Rep. Buddy Carter to lead House floor discussion on PBM transparency

On May 9th, Rep. Buddy Carter (R-Ga.) plans to host a Special Order on the House floor to discuss the need for PBM transparency and to express support for the Trump Administration’s proposed rules to eliminate retroactive pharmacy DIR fees and pass through manufacturer rebates to patients. Rep. Carter has invited other community pharmacy champions in the House of Representatives to join him to speak on the House floor. While the exact timing depends on the House’s vote schedule for the day, it is anticipated that the speeches should begin around 8:00 pm.

Former HHS Sec. Tommy Thompson voices support for CMS’ pharmacy DIR proposal

This week, former HHS Sec. Tommy Thompson tweeted support for CMS’ pharmacy DIR proposal, noting that it would save Part D beneficiaries $7-9 billion at the pharmacy counter and urged Sec. Azar “to fulfill the promise to reduce drug prices for Americans.” Help amplify his message to the Trump administration by liking, commenting on, and retweeting Sec. Thompson’s tweet.

House Judiciary Committee advances prescription drug pricing bills

This week, the House Judiciary Committee advanced 4 bills with unanimous bipartisan support aimed at lowering prescription drug prices by increasing competition. The Committee advanced the following legislation to the full House of Representatives by voice votes:

• H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act, introduced by Chairman Jerry Nadler (D-N.Y.) and Ranking Member Doug Collins (R-Ga.), to prohibit prescription drug companies from compensating other drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market;
• H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, introduced by Reps. David Cicilline (D-R.I.), Jim Sensenbrenner (R-Wis.), et al, to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar version of those drugs and biological products;
(FTC) to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns; and

• H.R. 2376, the Prescription Pricing for People Act, introduced by Rep. Collins (R-Ga.), to require the FTC to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations.

CBO issues cost estimate for HHS’ proposed “rebate” rule
This week, the Congressional Budget Office (CBO) released a financial score on the recently proposed HHS OIG Safe Harbor rule to pass through rebates to patients in Medicare Part D and Medicaid managed care programs. The CBO score states that if the proposed rule is finalized in its current form the change would increase federal spending by $177 billion between 2020 and 2029. NCPA submitted comments to this proposal in early April focusing on 7 minimum requirements that community pharmacists would need before supporting such a proposal.

E&C Health Subcommittee holds Medicare drug pricing hearing
This week, the House Energy and Commerce Health Subcommittee continued its focus on prescription drug pricing, holding a hearing to examine options to reduce prescription drug costs in Medicare Parts B and D. The hearing focused on recommendations by the Medicare Payment Advisory Commission (MedPAC), and discussed a range of policies, including restructuring the Medicare Part D benefit, modifying Medicare Part B physician reimbursement, and establishing site-neutral payments. Members of both parties, including Chairman of the full E&C Committee Frank Pallone (D-N.J.) and Rep. Larry Bucshon (R-Ind.), emphasized MedPAC’s role providing nonpartisan advice to Congress. Subcommittee Chairwoman Anna Eshoo (D-Calif.) cautioned that MedPAC must pay more attention to the effects of its recommendations on patients. Dr. James Mathews, MedPAC Executive Director, the only witness, testified that high prices for prescription drugs make it difficult to ensure patient access to appropriate medications while protecting taxpayers and beneficiaries. He described Commission recommendations to modify Medicare Parts B and D to address incentives leading to higher costs. Rep. Buddy Carter (R-Ga.) asked Dr. Matthews about the impacts of pharmacy DIR fees, who agreed with Rep. Carter on the problematic rise of pharmacy DIR fees since 2013 and the need to reform them.

House Rules Committee considers “Medicare for All”
On Tuesday, the House Rules Committee held a hearing on H.R. 1384, the Medicare for All Act of 2019, legislation intended to establish a comprehensive, national health insurance program for all Americans through an enhanced Medicare program. The hearing represented the first congressional hearing on “Medicare for All” and highlighted sharp partisan disagreements over the future of the U.S. health care system. Rules Committee Chairman James McGovern (D-Mass.) emphasized the legislation would improve access and reduce costs for Americans. Democrat Members generally supported the legislation, noting it would transfer burdens from patients to the government, while Republicans stressed the dangers of eliminating private coverage and finding ways to fund the program. Chairman McGovern indicated the Ways and Means Committee also plans to hold a hearing on a single payer health care system.

E&C Health Subcommittee to hold hearing on the drug supply chain/lowering prescription drug costs
Next week, the E&C Health Subcommittee will hold a hearing titled “Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain.” In announcing the hearing E&C Committee Chairman Frank Pallone (D-N.J.) and Health Subcommittee Chairwoman Anna Eshoo (D-Calif.) stated “The drug supply chain is comprised of drug manufacturers, pharmacy benefit managers, insurers, hospitals, physicians,
pharmacies, and patients—a stakeholder from each link in the chain will be testifying. This hearing will get to the root causes of high prescription drug costs, how prices are set, and how each stakeholder can lower prices so that Americans can afford the care they need.“ Additional Information for this hearing, witness list and testimony, and a live webcast, will be posted here as they become available.

