NCPA Advocacy Center Update
Week Ending June 11, 2016

Please Take Survey to Help NCPA Expose PBMs' DIR Fee Impacts: Here's your opportunity to shine more light on PBM practices that impact pharmacies and patients. Please complete this brief survey on direct and indirect remuneration (DIR) fees on pharmacies and PBM-imposed copay claw-back fees affecting patients. The survey will provide NCPA with more documentation and fresh evidence to make the case to address these problems through more PBM transparency and oversight.

NCPA, NACDS Fight for Inclusion of Community Pharmacy Pilot in NDAA: NCPA and the National Association of Chain Drug Stores are urging Congress to back a pilot program that would allow community pharmacies to dispense sharply discounted drugs to certain military retirees. The House version of the FY17 National Defense Authorization Act (NDAA) includes a provision that our organizations support that gives the Defense Department the ability to conduct a pilot that would allow any participating retail pharmacy, including small business pharmacies, to purchase brand name medications at the same discounted rates currently available via the TRICARE mail order program.

FDA Releases Final Guidance on 503A and 503B “Positive” Lists: This week FDA issued two final guidance documents regarding the use of bulk drug substances in compounding under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act. These guidance documents explain FDA’s policy regarding the conditions under which FDA does not intend to take action against state-licensed pharmacies, federal facilities, and licensed physicians (under section 503A) or outsourcing facilities (under section 503B) that compound drug products from bulk drug substances that cannot otherwise be used in compounding. The guidance documents describe three categories of bulk drug substances nominated by the public for use in compounding.

NCPA appreciates that the FDA seeks to avoid unnecessary disruption to patient treatment while considering bulk substances for the 503A “positive” list and does not intend to take action against those healthcare providers compounding with certain bulk substances (503A List 1). However, NCPA remains concerned that the FDA has separated which substances are eligible for this policy based on nothing more than if the Agency considers that adequate information to evaluate the substance was included as part of the nomination process. Not being able to compound with substances included on FDA’s 503A List 3 will cause impaired patient access.

In addition, FDA continues to indicate that it does not consider USP monographs for dietary supplements to be ‘applicable’ USP or NF monographs, therefore limiting compounding to only USP drug monographs. This is inconsistent with the plain language of the law and referenced language of the regulation. NCPA asks that FDA change its position as no basis exists for FDA to exclude USP or NF monographs for dietary supplements. NCPA will continue to fight for the ability of compounding pharmacists to continue to work with physicians to provide necessary medications to their patients.

For more information on the 503A “positive” lists, please click here: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf

NCPA Meets with FDA to Convey Compounding Concerns: This week, NCPA attended a “listening session” at the request of the FDA to share our views and provide information to the Agency regarding
compounding and related activities such as LTC repackaging practices. NCPA’s statement continued to reiterate our concerns with the FDA’s implementation in general of the DQSA compounding provisions. We focused on providing examples of impaired patient access to needed therapies as a result of the FDA’s draft Memorandum of Understanding (MOU), processes and activities associated with the FDA Pharmacy Compounding Advisory Committee (PCAC), FDA’s draft guidance on office use compounding, and inspection practices.

**NCPA, DQSA Coalition Request House Oversight Hearing on Compounding:** This week nine organizations, including NCPA, that are members of the DQSA Coalition formally requested that the House Committee on Oversight and Government Reform hold a hearing on the FDA’s implementation and enforcement of compounding provisions contained in the Drug Quality and Security Act (DQSA). We also requested recommendations for changes needed to better align the FDA’s actions with the plain language and congressional intent of the law. NCPA continues to have ongoing concerns with the FDA’s actions in several areas including: office use, inspections, the 503A “positive” list, and the Pharmacy Compounding Advisory Committee (PCAC).

*NCPA’s Advocacy Report provides a weekly detailed summary of recent and breaking legislative, regulatory and state developments impacting independent community pharmacy, and NCPA efforts to effect policies to the benefit of its membership and the industry. The weekly report is distributed to NCPA leadership, key committees, allied organizations/stakeholders and major contributors to the NCPA LDF and PAC.*

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