The *voice* of the community pharmacist.

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Legislative and Regulatory Update
State of Community Pharmacy

NPSC 2020 Expo
October 13, 2020

Anne Cassity, JD
Vice President, Federal and State Government Affairs
National Community Pharmacists Association

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

The strength of our numbers

NCPA represents the interests of America's community pharmacists, including the owners of **more than 21,000 independent community pharmacies**. Together they represent an **$80 billion health care marketplace** and **employ more than 250,000 people**.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Conflict of Interest Disclosure

- I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Objectives

1. Discuss current federal and state legislative and regulatory advocacy efforts in action today

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

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Self Assessment Questions

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?
2. How much have DIR fees increased since 2010?
3. Federal government has authorized pharmacists-in every state-to order and administer COVID-19 vaccinations for ages 3 and up?
4. When does required e-prescribing for Part D controlled substances go into effect?
5. When are Supreme Court oral arguments for Rutledge v. PCMA?

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA All Things COVID-19

- https://ncpa.org/coronavirus-information

- **HHS authorized all state-licensed pharmacists and pharmacy interns to order and administer vaccines for patients aged 3 through 18 years** during the COVID-19 public health emergency

- **HHS authorized all state-licensed pharmacists and pharmacy interns to order and administer the COVID-19 vaccine,** once one becomes available and FDA-approved, for patients aged 3 years and older during the COVID-19 public health emergency
- Opportunities for enhanced dispensing fees for Medicaid home delivery

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

COVID-19 Vaccine: What should pharmacies do right now?

- Check in with your state pharmacy association to understand and coordinate what efforts are being taken on your behalf to coordinate with other pertinent organizations in the state.
- Identify what your PSAO and wholesaler may also be doing to position your pharmacy to be a COVID-19 vaccinator.
- Assess your capacity for proper cold storage and temperature monitoring of vaccine.
- Update your **NCPDP pharmacy profile** to indicate that your pharmacy is an immunizer.

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

COVID-19 Vaccine: What should pharmacies do right now?

- **Register your pharmacy now on www.vaccinefinder.org – mandatory** to play a role.
- Make sure your pharmacy is able to report data DAILY WITHIN 24-HRS of vaccine administration to your state IIS system (registry) – **this or a CDC alternative method will be mandatory** to play a role.
- Make sure your pharmacy has a patient appointment scheduling system – **necessary / likely mandatory** to play a role.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA All Things COVID-19

- Families First Coronavirus Response Act
  - NCPA successfully lobbied
    - For broad exemption for health care providers from burdensome paid sick leave and FMLA requirements
    - To restrict FMLA for only childcare purposes
    - To exempt small business with fewer than 50 employees from FMLA requirements when it would jeopardize the viability of the business

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA All Things COVID-19

Coronavirus Aid, Relief and Economic Security (CARES) Act 3 and 3.5 packages

- NCPA successfully lobbied for
    - Immediate, readily accessible credit to small business community pharmacies
    - To restore the ability of small business community pharmacies to carryback any net operating losses against previous year tax payments
    - Additional funding for the Paycheck Protection Program (PPP) in legislative package 3.5

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA All Things COVID-19

Coronavirus Aid, Relief and Economic Security (CARES) Act 3 and 3.5 packages

- CARES Act Includes:
    - Paycheck Protection Program for pharmacies with fewer than 500 employees who maintain their payroll for SBA forgivable loans
    - 50 percent refundable payroll tax credits on wages paid (or health benefits provided) up to $10,000 during the crisis
    - Use of HSA/FSA Accounts for OTC Medications
    - Requires Medicare Part B plans to cover the COVID-19 vaccine without cost-sharing
    - Grants for eligible healthcare providers to reimburse health care-related expenses or lost revenues not otherwise reimbursed that are directly attributable to COVID-19

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA All Things COVID-19

- Potential Phase 4 Package
  - NCPA lobbying for:
    - End all retroactive pharmacy DIR fees
    - Hazard pay for pharmacists
    - Civil liability protection for pharmacies/pharmacists
    - Grant provider status to RPh for purposes of flu and COVID-19 testing during public health emergency
    - Additional funding to Small Business Administration for Paycheck Protection Program
    - Inclusion of pharmacists and pharmacy employees in hazard pay legislation
    - Secure liability protection protect independent pharmacies from frivolous lawsuits related to COVID-19
    - Small business relief related to tax, labor proposals

