

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 Congressional Pharmacy Fly-In coming up

Registration for NCPA's 2020 Congressional Pharmacy Fly-In is open. The April 21-22 Fly-In allows pharmacy owners to meet with legislators or their key staff about community pharmacy's legislative priorities. You'll fly in, spend a few hours with the NCPA Advocacy Center staff, and then have some face time with your members of Congress and/or their staff. It's your chance to tell them how their votes affect your business and the patients you serve. This year, there is also the added possibility that the Supreme Court may hear oral arguments in *Rutledge v. PCMA* during the Fly-In week. Don't miss out.



2020 CONGRESSIONAL PHARMACY FLY-IN
April 21-22, 2020
Alexandria, Va. / Washington, D.C.



DOJ, FTC CONSIDER CHANGES TO VERTICAL MERGER GUIDELINES

What happened: The Department of Justice and the Federal Trade Commission have proposed an overhaul of antitrust rules for vertical mergers. A vertical merger is the merger of two companies that operate in the same supply chain but don't directly compete with one another, such as CVS/Caremark/Aetna, Cigna/Express Scripts, and UnitedHealth/Optum Rx.

NCPA's take: NCPA believes guidelines need to be stricter and submitted comments to that effect by the Feb. 26 deadline. And NCPA also provided draft comments for NCPA members to submit prior to the deadline.

NCPA ASKS FOR PROTECTIONS IN TRANSPARENCY IN COVERAGE PROPOSED RULE

What happened: NCPA submitted comments to the IRS, Employee Benefits Security Administration, Department of Labor, and CMS on the Transparency in Coverage Proposed Rule.

What it does: The departments propose to require group health plans and health insurance issuers to make cost-sharing information available through an internet-based self-service tool.

NCPA's take: NCPA urged the departments to establish clear operating rules around such a tool, prohibit plans and issuers from using this tool to steer patients to select pharmacies, and ensure accurate information is provided to avoid the dissemination of misinformation regarding the cost of prescription drugs. NCPA also recommended that the departments work with NCPDP on a national standard for this tool to offer consistency throughout the industry.

NCPA JOINS INDUSTRY TO ENHANCE BIOSIMILAR INSULIN ACCESS

What happened: NCPA joined industry stakeholders to show support for FDA's assessment that if a manufacturer demonstrates its proposed biosimilar insulin is "highly similar" to its reference product, the agency may waive the need for the manufacturer to conduct additional immunogenicity studies in order for the product to be deemed interchangeable with its reference product.

NCPA's suggestions: NCPA and other organizations encouraged the agency to use its experience with insulin to further streamline regulatory requirements for biosimilar and interchangeable biologics broadly to enhance biosimilar availability.



THE AUDIT ADVISER

PBMs enforcing return to stock policies

It is common practice for PBMs to recoup claims in full for prescriptions with a patient pick-up (or delivery) date after the return-to-stock (also known as unclaimed prescriptions) timeframe listed in their provider manuals. An integrated point-of-sale system can generate a list of prescriptions near the end of the timeframe. This list can be used to call patients and remind them to pick up their prescription, offer delivery, or identify claims that should be reversed and the medication returned to stock. The Pharmacy Audit Assistance Service recommends that pharmacies implement a procedure to only allow medications to remain for the shortest outlined time, which is 10 days.

Major PBM return to stock timeframes:

- MeridianRx: 10 days
- Express Scripts: 13 days
- Aetna: 14 days
- Caremark: 14 days
- EnvisionRx: 14 days
- MagellanRx: 14 days
- MedImpact: 14 days
- OptumRx: 14 days
- Prime Therapeutics: 14 days
- Humana: 15 business days

Return-to-stock policies are not the only pick-up date issue that pharmacies should be aware of. PAAS has recently seen PBMs try to recoup for not having the “Do Not Dispense After” date noted on isotretinoin prescriptions. While the only isotretinoin risk evaluation and mitigation strategy (REMS) requirement is to have the RMA number from iPledge noted on the hard copy, pharmacies should have a system in place to make sure the prescription is not sold after the date iPledge mandates. This could be as easy as ordering stickers to place on prescription bags from iPledge or even simply writing the date on the bag itself.

