PBM & Legislative Update

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Disclosures

- **I do not have** (nor does any immediate family member have):
  - a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity
  - any affiliation with an organization whose philosophy could potentially bias my presentation

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Objectives

1. Discuss current and upcoming trends in the pharmacy policy space at the federal and state level, including drug pricing and dispensing of opioids.
2. Inform community pharmacists about the changes in Medicare's prescription drug benefit for CY 2020.
3. Understand potential ramifications and impacts on pharmacies and pharmacy benefit managers from Rutledge v. PCMA case that is pending before the US Supreme Court.

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Self assessment questions

1. How much have DIR fees increased since 2010?
2. What legislation would prohibit PBMs from reimbursing their own pharmacies more than they reimburse other pharmacies?
3. When does required e-prescribing for Part D controlled substances go into effect?
4. When must pharmacies start only accepting serialized product from their trading partners?
5. When will a decision in Rutledge v. PCMA be announced?

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The Strength of Our Numbers

Founded in 1898, the National Community Pharmacists Association is **the voice for the community pharmacist**, representing **21,000 pharmacies** that **employ 250,000 individuals** nationwide. Community pharmacies are **rooted in the communities where they are located** and are among **America's most accessible health care providers**.

https://youtu.be/FDDl_RMO6Gg

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NCPA Being Heard on Capitol Hill

- NCPA Advocacy resulted in wins for pharmacy with passage of gag clause and opioid legislation and two White House signing ceremonies
  - Gag Clauses were banned in Medicare Part D & commercial insurance plans
  - Pharmacy protections for Electronic Prescribing for Controlled Substances in Medicare
- 70+ House & Senate staff attend NCPA briefing on pharmacy issues
- 84 pharmacy visits by Members of Congress
  - Plus 2 visits by HHS Secretary Alex Azar

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There From the Beginning on DIR Advocacy

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	NCPA & Member Comments	Congressional Letters	Stakeholder Letters	Patient/Consumer Org. Letters
'14	NCPA submits comments to CMS — Mar.			
'15	NCPA submits comments to CMS — Jan.	Guidance on DIR — Jan. 11 REPRESENTATIVES		
'16	NCPA secures introduction of DIR federal legislation — Sept.	Guidance on DIR — Sept. 16 SENATORS 30 REPRESENTATIVES	Support first DIR bill — Sept. 99 SIGNATORIES	Asked CMS to finalize DIR guidance — June 8 SIGNATORIES
'17	NCPA submits comments to CMS on DIR reporting — June		Support DIR legislation — Mar. 118 SIGNATORIES	
'18	DIR Proposal — Jan. 992 MEMBER COMMENTS	Support DIR Proposal — Jan. 21 SENATORS 80 REPRESENTATIVES	Joint comment to DIR Proposal — Jan. 120 SIGNATORIES	Support elimination of pharmacy DIR — Jan. 9 SIGNATORIES
	Drug Pricing RFI — July 1,955 MEMBER COMMENTS	Address DIR in RFI — Aug. 21 SENATORS 83 REPRESENTATIVES	Response to POTUS on Drug Pricing Blueprint — July 153 SIGNATORIES	
'19	DIR Proposed Rule — Jan. 3,493 MEMBER COMMENTS	Support DIR Proposal — Mar. 29 SENATORS 62 REPRESENTATIVES	Response to DIR Proposed Rule — Jan. 155 SIGNATORIES	Urged CMS to finalize DIR proposal — Jan. 24 SIGNATORIES
	CMS fails to finalize DIR Rule — May	DIR Final Rule Failure — June 28 SENATORS 105 REPRESENTATIVES	Response to POTUS Expressing Disappointment — June NCPA, NACDS, APHA, NGA NASP & FMI	
		Senate Finance Support Administrative DIR Fix — Sept. 23 SIGNATORIES	Drug Pricing Package to Senate Finance — July 204 SIGNATORIES	