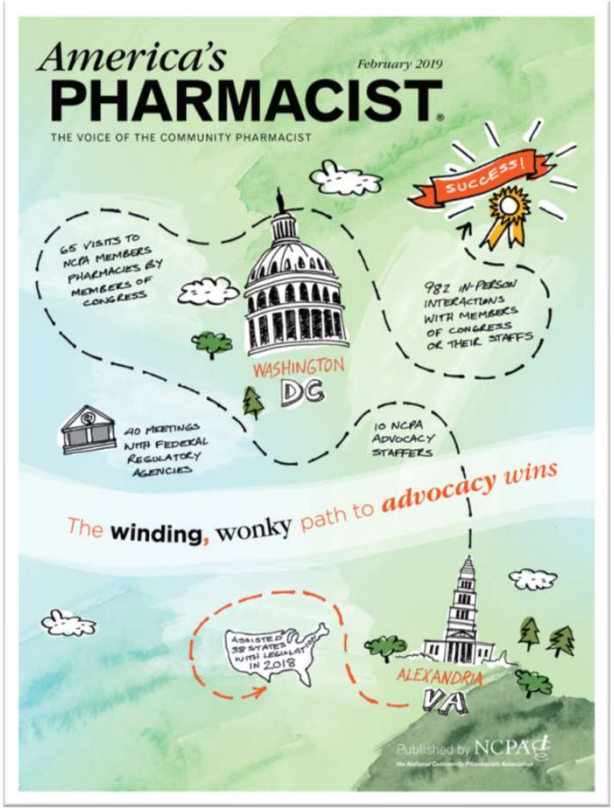
NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

COVID-19 Testing: Medicare Part B and Medicaid

- **Pharmacists' ability to perform COVID-19 diagnostic testing (including serological and antibody tests)under Medicare:**
  - 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
  - Apply for a CLIA certificate of waiver with a CMS 116 form
    - Fee may be waived based on state
  - Apply for a temporary "Independent Clinical Lab" Medicare Part B enrollment to bill Medicare Part B for tests performed.
    - This will result in an additional PTAN
    - Enrollment fee is waived during the Public Health Emergency
- **Pharmacists' ability to perform COVID-19 testing under Medicaid:**
  - **Medicaid may cover COVID-19 tests,** including tests administered in non-office settings (such as parking lots or other temporary outdoor locations), and laboratory processing of self-collected COVID-19 tests that are FDA-authorized for self-collection.
  - **The flexibility** would apply **during any subsequent periods of active surveillance to detect recurrence of the virus.**
  - Summary of NCPA's analysis of Medicare and Medicaid covered testing can be found on the website https://ncpa.org/sites/default/files/2020-05/cms-ifc-2-ncpa-member-summary.pdf

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Current Federal and State Legislative and Regulatory Activities



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

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

PBMs: Market Domination

- PBMs have extraordinary market power
  - 3 PBMs control as much as 76% of the market
  - Fortune 25: #6 United HealthGroup, #7 CVS/Caremark, #22 ExpressScripts
  - Administer plans that touch almost every citizen in every state

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

PBMs: Effect of Lack of Oversight and Regulation- Always Focus on Patient

- On Patients
  - PBM steering to PBM-owned retail, mail order or specialty pharmacies (with whom the patient has no relationship or which may not be geographically convenient)
  - Network access hurdles – particularly in preferred networks – limit patient access to pharmacies
  - PBM practices speed patients into the Medicare Part D "donut hole" more quickly by misrepresenting a medication's negotiated price

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

PBMs: Reality for Community Pharmacies

- ~91% of prescriptions are covered by insurance
  - If medication is covered by insurance, the patient's price is set by the PBM, not by the pharmacy
- What community pharmacies charge patients and are reimbursed is often determined by a competitor
  - PBMs own or are affiliated with competing retail and/or mail-order and/or specialty pharmacies
  - PBMs often require or incent patients to use the PBM-owned pharmacy

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

PBMs: How PBMs Make Money

- Rebates
  - Discounts the manufacturer gives to PBMs for formulary placement
- Spread pricing
  - Profit-taking that results from the difference between what the PBM reimburses the pharmacy for a medication and what it bills the health plan for that medication cost
- Administrative fees paid by plan sponsors
- Administrative fees paid by pharmacies
- Pharmacy price concessions in Part D

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Federal Legislative: NCPA Endorsed Bills

- **The Prescription Drug Pricing Reduction Act, S. 4199 (Sen. Chuck Grassley (R-IA)**
  - Requires pharmacy DIR fees to be included at the point of sale
  - Prohibits spread pricing by PBMs in Medicaid managed care
  - Prohibits Medicaid managed care programs from reimbursing BELOW the state fee-for-service (traditional Medicaid) reimbursement for both ingredient cost and professional dispensing fee
- **Drug Price Transparency in Medicaid Act of 2019, H.R. 5281**
  - Prohibits spread pricing by PBMs in Medicaid managed care
  - Prohibits Medicaid managed care programs from reimbursing BELOW the state fee-for-service (traditional Medicaid) reimbursement for both ingredient cost and professional dispensing fee
  - Similar language was included in House passed H.R. 3

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Federal Legislative: NCPA Endorsed Bills

- **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
  - Prohibits 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
  - Establish an appeals process for pharmacies to resolve drug reimbursement disputes when reimbursement is less than acquisition price
- **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

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

There From the Beginning on DIR Advocacy

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

	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, HHS*

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.*

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

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Pharmacy DIR Reform

Disappointing announcement from HHS/CMS on May 16, 2019-One Year Ago

- *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.*

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA Pharmacy DIR Fee Reform: Next Steps

- Immediate action: work with DIR stakeholders and enact legislation to fix DIR
- 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
- New leadership on White House staff?

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION