NCPA in Action

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

NCPA cheers SCOTUS decision to rule on states’ authority to regulate PBMs

NCPA cheered the U.S. Supreme Court’s decision Jan. 10 to hear an Arkansas case to decide whether ERISA preempts (supersedes) a state law that regulates PBMs.

“The pharmacy benefit managers have virtually no oversight, and as a result they behave like monopolies,” said NCPA CEO B. Douglas Hoey. NCPA pushes for state laws that would end PBM abuses. The latest battle comes from a case in Arkansas, where the state was blocked by a lower court ruling from enforcing Act 900, a law that effectively prohibits PBMs from reimbursing pharmacies below the pharmacies’ cost to acquire the medication and includes provisions that would disclose to consumers and plans the hidden profit motives of PBMs. NCPA together with the Arkansas Pharmacists Association filed a brief supporting the state before the U.S. Court of Appeals for the Eighth Circuit, and will file a similar brief before the U.S. Supreme Court. The court will likely hear oral arguments in early spring. It will render a decision before the end of June, which marks the end of the court’s current term.

Here are some of the actions that eventually brought the issue to the Supreme Court:

**What happened:** The United States Solicitor General filed an amicus curiae brief on behalf of the federal government arguing that the Supreme Court should review the Eighth Circuit’s holding that ERISA preempts state laws that regulate PBM-pharmacy reimbursements. In the view of the federal government, the Eighth Circuit’s ruling is “incorrect” and “contrary to [the Supreme] Court’s precedent and the decisions of other courts of appeals.” Further, in the brief, the federal government urges the Supreme Court to review the Eighth Circuit’s incorrect ruling.

The opinion by the OSG was seen as important because a favorable review greatly increased the likelihood that the Supreme Court would agree to grant cert or hear a particular case. NCPA was active in this effort from the beginning and commends the Arkansas Pharmacists Association for its work. NCPA has created a Battleground: SCOTUS webpage for updates as the case proceeds to the Supreme Court www.ncpanet.org/advocacy/federal-advocacy/scotus.

NCPA joined with the Arkansas Pharmacists Association in filing a brief supporting the state before the U.S. Court of Appeals for the Eighth Circuit, with the Supreme Court deciding to take the case.

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NCPA’S HAUSER TESTIFIES BEFORE SENATE JUDICIARY COMMITTEE

NCPA Vice President of Policy and Government Affairs Operations Ronna Hauser, PharmD, testified at a Senate Judiciary Committee hearing on opioids. Hauser urged the committee to consider expanding the pharmacist’s role to help combat the opioid crisis and recommended that the DEA update its pharmacists handbook, which details the DEA’s position on how pharmacists should handle, dispense, and dispose of controlled substances. The handbook has not been updated since 2010.

The bill would also require drug DEA-registrants (which includes pharmacies) to report the sale, delivery, or other disposal of all controlled substances to other DEA registrants monthly, rather than quarterly basis as current law requires.

‘PILL MILL’ LEGISLATION INTRODUCED IN SENATE

What happened: Sen. Dianne Feinstein (D-Calif.), along with Sens. Chuck Grassley (R-Iowa), Shelley Moore Capito (R-W.Va.) and Richard Durbin (D-Ill.), introduced S. 3070, the Preventing Pill Mills Through Data Sharing Act.

What the bill would do: The bill would give DEA additional tools to hold drug distributors, manufacturers, and pharmacies accountable for identifying, reporting and stopping suspicious orders of controlled substances. The bill would also require drug DEA-registrants (which includes pharmacies) to report the sale, delivery, or other disposal of all controlled substances to other DEA registrants monthly, rather than quarterly basis as current law requires.

NCPA’s input: NCPA secured an important exemption on the reporting requirements for all pharmacy transfers for specific patient need. This means a pharmacy is only required to report to ARCOS if the pharmacy is distributing/selling controlled substances to another DEA-registrant and that distribution/sale is not for a specific patient need.

NCPA TALKS DRUG PRICING WITH HHS

What happened: NCPA staff met with John Brooks, HHS senior advisor for drug pricing reform and CMS principal deputy director of the Center for Medicare, to discuss pharmacy DIR fees, spread pricing in Medicaid managed care, importation, and the role of pharmacists as service providers.

Looking ahead: NCPA continues to have frequent contact with HHS and CMS officials in an effort to advance NCPA’s top advocacy priorities.

HOUSE PASSES DRUG PRICING BILL

What happened: The House of Representatives passed H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, a bill that for the first time would require the government to directly negotiate prices for costly prescription drugs.

Pharmacy provisions: The bill includes language to standardize pharmacy quality measures as a step toward addressing pharmacy DIR fee reform. NCPA worked with other pharmacy partners and congressional champions to secure this provision.

NCPA support: NCPA supported an amendment by Rep. Mary Gay Scanlon (D-Pa.) to ban the use of spread pricing by PBMs as it relates to Medicaid. The amendment would require Medicaid managed care PBMs to reimburse pharmacies based on ingredient cost and a professional dispensing fee, which must be no less than the professional dispensing fee under the fee-for-service program. Ingredient cost would be based on data from the NADAC report.

Bleak forecast: Majority Leader Mitch McConnell (R-Ky.) has ruled out taking up the House package in the Senate, and President Trump has said he would veto the House bill should it reach his desk.

Looking ahead: NCPA will continue to work with the House and Senate in the hopes of getting a bipartisan drug pricing bill passed to meaningfully address pharmacy DIR fee reform, as well as ban spread pricing in Medicaid and set a reimbursement floor for pharmacies in the program.

