

## **NCPA Advocacy Center Weekly Update**

### **Week Ending January 21, 2012**

**NCPA Continues to Fight Merger of ESI-Medco:** NCPA continues working with Members of Congress to educate them about the potential harm an FTC approval of this merger would bring to our members and their patients. This week NCPA also had a follow up meeting with Sen. Mike Lee of Utah about the December Senate hearing, his questions, and the disastrous impact this merger could have for hundreds of thousands of Utah citizens. We expect some additional Members of Congress to send letters to the FTC over the next few weeks. We have generated new data to demonstrate to policymakers the negative impact this merger will have on patients and pharmacies, especially in states with large military bases, given that ESI administers the TRICARE program.

**NCPA Meets with House Pharmacy Caucus Chair:** NCPA CEO Doug Hoey and NACDS CEO Steve Anderson met with Congressman Cathy McMorris Rodgers (R-WA) this past week to thank her for co-chairing the House Pharmacy Caucus, as well as discuss strategy for addressing PBM issues in the 2<sup>nd</sup> session of this Congress.

**NCPA Participates in “Nurse As Agent” Congressional Meeting:** NCPA joined other stakeholders for a meeting with staff of Senate Select Committee on Aging Chairman Herb Kohl (D-WI) regarding our five recommendations for his legislation, S. 1560 Nursing Home Resident Pain Relief Act of 2011. It was a productive meeting and we will continue working with his office on our suggestions on an expedited process where nurses can receive authority to act on behalf of the prescriber in the facilitation of emergency pain care.

**Online Pharmacy Safety Act Meetings:** NCPA joined International Academy Compounding Pharmacists for two meetings with Sens. Cornyn (R-TX) and Feinstein (D-CA) regarding our concerns with S. 2002, the Online Pharmacy Safety Act. The bill seeks to create a publicly available “white list” of legitimate pharmacies to be managed by the FDA or its contracting organization for the purpose of educating consumers of legitimate online pharmacies. In addition, the legislation expands the definition of valid prescription. We are concerned that this bill would place new burdens on community pharmacies simply because they have an internet site that allows patients to order prescription refills. We will continue working with these offices and others to alleviate our concerns about the language as it is currently written.

**Energy and Commerce Committee PDUFA Hearings:** The House Energy and Commerce Health Subcommittee will hold a series of hearings on the Prescription Drug User Fee Act (PDUFA), and the Medical Device User Fee Act. On February 1, 2012, the Health Subcommittee will hold a hearing on the reauthorization of the Prescription Drug User Fee Act, which expires on September 30, 2012 and will address track and trace legislation. NCPA is preparing a statement for the record and will work with Members on the Subcommittee to ask or submit questions for the record on pharmacy specific issues. The Health Subcommittee will hold a separate hearing on the new Generic Drug User Fee proposal and Biosimilar User Fee proposal. Members will also continue to discuss the ongoing issue of drug shortages, and Dr. Janet Woodcock with the FDA will testify at the hearing. NCPA continues to work with a broad

group of stakeholders on possible off-track and traceable legislation to mitigate any potential burdens on community pharmacies.

**Congress Inquires about ADHD Drug Shortages:** On Tuesday, House Democrats sent a series of letters to generic drug makers, including Shire Pharmaceuticals and Novartis, launching an inquiry in the causes and contributing factors behind generic drug shortages of ADHD drugs, Adderall XR and Ritalin in particular. Members also sent a letter to the Drug Enforcement Agency (DEA), seeking clarification on the role that DEA quota system plays in limiting drug production. There are concerns that manufacturers may be manipulating the DEA quota system for these drugs to drive prices higher. While most of the focus of the drug shortage issue has been on hospital based and injectable products, we continue to help policymakers understand how shortages are affecting community pharmacy patients, and how PBMs are not keeping up with price changes that are occurring as a result of market shortages.

**AMCP Model PBM Audit Guidelines Fall Far Short:** NCPA completed a side by side comparison of the newly released AMCP's PBM pharmacy audit guidelines with the NCPA state model audit bill and H.R. 1971, the Pharmacy Access and Consumer Choice Act of 2011. While the AMCP guidelines do include a number of recommendations that are consistent with the NCPA documents, the AMCP guidelines do not address the more egregious PBM pharmacy audit abuses that NCPA is addressing such as the use of extrapolation and requiring recordkeeping in excess of that required by state boards of pharmacy. NCPA staff has created a one-pager that highlights the differences between the AMCP guidelines and NCPA's model legislation for use in advocacy efforts. Importantly, NCPA will be asserting the fact that voluntary guidelines are not sufficient to address the on-going pharmacy audit abuses that continue to take place and that the passage of federal and state legislation is necessary.

**Birth Control Coverage Mandate Starts in August:** Most healthcare plans will be required to cover birth control without charging co-pays or deductibles starting Aug. 1. The final HHS regulation retains the approach federal health officials proposed last summer, despite strong opposition from religious groups. Churches, synagogues and other houses of worship are exempt from the requirement, but religious-affiliated hospitals and universities only get a one-year delay and must comply by Aug. 1, 2013.

**NCPA Details Pharmacist Role in Averting Adverse Drug Reactions:** NCPA submitted a letter this week to HHS Secretary Sebelius highlighting the critical role community pharmacists play in ensuring safe and appropriate medication use. The letter provided an overview of the safety checks pharmacists perform during drug utilization reviews, highlighted the importance of medication adherence and discussed the advancement of patient care through health information technology and MTM. NCPA has shared this letter with the offices of Senators Michael Bennet (D-CO) and Olympia Snowe (R-ME), who recently have questioned the Secretary on what HHS is doing to prevent adverse drug reactions. Their inquiry is based on a November 24, 2011 publication of the *New England Journal of Medicine* (NEJM) in which the researchers analyzed data nationwide on hospitalization of Medicare beneficiaries resulting directly from adverse drug reactions. NCPA will remain engaged with HHS on a variety of initiatives aimed at improving medication safety and appropriate use. The letter can be found on the NCPA Advocacy Center website.

**NCPA's Part D Preferred Network Battle Continues:** NCPA sent a letter to CMS this week, detailing our continuing concerns with restrictive Part D networks, and the confusion that this has caused for beneficiaries. NCPA continues to receive complaints through the NCPA online complaint form from pharmacies whose patients feel misled by their preferred network Part D plan. NCPA has secured a communication channel at CMS to send these beneficiary-specific complaints, and try to get these patients into a new plan. In addition to working with CMS to allow these patients a special enrollment period, NCPA is working with Members of Congress as well as through communication vehicles to bring more light to this problem and work on solutions. A copy of the letter sent to CMS is included on the Advocacy Center website.

**LTC Ad Board Talks with CMS Regarding Upcoming DME Changes:** NCPA's LTC Advisory Board talked this week with CMS staff about the impact of the upcoming requirements that, once the national mail order competitive bidding program goes into effect in July 2013, only contract suppliers can deliver diabetes testing supplies to patients' homes, including assisted living facilities. This will prohibit pharmacies from home delivering these supplies, a policy that NCPA strongly opposes. Members of the Board described for CMS the difficulty this will create for patients, as well as the impact on quality of care. Patients or caregivers can still pick up the supplies directly from community pharmacies. CMS did not seem to be swayed by the arguments, and even if they were, it would require a change in regulations to change the policy. The Board discussed the potential need to change this through legislation, notable H.R. 1936, the Medicare Access to Diabetes Supplies Act, which would help in solving this issue. This would exempt community pharmacies with 10 or fewer sites under common ownership from the home delivery prohibitions, as well as many community pharmacies that serve ALFs. NCPA will be talking again with the bill sponsors, Rep. Shock (R-IL) and Welch (D-VT), about the impact of this prohibition on pharmacies that serve LTC facilities.

