State Legislation that Passed

SB2272 – Regulation of Pain Management Clinics

Senate bill 2272 added pain management clinics to the list of entities that are regulated under Florida statutes 456.037. That list includes but is not limited to dental laboratories, massage establishments and pharmacies. There were some exemptions to the requirement for certain clinics to register. These exceptions include the following:

- Clinics licensed under 395
- Clinics where the majority of physicians provide surgical services
- Clinics owned by entities with large assets
- Clinics affiliated with accredited medical schools
- Clinics that do not prescribe or dispense controlled substances used for pain
- Charitable clinics

The Department of Health was also granted authority to investigate possible violations related to pain management clinics without having to get a patient release or subpoena. The clinic must also designate a responsible physician. Physician cannot practice in unregistered clinics. The clinic must be owned by a Florida licensed physician with a clear license and has not been convicted or pled guilty to certain crimes. Anyone named in the registration of a clinic that has been revoked could not apply to operate a pain management clinic for 5 years after the registration is revoked. Only a licensed physician and dispense medication on the premises of a pain management clinic. Of interest to our members are provisions of SB2272 that require the following:

- The physician must perform a physical examination on the same day prior to prescribing or dispensing a controlled substance.
- Physician must document in the patient record a reason for prescribing or dispensing more than a 72 hour supply of a controlled substance for the treatment of nonmalignant pain.[1]
- Physicians practicing in pain clinics are responsible for the security of prescription blanks or any other method used to prescribe controlled substances
- The bill appears to require physicians to be compliant with the counterfeit proof prescription blanks laws in 896.065
- Physicians are required to notify the Department within 24 hours following theft or loss of a prescription blank or any other related breach of prescribing security of pain medications.
- The Department to adopt rules related to inspection and registration of clinics
- The bill directs the Department to write rules limiting the number of prescriptions for Schedule II or Schedule III controlled substances or alprazolam written over a 24 hour period.
- Requires the Department to write rules on standard of practice for physicians in privately owned pain clinics
- The Department of Health is granted new enforcement authority and the ability to asses penalties for violations
- Dispensing practitioner (in a registered pain clinic) who is registered under 465.0276 restricted from dispensing more than a 72 hour supply of controlled substances if the patient pays by cash, check or credit card.[23]

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[1] The FPA is concerned that pharmacists receiving prescriptions for more than a 72 hour supply may not be aware or have knowledge that a notation has been made in the patient's record. Pharmacists should not be held accountable for this issue.

[2] Violation is a 3rd degree felony

- Directs the prescription drug monitoring program manager to share information on possible violations with law enforcement agencies.
- Modifies the public records exemption language in 893.0551 to allow the Department of Health to disclose confidential information to law enforcement as articulated in the bullet point above

HB5603 – Reimbursement for Worker's Compensation Prescriptions

This bill revised 440.13 (12) (c) that defined current pharmacy reimbursement. The bill applied the current pharmacy reimbursement to all provider types. This should include dispensing practitioners who care for work comp patients. Dispensing providers who used repackaged products will have to bill using the average wholesale price of the original manufacturer and not the AWP price provided by the repackager. Also if the worker's compensation carrier has contracted for a lower rate the provider will have to bill at that rate. Another provision in the bill required the Division of Risk management to analyze return to work efforts of state agencies for workers compensation patients. This bill was vetoed by Governor Crist.

CS/CS/HB747 – Treatment of Diabetes for Students in Schools

This bill was designed to give guidance to school districts on their students who have diabetes. Not all schools have nurses or other trained personnel and as such some may have restricted assignment of students with diabetes to schools that did have them. Under this bill, districts could assign students with diabetes to schools without trained personnel if authorized by both the parent and physician. The State Board of Education working with the Department of Health is being encouraged by the bill to write rules on personnel training for the management and care of diabetes by students. This bill was signed by Governor Crist.

HB1565 – Revisions to Rulemaking Authority

Regulatory entities like the Florida Board of Pharmacy and Agency for Health Care Administration are given general authority to write rules defining how laws are implemented. HB1565 further defined rulemaking authority by revising the "Statement of Estimated Regulatory Cost" obligation. When rules are written each agency or board must evaluate the rule to determine if it would have an adverse fiscal impact on small businesses. Added into the bill is a section where if it were found that the rule would create over $200,000 in expenses to small businesses over a 5 year period that the rule will need to be ratified by the legislature. This bill was vetoed by Governor Crist.

