴² See *supra* note 1.

keeping the difference, which is referred to as “spread pricing.”

Response to 48: Undisputed.

49. The spread obtained in a lock-in contract is typically not shared by a PBM with a health plan customer.

Response to 49: Undisputed but immaterial.⁴³

50. Under such contracts, if a PBM should pay more to a pharmacist on a particular drug, there is no consequence to the health plan customer. Accordingly, any costs that a PBM passes on to a health plan for payment constitutes a business decision by the PBM.

Response to 50: This assertion is not supported by record evidence. Further answering, it is undisputed that beneficiaries in plans with cost-sharing will see a direct increase in out-of-pocket costs resulting from the higher reimbursement rates.⁴⁴

51. Lock-in contracts are usually offered by the top three PBMs who comprise as much as 90% of the PBM marketplace.

Response to 51: Undisputed but immaterial that lock-in contracts are usually offered by the top three PBMs. The record evidence does not support the asser-

⁴³ Act 900 does not govern PBMs’ ability to negotiate lock-in contracts with customers such that the PBM will retain a spread on prescription drug claims. Nor do any of PCMA’s claims rely on an assertion that PBMs will be unable to retain such spreads.

⁴⁴ See PCMA Ex. 6, Hyman Decl., ¶50 (stating that beneficiaries in plans with cost sharing will see a direct increase in out-of-pocket costs resulting on higher reimbursements).

tion that the top three PBMs comprise as much as 90% of the PBM marketplace, but this assertion is immaterial.⁴⁵

52. Pass-through contracts include those where the exact cost of the drug reimbursed to the pharmacy is charged to the plan sponsor. The PBM makes its money off of administrative fees on each transaction.

Response to 52: Undisputed.

53. In pass-through contracts, PBMs utilize financial performance guarantees in order to guarantee their health plan expenditures will not exceed a certain percentage at year end (e.g., 85% discount off of average wholesale price(AWP)).

Response to 53: Undisputed, but immaterial.⁴⁶

54. Larger health plan payers usually do have financial performance guarantees in the contract between the plan and the PBM.

Response to 54: Undisputed, but immaterial.⁴⁷

55. Thus, even though a pass-through contract arrangement suggests that a health plan incurs cost on a dollar-for-dollar basis, it does not. This is because the financial performance guarantees that PBMs utilize ensure that PBMs and health plans in

⁴⁵ See *supra* note 1.

⁴⁶ The means by which PBMs make money on their pass-through contracts are not implicated by Act 900.

⁴⁷ *Supra* note 46.

pass-through contracts arrive at the same result as a lock-in/spread contract.

Response to 55: Undisputed, but immaterial.⁴⁸



MAC Lists

57. Maximum allowable cost (“MAC”) pricing was developed by PBMs so that generic drugs were not priced according to manufacturer prices, but instead according to a price in between the most and least expensive manufacturer’s average wholesale price (“AWP”).

Response to 57: Undisputed that MAC pricing was developed so that generic drugs were not priced according to manufacturer prices. Disputed and immaterial that MAC was developed to be a price in between the most and least expensive manufacturer’s average wholesale price.⁵⁰

⁴⁸ *Supra* note 46.



⁵⁰ The Attorney General suggests various inconsistent definitions of what MAC is intended to capture. Although PCMA maintains that MAC is the average acquisition cost of a well-run pharmacy, none of these various definitions materially impact the claims or defenses in this case, because all of the definitions proffered by both parties include the fact that MAC is set on an average basis as opposed to a transaction-by-transaction basis. *See* PCMA Ex. 6, Hyman Decl., ¶22; *see also supra* note 3.

58. MAC price strategy was originally intended to limit the ingredient cost to the lowest price at which a generic drug product is widely and consistently available.

Response to 58: Disputed but immaterial.⁵¹ Further answered, paragraph no. 58 is inconsistent with the Attorney General's previously statements in paragraph no. 57.

59. MAC pricing methodologies are highly protected, confidential, and not subject to disclosure by PBMs.

Response to 59: Undisputed.

60. These methodologies are based upon the market intelligence that the PBMs have devised as their way of accounting for actual acquisition costs and forming MAC reimbursements.

Response to 60: Undisputed but immaterial.⁵² Further answered, the description of MAC in paragraph no. 60 is inconsistent with the descriptions in paragraph nos. 57 and 58.

61. These methodologies are not subject to any regulatory oversight except whatever the market will bear (*i.e.*, whether a health plan customer will buy the PBMs services or go elsewhere).

Response to 61: Undisputed.

62. A PBM may have different MAC lists for each chain or pharmacy services admin-

⁵¹ See *supra* note 50; *supra* note 3.

⁵² See *supra* note 50.

istration organization (“PSAO”) with which it contracts.

Response to 62: Undisputed.

63. PBMs will have at least one MAC list for managed care clients, one list for Medicare Part D clients and other lists for employer clients.

Response to 63: Undisputed.

64. A MAC price on one MAC list for one health plan may be entirely different (*i.e.*, higher or lower) than the MAC price on a similar list for another health plan.

Response to 64: Undisputed. Further answering, PCMA states that the difference in prices is due to different customers’ priorities, including drug mix.⁵³

65. The PBM may have a different MAC list for each line of business. Thus, a PBM may maintain dozens of MAC prices for the same drug on the same day for its numerous clients/Payers, pharmacies, by line of business.

Response to 65: Undisputed.

66. One PBM may maintain hundreds of MAC lists for a single plan, and each patient is tied to a specific MAC list.

Response to 66: Undisputed that each patient is tied to a specific MAC list. Disputed but immaterial that

⁵³ See AG Ex. B, Jones Dep., p. 66:17-21.

one PBM would maintain hundreds of MAC lists for a single plan.⁵⁴

67. Even if a PBM elected to have an Arkansas-specific MAC list, which it is not required to do, then it would mean the addition of one more MAC lists among hundreds of thousands.

Response to 67: This assertion is not supported by the record evidence.⁵⁵ Further answered, PCMA states that as the Attorney General recognizes in paragraph no. 66, each patient is tied to a specific MAC list, so having an Arkansas specific MAC list would eliminate the usefulness of having national MAC lists catered to each client.

68. The PBM industry is able to maintain all of these MAC pricing lists beneficial to the industry, in which sophisticated algorithms point a given claim to the desired MAC price upon adjudication which can take less than three seconds.

Response to 68: Undisputed that PBMs maintain multiple MAC pricing lists. Undisputed to the extent that the Attorney General is implying that it takes less than three seconds to notify the pharmacist of the appropriate MAC price. There is no evidence in the

⁵⁴ See AG Ex. B, Jones Dep., p. 64:11-52 (stating that a PBM would “typically not” have hundreds of MAC lists for a single plan). However, the number of MAC lists a PBM provides for a given health plan is not material to the claims or defenses in this case.