**Invite your legislator for a visit during the Memorial Day in-district work period**
The next in-district work period for Members of Congress is scheduled to coincide with Memorial Day, May 25-June 2. It is not too early to extend an invitation to your legislator to visit your pharmacy during this week or to schedule a group meeting with multiple community pharmacists with legislators and discuss priority issues. These carry extra value if your legislator is new to Congress so you can familiarize them with community pharmacy issues or if they are a member of the Energy and Commerce or Ways and Means health subcommittees, the starting points for much of community pharmacy’s legislation in the House.
Pharmacy visits and face-to-face meetings are tremendously effective ways to communicate with legislators and to establish yourself as a resource to them as issues arise. Visit NCPA’s pharmacy visits webpage or contact Michael Rule at michael.rule@ncpanet.org for tips on arranging a visit with your legislator.

**Oklahoma Governor vetoes unanimously passed pharmacy legislation**
Oklahoma Governor Kevin Stitt (R) vetoed SB 841, which would have protected patient access to pharmacy services by establishing “any willing pharmacy” network requirements and protecting pharmacies from opaque PBM reimbursement practices. The governor vetoed the bill, which passed the legislature unanimously, to avoid a potential lawsuit from the PBMs. Fortunately, there is still hope in Oklahoma in the form of HB 2632, which is going to Conference between the House and Senate. The bill contains similar protections against PBM abuses and advocates are working to address the governor’s concerns to ensure the bill will not be vetoed.

**HHS caps civil money penalties under HIPAA**
Last week, the HHS Office for Civil Rights (OCR) released a Notification of Enforcement Discretion to announce lower caps on Civil Money Penalties (CMPS) for lesser violations under the Health Insurance Portability and Accountability Act (HIPAA). The Health Information Technology for Economic and Clinical Health Act (HITECH) establishes four categories for HIPAA violations, with increasing penalty tiers based on the level of culpability associated with the violation. Currently, HHS applies the same cumulative annual CMP limit of $1.5 million across the board. In other words, even small violations are subject to the maximum penalty limit. Under the notice, HHS will apply different annual limits, ranging from $25,000 to $1.5 million, based on the level of culpability. More serious violations will remain subject to the higher limit. The cap for smaller violations, however, will be much lower. HHS has already started operating under the new tier structure. It will engage in rulemaking sometime in the future to codify the new system in regulation.

**NCPA asks CMS for recognition of medical-at-home services**
NCPA submitted a letter to CMS outlining the benefits of medical-at-home services and how community and long-term care pharmacists can aid in enhancing these services, as they already provide home care to many of their patients. Some of these services include medication management services, such as specialized packaging, medication reconciliation, hand-delivery, and consulting services, as well as review of any unnecessary drugs, duplication of therapies, or adverse reactions. NCPA pointed to improved patient outcomes and cost savings as just a few of the benefits of medical-at-home services. Specifically, we urged CMS to recognize, reimburse, and promote medical-at-home pharmacy services at
the same level as pharmacy services that are provided to skilled nursing patients, which would ultimately increase the value of patient care. Recognition of medical-at-home services is a priority for NCPA’s LTC Division.

**NCPA analyzing HHS’ final rule on conscience protections**
This week, the Health and Human Service’s Office for Civil Rights (OCR) released its final rule on conscience protections that apply to healthcare providers who refuse to perform, accommodate, or assist with certain health care services on religious or moral grounds. NCPA is analyzing the final rule and will release further information on how this final rule impacts community pharmacies/pharmacists.

**NCPA attends meeting on final implementation of “Track and Trace”**
This week, NCPA staff attended the Pharmaceutical Distribution Security Alliance’s (PDSA) public workshop to discuss the potential for an independent governance body to oversee the final implementation requirements under the Drug Supply Chain Security Act (DSCSA or what the dispenser industry calls the track-and-trace law). While trading partners up the supply chain that are involved in PDSA appear to be in support of constructing a governance body to function in this manner, NCPA does not have a current policy position on whether such a governance body is needed. Pharmacy owners that are interested in this governance concept can read PDSA’s white paper (attached), which outlines how a governance body could be constructed. Please reach out to NCPA with any comments or concerns regarding this white paper to kala.shankle@ncpanet.org.

**Community pharmacy represented at Small Business Administration roundtable**
This week, NCPA Officer and pharmacy owner, Justin Wilson,PharmD testified at a Small Business Administration’s (SBA) Regulatory Reform Roundtable in Oklahoma City. Mr. Wilson’s testimony focused on the extensive impact that pharmacy DIR fees have had on his small business community pharmacy and the dire need to finalize the proposed rule on pharmacy price concessions that has yet to be released by this administration. Second, Mr. Wilson addressed operational concerns regarding the recently proposed rule on changing the rebate safe harbor to assess all manufacturer rebates at the point of sale through a series of chargebacks to the pharmacy. Mr. Wilson focused on the need for the agency to conduct a proper small business impact analysis on community pharmacies before the proposed rule in finalized. Also, next week is Small Business week, stay tuned to NCPA social media platforms for posts highlighting small business community pharmacies.

**NCPA presents at MIPA Annual Meeting**
Last week, Anne Cassity, NCPA Vice President of Federal and State Government Affairs, presented at the Mississippi Independent Pharmacies Association annual meeting. Cassity provided updates on NCPA state and federal legislative priorities. In particular, Cassity discussed NCPA’s efforts to address pharmacy DIR fees and reform the pharmacy payment model in Medicaid.

**NCPA state legislative activity update**
NCPA tracks state legislation related to our top three state priorities: Medicaid reform, scope of practice and compensation for services, and PBM reform and regulation. Attached is a report of bills that have been introduced so far this session specifically dealing with these three issue areas. You can access the individual bill language and basic information on the bill by clicking on the bill numbers in the attached report. Bills that have moved this week are listed at the top in the “Recently Updated” section.