**CMS Releases Proposed Part D Plan LTC Waste/MTM Reporting Requirements:** CMS asked for comments on two new Part D plan reporting requirements that will impact community pharmacies and those that serve long term care facilities. Due on January 31, CMS asked for comments on proposed LTC drug waste reporting requirements, resulting from the new short cycle dispensing requirements that go into effect next year. CMS intends to use the plan reported data to determine the extent to which the new short cycle requirement reduce waste and whether the requirements should be expanded to generic drugs. CMS also has proposed some new plan reporting requirements for MTM programs for residents in LTC facilities. Working with our LTC members, NCPA will be responding to these proposals.

**EFT Required for Part B Suppliers' Payments:** CMS released a reminder that all Part B enrollment change requests or revalidations require the applicant to agree to receive Medicare payments through electronic funds transfer (EFT). This means that all Part B pharmacies who are not currently receiving EFT payments are required to submit the CMS-588 EFT form with the Provider Enrollment Revalidation application, or at the time any change is being made to the provider enrollment record by the provider or supplier, or delegated official.

**CMS Releases Fourth Draft FUL for Medicaid Generics List:** CMS released a fourth draft FUL list for generic drugs this past week. The list has more than 900 multiple source drugs with FULs, which are based on mostly undefined and variable average manufacturers prices (AMPs).

NCPA is analyzing the list to determine the impact on small independent community pharmacies and long term care pharmacies and communicate the concerns to CMS and Members of Congress. The past three lists show that implementation of these FULs would have a significant negative impact on community pharmacies. CMS is ignoring the requests of dozens of Members of Congress who have asked CMS to stop publishing these draft lists until a final AMP regulation is published.

**NCPA Responds to DOD TRICARE Reimbursement RFI:** NCPA submitted comments to TRICARE in response to their request for information about possible pricing benchmarks in the new 2015, 5-year contract that will go out to bid shortly. NCPA suggested that DOD retain WAC as the reimbursement benchmark for brands and single source generics, and MAC for generics. However, we strongly urged that the MAC setting process be more transparent to DOD and to pharmacies as we continue to hear complaints and communicate them to DOD and that ESI changes MACs at will, without any notice to pharmacies, and without any regard to the cost of the drug. It is also not clear that DOD benefits from these reductions in reimbursement to pharmacies. NCPA will be meeting with DOD shortly to discuss a wide range of issues relating to the next 5-year contract.

**CBO Questions Disease Management Programs but Highlights Pharmacists' Role:** In the past two decades, CMS has conducted demonstration projects aimed at improving both the quality and efficiency of health care delivery in Medicare's fee-for-service program. In order to reduce total Medicare spending, a disease management or care coordination program was required to cut expenditures by more than enough to offset the fees paid, which they did not do. While the major take-away was the need to restructure the payment system that incentivizes care coordination, an important note was made about including pharmacists on the care team. Demonstrations that provided close collaboration between care managers and physicians especially those with larger teams that included pharmacists appeared to have fewer hospital admissions.

### **In the States**

**NCPA Develops Model Bills on Mail Order, MAC Pricing:** NCPA has developed new model state bills on halting mandatory mail order programs, and on requiring greater disclosure in pharmacy contracts regarding PBM Mac pricing. The bills were developed with the input of state pharmacy associations and NCPA Committees. They are posted on the "members only" section of the advocacy center website.

NCPA State Government Affairs staff worked with pharmacy organizations in Alaska to support their recently introduced Pharmacy Fair Audit legislation (HB259). NCPA provided supporting materials regarding the fair audit issue as well as a letter of support for the recently introduced bill.

NCPA State Government Affairs Staff has updated their State Resources One Pager and has posted this document on the "members only" section of the NCPA website. This one pager provides a review of NCPA's most notable informational pieces which state organizations can utilize to support their legislative and regulatory advocacy efforts.