

**HEALTHCARE REFORM
IMPACT ON COMMUNITY PHARMACY
March 22, 2010**

On March 21st, the U.S. House of Representatives passed H.R. 3590, the Patient Protection and Affordable Care Act. This is the same health care reform bill that cleared the Senate on December 24th, 2009. However, the House also passed H.R. 4872, the Health Care Reconciliation Bill, which makes amendments to H.R. 3590 (the Senate Health Care Reform bill).

The Senate must still act on the reconciliation bill, but NCPA wanted to ensure that pharmacists had current information about the bill's impact on pharmacy. This document represents NCPA's best interpretation at this time of the new law, once signed by the President. In many cases, new regulations will have to be drafted, and NCPA will assure that the intent of Congress is followed by the agencies.

Medicaid Generic Drug Pharmacy Reimbursement (AMP Fix)

Background: The Deficit Reduction Act of 2005 (DRA) would have reimbursed pharmacies below their acquisition cost for Medicaid generic drugs. Since 2007, these cuts have been delayed because of a December 2007 court injunction that was won by NCPA and NACDS. NCPA has advocated a legislative solution to permanently reverse these generic drug cuts, and this bill provides that relief in part.

The health care reform bill improves the definition of Average Manufacturers Price (AMP) so that it includes only manufacturers' sales to retail pharmacies. It directs the Center for Medicare and Medicaid Services (CMS) to set Medicaid Federal Upper Limit (FUL) for reimbursement of generics a rate of "no less than 175% of average weighted AMP." NCPA secured report language to the bill that encourages the Secretary to increase the reimbursement even higher for small independent community pharmacies.

This increase in the FUL is especially important now because the bill also expands Medicaid coverage – starting in 2014 - to individuals up to 133% of the Federal poverty level. This is expected to add 16 million more individuals to the Medicaid program.

What this means for YOU:

- The bill requires the Secretary to implement the new Medicaid generic rates as early as October 2010. This means that pharmacies in some states may see a reduction in generic drug reimbursement at that time. However, this new law mitigates the impact of the more draconian generic drug cuts that would have gone into effect had these changes not been made, saving pharmacies approximately \$3 billion in Medicaid generic drug cuts.

- AMPs for brand and generic drugs will be made public later this year. This will give payers access to more AMP data, which are generally assumed to be close to retail pharmacy's acquisition costs for drugs.

Pharmacy Benefit Manager (PBM) Transparency in Health Exchanges

Background: PBMs continue to operate in relative secrecy, with payers and the Federal government having little information on whether PBMs actually reduce drug costs, or pass through rebates and discounts to plan sponsors. To begin to rectify unacceptable situation, the health care reform bill requires the PBMs to confidentially disclose important financial information to the Secretary of Health and Human Services for those health plans operating in new health insurance exchanges and Medicare Part D plans. These new state-based exchanges are set to begin in 2014. This is the first federal requirement for oversight and accountability in the PBM marketplace. These provisions also establish an important initial Federal framework for the regulation of these unregulated entities, which can be enhanced in the future.

What this means for YOU:

- Transparency helps to level the playing field between mail order and community pharmacy by encouraging plans to hold PBMs accountable for excessive profits and the tactics used to drive those profits up.
- This new law creates an important foundation for future federal regulation. As federal officials learn more about the games PBMs play, they may strengthen disclosure requirements or apply them to additional federal health programs. Hopefully, the private sector will follow suit.

Pharmacists Exempted from Medicare DME Accreditation Requirement

Background: The bill provides an exemption for most pharmacies from the burdensome accreditation requirements to provide Medicare DME, and changes current law so that pharmacy accreditation requirements are not effective until January 2011. (Pharmacies that want to competitively bid would still be required to be accredited regardless). A pharmacy can be exempt from the accreditation requirements if the pharmacy:

- Has total Medicare DME billings that are 5 percent or less of total prescription sales.
- Has had no adverse fraud or abuse determination against it for the last 5 years
- Submits an attestation that its total Medicare DMEPOS billings are and continue to be less than a rolling three year average of five percent of total pharmacy sales.
- Submits documentation to the Secretary (based on a random sample of pharmacies) that would allow the Secretary to verify the information.

What this means for YOU:

- If you're already accredited under current CMS guidelines, you are exempt from the re-accreditation requirements if you meet the criteria above. This will save you thousands of dollars and countless hours to comply.
- If you're not accredited now, you are required to be accredited after January, 2011, but only if you do not meet the criteria above. Most pharmacies are likely going to meet the criteria above and will not have to be accredited. If you have already stepped down from selling DME, anticipating that Congress would enact an exemption, we expect CMS to allow pharmacies to step back up soon. This will likely require the submission to the NSC of an application to "step up".