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

NCPA Advocacy Center Meetings with Administration

April 2018: *White House, OMB;* ***May 2018:*** *CMS;* ***July 2018:*** *HHS;* ***August 2018:*** *HHS;* ***September 2018:*** *White House, Domestic Policy Council;* ***October 2018:*** *HHS, Small Business Administration;* ***November 2018:*** *HHS, CMS, White House, OMB;* ***December 2018:*** *HHS, White House, Political Office;* ***January 2019:*** *White House, Domestic Policy Council;* ***February 2019:*** *HHS;* ***April 2019:*** *HHS, Small Business Administration;* ***May 2019:*** *HHS, White House, Domestic Policy Council, CMS;* ***July 2019:*** *CMS;* ***October 2019:*** *CMS;* ***December 2019:*** *CMS*

National Survey Supports Pharmacy-Related Part D Reforms

June 2018: *NCPA commissioned Morning Consult national survey showed overwhelming support for prohibiting PBMs from charging DIR fees to pharmacies – fees that also artificially raise seniors' out-of-pocket costs.* ***October 2019:*** *A recent NCPA member survey shows that 58% of independent pharmacies are somewhat or very likely to close in the next 2 years without relief from pharmacy DIR fees. More so, 63% of respondents said that pharmacy DIR is the number one problem facing their pharmacy.*

Pharmacy DIR Reform

- Disappointing announcement from HHS/CMS on May 16
  - *In the proposed rule, CMS announced that the agency was considering a policy to ensure that beneficiaries pay the lowest cost for the prescription drugs they pick up at a pharmacy, after taking into account back-end payments from pharmacies to plans.* ***Although CMS is not implementing this policy for 2020, the agency appreciates the over 4,000 comments that were received on this issue****. CMS is continuing to carefully review these comments as* ***we continue to consider policies that would lower prescription drug costs, address challenges that independent pharmacies face, and improve the quality of pharmacy care.***
- Why no fix?
  - From proposed rule: *If this policy were adopted for 2020 or a future year, there would be an impact on beneficiaries, the government, and manufacturers.* ***Beneficiaries would save $7.1 to $9.2 billion over 10 years (2020 to 2029),*** *resulting from reduced cost-sharing, offset by slightly higher premiums. However, the provision would be estimated to* ***cost the government $13.6 to $16.6 billion over that span****. Manufacturers would also save, about $4.9 to $5.8 billion from 2020 to 2029. Part D sponsors would incur a first year cost of $0.1 million in additional administrative activities related to submission of PDE data.*

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Next Steps to #FixDIR

- Immediate action: work with DIR stakeholders and enact legislation to fix DIR
  - NACDS, APhA, NASP, Walgreens, FMI, and NGA
- Exploring potential legal options
- Utilizing U.S. Small Business Administration (SBA)
- Meetings with Senate Finance Committee, House Energy & Commerce and Ways & Means committee staff
- Working with Phair Pricing Act sponsors
- Met with HHS Sec Azar and Domestic Policy Council Chair Joe Grogan; both promised support for Congressional action

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Impact of Pharmacy DIR Fees: Small Business

- Actual pharmacy price concessions have increased from $229 million in 2013 to $4 billion in 2017
- From 2010 to 2017, pharmacy DIR fees have increased **45,000%** in Medicare Part D, with a steep increase occurring between 2013-2017 (the most recent year data is available)
- Today, DIR fees impact about 1.5-3.5% of total revenue of a community pharmacy
- More narrowly, in 2018, DIR fees impact about 3-5% of Part D prescription revenue of a community pharmacy

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Congressional Drug Pricing Packages

- S. 2543 – Grassley Wyden Senate Finance package
  - Pharmacy DIR assessed at the point of sale in Part D
  - HHS to standardize pharmacy quality measures in Part D
  - Limit spread pricing practice and use NADAC pricing as floor in MMC
- H.R. 3 – Pelosi bill passed the House in December
  - HHS to standardize pharmacy quality measures in Part D
  - Limit spread pricing practice and use NADAC pricing as floor in MMC
- H.R. 19 / S. 3129 – GOP alternative
  - HHS to standardize pharmacy quality measures in Part D
- HELP Package
  - Limit spread pricing in commercial plans

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Controversial Issues: Rebate Inflation Caps, Government Price Negotiations

