Federal Regulatory: Part D Final Rule/Call Letter for CY 2020

- *Protected Classes*: Allows plans/PBMs to utilize prior authorizations and step therapy for drugs in protected classes, but only for new start therapies (an NCPA ask)
- *Gag Clauses*: codifies the statutory prohibition of gag clauses in the Medicare program into Part D
- *Real Time Benefit Tool ("RTBT")*: Requires plan sponsors to implement an electronic RTBT that integrates prescribers' e-prescribing and electronic medical records. CMS is delaying the required implementation date until Jan. 1, 2021
- *Step Therapy for Part B Drugs*: Establishes requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs
- *Explanation of Benefits*: Requires the inclusion of negotiated drug pricing information and lower cost alternatives in Part D EOBs beginning on Jan. 1, 2021

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Federal Regulatory Update: Controlled Substances

- SUPPORT Act
  - Required e-prescribing for Part D controlled substances (starting Jan. 1, 2021) **NOW DELAYED UNTIL JAN 1 2022**
  - Required drug management programs (prescriber and/or pharmacy lock-ins) in Part D (starting Jan. 1, 2022)
  - Required electronic prior authorization for Part D drugs (starting Jan. 1, 2021) **NOW DELAYED UNTIL JAN 1 2022**
  - Expanded eligibility for medication therapy management programs in Part D (starting Jan. 1, 2021)
  - For more information, check out NCPA's summary: http://www.ncpa.co/pdf/ncpa-member-summary-hr6.pdf

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Federal Regulatory Update: Controlled Substances (continued)

- NCPA successes in SUPPORT Act:
  - Ensured PBMs cannot use e-prescribing to steer patients
  - Secured exemption for long-term care patients from e-prescribing requirements under the Act
  - Backed language that requires HHS and DEA to put out guidelines on when pharmacists can refuse to fill opioids
  - Prevented PBMs from having the authority to suspend payments to a pharmacy pending investigation of credible allegations of fraud
  - Prevented pharmacists from being mandated to check prescription drug monitoring programs under state Medicaid programs

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Federal Regulatory: Other Drug Pricing Initiatives

- Importation
  - Proposed Rule - States can create and submit to the FDA an importation plan
  - Guidance - Brand drug companies can import any drug they sell in foreign countries back into the U.S. to sell for less than they typically charge in the U.S.
- Final Rule to require disclosure of "list prices" in TV ads
  - On appeal
- Several regulatory items still pending on the regulatory dashboard
  - Index Pricing Rule Proposed Rule
  - Medicaid Managed Care Final Rule
  - Part D Proposed Rule for CY 2021

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Federal Regulatory Update: DSCSA Phase I

Drug Supply Chain Security Act = the "DSCSA" = the "Track-and -Trace" Law

- Became law in 2013
- State pedigree laws are dead
- By Law, Pharmacies are Required to do the Following Right Now:
  1. Confirm the entities you do business with are appropriately licensed or registered
  2. Receive, store, and provide product tracing documentation
  3. Investigate and properly handle suspect and illegitimate drugs

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Federal Regulatory Update: DSCSA Phase II

- After Nov. 27, 2019, wholesalers can only accept pharmaceutical products that have a DSCSA-compliant product identifier
  - FDA enforcement discretion delays this to Nov. 27, 2020 (NCPA ask)
  - Wholesalers will be required to verify with the manufacturer of a product the DSCSA-compliant product identifier before redistributing a saleable return
- **It is important for pharmacists to know this date because the change may impact saleable returns and inventory management at the pharmacy level**

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Federal Regulatory Update: DSCSA Phase II Continued

- After Nov. 27, 2020, pharmacies can also only accept pharmaceutical products that have a DSCSA-compliant product identifier
- **NCPA recommends that pharmacy owners immediately ask their trading partners how this compliance date may impact your pharmacy and plan accordingly**

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What's a DSCSA-compliant product identifier?