Pharmacist-Delivered Medication Therapy Management Services

Background: The health care reform bill envisions an expanded patient care role for pharmacists in new health care system models. These new responsibilities will help assure more appropriate use of prescription medications, especially for those patients who have chronic illnesses. These include pharmacist roles in accountable care organizations, medical homes, "transitions of care" teams, and medication reconciliation activities.

The bill also includes a Medication Therapy Management (MTM) grant program that will help test new and innovative methods to provide medication therapy management, which will help to reduce the estimated \$290 billion in health care expenditures that result from inappropriate medication use or non compliance with taking medications.

What this means for YOU:

- Community pharmacies may be eligible for grant funding to help provide MTM services, though the government's process for establishing grant criteria, applications, etc. will take many months and will be subject to the annual appropriations process.

Closes the Medicare Part D "Donut Hole"

Background: The health care reform bill closes the Medicare Part D "donut hole" over the next ten years (2010-2020), through new Federal funds as well as discounts from pharmaceutical manufacturers on brand name drugs. Beneficiaries that hit the donut hole in 2010 would receive a one-time \$250 rebate. Beginning January 1 2011, beneficiaries would also automatically receive a 50 percent discount off the negotiated price for brand-name prescription drugs that are covered under Part D and covered by their plan's formulary or are treated as being on plan formularies through exceptions and appeals processes. These discounts would be provided by the pharmacy at point of sale.

The discount increases to 75% on brand-name and generic drugs by 2020. The bill also allows 100% of the negotiated price of discounted drugs (excluding dispensing fees) to count toward the annual out-of-pocket threshold that is used to annually define the coverage gap. Beginning in 2020, the 25% copay applies until Medicare's catastrophic coverage kicks in.

What this means for YOU:

- Medicare patients who previously struggled financially when in the “donut hole” should be able to purchase their full medication regimen as prescribed – leading to increased adherence. However, the law requires that these brand name manufacturer discounts be paid to the pharmacy by a third party entity under contract with the Secretary. The new prompt pay provisions apply to the payments that these third party entities would have to make to pharmacies, which means that pharmacies should be paid within 14 days of dispensing the brand name drug.

New Requirements for Long Term Care Pharmacies

Background: The health care reform bill requires Part D plans to use specific dispensing techniques to reduce pharmaceutical waste in long term care facilities. In order to reduce waste associated with unused medications, starting in 2012, Medicare Part D drug plans and MA-PD plans must have in place utilization management techniques such as daily, weekly, or automated dose dispensing to reduce the quantities of part D drugs dispensed to enrollees residing in long-term care facilities.

The Health and Human Services Secretary will consult with appropriate stakeholders, including State Boards of Pharmacy and pharmacy and physician organizations, to study and determine additional methods to reduce waste.

What this mean for YOU:

- You may have to provide dispensing services to long term care facilities more frequently, with no statutory requirement that there would be corresponding increases in dispensing fees. NCPA is already advocating with the Centers for Medicare and Medicaid Services (CMS) that full dispensing fees be paid for an increase in the frequency of providing medications to residents of long term care facilities.

Small Business Provisions

Background: The health care reform bill includes provisions that would penalize businesses that do not provide health insurance and whose employees purchase plans through the exchange. However, there are no penalties on businesses with 50 or fewer employees that do not provide health care coverage. The bill also includes small business tax credits to encourage small employers to purchase insurance for their employees, but NCPA is concerned about the income caps and other eligibility requirements.

What this means for YOU:

- You are not required under law to provide health insurance for your employees.
- If you do not provide health insurance coverage for your employees and have more than 50 employees, you may be subject to a \$2,000 fine for some of the employees if any of the employees is subsidized to obtain coverage through the new health insurance exchanges.
- If you have fewer than 25 employees you may be eligible for tax credits to provide health insurance coverage to your employees.

340B Provisions

Background: The health care reform bill substantially expands the number of entities eligible to obtain pharmaceutical discounts under the 340B program. These 340B entities are supposed to provide discounted prescription medications to uninsured individuals. However, many NCPA members report that eligible entities are using these 340B drugs for ineligible patients, such as a hospital's own employees and for patients that have good insurance.

The final bill prevents the extension of 340B discount pricing to inpatient services provided by a hospital, which will reduce the number of discounted prescriptions dispensed to potentially inappropriate patients.

What this means for YOU:

- While the bill's expansion language will mean that an increasingly larger number of covered entities will be able to provide discount 340B drugs, NCPA members also have an increased opportunity to participate in the 340B program due to a recently issued HRSA guidance that allows 340B covered entities to contract with multiple pharmacies to provide pharmacy services.