FDA Reform Bill Moves Forward Without Supply Chain Security: Key House and Senate staff continued to hold meetings this week with stakeholders on ironing out differences between the two FDA bills passed in the House and Senate. Negotiations are expected to conclude in the next few days followed by final passage, before the U.S. Supreme Court rules on the Affordable Care Act in the coming weeks. NCPA has been meeting with key staff members all week and is also focusing on Reps. Frank Pallone (D-NJ), John Dingell (D-MI) and Senators Tom Harkin (D-IA) and Chuck Grassley (R-IA) on the following issues:

- **Moving Hydrocodone Products to Schedule II:** NCPA continues to have strong concerns about the patient care impact and the pharmacy operations impact of an amendment added to the Senate FDA bill by Senator Manchin (D-W.Va), which reschedules hydrocodone-containing products from Schedule III to Schedule II.
- **Track and Trace** – The Senate bill included a new national lot level tracing system for pharmaceuticals – affecting the manufacturers, wholesalers and pharmacies. However, after a long weekend of negotiations between Congressional staff, FDA and stakeholders including NCPA, it was determined on Sunday night that there was not enough time to come to agreement on downstream supply chain security language, so it will not be included in the bill that moves through Congress this week. It is possible that further discussions will lead to a consensus that can move later this year. However, FDA has been seeking to create more burdens on pharmacies, such as requiring paper pedigrees for drug purchases, and creating paperwork requirements for pharmacies to return drugs to wholesalers. NCPA is opposing these requirements.

NCPA Supports GAO Report on Rogue Online Pharmacies: Separately, NCPA and other stakeholders sent a letter urging the inclusion of Section 1134 of S. 3187, the “Food and Drug Administration Safety and Innovation Act” in the final version of legislation to reauthorize the U.S. Food and Drug Administration (FDA). Section 1134 requires the U.S. Government Accountability Office (GAO) to prepare a report to Congress on illegal online drug sellers (aka “rogue online pharmacies”). NCPA supports this critical study about internet pharmacies, and strongly encourages the Committee to include the Senate’s GAO Report in the final legislation. NCPA along with eight other organizations signed on to the letter.

**Senate Holds Hearing on Medicaid Fraud:** Following last week’s hearings in the U.S. House of Representatives on Medicare and Medicaid fraud and program integrity, this week the Senate Homeland Security and Government Affairs Committee held a hearing entitled “Saving Taxpayer Dollars by Curbing Waste and Fraud in Medicaid”. Similar to recent House hearings on this issue, members of the Subcommittee on Federal Financial Management, Government Information, Federal Services, & International Security focused on the challenges facing Medicaid at the Federal and State level. Subcommittee members probed witnesses from HHS, GAO, OIG and CMS on the reasons for widespread fraud within Medicaid. All the witnesses agreed that inaccurate audit data was the primary reason for combating fraud nationwide.
NCPA Attends Pharmacy Quality Alliance (PQA) Annual Meeting: NCPA participated in this week’s Annual Meeting of PQA, a consensus building organization that develops quality measures, some of which have already been adopted by CMS for use in the Medicare star ratings program. During the meeting, PQA membership voted to endorse a measure that can be used to determine the percentage of individuals (65 years and older) with dementia who are receiving an antipsychotic medication without evidence of a psychotic disorder or related condition. This measure could be used in the future by CMS to rate plans, and could be used by the plans to calculate how well pharmacies adhere to the metrics. Also discussed at the meeting of interest to independent pharmacies was the EQuIPP Initiative (Electronic Quality Improvement Platform for Plans and Pharmacies). EQuIPP provides pharmacies with the opportunity to review “dashboards” to see how they are performing relative to specific quality measures. The 2012 “beta phase” will allow health plans and pharmacies in PA, FL and AL to view performance dashboards and take action to improve scores. Of note 50 independent pharmacies in PA will be participating in the beta phase.

NCPA and Pain Advocates Meet with FDA to Discuss Prescription Drug Abuse: NCPA, as a member of the Pain Care Forum, had the opportunity to meet this week with Dr. Douglas Throckmorton, the Director of the FDA’s Center for Drug Evaluation and Research (CDER). Dr. Throckmorton updated the Forum on activities within the Agency related to the abuse of prescription drugs.· Regarding the upcoming extended release/long-acting opioid REMS, individual drug manufacturers were required to submit their final REMS by the end of this week for FDA approval (anticipated in 1-2 weeks). Each REMS will be the same and components include a mandatory prescriber education program (NCPA commented on the blueprint for this education several months ago) as well as updated Medication Guides and patient education materials.· Related to abuse deterrent formulations of opioids, the FDA is drafting a guidance document that should be available by the end of this year. FDA is very sensitive to avoiding the negative impact on generic development that comes with these formulations.· Lastly, a FDA Advisory Committee will meet October 29-30 to discuss the up scheduling of hydrocodone containing products. The FDA was asked by the DEA to assess the scientific data regarding these products. Note that Congress is currently considering rescheduling these products to Schedule II. NCPA has been very vocal in opposition to this and asks that Congress look to the expert advice of the FDA Advisory Committee before making any decisions to reschedule these products.