CS/CS/SB1050 – Regulating the Sale of Ephedrine

While there are Federal laws governing the sale of Ephedrine the Florida legislature has further defined this in SB1050. It is now prohibited to knowingly obtain or deliver ephedrine or related compounds in excess of the following amounts:

- In any single day, any number of packages that contain a total of 3.6 grams of ephedrine or related compounds;
- In any single retail, over-the-counter sale, three packages, regardless of weight, containing ephedrine or related compounds; or
- In any 30-day period, in any number of retail, over the-counter sales, a total of 9 grams or more of ephedrine or related compounds

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[3] Exceptions are worker's compensation prescriptions, patients with insurance paying by cash, check or credit card paying copay or deductible or the dispensing of complimentary drugs

These products as before will need to be kept behind the counter where the public is not permitted or other location not accessible to the public. Employees will be required to go through training on state and federal regulations. It is our understanding that the Federal government requires this training to be done annually. Any person who obtains ephedrine related products must:

- Be at least 18 years of age
- Produce an appropriate government issued ID
- Sign a record of the purchase either on paper or electronic form

The Florida Department of Law Enforcement (FDLE) is designated with the task of approving the electronic recordkeeping system. The bill also requires the electronic record keeping system be provided to pharmacies or retailers without any cost or expense. The bill also requires pharmacies that get this system to use it for purposes of submitting sales data to the electronic recordkeeping system. This data would have to be submitted before the transaction is completed or in real time. This data in the electronic system would have to be kept for at least 2 years. Pharmacies that lack the ability to use this technology can file for an exemption through FDLE provided that they do not sell more than 72 grams of ephedrine or related compounds over a 30 day period. The electronic recordkeeping system must include the following features:

- The date and time of the transaction.
- The name, date of birth, address, and photo identification number of the purchaser, as well as the type of identification and the government of issuance.
- The number of packages purchased, the total grams per package, and the name of the compound, mixture, or preparation containing ephedrine or related compounds.
- The signature of the purchaser, or a unique number relating the transaction to a paper signature maintained at the retail premises.
- Real-time tracking of nonprescription over-the-counter sales and
- The ability to block nonprescription over-the-counter sales in excess of those allowed by the laws of this state or federal law.

Entities that are exempted from this electronic recordkeeping program include licensed manufacturers, wholesalers, hospitals or facilities licensed under F.S.395, licensed long term care facilities, government operated health departments, physicians' offices, public prisons or other related facilities, public or private educational institutions with health care programs and government or industry operated medical facilities serving their employees. The electronic data in the system can only be disclosed to law enforcement or used for purposes of managing product recalls. There is some immunity from liability for releasing this information to law enforcement.

CS/HB 573 – Relaxing of Physician Assistant Law

Before physician assistants could prescribe or dispense there was a requirement that they file evidence with the Department of Health that they have taken a minimum of 3 months of clinical experience in the specialty area of their supervising physician. HB573 removed this requirement from Florida law. This bill was signed by Governor Crist.

SB1484 – Medicaid Reform

The House version of Medicaid reform was designed to move all of Florida Medicaid into the managed care market greatly expanding the pilot projects in Broward, Duval, Clay, Baker and Nassau counties. The Senate version which passed is much more conservative in its approach. Included in this bill are the following:

Directs the Agency for Health Care Administration (AHCA) to request an extension of the current Medicaid Reform waiver obtained under section 1115 of the Social Security Act and to preserve the Low Income Pool provisions of the waiver by no later than July 1, 2010. The AHCA is required to provide the Legislature and the Governor with monthly progress reports on the waiver extension negotiations with the federal Centers for Medicare and Medicaid Services.

Directs the AHCA to develop methodologies to maintain the use of intergovernmental transfers and certified public expenditures in a Medicaid managed care environment. Requires the Secretary of the AHCA to convene a workgroup of stakeholders that will include individuals representing hospitals, counties, medical schools, managed care plans, and Medicaid provider-service-networks and directs the AHCA to provide a report by January 1, 2011, on the developed methodologies.

Creates the Medicaid and Public Assistance Fraud Strike Force (Strike Force) within the Department of Financial Services (DFS) to develop a statewide strategy and coordinate state and local efforts and resources to prevent, investigate and prosecute Medicaid and public assistance fraud.