- Includes the product's lot number, expiration date, national drug code (or NDC), and a serial number
- The serial number is different for each package or case
- This creates a unique identifier – human and machine readable – to enable product tracing throughout the supply chain

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Helpful Tools on DSCSA

- NCPA's Webinars
- FDA's "Utilize DSCSA requirements to protect your patients" presentation: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm606945.htm
- FDA Guidances: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm
- FDA one-pager: https://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/UCM607076.pdf

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Federal Regulatory Update: USP

- USP <795> (nonsterile) and <797> (sterile) delays
  - Hearing: Jan. 21-22, 2020
- USP <800> (hazardous drugs) Implementation: Dec. 1, 2019
  - "Compendially applicable": only those held to <795> and <797> are held to <800>
  - Verify with your State Board of Pharmacy
- USP <800> Resources
  - NCPA's risk assessment template to help you create your own: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare
  - College of Psychiatric and Neurologic Pharmacists' detailed USP <800> compliance toolkit: https://cpnp.org/medication/usp800

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Federal Regulatory Update: USP Continued

- Even if your state has not yet adopted USP 800, be aware of the following guidances/rules that address hazardous drugs:
  - EPA Final Hazardous Waste Rule
  - Food and Drug Administration (FDA) Draft Insanitary Conditions Guidance
  - Occupational Safety and Health Administration (OSHA) Hazardous Waste Standards
- FDA sent draft guidance on USP 800 to the Office of Management and the Budget (OMB) in July 2020

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State Activities Impacting Community Pharmacies

- Medicaid pharmacy payment reform
  - Carve-out
  - PBA model/pass through
  - Enhanced pharmacy payments/reimbursements
- Comprehensive PBM regulation
  - Address MAC price lists
  - Post sale claim adjustment/“claw-backs”
  - GER
  - NCOIL model bill
  - Supreme Court case: Rutledge v. PCMA
- Expansion of scope and compensation for patient services

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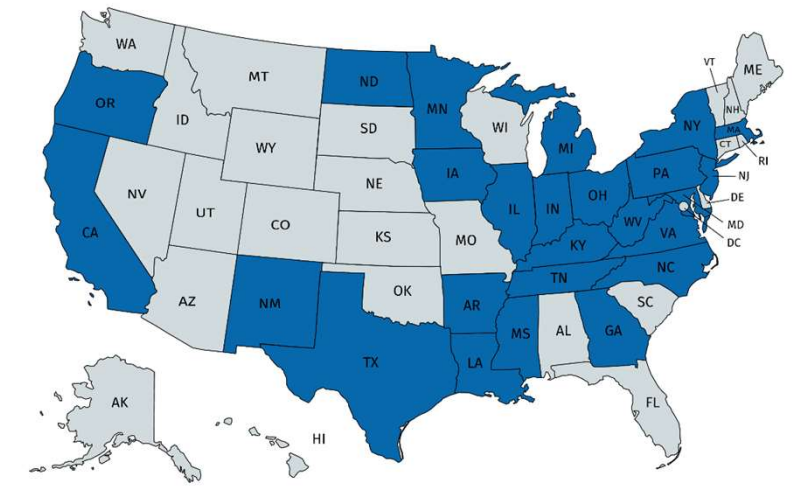
State Update: Legislation

- Medicaid managed care reform
  - CMS Memo on spread pricing
  - Federal MMC Final Rule pending
  - Investigations
  - MMC program payment reforms
    - Legislations
    - Regulatory changes



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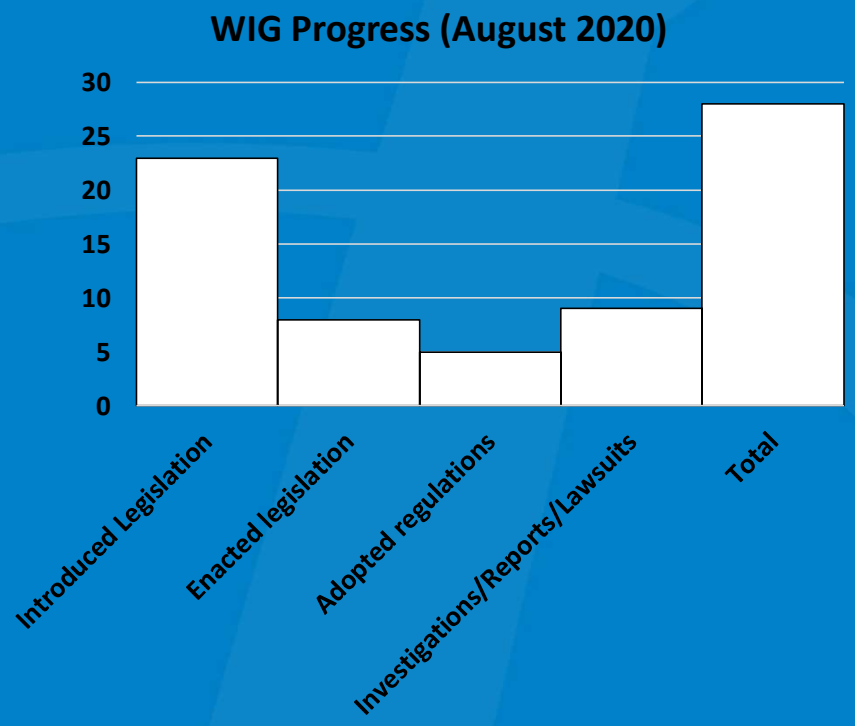
WIG: 2019-2020—Changing the Pharmacy Payment Model: MMC Reform Progress