Transparency Legislation

- The House unanimously passed a pair of NCPA-endorsed drug pricing transparency bills in 2019. The bills would shine a light on rebates and DIR fees and obtain more data on how PBMs may be contributing to higher drug prices.
  - H.R. 2115, the *Public Disclosure of Drug Discounts Act*, sponsored by Reps. Abigail Spanberger (D-Va.), Jodey Arrington (R-Texas), and Brendan Boyle (D-Pa.), would require PBMs to disclose the aggregate amount of rebates, discounts, and price concessions, including DIR fees, that PBMs negotiate with drug manufacturers, and make this information publicly available. NCPA was the only national organization to endorse the bill and was quoted in Rep. Spanberger's press release on the bill.
  - H.R. 1781, the *Payment Commission Data Act*, sponsored by Rep. Buddy Carter (R-Ga.), would provide drug pricing and rebate data to the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission. Access to this data would help the independent commissions provide better policy recommendations to Congress.

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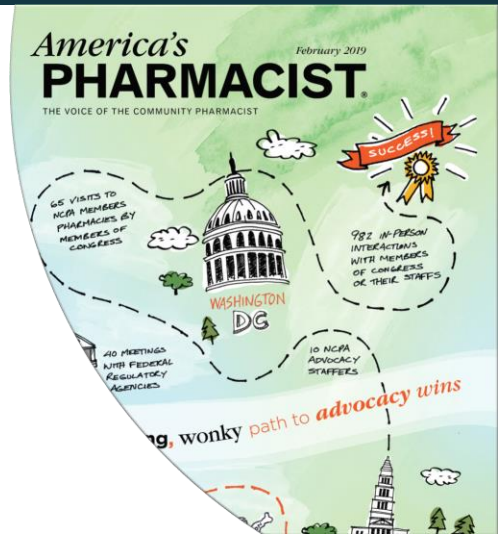
Current NCPA Federal Legislative & Regulatory Activities

- Priorities for Independent Pharmacies:
  - DIR fees
  - MAC pricing
  - Fair and reasonable Medicaid reimbursement
- All boils down to PBMs



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Federal Legislative: NCPA Priority Bills

- *Phair Pricing Act* S. 640/H.R. 1034
  - Direct pharmacy DIR fees to be included at the point of sale.
  - Require claims level data reporting.
  - Direct HHS Secretary to establish standardized pharmacy-specific quality measures.
- *Ensuring Seniors Access to Local Pharmacies Act* H.R. 4946
  - Allow community pharmacies in underserved areas to participate in Part D preferred pharmacy networks.
  - Requires reasonable reimbursement that covers acquisition and dispensing costs
  - Preventing PBMs from reimbursing their affiliate pharmacies more than they reimburse others
- *Prescription Drug Price Transparency Act* H.R. 1035 – MACs/generic drug reimbursement
  - Require PBMs to identify how they set MAC prices and require MAC lists to be updated more frequently.
  - Prohibits PBMs from requiring or incentivizing patients to use the mail order and specialty pharmacies they own
- *Preserving Patient Access to Compounded Medications Act* H.R. 1959
  - Allow for 503A office use compounding where allowed by state law, define in statute "distribution" and "dispense," and require FDA to follow formal rule-making procedures.

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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, only for new start therapies (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 info and lower cost alternatives in Part D EOBs beginning on Jan. 1, 2021.

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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: AKS & Stark Proposed Rules

- HHS released two proposed rules on October 9, 2019 regarding the Federal Anti-Kickback Statute (AKS) and Physician Self-Referral Law (Stark Law).
- AKS Proposed Rule: considers excluding pharmacies from the new value-based enterprise (VBE) proposed safe harbors.
- OIG acknowledges that some pharmacies have the potential to contribute.
- NCPA submitted comments on 12/31/19.

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Federal Regulatory Update: Controlled Substances

- SUPPORT Act
  - Required e-prescribing for Part D controlled substances (starting Jan. 1, 2021)
  - Required drug management programs (prescriber and/or pharmacy lock-ins) in Part D (starting Jan. 1, 2022)
  - Suspension of payments for fraud (starting Jan. 1, 2020)
  - Required electronic prior authorization for Part D drugs (starting Jan. 1, 2021)
  - 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: SUPPORT Act 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 Update: Track and Trace

- Nov. 27, 2018: Serialized product now coming from manufacturers
- Nov. 27, 2019: Verification of saleable returns
  - Wholesalers can only accept pharmaceutical products that have a compliant product identifier
  - FDA enforcement discretion delays this to Nov. 27, 2020 (NCPA ask)
  - **It is important for pharmacists to know this date because the change may impact saleable returns and inventory management at the pharmacy level**
- Nov. 27, 2020: Pharmacies can only accept serialized product
  - **NCPA recommends that pharmacy owners immediately ask their trading partners how this this compliance date may impact your pharmacy and plan accordingly**

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What's a 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

- 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: CBD

- Farm Bill - December 2018
- FDA's request for information - July 2019
- FDA's FAQ:

Is it legal for me to sell CBD products?