OIG Report Finds Documentation Lacking for Test Strip Claims: For the year 2007, the OIG reviewed the four DME MAC jurisdictions and sampled 400 high utilization claims for test strips and/or lancets. The OIG found that only 97 claims had proper supporting documentation for high utilization. With regard to the same sample of claims, the OIG also found that 23% of the claims involved suppliers dispensing supplies when the beneficiaries had not nearly exhausted their supplies, meaning that billing dates overlapped for the same beneficiary. Finally,
the OIG found that for approximately half of the claims, physicians were failing to adequately document the need for higher testing frequencies that were being ordered. Please note the study did not differentiate pharmacy channel.

**CMS Releases 2013 Part D Marketing Guidelines for 2013:** In its final guidelines, CMS adopted several policies of concerns to patients and community pharmacy: CMS did not concur with NCPA’s request that CMS prohibit co-branding of PBM names on member ID cards. The agency also did not agree with NCPA’s that pharmacy directories indicate whether or not a given pharmacy is a preferred network pharmacy or not. In addition, CMS reversed its prior policy and ignored NCPA’s request to require providers, who provide Part D plan enrollment links on the provider website, to provide enrollment links to all Part D plans with whom the provider participates. Now CMS requires providers to provide links to all such plans only if each plan requests such a link. Finally, plan sponsors must submit all PDP websites for review. Plan sponsors may make the website available for public use during the CMS review period; however, plan sponsors must include the status pending on their website until CMS has granted final approval/disapproval. Use of the website while under CMS review applies only to the website text and not documents contained on the website, (e.g., a plan may not post an unapproved member handbook on the website). If any portion of a plan sponsor’s website is disapproved, the plan sponsor must remove the disapproved portion immediately.

**NCPA Submits Comments to CMS Regarding Consultant Pharmacist Separation:** NCPA’s comments are in response to the 2013 Medicare Part D final rule. In that rule, CMS decided not to require separation but instead seek further input from industry. NCPA encourages CMS to enforce current regulations already in place and let the industry further address this issue by adopting the suggested changes to increase transparency and through its work with PQA. The vast majority of LTC consultant pharmacists strive to be objective, unbiased, and work with the best interest of nursing home residents in mind.

**CMS Weighs in on Caremark Audit of LTC Pharmacies at NCPA Urging:** NCPA has been working with CMS officials to address LTC independent pharmacy concerns related to an audit of LTC claims by Caremark. On May 15, 2012, Caremark issued an audit alert for all Medicare Part D Providers with long-term care claims submitted for partial payment under Medicare Parts A and D, citing the Prescription Drug Benefit Manual, Chapter 9 – prescription splitting to receive additional dispensing fees. The audit requires pharmacies to identify all claims from 2006 and thereafter that have been partially paid by Part A and partially paid by Part D (split billed) and report these claims to Caremark by June 15, 2012.

NCPA contacted CMS to share our concerns that: 1) this audit is unduly burdensome to the pharmacies because there was no method for identifying these claims as split billing from 2006 to January 1, 2012, when the new NCPDP submission clarification code of 19 was implemented; and 2) such information dating all the way back to 2006 is not readily retrievable by the pharmacies and it is inappropriate to require a response within 30 days.

We understand from CMS that the issue Caremark is auditing for is not the same type of duplicate dispensing fee billing fraud referenced by Chapter 9 in the Prescription Drug Benefit Manual. It is also our understanding from CMS that if neither the pharmacy’s contract with the
plan/PBM and/or the HIPAA transaction standard required the information submission to suppress payment of the second dispensing fee, the payment thereof does not constitute an overpayment. Please note CMS has shared their concerns with Caremark. However, this ultimately needs to be determined between the pharmacy and Caremark. Please work with your group purchasing organization or related entity to determine your responsibilities in light of this information.

New York Reschedules Hydrocodone Containing Products and Requires Electronic Prescribing: This week, the state of New York passed A.10623. This legislation was a “fast tracked” bill that made its way through the New York legislature in a number days. The legislation is intended to overhaul the manner in which prescription drugs are distributed and tracked in New York State. The legislation will ultimately result in a “real time” prescription monitoring registry, require all prescriptions to be electronically transmitted, reschedule a number of highly abused drugs including Hydrocodone to Schedule II, institute a workgroup with the responsibility of guiding the development of medical education courses regarding pain management and prescription drug abuse, and require the Department of Health to establish a safe disposal program for unused medications. There are notable items included in this legislation that will need to be clarified during the state’s regulatory process. NCPA intends to keep a close eye on this issue as it may be precedent setting for other states during upcoming state legislative sessions.

NCPA Political Events NCPA attended political events this past week for:

- Sen. Roy Blunt (R-MO): Vice Chairman of the Senate Republican Conference with special guest Sen. John Boozman (R-AR)
- Sen. Tim Johnson (D-SD): Co-sponsor of the Pharmacy Competition and Consumer Choice Act (S. 1058)
- Republican Senators Classic: NCPA participated in this annual event with over 20 Republican Senators in attendance including pharmacy champions Sen. John Boozman (R-AR), Sen. Saxby Chambliss R-GA) and Sen. Roger Wicker (R-MS)