Another frequent target for recoupment is dispensing a medication before the date it was billed. PAAS recommends setting up your pharmacy billing to make sure medication is billed the same day, or before, it is picked up or delivered.

Finally, Medicare Part B only allows a medication to be filled on the same day it is picked up or delivered. Remember that if patients are coming into the store to pick up their medication, you need to have documented proof of the refill request.

By Jason Crawford, RPh, PAAS National®, the Pharmacy Audit Assistance Service. For more information, call 888-870-7227 toll-free, or visit www.paasnational.com.

NCPA COMMENTS ON PROPOSED CALIFORNIA REGULATIONS

What happened: NCPA submitted comments to the California Board of Pharmacy commending its efforts on adopting regulations for the independent furnishing of HIV PrEP and PEP medications by pharmacists.

NCPA's comments: NCPA urged the board to allot sufficient training time to address the challenges and knowledge gaps in counseling unique populations, recommending appropriate vaccinations, and understanding HIV disease state and HIV medications along with how and when to exercise appropriate patient follow-up or refer the patient to necessary resources and health care providers. NCPA recommended a minimum of three hours of HIV training to ensure a high standard of care in carrying out the responsibilities to lower the rates of HIV infection throughout the state.

NCPA URGES OIG TO INCLUDE PHARMACIES UNDER NEW SAFE HARBORS

What happened: HHS released two proposed rules in October to modernize and clarify the regulations that interpret the federal anti-kickback statute and physician self-referral law (Stark Law). The anti-kickback statute and Stark Law proposed rules are part of HHS' sprint to remove potential regulatory barriers to care coordination and value-based care.

NCPA's involvement: NCPA submitted comments to HHS' Office of Inspector General on the anti-kickback statute proposed rule, which modifies existing safe harbors and creates new ones. Of particular concern to community pharmacy was OIG's proposal to not include pharmacies under its new value-based arrangement safe harbors. These safe harbors aim to promote care coordination and remove barriers to value-based care. OIG expressed concern that because pharmacies

primarily provide items, that pharmacies' participation in value-based arrangements may not further care coordination. NCPA provided numerous examples of how pharmacies are successfully providing value-based services to their patients on a regular basis through medication adherence counseling, chronic disease management, and by participating in clinically integrated networks.

NCPA URGES CMS TO RECOGNIZE PHARMACIST SERVICES BEYOND DISPENSING

What happened: Following President Trump's *Protecting and Improving Medicare for Our Nation's Seniors* executive order, CMS requested additional input on eliminating specific Medicare regulations that require more stringent supervision than existing state scope of practice laws or that limit health professionals from practicing at the top of their license.

NCPA's take: In comments to CMS, NCPA said that pharmacists improve patient care and outcomes when they collaborate with health care professionals. However, restrictive regulations hinder pharmacists' ability to continue providing this care at the federal level, especially when state laws are already expanding scope of practice. NCPA urged CMS to enhance coverage of pharmacist-provided care services and reevaluate strict supervision requirements as well as coverage policies for incident-to services. NCPA also joined forces with other national pharmacy organizations encouraging increased access and reimbursement for pharmacist provided services at the federal level.

Going forward: NCPA will continue engaging with CMS to educate the agency about the importance of allowing pharmacists to practice at the top of their professional licenses and education.

HHS RELEASES FINAL RULE ON SCHEDULE II PHARMACY TRANSACTIONS IN MEDICARE PART D

What happened: HHS issued a final rule modifying the requirements for use of existing standards for the electronic transmission of retail pharmacy transactions for drugs subject to Schedule II of the Controlled Substances Act.

About the rule: HHS indicates that HIPAA requires HHS to adopt standards for the electronic transmission of certain health care administrative transactions conducted between health care providers, health plans, health care clearinghouses, and other entities. HHS indicates the modification in the final rule will enable covered entities to determine whether a prescription is a "partial fill," or a



refill. According to information in the final rule, the standards apply in the Medicare Part D program. Once the rule goes into effect 60 days from its Jan. 24, 2020, publication in the *Federal Register*, pharmacies should be able to use "quantity prescribed" and "quantity dispensed" fields when dispensing CII prescriptions.

Why the change: The department said this is a technical fix to take advantage of a clarification that incrementally filling a CII prescription is not the same as a refill, which DEA still forbids.