⁵⁵ There is no evidence in the record to support the claim that each PBM has hundreds of thousands of MAC lists. See AG Ex. B, Jones Dep., p. 62:2 (stating that each PBM has “hundreds to thousands” of MAC lists) (emphasis added).

record to support this assertion if the Attorney General is implying that it takes three seconds for a PBM to update the MAC price.⁵⁶

69. In order to develop MAC prices, PBMs must purchase some pricing guide such as Medispan. Accordingly, PBMs have access to wholesale pricing information.

Response to 69: Undisputed but immaterial.⁵⁷

70. ESI, the largest PBM in the United States, has access to two wholesalers' pricing data.

Response to 71: Undisputed, but immaterial.⁵⁸

71. OptumRx, the third largest PBM in the United [sic], likewise has data feed access (*i.e.* automated computer access) from two of the three major wholesalers' wholesale pricing data as well as the National Average Drug Acquisition Cost (NADAC) data.

Response to 71: Undisputed, but immaterial.⁵⁹

72. OptumRx has not explored the possibility of obtaining a direct data feed with wholesalers for invoice cost data from wholesalers, which would reflect any off-invoice discounts obtained by pharmacists. Such information, however, would be useful to

⁵⁶ There is no record evidence indicating that it takes a PBM three seconds to update their MAC list.

⁵⁷ There is no evidence in the record tending to show that PBMs are able to access wholesale pricing information specific to Arkansas pharmacies.

⁵⁸ See *supra* note 57; see also *supra* note 10; *supra* note 1.

⁵⁹ See *supra* note 57; see also *supra* note 10; *supra* note 1.

OptumRx in determining actual costs for reimbursement.

Response to 72: Undisputed. Further answering, PCMA states that obtaining a direct data feed from wholesalers for invoice cost data from wholesalers would be “an insurmountable act.”⁶⁰

73. Express Scripts executives do not want to know pharmacy acquisition costs in setting their MAC reimbursement methodologies.

Response to 73: This assertion is not supported by record evidence and it is immaterial.⁶¹

74. It is possible that a PBM may create a MAC price for a product using a national drug code (“NDC”) listed in a national pricing compendium but no longer actively marketed or may use the price for a NDC that is temporarily unavailable (*i.e.*, a price at which the pharmacist cannot acquire the drug).

Response to 74: Undisputed, but immaterial.⁶²

PBM/Pharmacy Contracts

75. Among other things, the contracts between PBMs and their network pharmacies gen-

⁶⁰ See AG Ex. B, Jones, Dep. 141:1.

⁶¹ In the testimony cited by the Attorney General, Ms. Bricker did not speak for all Express Scripts executives, and her statement is taken out of context. Further answering, Ms. Bricker stated that Express Scripts does not want to know acquisition cost “because [it is] confidential in nature.” See Exhibit A, PI Hearing, Test. of Bricker at 132; *see also supra* note 50.

⁶² See *supra* note 50; *supra* note 4.

erally provide: (1) that a pharmacist, in agreeing to the contract, must accept the reimbursements that the PBM determines are appropriate based on their proprietary MAC lists; (2) that a pharmacist must dispense all prescriptions regardless of the amount of the reimbursement; (3) that pharmacists are allowed to appeal certain reimbursements; and (4) that a pharmacist will receive a set dispensing fee on all prescriptions filled.

Response to 75: Undisputed.

76. PBMs also contract with pharmacies for reimbursement financial guarantees.

Response to 76: Undisputed.

77. Due to the need to have the most chain pharmacies in a pharmacy network, chain pharmacies can command the best financial terms.

Response to 77: Undisputed and immaterial.⁶³

78. With nearly 90% of pharmacy consumers subject to third-party payer arrangements, pharmacists do not have freedom to decline a PBM pharmacy network contract. When Walgreens (a large chain drug store) did not contract with Express Scripts in 2012, Walgreens' prescription drug sales decreased by 6.1 percent.

Response to 78: The record evidence does not support the assertion that pharmacists do not have the

⁶³ See *supra* note 4.

freedom to decline a PBM pharmacy network contract.⁶⁴ Undisputed but immaterial that Walgreens reported a decrease in drug sales after leaving Express Scripts' network.⁶⁵

79. Because small pharmacies have little negotiating power, PBMs provide take-it-or-leave-it contracts with low reimbursement rates that put pharmacies in the "Catch-22" position of deciding between the low reimbursement rate or losing customers.

Response to 79: Disputed and immaterial.⁶⁶ Further, PCMA moves to strike the State's use of "take-it-or-leave it" and "Catch-22" as such phrases are inflammatory and not factual.

80. Often, PBMs are selecting pharmacies who are willing to take a lower reimbursement rate in exchange for being in a preferred network, which PBMs in turn encourage their plan beneficiaries to utilize.

Response to 80: Undisputed, but immaterial.⁶⁷

⁶⁴ See AG Ex. P, West-Strum Dep., p. 157 (stating that pharmacies make a business decision that agreeing to be part of PBM pharmacy network helps the pharmacy stay in business).

⁶⁵ See *supra* note 22.

⁶⁶ Small pharmacies have negotiating power because PBMs need broad pharmacy networks to remain competitive. See Exhibit A, PI Hearing, Bricker Test., p. 174:21-25 (stating that independent pharmacies in rural areas have leverage in contract negotiations); PCMA Ex. 12, Jones Report, ¶52 ("A customer's need for a broad-access network gives a pharmacy more leverage to negotiate with the PBM to achieve the pharmacy's profit margin targets"); see also *supra* note 4.

⁶⁷ See *supra* note 4.

81. The contracts authorize the PBM to adjust the pricing as desired such that in theory, a PBM could decide to decrease reimbursement for all generics to one cent per dose regardless of the pharmacist's acquisition cost, and the contracting pharmacy would be bound to dispense all generic medications for that reimbursement.

Response to 81: Undisputed. Further answering, the contracts allows pharmacies to unilaterally terminate on some notice, and PBM need to maintain broad-access pharmacy networks to remain competitive.⁶⁸

Act 1194 of 2013

82. Act 1194 of 2013 was the precursor to Act 900 of 2015.

Response to 82: Undisputed.

83. Act 1194 defined a “[p]harmacy benefits plan or program” as “a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals”

Response to 83: The meaning of Act 1194 is a question of law, not an assertion of fact.

84. It required that MAC list drugs must be available for purchase by pharmacists

⁶⁸ PCMA Ex. 12, Jones Report, ¶53-54. The “facts” alleged by the Attorney General in Paragraph 81 are highly speculative and inflammatory. There is no record evidence that a PBM has ever decreased reimbursements in such a manner. Moreover, the record evidence demonstrates that approximately 90% of the time, PBMs reimburse pharmacies at a price equal to or higher than their acquisition cost.

from national and regional wholesalers operating in Arkansas.

Response to 84: The meaning of Act 1194 is a question of law, not an assertion of fact.

85. It required that a PBM must update its MAC lists on a timely basis, but in no event longer than 7 days from a change in methodology.

Response to 85: The meaning of Act 1194 is a question of law, not an assertion of fact.