TOTAL: Over half of the states (27) plus CMS have taken- action in the Medicaid Managed Care reform space since Jan. 2019

- **23 states introduced legislation**
- **9 states passed 10 pieces of legislation**
- **4 states plus CMS adopted regulations/guidance**
- **9 states have conducted investigations, issued reports or filed lawsuits**



WIG: Medicaid Managed Care Reform

Highlight: Pharmacy Benefit Carve-out

- 8 states have carved-out pharmacy, in the process of carving out or attempting to carve-out pharmacy from Medicaid managed care.
  - West Virginia-$54 million savings after year 1 of carve-out
  - California-in progress
  - New York-effective April 2021
  - Louisiana-state has authority
  - North Dakota
  - Kentucky-attempted this year-compromise bill with meaningful reforms
  - Michigan-attempted through proposed rule-will try via legislation
  - Illinois-pending legislation

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Counter Campaign to PCMA's Direct Attacks on Independent Pharmacies

- September-PCMA launched an aggressive attack against independent pharmacies via multiple media platforms
  - Rolled out attacks in 16 states in a 2-week time frame
- NCPA launches counter campaign to rebut ridiculous allegations, such as:
  - "Powerful bargaining power" of independent pharmacies
  - PBMs controlling cost
  - PBMs fight for patients
  - PBMs save states millions
- Campaign Objective: Educate consumers, state legislators, and state media on:
  - Role of PBMs in the high cost of drugs
  - Unfair PBM busines practices that destroy locally owned pharmacies and limit patient care
  - Role of independent pharamcies in providing critical care
  - Role of PBMs in increasing cost of taxpayer-funded health programs controlling cost
- Campaign Tools:
  - Social Media
  - Campaign Website
  - Earned Media
  - LTEs (members and patients)
  - Op-eds

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BATTLEGROUND: SCOTUS

Rutledge v. PCMA: 15 Years in the Making

'05

***PCMA v. Rowe*, No. 05-1606, (1st Cir.).**

- Maine's Unfair Prescription Drug Practices Act ("UPDPA"), enacted in 2003, was one of the first PBM laws in the nation to be challenged by PCMA
- NCPA provided support to Maine Attorney General in successfully defending statute before the U.S. Court of Appeals for the First Circuit

'14

***PCMA v. Gerhart*, No. 14-cv-345 (D. Iowa), *on appeal*, No. 15-3292 (8th Cir.).**

- PCMA files its first lawsuit against a State law regulating PBM-pharmacy relationships and argues that the law is preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA)

'15

- NCPA works with the Iowa Pharmacy Association (IPA) to oppose PCMA's lawsuit
- The District Court dismisses PCMA's lawsuit
- PCMA appeals to the U.S. Court of Appeals for the Eighth Circuit

***PCMA v. Rutledge*, No. 15-cv-510 (E.D. Ark.), *on appeal*, No. 17-1609 (8th Cir.), *pet. for cert. granted*, No. 18-540 (U.S.).**

- PCMA files a second lawsuit, this time against an Arkansas law arguing that the law is preempted by ERISA

'16

- NCPA works with IPA to file an *amici curiae* ("friends of the court") brief with the Eighth Circuit defending Iowa's PBM regulations
- NCPA and IPA work with the Iowa Attorney General's Office to prepare for oral argument
- Eighth Circuit hears oral argument

- NCPA works with the Arkansas Pharmacists Association (APA) to provide support to the Arkansas Attorney General's Office throughout the District Court proceedings

'17

- Eighth Circuit reverses the District Court, ruling that Iowa's law is preempted by ERISA
- NCPA and IPA support Iowa's effort to seek rehearing, Eighth Circuit denies the State's petition