USP HOLDS HEARING ON <795> AND <797>

What happened: The USP Appeals Panel heard from compounding industry stakeholders during a hearing to review compounding pharmacies' concerns with overly restrictive beyond-use-dates in USP chapters <795> and <797>.

NCPA support: NCPA attended the hearing to support these concerns, as outlined in a letter submitted to USP with the American Pharmacists Association.

Going forward: Due to these appeals, USP has indefinitely postponed enforcement of <795> and <797> until the current appeals process resolves. The decision of the Appeals Panel will be final.

IN THE STATES

Florida

What happened: A report released by the Florida Pharmacy Association and American Pharmacy Cooperative Inc. exposes the way PBMs and Medicaid managed care organizations push prescriptions and taxpayer dollars to pharmacies they own or control.

NCPA's take: "This report reinforces the need for Congress to reform Medicaid managed care," NCPA CEO Douglas Hoey said. "It's also a bright red flag for policymakers in every state to scrutinize their respective Medicaid programs for this kind of anti-competitive, anti-patient behavior."

What happened: Florida pharmacists also rallied in Tallahassee to show support for PBM legislation under consideration in the Florida Legislature, demonstrating that it's time the state legislature puts patients, taxpayers and Floridian-owned community pharmacies before the interests of out-of-state unregulated PBMs.

NCPA's involvement: NCPA was a sponsor of the PBM reform rally and will continue to work with pharmacy allies in the state to enact meaningful PBM reform.

Pennsylvania

What happened: Pennsylvania Auditor General Eugene DePasquale (D) urged the state Senate to pass legislation to increase PBM transparency and accountability

in the commonwealth, specifically highlighting HB 941, HB 943, and HB 944. In December 2018, DePasquale released an audit that found that the commonwealth's Medicaid drug spend more than doubled since PBMs begin administering the Medicaid drug benefit in 2013. Additionally, PBMs were able to operate with little to no state or federal oversight.

NCPA's involvement: NCPA has been working with DePasquale since 2018 to shed light on PBM abuses in Pennsylvania. During that time, NCPA staff has testified before the auditor general in Harrisburg, attended a press conference at a community pharmacy outside Scranton, and hosted the auditor general and his staff at NCPA's offices.

New Mexico

What happened: NCPA, along with the American Society of Health-System Pharmacists, National Association of Chain Drug Stores, and National Alliance of State Pharmacy Associations, sent a letter urging New Mexico Gov. Michelle Lujan Grisham (D) to support HB42.

About the bill: The bill would require reimbursement of patient-care services provided by appropriately-certified pharmacists.

Virginia

What happened: The Virginia Senate Committee on Commerce and Labor reported SB 251 is out of committee.

About the bill: The bill would require PBMs to register with the commonwealth, limit PBM adjudication fees, and protect patient choice of pharmacy. NCPA sent a

letter to the Virginia Senate Commerce and Labor Committee supporting the bill.

Wisconsin

What happened: The Wisconsin Assembly Committee on Health heard testimony on AB 114.

About the bill: Bill advocates say AB 114 provides common-sense solutions by increasing PBM transparency and accountability. Specifically, AB 114 prohibits clawbacks greater than the patient's copay, prohibits penalizing pharmacies for sharing lower-cost payment options with their patients (gag clauses), limits drug substitution, and prohibits misleading advertising by PBMs for the purpose of steering patients. NCPA Director of State Government Affairs **Matt Magner** testified at the hearing.

NCPA ON THE ROAD

- NCPA's Director of Policy and Regulatory Affairs **Reema Taneja** presented on a 2020 Federal Update for Community Pharmacies at the Florida Pharmacy Association's Regulatory and Law Conference.
- NCPA's VP of Policy and Government Affairs Operations **Ronna Hauser** was a panelist at the 2020 State of Reform Health Policy Conference in Austin. Hauser presented on "Measuring Value in the PBM and Pharmacy Space" with representatives from Navitus and Methodist Hospital.

Information is current as of Feb. 10, 2020.



Above: Matt Magner and Wisconsin pharmacists rally in support of AB 114. Left: Magner testifies at the hearing on Wisconsin AB 114.