86. It required that PBMs provide an appeal procedure by which pharmacists may appeal within three days in order to challenge negative reimbursements.

Response to 86: The meaning of Act 1194 is a question of law, not an assertion of fact.

87. It required that, if an appeal is upheld, a PBM must allow the pharmacist to reverse and rebill the claim.

Response to 87: The meaning of Act 1194 is a question of law, not an assertion of fact.

88. It required that, if an appeal is denied, then the PBM must supply the national drug code number for the drug in question.

Response to 88: The meaning of Act 1194 is a question of law, not an assertion of fact.

89. In October 2013, the Office of the Arkansas Attorney General wrote a letter to the PBMs explaining the provisions of Act 1194 of 2013 (codified at Ark. Code Ann. § 17-92-507).

Response to 89: Undisputed.

90. The Attorney General's Office explained that it had received numerous complaints from Arkansas pharmacists regarding PBMs reimbursing pharmacists below market costs on drug transactions. It was also explained that "the fact that filling certain prescriptions causes the contracting pharmacist to incur an out-of-pocket loss raises concerns regarding the methodology used to compute the Maximum Allowable Cost for those prescriptions." The Office also posed a series of questions to PBMs regarding their MAC methodologies under the authority of Ark. Code Ann. § 4-88-111.

Response to 90: Undisputed.

91. The Attorney General's Office also received at least 150 consumer complaints from Arkansas pharmacists concerning negative reimbursements. These consumer complaints were provided to PBMs for review and response in the ordinary course of the consumer complaint process.

Response to 91: Undisputed.

Act 900 of 2015 Provisions, Compliance, and Effects

92. Act 900 requires that MAC lists must be updated on a timely basis, but not longer than seven (7) days from an increase of ten (10 (sic) percent in the pharmacy's acquisition cost from 60% or more of the pharmaceutical wholesalers doing business in the state or change in the methodology on which the MAC list is based.

Response to 92: The meaning of Act 900 is a question of law, not an assertion of fact.

93. PBMs can determine whether a drug has increased in price by making two phone calls to two of the three dominant wholesalers in the United States (*i.e.*, McKesson, Cardinal and Amerisource Bergen).

Response to 93: Disputed, but not material because it relies upon assumptions regarding the requirements of Act 900, which is a question of law, not an assertion of fact.⁶⁹

94. It requires PBMs to provide a reasonable appeal procedure to allow pharmacies to challenge MAC costs and reimbursements made under a MAC, which includes a dedicated telephone number and email address or website for the purpose of submitting administrative appeals and the right to go directly to the PBM instead of through a PSAO.

Response to 94: The meaning of Act 900 is a question of law, not an assertion of fact.

95. It provides that if a MAC appeal is upheld, PBMs must allow the pharmacy to reprocess the claim in question and apply the MAC price to similarly situated pharmacies.

Response to 95: The meaning of Act 900 is a question of law, not an assertion of fact.

96. If an appeal is denied, it requires PBMs to provide the appealing pharmacy with the

⁶⁹ See *supra* note 10; *supra* note 11; *supra* note 12.

name of the wholesaler that offers the drug at a price that is at or below the MAC price and at which a supply is actually available.

Response to 96: The meaning of Act 900 is a question of law, not an assertion of fact.

97. Having such information will lower acquisition costs on a going-forward basis as it will instruct pharmacists on where they can obtain drugs at the prices available to PBMs.

Response to 97: Disputed but immaterial.⁷⁰

98. If the drug is not available from the wholesaler in which the pharmacy purchases its drugs at the stated MAC price, then the PBM must adjust the MAC price above the pharmacist's acquisition cost and permit the pharmacy to rebill the prescription.

Response to 98: The meaning of Act 900 is a question of law, not an assertion of fact.

99. Very few PBM personnel would be needed in order to comply with the MAC price update provisions and appeal provisions. For each appealed MAC price, a PBM would contact one or two people at two of the three major wholesalers, inquire as to the list price, and then determine if there

⁷⁰ Even if the PBM can point to an NDC at or below the MAC price, it is possible that the pharmacy cannot access the drug at that price, because the wholesaler may not make that price available to that particular pharmacy. *See* PCMA Ex. 2, PI Hearing, Bricker Test., p. 144; PCMA Ex. 12, Jones Report, ¶85; PCMA Ex. P, West-Strum Dep., 52:4; *see also supra* note 4.

is a non-exclusive list acquisition price for a given generic drug that is lower than the PBM's MAC price. If there is a lower-priced source available, then the MAC appeal would be denied. If there is not, then the MAC appeal would be granted and the pharmacy permitted to re-adjudicate the claim.

Response to 99: Disputed, but immaterial because it relies upon an interpretation of the requirements of Act 900, which is a question of law, not an assertion of fact.⁷¹

100. Express Scripts has explained that it has hired one or two employees to comply with Act 900 and estimates that a “handful of [full-time equivalents]” would be needed to comply with Act 900's appeal provisions.

Response to 100: Undisputed.

101. Act 900 will generate fewer MAC appeals, and thus prevent added work for PBMs, because, pursuant to the Act, MAC prices will accurately reflect acquisition costs.

Response to 101: Disputed, but not material.⁷²

102. Because at least 90% of the market utilizes lock-in (or traditional) pricing, any

⁷¹ See *supra* note 10; *supra* note 11; *supra* note 12. PCMA Ex. 6, Hyman Decl., ¶59.(stating that Act 900 will result in more appeals being filed, because pharmacists have a better chance of winning).

⁷² Even if PBMs inflate their MAC prices to avoid appeals, PBMs will still have to deal with appeals from pharmacies that have actual acquisition costs that exceed the now-inflated MAC. See PCMA Ex. 6, Hyman Decl., ¶39.

higher MAC reimbursements as a result of Act 900 would overall have no impact on the industry unless the PBMs made the business decision to pass costs on to the health plan payers.

Response to 102: This assertion is not supported by record evidence.⁷³ Further answering, it is undisputed that beneficiaries in plans with cost-sharing will see a direct increase in out-of-pocket costs resulting from the higher reimbursement rates.⁷⁴

103. If the pharmacy will be paid less than the acquisition cost via a MAC price of the PBM, then the pharmacy can refuse service to the patient.

Response to 103: The meaning of Act 900 is a question of law, not an assertion of fact.

104. Act 900 does not mandate that Arkansas pharmacies make a profit on all generic

⁷³ Beneficiaries of health plans will see increased costs right away at the counter. *See* PCMA Ex. 6, Hyman Decl., ¶50 (stating that beneficiaries in plans with cost sharing will see a direct increase in out-of-pocket costs resulting on higher reimbursements). Furthermore, health plans that have pass-through contracts with PBMs will be impacted immediately. *See* PCMA Ex. 3, Kracke Decl., ¶6 (stating that under pass-through contracts the price at which the pharmacy is reimbursed is the same as the price the plan is charged). Lastly, increased prescription drug reimbursements are likely to be passed on from the PBMs to the health plans, either through direct drug price increases or through administrative fees. *See* AG Ex. G, Hayes Dep., 183:14-22 (admitting that PBM would “probably not” opt out of passing along higher costs).