- It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.
- We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.
- https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#legaltosell.

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Federal Regulatory Update: Provider Status

- CMS RFI: scope of practice
  - Part of the President's Executive Order (EO) #13890 on Protecting and Improving Medicare for Our Nation's Seniors.
  - EO directs HHS to propose Medicare reforms, including ones that eliminate supervision and licensure requirements that are more stringent than other federal or state laws.
  - Focuses on Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs)
- NCPA filed comments
  - Pharmacists improve patient care and outcomes when collaborating with health care professionals.
  - Restrictive regulations currently hinder pharmacists' ability to continue providing this care at the federal level, especially when state laws are already expanding to allow health care practitioners to contribute fully to patient care.

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Federal Regulatory Update: Compounding

- FDA
  - Memorandum of Understanding (MOU)
  - 503A Bulks List Proposed Rule
- FDA funded-study with the National Academies of Science, Engineering, and Medicine (NASEM)
  - Compounded bioidentical hormone therapy
  - Topical pain creams

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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

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Federal Regulatory Update: EPA

- EPA's Final Rule on Management Standards for Hazardous Waste Pharmaceuticals: Effective Aug. 21, 2019
- Outlines what products are considered solid waste and thus subject to EPA's streamlined regulations.
- Requires healthcare facilities (including pharmacies) to determine what are hazardous or non-hazardous waste pharmaceuticals and whether this waste is potentially creditable or non-creditable at their pharmacy prior to sending the pharmaceutical to a reverse distributor.

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Federal Regulatory Update: Pass-Through Deduction

- Jan. 2019: IRS finalized its rules on the pass-through deduction, a result of the 2017 Tax Cuts and Jobs Act.
- NCPA recommends that pharmacy owners talk to their accountant or tax counsel on the applicability of this pass-through deduction to their business based on the types of services and product dispensing conducted at their pharmacy.

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Road to the Supreme Court: Rutledge v. Pharmaceutical Care Management Association

- Arkansas passed a state law regulating PBMs' relationship with pharmacies:
  - Restricts 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 MAC price lists based on changes in average wholesale prices
  - Permits pharmacies to decline to dispense in face of a negative reimbursement.
- PCMA files a lawsuit in the U.S. District Court for the Eastern District of Arkansas claiming that Arkansas's law is preempted by the Employee Retirement Security Act (ERISA)
- District Court rules Arkansas's law is preempted by ERISA
- Arkansas appeals to the U.S. Court of Appeals for the Eighth Circuit

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Rutledge v. PCMA

- NCPA and the Arkansas Pharmacists Association filed an *amicus curiae* ("friend of the court") brief supporting the State of Arkansas and urging the Eighth Circuit to reverse the district court decision
- The Eighth Circuit Holds that the Arkansas Law is Preempted by ERISA
- Arkansas files a petition asking the Supreme Court to review the Eighth Circuit's decision

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SCOTUS

- Arkansas's Petition: Arkansas argued that the Eighth Circuit's decision is contrary to Supreme Court precedent, and that it involves an important question that the Supreme Court should settle.
- 32 States and D.C.: Filed a brief arguing that the Eighth Circuit's decision is wrong and that the Court should take the case.
- Supreme Court: Asked the U.S. Government for Its Views
- 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.

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Cert Granted

- On January 10th, the Supreme Court granted cert for Rutledge v. PCMA
  - The Supreme Court receives roughly 8,000 petitions each term and grants certiorari in only 80 or so cases.
- The parties and *amici curiae* will file briefs in February and March
  - NCPA and the Arkansas Pharmacists Association will file an *amicus curiae* brief in support of Arkansas (and they will solicit participation from other State associations to join the brief).
- Oral argument will occur in April
- The Court is expected to issue a decision by the end of June.

