NCPA IN ACTION

What have we done for you lately? Here's the lowdown on NCPA's recent advocacy activity — and why it matters.

Supreme Court sets date for PBM case

The Supreme Court will hear the *Rutledge v. PCMA* case on Tuesday, Oct. 6, at 10 a.m. ET. The case was originally scheduled to be heard in April but was pushed back due to COVID-19. The case marks the first time in history that the high court will rule on a case involving PBMs. NCPA and the Arkansas Pharmacists Association jointly commissioned an amicus to support Arkansas Attorney General Leslie Rutledge's appeal to enforce the 2015 pro-pharmacy, pro-consumer legislation that prohibited PBMs from paying pharmacies below cost and allowed pharmacies to refuse to dispense below-cost prescriptions. NCPA's involvement in PBM-related legal cases began 15 years ago, and NCPA's efforts and collaboration with APA began some five years ago.

NCPA LAUNCHES ADVOCACY CAMPAIGN FOR PHARMACY PROTECTIONS

In July, NCPA launched a campaign advocating for legislation that will shield essential small businesses from opportunistic lawsuits, extend the Paycheck Protection Program, provide or ensure hazard pay, and let pharmacists administer tests and vaccines. The "Essential" campaign is aimed at rallying pharmacists and other small business owners to pressure Congress to:

- Expand the Paycheck Protection Program. Continue improving this program, allow businesses that received PPP loans to deduct eligible expenses from their taxes and qualify for the Employee Retention tax credit.
- Recognize pharmacists as health care providers. Pharmacists have been given limited authority to order and administer coronavirus tests during the public health emergency, but obstacles remain. Congress should recognize pharmacists as health care providers and remove barriers to expand testing.
- Approve hazard pay for front-line workers. Congress must provide hazard pay to front line employees, including pharmacy employees. NCPA supports the passage of federally supported premium pay in addition to regular wages for essential workers, including pharmacy staff.
- Offer tax credits to offset costs of safety precautions. Congress needs to recognize the increased financial burden on businesses to safely operate, including the necessity to purchase personal protective equipment and increased expenses for cleaning and sanitation.

"Some of the most vulnerable patients and communities rely on independent pharmacies for care. These are family-owned small businesses, but many are on the brink," says NCPA CEO Douglas Hoey. "Congress and the administration must fix pharmacy direct and indirect remuneration fees, a top priority in ensuring neighborhood pharmacies' long-term survival. And as the pandemic continues, policymakers should also include safeguards in future coronavirus relief legislation so essential businesses can have the resources to cover their expenses, workers can remain employed, and the essential neighborhood pharmacy safety net can serve communities during the pandemic and beyond."

PRESIDENT TRUMP ISSUES DRUG PRICING EXECUTIVE ORDERS

What happened: President Trump issued four executive orders aimed at decreasing the cost of drugs in the United States.

Details: One executive order revives last year's proposed rebate rule for Medicare Part D, and passes rebate savings to patients at the point of sale at the pharmacy counter and directs

THE AUDIT ADVISER

Dispense in original container

PAAS National, the Pharmacy Audit Assistance Service, continues to see audits on medications that should be dispensed in their original container. When a pharmacy dispenses this type of medication in a quantity that is not divisible by a full bottle size, it is a red flag to the PBM and easily recoupable on audit. Common medications we see audited are Onfi, Linzess, and oxcarbazepine suspensions. Reasons medications are required to be dispensed in the original container vary, including sensitivity to light or moisture and possible interactions with pharmacy containers. In some cases, the manufacturer has just simply not studied the medication for storage outside of their own container. No matter the reason, pharmacies must be vigilant in ensuring FDA packaging instructions are followed to avoid audit recoupment.

Additionally, PAAS has started to see unannounced credentialing visit audits for unbreakable packages. Auditors inspect inventory of unbreakable medications, and if discovered opened within the active drug inventory, it will be marked as a deficiency for failing to adhere to the provider agreement. Pharmacies will then need to draft an immediate corrective action plan. When coupled with other deficiencies, and dependent on the severity/frequency, this can lead to termination from the network.

PAAS Tips:

- PAAS National audit assistance members can download our Dispense in Original Container chart at portal.paasnational.com in the Tools & Aids section for a list of common medications that should be kept in their original bottles.
- Label shelves with "Dispense in Original Container" for those products.