- District Court rules that Arkansas's law is preempted by ERISA and Arkansas appeals to Eighth Circuit
- NCPA works with APA to file an *amici curiae* brief with the Eighth Circuit defending Arkansas's PBM regulations

'18

- Eighth Circuit rules that Arkansas's law is preempted by ERISA, and in response, Attorney General's Office files a petition with the Supreme Court to review the Eighth Circuit's decision
- NCPA helps secure an *amici curiae* brief from 32 States and the District of Columbia urging the U.S. Supreme Court to review the case

'19

- Supreme Court calls for the U. S. Solicitor General to file a brief expressing the views of the federal government
- Solicitor General files brief on behalf of the United States arguing that the Eighth Circuit's decision was wrongly decided and urges Supreme Court to take the case

'20

- Supreme Court agrees to review case and its decision could have far-reaching implications for the authority of the States to regulate PBMs that process claims for employer- or union-sponsored health plans

This summary is not an all inclusive analysis of our efforts just a highlight of major NCPA activity.

Supreme Court Case: 2015 Arkansas legislation

- Oral arguments take place on October 6th-originally scheduled for April 29th
- The flawed interpretation of Employee Retirement Income Security Act (ERISA) has been used to restrict a state's ability to regulate PBMs
- Could be a gamechanger in state regulation of PBMs-remove the ERISA protection?
- Main parts of the law:
  - Restricts so-called "negative reimbursements" by requiring PBMs to demonstrate that a drug could have been purchased at a lower price through a wholesaler who does business in the State, and if the PBM fails to meet this burden, mandating that the PBM reimburse the pharmacy at the cost of acquisition;
  - Requires PBMs to update their MAC price lists based on changes in average wholesale prices; and
  - Permits pharmacies to decline to dispense in face of a negative reimbursement.

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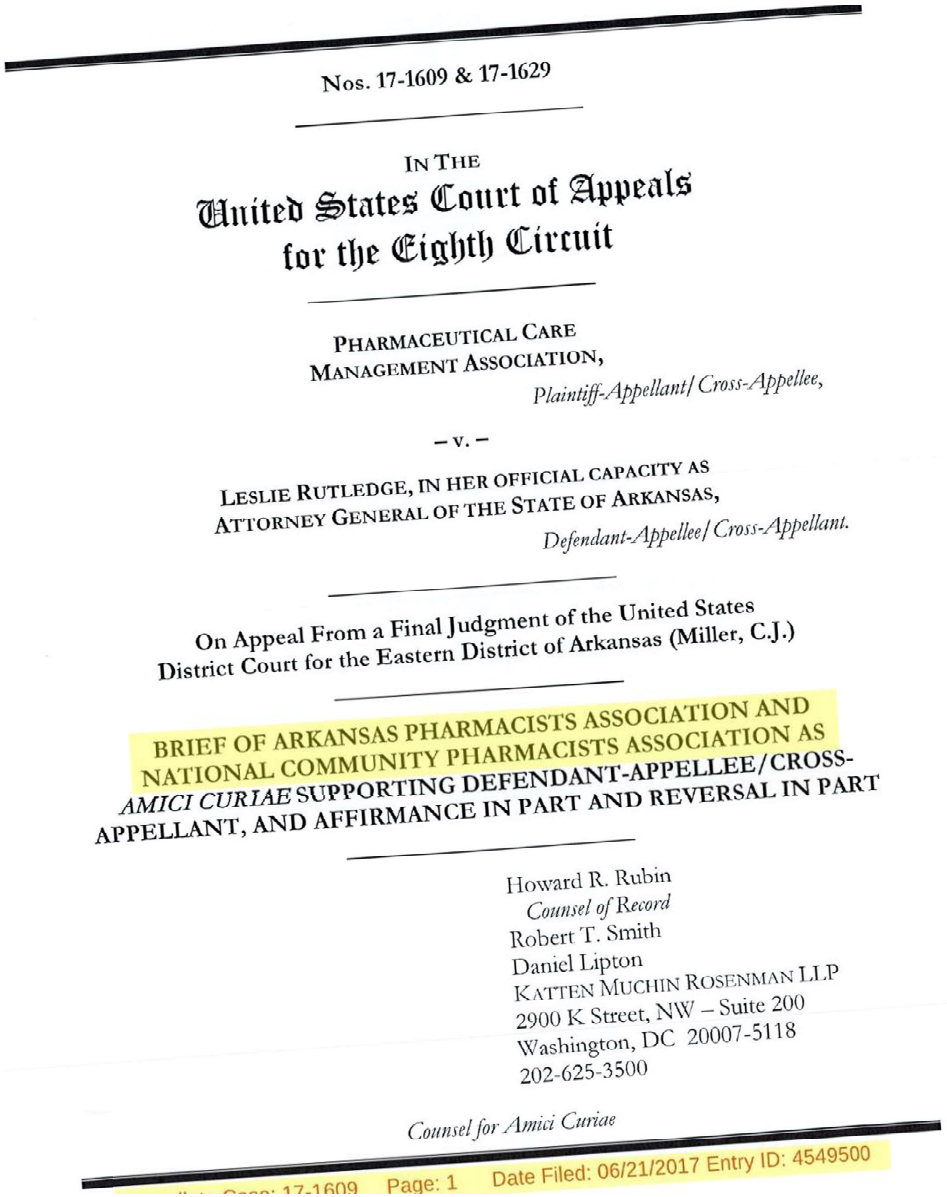

Nos. 17-1609 & 17-1629

IN THE
United States Court of Appeals
for the Eighth Circuit

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff-Appellant/Cross-Appellee,

– v. –

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF ARKANSAS,
Defendant-Appellee/Cross-Appellant.

On Appeal From a Final Judgment of the United States District Court for the Eastern District of Arkansas (Miller, C.J.)

BRIEF OF ARKANSAS PHARMACISTS ASSOCIATION AND NATIONAL COMMUNITY PHARMACISTS ASSOCIATION AS *AMICI CURIAE* SUPPORTING DEFENDANT-APPELLEE/CROSS-APPELLANT, AND AFFIRMANCE IN PART AND REVERSAL IN PART

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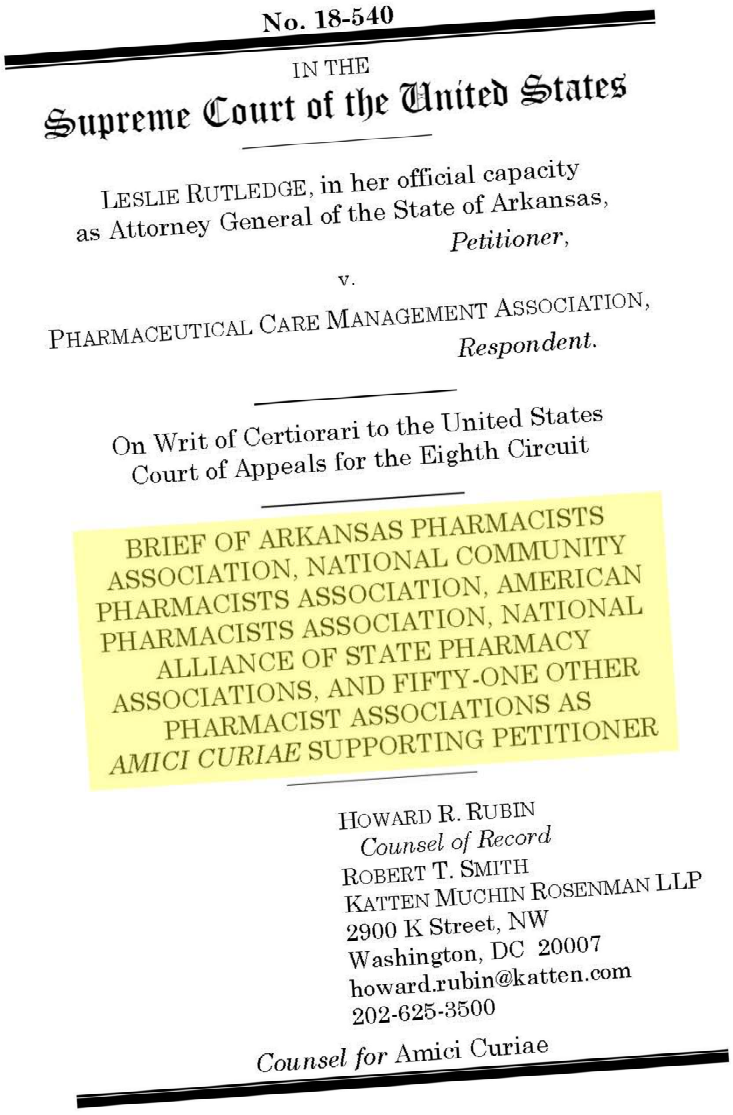
Case: 17-1609 Page: 1 Date Filed: 06/21/2017 Entry ID: 4549500