⁷⁴ *See* PCMA Ex. 6, Hyman Decl., ¶50 (stating that beneficiaries in plans with cost sharing will see a direct increase in out-of-pocket costs resulting on higher reimbursements).

claims (because profit differs from reimbursement as it takes into account time, labor and overhead).

Response to 104: Disputed but immaterial.⁷⁵

105. No Arkansas-specific MAC lists are needed in order for PBMs to comply with Act 900.

Response to 105: Undisputed. Further answered, PCMA states that, alternatively, a PBM could opt to implement Act 900's requirements nationwide.

106. Act 900 does not render MAC pricing obsolete.

Response to 106: The record evidence does not support this assertion, as the State's experts have agreed that MAC pricing is an average, while Act 900 requires reimbursement for actual acquisition cost. Therefore, Act 900 requires that PBMs use a pricing method other than MAC for reimbursements in Arkansas.⁷⁶ Further answering, to the extent this assertion relies on an interpretation of Act 900, such interpretation is a matter of law, not a question of fact.

107. Act 900 preserves the prevalence of MAC pricing by making it less opaque and less problematic for pharmacies.

Response to 107: The record evidence does not support this assertion, as the State's experts have agreed that MAC pricing is an average, while Act 900 requires reimbursement for actual acquisition cost. Therefore, Act 900 requires that PBMs use a pricing method

⁷⁵ See *supra* note 4.

⁷⁶ It is undisputed that at least some prescription drug reimbursements will increase under Act 900's requirements. See AG Ex. C, West-Strum Decl., ¶42; AG Ex. E, Hayes Decl., ¶31.

other than MAC for reimbursements in Arkansas.⁷⁷ Further answering, to the extent this assertion relies on an interpretation of Act 900, such interpretation is a matter of law, not a question of fact.

108. It prevents independent pharmacies from being forced to bear the costs of generic drug price increases.

Response to 108: Disputed and immaterial.⁷⁸

109. Act 900 does not discontinue the pharmacist's interest in finding low cost drug acquisition options, which is always required in order to increase gross margin.

Response to 109: Disputed and immaterial.⁷⁹

110. Act 900 will require PBMs to be diligent in monitoring the marketplace to ensure that current MAC prices reflect wholesaler prices that are widely and consistently available to Arkansas pharmacies.

Response to 110: Disputed and immaterial.⁸⁰

111. If a health plan incurs added costs as a result of Act 900's reimbursement provisions, then it is not because drugs are more expensive, rather it is because the PBM elected to charge its health plan customer more.

⁷⁷ See *supra* note 76.

⁷⁸ See *supra* note 4.

⁷⁹ See *supra* note 27.

⁸⁰ Act 900 makes no reference to wholesaler prices that are "widely and consistently" available.

Response to 111: Disputed and immaterial.⁸¹ Further answering, it is undisputed that health plans with pass-through contracts and beneficiaries with cost-sharing arrangements such as deductibles and co-insurance will bear the added costs of Act 900's reimbursement provisions.⁸²

112. Act 900's provision allowing pharmacists to decline to fill a prescription if it will result in a negative reimbursement ("opt-out provision") should not be viewed as a right to refuse care to a patient.

Response to 112: The meaning of Act 900 is a question of law, not an assertion of fact.⁸³

113. Rather, the opt-out provision constitutes an indirect pressure on PBMs to comply with Act 900, which compliance, as demonstrated by the many consumer complaints to the Attorney General's Office under Act 1194 of 2013, is a problem.

Response: The meaning of Act 900 is a question of law, not an assertion of fact.⁸⁴

⁸¹ The reimbursement paid by the PBM to the pharmacy is the drug cost. Ultimately, the PBM customer will end up spending more money for services rendered. AG Ex. B, Jones Dep., 113:8-11; *see also* AG Ex. G, Hayes Dep., 183:14-22 (admitting that PBM would "probably not" opt out of passing along higher costs).

⁸² *See supra* note 73.

⁸³ The plain language of Act 900 gives the pharmacist a right to refuse care to a patient. Ark. Code. § 17-92-507(e). Further, pharmacists have already begun declining to fill prescriptions for beneficiaries of health plans served by PBMs. *See Village Apothecary, Inc. v. Aetna*, No. 63cv-16-571 (Cir. Ct. of Saline County, 2016), Complaint.

⁸⁴ *See supra* note 83.

114. Because of their commitment to patient care and the “Oath of a Pharmacist” that they abide by (i.e. devoted to serving others, to consider the welfare of humanity and relief of suffering as their primary concern), pharmacists are not be inclined to actually decline prescription fills. Instead of declining service, among other solutions, a pharmacist may: (1) contact the prescriber to discuss alternative therapies or alternative drugs; (2) assist the consumer in finding another pharmacist who can fill it; (3) refer the patient to mail-order; or (4) dispense a small supply of the medication while additional options are determined.

Response to 114: Disputed and immaterial.⁸⁵

115. At the very least, the opt-out provision grants the small business pharmacist with some autonomy over his or her business in order to determine the best steps to preserve the pharmacy’s ability to remain in business.

Response to 115: Disputed and immaterial.⁸⁶

Medicare Part D

116. Medicare Part D regulations require plan sponsors to report to the Centers for Medicare and Medicaid Services (CMS) price concessions and rebates that PBMs obtain from pharmaceutical manufacturers and do not require any computation or

⁸⁵ See *supra* note 83.

⁸⁶ See *supra* note 83.

determination of off-invoice discounts obtained by pharmacists.

Response: The meaning of Medicare Part D regulations is a question of law, not an assertion of fact.

117. Consultants who conduct audits of such reported information have observed that such reports by health plans to CMS do not contain any information from pharmacies.

Response: Disputed and immaterial.⁸⁷

⁸⁷ There is no evidentiary basis in the record to support this conclusion. The Attorney General cites to the testimony of one consultant, who spoke only on her own behalf, nor did she provide any copies of such reports as the basis for her purported expert opinion. These reports are not material, however, because PCMA does not argue that Act 900 acts “with respect to” the standard set forth in 42 C.F.R. 423.104(g)(3).