See FDA's DailyMed website (dailymed.nlm.nih.gov) for product labeling information.

Trenton Thiede, PharmD, MBA, is chief operating officer at PAAS National, providing expert third party audit advice and FWA/HIPAA compliance.

PAAS National, the Pharmacy Audit Assistance Service, is committed to serving community pharmacies and helping keep hard-earned money where it belongs. Contact us today at 608-873-1342 or info@paasnational.com to see why membership might be right for you.

HHS Secretary Alex Azar to complete the rulemaking process begun in 2019.

More: Trump issued a directive to CMS, effective on Aug. 25, 2020, to set reimbursement rates to the lowest price paid in comparable OECD countries (most favored nation) for Medicare Part B drugs. The administration would permit states, wholesalers, and pharmacies to import FDA-approved drugs from foreign countries to the U.S. for resale. There is also a directive for federally funded community health centers to pass 340B discounts they receive for insulin and EpiPens directly to low-income patients.

NCPA's involvement: Before the orders were signed, NCPA sent a letter to the White House reiterating the association's stance on the removal of the current system of safe harbor protections for rebates involving prescription pharmaceuticals and the creation of a safe harbor protection for certain point of sale reductions in price on prescription pharmaceuticals. NCPA followed the action with a press release.

Looking ahead: NCPA will continue to provide comments as HHS moves these regulatory actions, including the rebate rule, through the rulemaking process.

OKLAHOMA PREVAILS OVER PCMA IN DISTRICT COURT RULING

What happened: A federal district court in the U.S. District Court for the Western District of Oklahoma issued a ruling substantially granting the state of Oklahoma's request to implement its PBM law while it is being challenged before the court in *PCMA v. Mulready*.

Details: The court held that PCMA was unlikely to prevail on the merits of its claims that ERISA preempts the state law provisions that it challenges, meaning the court rejected every one of PCMA's ERISA arguments and rejected the bulk of PCMA's Medicare Part D arguments as well. The ruling provides a pathway for Oklahoma to implement the overwhelming majority of its PBM law while the case is pending.

What it means: The ruling is a positive outcome for

independent pharmacy in Oklahoma. The Oklahoma Pharmacists Association has been working tirelessly on getting this law implemented. NCPA will continue to monitor this case, among others that impact PBM practices across the country.

NCPA, PHARMACY ALLIES DEMAND ACTION ON DIR FEES

What happened: NCPA, along with the American Pharmacists Association, FMI-The Food Industry Association, National Association of Chain Drug Stores, National Association of Specialty Pharmacy and National Grocers Association, sent a letter to HHS Secretary Alex Azar to demand action on pharmacy DIR fees.
The details: The letter emphasized that failure to enact pharmacy DIR reform along with the rebate rule called for in President Trump's executive order will be disastrous for patients and pharmacies. The organizations also noted that eliminating retroactive pharmacy DIR fees would save Medicare beneficiaries at least $7 billion in reduced cost sharing over 10 years. Eradication of pharmacy DIR fees remains NCPA's top priority and has been the focus of numerous previous meetings and calls with CMS, members of Congress, and the administration. NCPA will continue to aggressively advocate for this reform.



PHARMACY OWNER WINS CONGRESSIONAL PRIMARY

What happened: Candidate and pharmacy owner Jerry Carl won the Republican primary in Alabama's 1st District on Tuesday. Carl advances to the November general election for a House seat, where he will face Democratic candidate James Everhart to succeed Rep. Bradley Byrne (R), who did not seek reelection.
About Carl: Carl owns a specialty pharmacy that serves patients with hemophilia and he will be an advocate for community pharmacy if elected in November. The NCPA PAC was proud to support Carl with a contribution to his campaign and urged NCPA members in his district to support him at the polls.
Give to the PAC: If you're an NCPA member, it is quick and easy to support the NCPA PAC and, in turn, pro-pharmacy political candidates like Jerry Carl. Just text PAC to 703-688-8086.

OHIO SUES EXPRESS SCRIPTS

What happened: Ohio Attorney General Dave Yost filed a lawsuit against Express Scripts, alleging millions in overcharges to the state, specifically the Ohio Highway Patrol Retirement System.
Details: "This particular PBM egregiously charged for services it didn't deliver," Yost said. "Its repeated breaches cost Ohioans millions, and we want our money back." Yost filed a lawsuit against OptumRx last year alleging overcharges to the Ohio Bureau of Workers' Compensation. That case is still pending.