Pharmacy Visit

Rep. Cynthia Axne (D-Iowa) visited Montross Pharmacy in Winterset, Iowa, and met with owner Jeff Olson.
NCPA SHARES RECOMMENDATIONS WITH CALIFORNIA PBM TASK FORCE

What happened: NCPA submitted comments to the California PBM Reporting Task Force. The task force must recommend data points to be reported by PBMs to the state so that the state can better control drug prices.

Our two cents: NCPA focused its comments on the importance of requiring the reporting of manufacturer rebates, spread pricing, and retroactive claim adjustments and fees.

NCPA TO FDA: RECONSIDER PROCESSES AND SUBSTANCES UNDER 503A

What happened: NCPA submitted comments to FDA on its amendments to the list of bulk drug substances that can be used to compound drug products under Section 503A of the Federal Food, Drug, and Cosmetic Act (503A Proposed Rule).

NCPA’s recommendation: NCPA wants the FDA to revise the process it uses to develop the list of bulk drug substances as there is a lack of clear guidance. NCPA supports the addition of six substances: 7-Keto Dehydroepiandrosterone (DHEA), Acetyl-L-Carnitine (ALC), Chondroitin Sulfate, Chrysin, Deoxy-D-Glucose, and Kojic Acid.

Looking ahead: NCPA will continue to engage with the FDA to ensure continued access to medically necessary compounded medications.

IN THE STATES:

• New Jersey

The New Jersey Legislature again has passed a bill addressing retroactive PBM fees and claim adjustments. The legislature passed the legislation over the summer, but Gov. Phil Murphy (D) conditionally vetoed it. After tweaking the bill, the legislature passed it again. The bill:
  – Prohibits a PBM from retroactively reducing a claim after adjudication.
  – Applies MAC transparency laws to all reimbursement methodologies, including generic effective rate.
  – Prohibits a PBM from requiring arbitrary accreditation/certification requirements as a condition of network participation.
  – Protects a pharmacy’s authority to offer delivery services.
  – Permits the insurance commissioner to review PBM compensation programs to ensure they are fair and reasonable.

• New York

Common-sense PBM reform suffered a blow in the final days of 2019, with news that New York Gov. Andrew Cuomo (D) vetoed legislation that would have finally forced transparency and accountability on the PBMs. NCPA, along with state-based pharmacy groups, lobbied aggressively for the bill and expressed disappointment with the governor’s decision.

In a statement, NCPA CEO B. Douglas Hoey said, “Community pharmacists are very disappointed that Gov. Cuomo has rejected common-sense PBM reform. As a result of this veto, PBMs will be able to continue operating as largely unregulated middlemen in the drug supply chain in New York, driving up health care costs for consumers and plan sponsors.”

The Pharmacists Society of the State of New York and FixRx sponsored a rally in Albany, N.Y., on Jan. 8 to protest Gov. Andrew Cuomo’s (D) veto of a PBM regulation bill (S6531). NCPA advocacy team member Anne Cassity also attended the rally.
Florida State Rep. Jackie Toledo (R-Tampa) has introduced HB 961, a comprehensive PBM regulation bill. The bill’s introduction is the result of the efforts of Small-business Pharmacies Aligned for Reform (SPAR), the Florida Pharmacy Association, and other community pharmacy advocates across the state. The bill would:

- Prohibit the practice of spread pricing.
- Apply “maximum allowable cost” protections to all reimbursement methodologies.
- Prohibit PBMs from charging certain adjudication fees.
- Prohibit PBMs from reimbursing pharmacies at a rate that is less than the actual cost of the drug, including a dispensing fee.
- Prohibit PBMs from retroactively denying or reducing a claim amount.
- Establish several network requirements protecting patient access to pharmacy services.
- Prohibit PBMs from making referrals.
- Establish that a PBM has a fiduciary duty to covered individuals and payers.
- Require PBMs to file quarterly drug pricing reports with the state.

**NCPA ON THE ROAD**

- **Reema Taneja**, NCPA’s director of policy and regulatory affairs, attended the American Bar Association’s Annual Washington Health Law Summit.

*Information is current as of Jan. 13, 2020.*

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**THE AUDIT ADVISER**

**Clinical notation requirements**

Making clarifications and changes to prescriptions is part of the daily routine in pharmacies, and the continuous changes in formularies and required documentation for audit purposes is never ending.

While it is imperative that the prescription you are dispensing is complete, you also need to make sure any additional documentation you add has all the required elements. During an audit review, a prescription could be marked invalid if the pharmacy does not have enough documentation included in the clinical notation. This was the case on a recent set of results from EnvisionRx.

Several of the PBM provider manuals, including those from EnvisionRx, MedImpact, Express Scripts, and Prime Therapeutics, state that the name of the caller at the prescriber’s office must be documented for any verbal communication authorizing changes. Like a verbal or telephone order, some states also require specific information, such as first and last names, and title to be documented on the prescription. The initials or name of the person from the pharmacy who made the call should also be included in the notation. This information helps support that the claim is accurate and verifiable.

**PAAS Tips:**

- When verifying instructions or max daily dose with a prescriber, be sure that same information is included on the patient’s label.
- Clinical notations should contain four elements:
  1. Date call was made to prescriber’s office
  2. Name of person you spoke with, and credentials. Pharmacies should avoid using “OK’d by MD.”
  3. Information that was clarified or confirmed
  4. Initials or name of pharmacy personnel who made the call
- If the prescription is audited, an auditor will need to see the documentation, whether on the prescription or in an electronic notation. If you documented on the prescription, you may need to re-scan it into your computer system afterward.
- Talk to your pharmacy system vendor about using the RxChange message type to keep prescription changes in the electronic workflow. If your system has enabled RxChange, ask what controls are in place to ensure that when you sent an RxChange request that it only goes to prescribers who are likewise enabled. This is a relatively new type of message for pharmacies and prescribers so it might be bumpy to start, but may provide better documentation in the long run.

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