STATEMENT OF ADDITIONAL MATERIAL
FACTS BY PCMA

118. PCMA incorporates by reference Plaintiff's
Local Rule 56.1 Statement of Undisputed
Material Facts (Dkt. 75-2).

Respectfully Submitted,
By its attorneys,

/s/ Dean Richlin

Lyn P. Pruitt, Ark. Bar No. 84121
Mitchell, Williams, Selig,
Gates & Woodyard, P.L.L.C.
425 West Capitol Avenue, Suite 1800
Little Rock, Arkansas 72201
Phone: (501) 688-8869
Facsimile: (501) 918-7869
Email: lpruitt@mwlaw.com
Dean Richlin (admitted *pro hac vice*)
Kristyn DeFilipp (admitted *pro hac vice*)
Andrew London (admitted *pro hac vice*)

FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts
02210 (617) 832-1000
drichlin@foleyhoag.com
kbuncedefilipp@foleyhoag.com
alondon@foleyhoag.com

Date: September 9, 2016

CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2016, a true and correct copy of the above and foregoing document was electronically filed with the Clerk of Court using the CM/ECF system, which shall send notification of such filing to the following:

Shawn Johnson
Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Telephone: (501) 682-1178
Facsimile: (501) 682-8118
shawn.johnson@arkansasag.gov

Andrew London

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
LITTLE ROCK DIVISION

No. 4:15-cv-00510-BSM

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity
as Attorney General of Arkansas

Defendant.

STATE'S RESPONSE TO PCMA'S
LOCAL RULE 56.1

STATEMENT OF UNDISPUTED
MATERIAL FACTS

For the State's Response to PCMA's Local Rule 56.1 Statement of Undisputed Material Facts, the Attorney General states the following:

1. PCMA is the national trade association for pharmacy benefit managers ("PBMs"), and represents the eleven largest PBMs in the country. None of PCMA's member PBMs are located in Arkansas. Exhibit 1, Declaration of Brian McCarthy, ¶¶3, 8.

Response: Admit.

2. PBMs are engaged by health benefit plans including ERISA plans (including plans insured by health insurance companies and employer self-insured plans), Medicare Part D plans, and commercial

health insurance plans to manage the plans' prescription drug benefits, including by calculating benefit levels and making disbursements. Exhibit 2 - Excerpts from Transcript of Hearing on Motion for Preliminary Injunction, November 4, 2015 ("PI Hearing Tr."), Testimony of David Hyman ("Hyman Testimony"), p. 42-44; PI Hearing Tr., Testimony of Amy Bricker ("Bricker Testimony"), p. 118, 123-124; PI Hearing Tr., Testimony of Melanie Kracke ("Kracke Testimony"), p. 179; Exhibit 3 - Declaration of Melanie Kracke ("Kracke Decl."), Dkt. #3-1, ¶4; Exhibit 4 - Declaration of Amy Bricker ("Bricker Decl."), Dkt. #3-1, ¶4; *see also* Exhibit 5 - AG-001173 - 001191 (Contract with employee benefits plan governed under ERISA).

Response: Admit that PBMs are engaged by health plans to manage prescription drug plans according to various negotiated terms and provisions, but deny that PBMs make all decisions regarding benefit levels and disbursements as health plans commonly retain such discretion.¹

3. Out of approximately 3 million residents, approximately 1.76 million Arkansans have prescription drug coverage provided by a PBM. Exhibit 6 - Declaration of David Hyman ("Hyman Decl."), ¶¶27-28. Approximately 1.3 million Arkansans receive prescription drug benefits through an employment-based benefits plan. Exhibit 7 - U.S. Census Bureau, Annual Social and Economic Supplements, Issued September 2015 (Current Population Survey) available at <http://www.census.gov/library/publications/2015/demo/p60-253.html>.

¹ *See, e.g.*, Sealed Exhibit H (Doc. 77-8) at p. 20 (¶ 3.8); Sealed Exhibit I (Doc. 77-9) at p. 13 (¶ 3.9); Sealed Exhibit Q (Doc. 77-17) at p. 10 (¶ 6.2).

Response: The State has no present information that disputes these figures.

4. Approximately 375,000 Arkansans receive prescription drug benefits through a Medicare Part D plan. Exhibit 8 - Jack Hoadley, Juliette Cubanski, and Tricia Neumann, Medicare Part D at Ten Years, Appendix, The Kaiser Family Foundation (2015) available at <http://files.kff.org/attachment/report-medicare-part-d-at-ten-years-the-2015-marketplace-andkey-trends-2006-2015>.

Response: The State has no present information that disputes this figure.

5. Maximum Allowable Cost (“MAC”) specifies the allowable reimbursement by a PBM for a particular strength and dosage of a generic drug that is available from multiple manufacturers but sold at a different price. Exhibit 9 - Expert Report of Donna West-Strum (“West-Strum Report”), ¶¶31, 33; Exhibit 10 - Expert Report of Susan Hayes (“Hayes Report”), ¶15. MAC pricing is designed to set reimbursements at an average acquisition cost for a well-run pharmacy. Exhibit 10 - Hayes Report, ¶15; Exhibit 6 - Hyman Decl., ¶24. MAC programs have resulted in a more efficient pharmaceutical market and lower drug costs overall. Exhibit 6 – Hyman Decl., ¶20. MAC is nearly universally used by prescription drug benefit plans to calculate generic drug reimbursements, and is used by more than forty states for their Medicaid programs. Exhibit 6 - Hyman Decl., ¶¶ 18, 21.

Response: Admit that MAC is based upon an average of available acquisition costs and that it was originally developed to represent prices that are widely and consistently available, but deny that any so-called

“well-run pharmacy” concept is part of a MAC reimbursement.² Admit that MAC programs have been useful in the industry and that MAC is used by many PBMs and health reimbursement systems.

6. PBMs create MAC lists which include anywhere from dozens to thousands of drugs, the price for each of which is set on a drug-by-drug basis. Exhibit 2 - PI Hearing Tr., Hyman Testimony, 49:9-12; Exhibit 11 - Excerpts from July 13, 2016 Deposition of Susan Hayes (“Hayes Tr.”) 64:11-65:6; Exhibit 12 - Expert Report of John Jones (“Jones Report”), ¶60. PBMs maintain multiple MAC lists, and each list may take into account factors that are specific to the health plans and/or pharmacy networks to which the MAC applies. Exhibit 6 – Hyman Decl., ¶21; Exhibit 13 - Excerpts from July 15, 2016 Deposition of John Jones (“Jones Tr.”), 60:18-62:25. In setting MAC, PBMs will typically look at the overall cost of acquiring the drugs for pharmacies (including off-invoice discounts), as well as availability, client expectations, and drug mix. Exhibit 13 - Jones Tr. 65:17-67:6; Exhibit 14 - Excerpts from July 20, 2016 Deposition of Dr. Donna West-Strum (“West-Strum Tr.”) 44:24-45:1.

Response: Admit that PBMs creates and maintains hundreds of MAC lists containing thousands of drugs each. Deny that MAC prices for drugs listed within each MAC list are necessary specific to health plans and/or pharmacy networks as such MAC lists are typically included in the request for proposals when

² See Ex. C to State’s Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶¶ 33 and 37; Ex. E to State’s Mot. Summ. J. (Doc. 77-5), Susan Hayes Decl. at ¶ 15.

the health plan chooses a PBM.³ Deny that all PBMs will “look at” such items, but admit that PBMs create market intelligence systems in order to guide such cost estimates.⁴

7. Health plans, including ERISA and Medicare Part D Plans, use MAC pricing to guarantee that plan beneficiaries will fill their generic drug prescriptions at standardized set prices. Exhibit 10 - Hayes Report, ¶15; Exhibit 9 - West-Strum Report, ¶¶27-28; Exhibit 2 – PI Hearing Tr., Testimony of David Hyman, p. 56; Exhibit 3 - Kracke Decl., ¶ 7, 27.

Response: Deny that such plans utilize MAC pricing in order to guarantee standardized prices. Rather, MAC pricing is a tool that is controlled by the PBM that a health plan purchases as part of its relationship with the PBM.⁵

8. MAC encourages price competition among generic drug manufacturers and drug wholesalers, because MAC encourages pharmacies to shop for the best deal to maximize their margin on each prescription. Exhibit 6 - Hyman Decl. ¶25; Exhibit14 - West-Strum Tr. 28:16- 19; 89:21-90:2.

Response: Deny that MAC alone encourages market participants to compete as pharmacists are always

³ See Ex. G, Susan Hayes Dep. (Doc. 77-7) at p. 66.

⁴ Ex. E to State’s Mot. Summ. J. (Doc. 77-5), Susan Hayes Decl. at ¶ 23; Ex. B to State’s Mot. Summ. J. (Doc. 77-2), John Jones Dep. at pp. 100-106.

⁵ Ex. C to State’s Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶ 28.

incentivized to find the lowest price for any inventory in order to increase their gross margin.⁶

9. Poor purchasing practices, negligence in research, and inadequate management of inventory can cause pharmacies to fail to acquire a drug at a price less than or equal to the MAC list price. Exhibit 6 - Hyman Decl., ¶ 25; *see also* Exhibit 14 - West-Strum Tr. 45:2-11.

Response: Deny that this is an adequate representation of the cause for a pharmacy's inability to obtain generic drugs at a price less than or equal to the MAC list price for that drug. Manufacturer price increases have caused prices to increase dramatically in recent years, and PBMs fail to adjust the MACs quickly in order to match such price fluctuation.⁷

10. Pharmacies receive less than their acquisition cost in a very small number of prescriptions dispensed. Exhibit 2 - PI Hearing Tr., Testimony of Melanie Kracke, 183:19- 184:4 (95% of MAC reimbursements are above acquisition cost); Exhibit 2 - PI Hearing Tr., Testimony of Amy Bricker, 134:10-25 (number of "negative reimbursements" is "very nominal with respect to the total number of claims that are processed and reimbursed to pharmacies"); Exhibit 14 - West-Strum Tr. 72:3-73:12. MAC is designed to ensure that pharmacies profit from the network reimbursements as a whole, rather than on a transaction by transaction basis. Exhibit 2 - PI Hearing Tr., Testimony of David Hyman, 50:24-51:10.

⁶ Ex. C to State's Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶ 18.

⁷ Ex. C to State's Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶¶ 29, 34-36.

Response: Deny that the number of negative reimbursements is a “very small” number. Rather, negative reimbursements account for approximately 10% of all generic drugs.⁸ Deny that MAC is designed to ensure any pharmacy profit because profit differs from reimbursement (profit takes into account the cost of dispensing (i.e. time, labor, overhead, materials, etc.)).⁹

11. PBMs, on behalf of their health plan customers, including ERISA and Medicare Part D plans, enter into contracts with both chain and independent retail pharmacies in every state (“PBM-Pharmacy Contracts”). *See e.g.* Exhibit 15 - AG00822-AG00871; Exhibit 16 - AG00943-AG00955.

Response: Admit that this is true within the State of Arkansas.

12. PBM-Pharmacy Contracts create pharmacy networks, *see e.g.* Exhibit 15 -AG00822-AG00871; Exhibit 16 - AG00943-AG00955, which a PBM’s health plan customers, including ERISA and Medicare Part D plans, use to guarantee their beneficiaries (plan members, employees, and their families) access to pharmaceutical benefits. Exhibit 12 - Jones Report, ¶56. These service guarantees are essential for a PBM to provide competitive networks to employers and insurers and, in the case of Medicare Part D plans, to satisfy the local access requirements under that statutory scheme. *See* Exhibit 3 - Kracke Decl., ¶¶ 7-8. If a pharmacy in a PBM’s network refuses to fill a beneficiary’s prescription, the central purpose of the pharmacy net-

⁸ Ex. C to State’s Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶ 29.

⁹ Ex. E to State’s Mot. Summ. J. (Doc. 77-5), Susan Hayes Decl. at ¶ 35.

work contract is unraveled. Exhibit 12 - Jones Report ¶79.

Response: Admit that PBMs and pharmacies enter into contracts that create pharmacy networks, but the State denies that plans utilize such networks in order to guarantee access as PBMs can remove pharmacies from their networks as desired.¹⁰ Deny that a pharmacist's refusal to fill a prescription unravels a PBM's pharmacy network as pharmacists will work to avoid filling such prescriptions (out of duty to their patients) and because pharmacies must avoid losses to gross margin in order to remain in business and to serve their patient base.¹¹

13. Pharmacies in the network commit to be reimbursed at the MAC price set by the PBM. Exhibit 12 - Jones Report ¶37; Exhibit 9 - West-Strum Report, ¶29. In exchange, pharmacies in the network can expect to receive business from beneficiaries of the plans serviced by the contracting PBM. Exhibit 4 -Bricker Decl., ¶18; Exhibit 3 - Kracke Decl., ¶18; Exhibit 14 - West-Strum Tr. 155-157.

Response: Admit that pharmacies agree to be reimbursed according to MAC pricing, which is set by the PBM, but such contracts also typically include appeal procedures in order to address errors and unsupported reimbursement pricing amounts.¹²

¹⁰ See Sealed Exhibit K to State's Mot. Summ. J. (Doc. 77-11) at 15 (¶¶ 8.5 and 8.6).

¹¹ Ex. C to State's Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶¶ 17 and 46.

¹² See Sealed Exhibit K to State's Mot. Summ. J. (Doc. 77-11) at 42.

14. The contracts between a pharmacy and PBM also include provisions allowing the pharmacy to appeal certain reimbursements. *See* Exhibit 17 - AG001012-1013 (setting forth procedure for a pharmacy to appeal reimbursements). Appeals provisions in PBM-Pharmacy Contracts allow the PBM to review the MAC pricing and all available information to deduce appropriate pricing. *Id.*; Exhibit 12 - Jones Report ¶69. At least one PCMA member requires pharmacies to submit their “actual acquisition cost (including any rebates) for each item being reviewed.” Exhibit 17 - AG001013.

Response: Admit that PBM-pharmacy contracts include appeal procedures and that such procedures might allow PBM review of available information to determine proper MAC reimbursement. Admit that the above-referenced PCMA member takes into account off-invoice discounts when determining reimbursements, but deny that such terms would be effective as that same member explains that state law supercedes that member’s rules regarding such appeals.¹³

15. PBMs also contract with their customers, health benefit plans, including health insurance companies and employers who self-insure health benefits for their employees. Exhibit 12 - Jones Report ¶¶ 31; 35-48. PBMs compete for customer contracts with one another, and price is most often the determining factor in winning a bid. Exhibit 12 - Jones Report ¶ 35; *see also* Exhibit 2 - PI Hearing Tr., Testimony of Amy Bricker, 124:10-19.

