

National Community Pharmacists Association (NCPA)

Government Affairs Update - Week Ending April 22nd, 2011

Congressional Recess

- House and Senate are in recess this week and next so little legislative activity has or will occur.
- We are working on pharmacy visits for recess and will update once we have a number finalized.
- We continue to meet with Senate Commerce Committee Members regarding the FTC investigation of CVS Caremark and House and Senate Armed Service Members regarding the Tricare pharmacy program.

Summary of Pending and Proposed Legislation

Medication Therapy Management (MTM)

H.R. 891: Medication Therapy Management Benefits Act of 2011 – The bill will require a licensed pharmacist for the initial MTM review as well as for the targeted quarterly MTM reviews. Sponsors – Reps. Cathy McMorris-Rodgers (R-WA) and Mike Ross (D-AK).

S. 274: Medication Therapy Management Benefits Act of 2011, the Senate companion bill was introduced by Sen. Kay Hagan (D-NC) and does not specifically require a licensed pharmacist.

Pharmacy Benefit Managers (PBM)

H.R. ____: Pharmacy Competition and Consumer Choice Act – The bill will ensure transparency and proper operation of pharmacy benefit managers. Likely sponsors – Reps. Anthony Weiner (D-NY) and Cathy McMorris-Rodgers (R-WA). **Not yet introduced**

Anti-Trust Exemption

HR. 1409: The Quality Health Care Coalition Act of 2011 - The legislation would exempt health care professionals, including pharmacists, from federal antitrust laws for the purposes of contract negotiations with health plans and it would allow patients to enjoy the benefits of greater competition among pharmacies and other providers of medical care. Sponsors - Reps. John Conyers (D-MI), Ron Paul (R-TX), Jeff Miller (R-FL) and Donna Edwards (D-MD).

Competitive Bidding Program

H.R. 1041: Fairness in Medicare Bidding Act – The bill will repeal the competitive bidding program in the Medicare Part B durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) program in a budget-neutral manner. Sponsor – Reps. Jason Altmire (D-PA) and Glenn Thompson (R-PA).

H.R. ____: Medicare Access to Diabetes Supplies Act – The bill will keep retail diabetic supplies outside of competitive bidding and is a sensible, targeted approach to preserve patient access and the quality of care. Likely sponsor – Peter Welch (D-VT). **Not yet introduced**

TRICARE

H.R. ___ and S. ___: FY12 Defense Authorization bill-The defense bills will not be released until early June but we continue to lobby against mandatory mail order or coercive co-pay structures in the Tricare pharmacy program.

Health Care Reform Repeal Initiatives

H.R. 605: Patients' Freedom to Choose Act - The bill will repeal the health law's restrictions on payments to HSAs, FSAs and medical savings accounts. Sponsor – Rep. Erik Paulsen (R-MN).

S. 312: the Senate companion introduced by Sen. Kay Bailey Hutchison.

340B Drug Discount Program: No legislation introduced in Congress. NCPA Position - to clearly define the definition of a patient in the 340B program.

1099 Form Filing Repeal - President Obama signed H.R. 4, the 1099 form filing repeal, into law.

National Prescription Drug Abuse Plan Announced

This week, the White House Office of National Drug Control Policy (ONDCP), HHS, FDA, and DEA announced the release of the Obama Administration's action plan to address the problem of prescription drug abuse. The Administration's *Epidemic: Responding to America's Prescription Drug Abuse Crisis* provides a national framework for reducing prescription drug diversion and abuse by supporting the expansion of state-based prescription drug monitoring programs; recommending more convenient and environmentally responsible disposal methods to remove unused medications from the home; supporting education for patients and healthcare providers; and reducing the prevalence of pill mills and doctor shopping through enforcement efforts. ONDCP also announced efforts to pursue legislation to amend the Controlled Substance Act to require prescriber education upon DEA registration and re-registration.

FDA Announces Opioid REMS

As part of the prescription drug abuse initiative, FDA also announced the final REMS for long-acting and extended release opioid medications. Manufacturers will have 120 days to submit a joint proposal to FDA. FDA expects the REMS to become effective in 2012. The REMS will require all manufacturers of these products to work together to develop prescriber education related to proper pain management. This education is voluntary until such time that legislation is enacted that will require proof of education at point of DEA registration. Medication guides must be presented when these products are prescribed (voluntary) and it is mandatory that Medication guides be distributed by pharmacists when dispensing these products. Lastly, the REMS will require that manufacturers assess prescriber education and patient access to these medications.

NCPA Submits Track and Trace Comments to FDA

NCPA submitted comments to the FDA regarding track and trace technologies in response to a public workshop the FDA hosted earlier this year. Below are highlights of our comments:

- The FDA should clearly define the functional requirements needed in the track and trace system as well as clearly determine the specific data that needs to be captured and a clear definition of authentication. NCPA recommends that FDA may wish to consider utilizing a risk-based approach to determine the scope of products to be included in any track and trace system, at least at the outset of any program.
- In order to incentivize the voluntary adoption of track and trace technology, and if such a system were to be mandated, NCPA contends that federal grants must be made available to smaller supply chain participants—like independent pharmacies—so that these small businesses are able to implement and maintain track and trace systems.
- NCPA would request that the FDA provide a clear definition of authentication—and at which point in the supply chain such authentication should occur.

Other Issues

Promoting Generic Drug Utilization: No legislation introduced in Congress. NCPA Position – we support increased use of lower-cost generic medications in Federally-funded programs, including Medicare Part D, Medicaid, TRICARE, FEHBP and state employee benefits programs. Generics cost about one-fifth the price of the average brand name drug.

Pedigree/Track and Trace: No draft legislation introduced in this Congress. NCPA Position - Ensure Track and Trace Legislation is Not Overly Burdensome to Pharmacies.

Long Term Care: No draft legislation introduced in this Congress. NCPA Position - Support the ability of nurses in long term care facilities to act as agents of prescribers in the transmittal of all controlled substance prescriptions to pharmacies. This is critical to assure that nursing home patients in pain can receive timely medications. We also believe that, as is the case in hospitals, chart orders should be recognized as valid prescriptions in nursing homes.

We expect legislation to be introduced in the near future which would address the nurses-as-agents issue.

Diversion/Abuse of Controlled Substances Legislation: Four bills have been introduced which would tackle the growing problem of drug diversion in various ways, including a crackdown on pill mills which would change and direct what is and what is not a Schedule II controlled substance and could cause problems for community pharmacy's ability to serve its patients. We believe that community pharmacists play an integral role in assuring that patients have timely access to opioids and in the process vital counseling to ensure medications are not misused, abused, or diverted, but must also emphasize that any solution should not include more burdens on the independent pharmacies.

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