FDA TO REQUIRE OPIOID DRUG LABELS TO INCLUDE NALOXONE INFORMATION

What happened: On July 23, the FDA announced that providers should discuss the availability of naloxone to all patients who are prescribed opioid pain relievers.
Details: They should also consider prescribing it to patients who are at increased risk of opioid overdoses, such as patients who are also using benzodiazepines or other medicines that depress the central nervous system, have a history of opioid use disorder, or who have experienced a previous overdose.

NCPA PROVIDES FEEDBACK TO USP ON BIOSIMILAR NAMING

What happened: In a joint letter with NACDS, NCPA shared the perspectives and concerns of community and long-term care pharmacists in response to USP's request for stakeholder feedback on their proposal regarding biologics nomenclature.
Details: Naming policies for biological and biosimilar drugs have significant patient safety implications, and NCPA supports nomenclature consistent with the naming conventions for brand and generic small molecule drugs, which promotes confidence in biologicals.

FEDS REPORTEDLY INVESTIGATING LARGEST MEDICAID MANAGED CARE PROVIDER

What happened: According to the *Ohio Capital Journal*, federal officials are investigating Centene, the nation's largest Medicaid managed care provider.
Details: The investigation is said to be related to a report that the company effectively billed the state of Ohio for duplicate services while working with CVS Health. Results of the investigation could shine a light on PBM practices in Ohio and other states and lead the way toward an alternative payment model such as NADAC. The *Ohio Capital Journal* is an independent, non-profit publication that focuses on Ohio government.

NCPA SUPPORTS IMPLEMENTATION OF EPCS RULE

What happened: NCPA joined a coalition of stakeholders in support of implementation of the e-Prescribing for Controlled Substances rule on the statutory deadline of Jan. 1.
About the rule: EPCS is a tool in combatting the opioid epidemic and can assist in reducing fraudulent prescriptions without negative impacts on care or significant interruptions of access to prescription drugs under

Medicare Part D. Currently, more than 98 percent of pharmacies are equipped to comply with EPCS.

NCPA SUPPORTS LEGISLATION TO SIMPLIFY PPP LOAN FORGIVENESS

What happened: NCPA joined more than 130 other organizations on a letter of support for S. 4117, *The Paycheck Protection Program Small Business Forgiveness Act*.
About the bill: This bipartisan legislation would forgive PPP loans of less than $150,000 upon the borrower's completion of a simple, one-page forgiveness document. PPP loans of $150,000 and under account for 86 percent of total PPP recipients, but less than 27 percent of PPP loan dollars.

CARTER, HOEY OP-ED STRESSES IMPORTANCE OF PHARMACISTS DURING PANDEMIC

What happened: *The Hill* published an op-ed by U.S. Rep. Buddy Carter (R-Ga.) and NCPA CEO Douglas Hoey titled "Pharmacists Play a Critical Role in Defeating COVID-19."
What they said: In the piece, Carter and Hoey stress the importance of allowing pharmacists to practice at the top of their license in addressing the COVID-19 pandemic.

COVID-19 PUBLIC HEALTH EMERGENCY DECLARATION RENEWED

What happened: On July 25, HHS Secretary Alex Azar extended the nationwide COVID-19 public health emergency that was declared earlier this year for an additional 90-day period.

NAIC RELEASES DRAFT PBM MODEL LEGISLATION

What happened: The National Association of Insurance Commissioners' PBM Regulatory Issues Subgroup released a first draft of its PBM model legislation.
Details: Although still a work in progress, the draft language would require PBMs to obtain a license from the state's insurance commissioner, permit the commissioner to adopt PBM regulations, and prohibit certain PBM abuses (such as retroactive payment reductions, spread pricing, and self-dealing).
About the group: The subgroup, which has been working on this legislation for over a year, is made up of insurance commissioners and their staffs from across the country. NCPA has worked with NAIC throughout this process and had the opportunity to present to the subgroup on the impact PBMs are having on pharmacies, patients, and payers/taxpayers.

Information is current as of Aug. 4, 2020.

Do you know what to do?



SafeNeedleDisposal.org

Information & free resources on safe needle disposal