¹³ Ex. 17 to PCMA’s Mot. Summ. J. (75-3) at p. 51 (Bates No. AGO-001013).

Response: Admit that price is an important factor in PBM's efforts to gain business and to compete.

16. Some contracts between a PBM and their customers ("PBM-Customer Contracts") are "pass-through" agreements in which the price that a pharmacy is reimbursed for any particular prescription is the same price the plan is charged. Exhibit 3 - Kracke Decl., ¶7. In a pass-through arrangement, the PBM is paid via administrative fees. Exhibit 12 - Jones Report, ¶48.

Response: Deny that a "pass-through" arrangement means that a health plan incurs costs for each dollar the corresponding PBM pays to a pharmacy as such a statement fails to take into account the financial performance guarantees. Such guarantees ensure that despite the health plan's costs, its aggregate costs are guaranteed in the PBM-health plan contract.¹⁴

17. Other PBM-Customer Contracts are "locked-in" pricing arrangements, whereby the PBM guarantees the customer certain pricing on pharmaceuticals. Exhibit 12 - Jones Report, ¶48. In those contracts, the PBM is paid for its services by retaining the difference between what the health plan pays the PBM and the PBM pays the pharmacy. *Id.* Prescription drug plans, including ERISA and Medicare Part D plans, can include a consumer cost sharing mechanism - such as co-insurance or a deductible - in their pharmacy benefits. When there is cost-sharing, the price paid by the plan beneficiary - the plan member, employee or their families - is determined by the price charged to the health

¹⁴ Ex. E to State's Mot. Summ. J. (Doc. 77-5), Susan Hayes Decl. at ¶¶ 19-20.

plan, by the pharmacy, through the PBM. Exhibit 2 – PI Hearing Tr., Hyman Testimony, 53:17-54:3.

Response: Deny that cost-sharing necessarily implies any connection with a beneficiary's cost as cost-sharing often takes into account tiered drugs and not necessarily a specific amount. Regardless, such costs passed along to beneficiaries, if at all, would be discretionary business decisions by health plans. Additionally, this statement of fact is erroneous because the pharmacies do not determine what to charge beneficiaries under such arrangements – rather, PBMs do.

18. A prescription drug benefits plan will cover its beneficiaries' prescription drug purchases at network pharmacies, whatever the geographic location, even across state lines. Exhibit 2 - PI Hearing Tr., Hyman Testimony, p. 68-69; Exhibit 12 - Jones Report, ¶51; Exhibit 3 - Kracke Decl., ¶ 16.

Response: Admit that some level of coverage is likely provided regardless of beneficiary's location.

19. Health plans served by PBMs include plans sponsored by multi-state employers with beneficiaries residing both inside and outside Arkansas. Exhibit 6 - Hyman Decl., ¶31; Exhibit 4 - Bricker Decl., ¶¶4-5; Exhibit 12 - Jones Report, ¶51. A PBM will serve a health plan on a national basis. Exhibit 12 - Jones Report, ¶¶49-51; Exhibit 3 - Kracke Decl., ¶ 16. Multistate employers based in Arkansas include Alltell, Emerson Electric, Federal Express, J.B. Hunt Transport Services, Tyson Foods, UPS, and Wal-mart. Exhibit 6 - Hyman Decl., ¶29.

Response: Admit that PBMs serve multi-state employer plans with beneficiaries residing inside and outside of Arkansas.

20. Prime Therapeutics has identified more than 5,000 prescriptions that were filled in Arkansas by beneficiaries with out of state addresses from January 1, 2016 through June 30, 2016. Exhibit 18 - Supplemental Declaration of Melanie Kracke, ¶2. These prescriptions constituted 16% of the total prescription reimbursement claims submitted to Prime by Arkansas pharmacies during that time period. *Id.* at ¶3. All of those prescriptions were filled for beneficiaries of health plans based outside of Arkansas. *Id.* at ¶4.

Response: The State lacks information presently to dispute Prime Therapeutics' data.

21. The market for purchasing prescription drugs is national. Pharmacies will typically purchase drug from national or regional wholesalers and manufacturers. Exhibit 2 – PI Hearing Tr., Testimony of John Trainor-Namir, 203:22-204:9. There are 1,515 wholesalers licensed to sell prescription drugs in Arkansas. Exhibit 13 - Jones Tr. 15:8.

Response: Admit that prices of drugs do not vary nationally. Deny that purchasing is always done nationally, however, as many regional wholesalers also exist for the sale of prescription drugs. Deny that 1,515 is the correct number of Arkansas-permitted wholesalers.¹⁵

22. The price a wholesaler charges a pharmacy for a given drug varies based on the purchasing agreement between the pharmacy and the wholesaler. *See* Exhibit 2- PI Hearing Tr., Bricker Testimony, p. 144; Exhibit 12 - Jones Report, ¶85; Exhibit 9 - West-Strum Tr. 52:4. Wholesalers will offer dis-

¹⁵ Ex. B, State's Resp. Mot. Summ. J., Kirtley Decl. at ¶ 7-8.

counts and/or different pricing to different pharmacies based on a variety of factors, including volume of purchasing, whether or not the pharmacy is purchasing exclusively or nearly-exclusively from that wholesaler, and the pharmacy's credit-worthiness. Exhibit 13 - Jones Tr. 60:23-61:6; 117:18-118:7. Some discounts offered to pharmacies by their wholesalers, such as prompt payment discounts and bulk purchasing discounts are not listed on the wholesalers' invoice. Exhibit 6 - Hyman Decl., ¶40, n. 38; Exhibit 14 - West-Strum Tr. 61:13-64:10.

Response: Deny that prices that a wholesaler charges are exclusively based on a purchasing agreement between a pharmacy and a wholesaler. Drug costs are affected by manufacturer prices, which have increased dramatically in recent years.¹⁶ Admit that wholesalers may offer off-invoice discounts for various reasons but that such discounts are known to be negligible in their amounts.¹⁷

23. While PBMs rely on data from wholesalers with whom the PBM has a relationship, they do not have access to the complete set of price lists from every wholesaler. Exhibit 2 - PI Hearing Tr., Testimony of Amy Bricker, 149:7-14; Exhibit 13- Jones Tr. 63:19-22.

Response: Deny that PBMs do not have access to the complete set of prices from wholesalers necessary for compliance with Act 900. OptumRx and Express Scripts have access to at least two sources of wholesale

¹⁶ Ex. C to State's Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶¶ 29, 34-36.