- **U.S. Solicitor General:** Filed a brief arguing that the Eighth Circuit's decision is wrong and urges the Supreme Court to take the case.
- The Supreme Court reviewed the Eighth Circuit's ruling and will potentially provide clarity on the extent to which states can regulate PBMs that serve ERISA plans.
- The Federal Government has taken the position that Federal Law (i.e. ERISA) **does not preempt states from regulating PBMs**, including PBMs that serve ERISA plans!



No. 18-540

IN THE

Supreme Court of the United States

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

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

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

BRIEF OF ARKANSAS PHARMACISTS ASSOCIATION, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS, AND FIFTY-ONE OTHER PHARMACIST ASSOCIATIONS AS *AMICI CURIAE* SUPPORTING PETITIONER

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- NCPA joined the Arkansas Pharmacists Association, APhA, NASPA and 51 pharmacy organizations in filing *Amici Curiae* brief with Supreme Court.
- Forty-six state attorneys general file *Amici Curiae* supporting the state of Arkansas.
- Supreme Court heard oral arguments on October 6, 2020. Arguments originally scheduled for April 29, 2020.

Fight4Rx: Patient Engagment

- Fight4Rx is NCPA's consumer facing platform to engage patients, caregivers, pharmacists, and patient advocates
- Advocates simply text Fight4Rx to 52886 and follow the link they receive in response
- Since its launch, over 11,000 advocates have joined and nearly 5,000 connections to legislators have called for PBM and DIR reform
- Fight4Rx already has over 400 followers on Twitter and over 700 followers on Facebook

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NCPA PAC Supporting Pharmacist Candidates

Diana Harshbarger
Congressional candidate, TN-01
Election Day: November 3rd
NCPA Member

Will Douglas
State House candidate, TX-113
Election Day: November 3rd
NCPA Member

Jerry Carl
Congressional candidate, AL-01
Election Day: November 3rd
Owns a specialty pharmacy that serves patients with hemophilia

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Assessment Question #1

- Medicare will cover certain COVID-19 tests performed by pharmacists if they are enrolled in Medicare as a laboratory, in accordance with scope of practice and state laws.

  True or False?

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Assessment Question #1: Answer

- Medicare will cover certain COVID-19 tests performed by pharmacists if they are enrolled in Medicare as a laboratory, in accordance with scope of practice and state laws.
  True or False?
- TRUE

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Assessment Question #2

How much have DIR fees increased since 2010?

A. 500%

B. 1000%

C. 25,000%

D. 45,000%

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Assessment Question #2: Answer

How much have DIR fees increased since 2010?

A. 500%

B. 1000%

C. 25,000%

D. 45,000%

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Assessment Question #3

United State Department of Health and Human Services (HHS) has authorized pharmacists to order and administer COVID-19 vaccinations in every state-despite state law.

True or False?

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Assessment Question #3: Answer

United State Department of Health and Human Services (HHS) has authorized pharmacists to order and administer COVID-19 vaccinations in every states-despite state law.

True or False?

- TRUE

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Assessment Question #4

When does required e-prescribing for Part D controlled substances go into effect?

A. Jan. 1, 2020

B. July 1, 2020

C. Jan. 1, 2022

D. July 1, 2022

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Assessment Question #4: Answer

When does required e-prescribing for Part D controlled substances go into effect?

A. Jan. 1, 2020

B. July 1, 2020

D. Jan. 1, 2022

C. July 1, 2022

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Assessment Question #5

In Rutledge v. PCMA, the US Supreme Court will determine the impact of which federal law on a state's authority to regulate PBMs?

A. Medicare
B. Employee Retirement Income Security Act (ERISA)
C. Medicaid
D. Affordable Care Act

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Assessment Question #5: Answer

In Rutledge v. PCMA, the US Supreme Court will determine the impact of which federal law on a state's authority to regulate PBMs?

A. Medicare
B. Employee Retirement Income Security Act (ERISA)
C. Medicaid
D. Affordable Care Act

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Questions?

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