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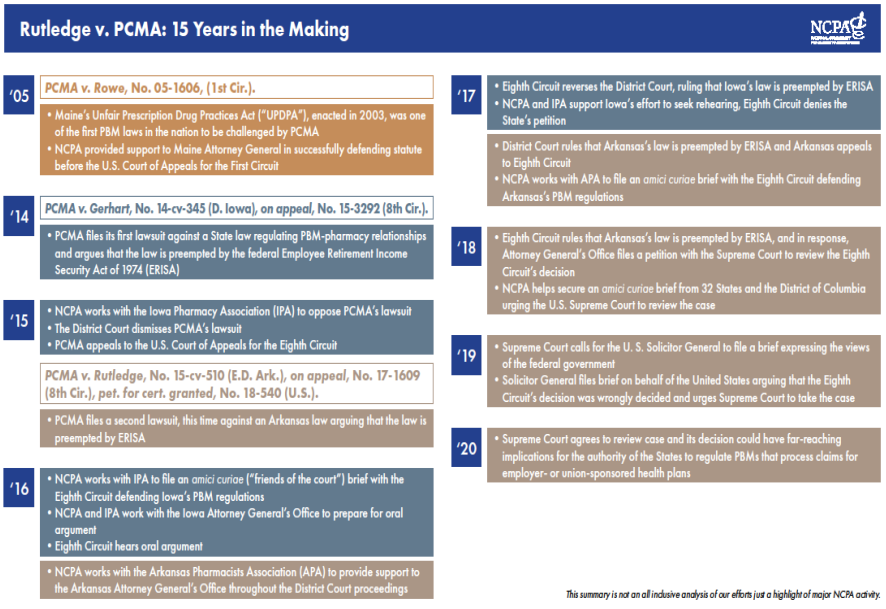

How Should the Court Rule?

- Consensus among the federal government and the vast majority of States that the Eighth Circuit is wrong on ERISA preemption, but there are no guarantees.
- The Supreme Court decides the case that is in front of it and sets nationwide precedent.
  - A decision from the Supreme Court could clarify that ERISA does not preempt State laws that regulate the relationship between PBMs and pharmacies.
  - In addition, the Supreme Court could issue a decision that makes it easier for States to regulate the relationship between PBMs and ERISA plans.
  - For example, states could pass laws providing that PBMs owe fiduciary duties to plans, and that PBMs are required to disclose their profits to the plans they serve.

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Next Steps after SCOTUS Decision

- NCPA and state associations will want to review existing state laws and pending legislation to ensure that they are in line with the Supreme Court's decision.
- Depending on the Supreme Court's ruling, NCPA, state associations, and pharmacists may be able to press for new forms of state regulation of PBMs.
- Alternatively, the Supreme Court could hold that ERISA preempts any State law that regulates PBMs.
  - Even if the Supreme Court declared that ERISA preempts State laws regulating PBM reimbursements to pharmacies, States could continue to apply these laws to non-ERISA plans.

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Self assessment question #1

- How much have DIR fees increased since 2010?
  A. 500%
  B. 1000%
  C. 25,000%
  D. 45,000%

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Self assessment question #2

- What legislation would prohibit PBMs from reimbursing their own pharmacies more than they reimburse other pharmacies?
  A. Phair Pricing Act
  B. Ensuring Seniors Access to Local Pharmacies Act
  C. SUPPORT Act
  D. Prescription Drug Transparency Act

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Self assessment question #3

- When does required e-prescribing for Part D controlled substances go into effect?
  A. Jan. 1, 2020
  B. July 1, 2020
  C. Jan. 1, 2021
  D. July 1, 2021

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Self assessment question #4

- When must pharmacies start only accepting serialized product from their trading partners?
  A. Jan. 1, 2020
  B. Nov. 27, 2020
  C. Jan. 1, 2021
  D. Sept. 1, 2021

Self assessment question #5

- When will a decision in Rutledge v. PCMA be announced?
  A. June
  B. April
  C. August
  D. October

Questions?

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For more information on the SCOTUS case,
visit https://www.ncpanet.org/advocacy/federal-advocacy/scotus

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