¹⁷ Ex. P, State's Mot. Summ. J. (Doc. 77-16), Donna West Dep. at pp. 59-61.

data we as well as NADAC pricing. Express Scripts does not want to know pharmacy wholesale invoice pricing, and OptumRx has not tried to obtain such information.¹⁸

24. In the past ten years, independent pharmacies have been challenged by many factors other than MAC pricing, including the increase in the use of generic prescription drugs, the creation of Medicare Part D prescription drug coverage, the recent recession, and the increase in the use of mail order pharmacies. Exhibit 14 - West-Strum Tr. 131:24-136:18; Exhibit 9 - West-Strum Report ¶8.

Response: Admit that other factors contribute to independent pharmacy challenges, but deny the above statement as stated. MAC pricing is indeed one of the important reasons why independent pharmacies have been financially challenged in recent years.¹⁹

25. The record contains no data to show that Arkansans are currently unable or failing to fill prescriptions, or that any reduction in numbers of pharmacies has caused Arkansans to refrain from filling prescriptions. Exhibit 14 - West-Strum Tr. 97:21-98:5; 114:25-115:20.

Response: Admit that that no data has been supplied to reflect the rates at which Arkansans are filling prescriptions. The State denies any suggestion, however, that allowing the pharmacies current in business

¹⁸ Ex. F, State's Mot. Summ. J. (Doc. 77-6), Excerpts of Hr'g Tr., Test. of Amy Bricker at pp. 132, 157-58; Ex. B, State's Mot. Summ. J. (Doc. 77-2), John Jones Dep. at pp. 63-64, 140-42.

¹⁹ Ex. C to State's Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶ 17.

to continue to dwindle in number has not affected and will not affect patient access to pharmacy care.²⁰

26. The effect of Act 900 is to require PBMs to set higher MACs in advance based on pharmacy acquisition cost for at least some drugs. Exhibit 6 - Hyman Decl., ¶ 39; Exhibit 12 - Jones Report ¶ 73. Therefore, PBMs will pay more in reimbursements to pharmacies. *Id.* at ¶ 44.

Response: Admit that Act 900 may affect that cost of at least some generic drugs and that PBMs may be required to reimburse pharmacies more for those drugs.

27. Increased prescription drug reimbursements are likely to be passed on from the PBMs to the health plans, either through direct drug price increases or through administrative fees. Health plans are likely to pass those increased costs through to their beneficiaries, regardless of where they reside. Exhibit 6 - Hyman Decl., ¶ 51. Beneficiaries that are required to pay co-insurance or deductibles will be subject to increased costs. Exhibit 6 - Hyman Decl., ¶50.

Response: Deny. Any cost increases incurred by PBMs as a result of Act 900's provision will only be passed on to health plans if they make the business decision to do so.²¹ Additionally, any such changes are governed by the costs of drugs in the first instance; any pharmacy appeals occur in order to correct negative reimbursements in line with the reimbursement expectations of the parties.

²⁰ Ex. P, State's Mot. Summ. J. (Doc. 77-16), Donna West Dep. at p. 102 (as supplemented by errata sheet at 1).

²¹ Ex. B, State's Mot. Summ J. (Doc. 77-2), John Jones Dep. at p. 113; Ex. E to State's Mot. Summ. J. (Doc. 77-5), Susan Hayes Decl. at ¶ 43.

28. If PBMs applied the Act 900 pricing structure nationwide, the price of prescription drugs to health plans will increase nationwide. Exhibit 12 - Jones Report, ¶¶81-82.

Response: Deny. Even assuming the unlikely event that PBMs decided to apply Act 900's pricing provisions outside of Arkansas (which they are not required to do), any price increases passed to health plans constitute discretionary business decisions by PBMs.²²

29. The practice of reimbursing at wholesaler invoice price provides an incentive for wholesalers to provide more off-invoice discounting, thereby reducing transparency and pricing competition in the generic drugs market. Exhibit 6 - Hyman Decl., ¶40; Exhibit 12 - Jones Tr. 99:5-100:9.

Response: Deny. Pharmacists, like any other business, are always incentivized to seek the lowest cost. Accordingly, wholesalers would likewise be moved by competitive forces to lower costs.²³

30. If prescription drug prices increase, patient access to drugs will decrease because some patients will not be able to afford to purchase their prescription medication. Exhibit 6 - Hyman Decl., ¶¶ 35-40.

Response: Admit that prices rises on any goods discourages purchasing of that item.

31. At least one Arkansas pharmacy has alleged in a verified complaint that it has turned away a Medicare Part D beneficiary because Act 900

²² Ex. B, State's Mot. Summ J. (Doc. 77-2), John Jones Dep. at p. 113; Ex. E to State's Mot. Summ. J. (Doc. 77-5), Susan Hayes Decl. at ¶ 43.

²³ Ex. C to State's Mot. Summ. J. (Doc. 77-3), Donna West Decl. at ¶ 18.

allowed the pharmacy to decline to dispense where it would not receive a high enough reimbursement. Exhibit 19 – *Village Apothecary, Inc. v. Aetna*, No. 63cv-16-571-3 (Cir. Ct. of Saline County, 2016), Complaint.

Response: Deny that Village Health Mart failed to dispense the prescription at issue in that case. Deny also that any denial was occasioned by the inability of the pharmacist to obtain a “high enough” reimbursement as that negative reimbursement amounted to approximately \$214 on a single prescription.²⁴

32. Act 900 does not specify whether “sixty percent of wholesalers doing business in the state” should be calculated by reference to the volume of drug sales, or the number of wholesalers. Exhibit 11 - Hayes Tr. 148:6-15; Exhibit 14 - West-Strum Tr. 57:3-15.

Response: Admit that Act 900 does not specify whether the 60% provision is calculated by volume of drug sales or the number of wholesalers.

Respectfully submitted,

LESLIE RUTLEDGE
ATTORNEY GENERAL

By: /s/ Shawn Johnson
Arkansas Bar No. 2004181
Assistant Attorney General
Attorney for Defendant
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Telephone: (501) 682-1178
Facsimile: (501) 682-8118
shawn.johnson@arkansasag.gov

²⁴ Ex. A, State’s Resp. PCMA’s Mot. Summ J. (Doc. 87), Butler Decl. at ¶ 8.

CERTIFICATE OF SERVICE

I, Shawn Johnson, Assistant Attorney General, do hereby certify that on September 9, 2016, I electronically filed the forgoing with the Clerk of the Court using the CM/ECF system, which shall electronically notify the following individuals:

Ms. Lyn P. Pruitt
Mitchell, Williams, Selig,
Gates & Woodyard, PLLC
425 West Capitol Avenue, Ste. 1800
Little Rock, AR 72201
Phone: (501) 688-8869
Facsimile: (501) 918-7869
Email: lpruitt@mwlaw.com

Mr. Dean Richlin
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000
Email: DRichlin@foleyhoag.com

Ms. Kristyn DeFilipp
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000
Phone: 617-832-1218
Email: KBunceDeFilipp@foleyhoag.com

Mr. Andrew London
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000

COUNSEL FOR PLAINTIFF

/s/ Shawn Johnson