The Strike Force will hold its organization meeting by no later than March 1, 2011, and is required to meet at least four times annually. The Strike Force will consist of 11 members with Chief Financial Officer (CFO) serving as chair, and the Attorney General serving as vice-chair.

Directs the Strike Force to provide recommendations and advice to the CFO on initiatives that include, but are not limited to:

- Conducting a census of current Medicaid and public assistance fraud efforts;
- Developing a strategic plan targeting state and local resources to prevent, detect, and deter Medicaid and public assistance fraud;
- Developing innovative technology and data sharing among affected entities;
- Establishing a program that provides grants to state and local agencies to implement effective anti-fraud measures;
- Providing grants, contingent upon appropriation, for multiagency Medicaid and public assistance fraud efforts;
- Providing assistance to state attorneys for support services or for the hiring of assistant state attorneys to prosecute Medicaid and public assistance fraud; and
- Providing assistance to judges for support services or for the hiring of senior judges so that Medicaid and public assistance fraud cases can be heard expeditiously.

Requires the CFO to develop model interagency agreements to coordinate the investigation of Medicaid and public assistance fraud.

Transfers the Public Assistance Fraud Division from the Florida Department of Law Enforcement to the DFS on January 1, 2011.

Authorizes Medicaid related fraud units to be collocated, to the extent possible and requires the Medicaid managed care fraud investigators within the Attorney General’s Office to collocate with the Division of Insurance Fraud within the DFS.

Requires the Auditor General and the Office of Program Policy Analysis and Government Accountability to review and evaluate the AHCA's Medicaid fraud and abuse systems and requires a report to the Legislature and Governor by December 1, 2011.

Requires each Medicaid managed care plan to adopt an anti-fraud plan to address overpayment, abuse, and fraud in the provision of Medicaid services and to submit the plan for approval to the Office of Medicaid Program Integrity within the AHCA. The amendment establishes minimum standards for anti-fraud plans and requires each Medicaid managed care plan to establish a fraud investigative unit or contract with such an entity. In addition, the amendment provides penalties for Medicaid managed care plans that fail to comply with these provisions.

Requires all Medicaid managed care plans to report any suspected instance of overpayment, fraud, or abuse to the Office of Medicaid Program Integrity within 15 days.

Revises the requirements for the selection of a behavioral health care provider in Broward County for children who have a case open in the Department of Children and Family Services's HomeSafeNet (HSN, Florida's child welfare reporting system), to allow those children who are in the custody of the State to enroll in a managed care plan which provides both physical and mental health care services. Authorizes a participating specialty plan to receive an administrative fee for coordination of services based upon the receipt of the state share of the fee from intergovernmental transfers.

Allows a provider service network to provide behavioral health services in addition to physical health services in areas of the state not under Medicaid reform.

Extends the guidelines for phasing in financial risk for approved provider service networks and Children's Medical Services Networks over the period of the waiver and the extension thereof.

This bill was signed into law by Governor Crist.

CS/CS/CS/HB 1143 – Legislation Designed to Reduce and Simplify Health Care Provider Regulation

This bill had 137 pages of various issues that affect the regulation of health care provider as well as some unrelated health care issues. We will report on those issues that we believe may have a direct effect on or relationship to pharmacy providers.

The bill amends regulation of prescription drug wholesale distribution by DOH. The Original version of the bill attempted to eliminate the requirement for exempt entities to maintain separate inventories for drugs purchased under the federal 340B discount drug program and other drugs however it appears that was removed. The bill does clarify that claims billed to the state Medicaid program using 340B drugs must have an NDC code and be billed at actual acquisition cost or payment will be denied. The bill replaces the named organization "Joint Commission on Accreditation on the Accreditation of Health Organizations to "The Joint Commission". The bill exempts sealed medical convenience kits meeting certain specifications from pedigree paper requirements. These specifications are as follows:

1) The medical convenience kit is assembled in an establishment that is registered as a medical device manufacturer with the United States Food and Drug Administration;

2) The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;

3) The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and

4) The drugs contained in the medical convenience kit are:
   a) Intravenous solutions intended for the replenishment of fluids and electrolytes;
   b) Products intended to maintain the equilibrium of water and minerals in the body;
   c) Products intended for irrigation or reconstitution;
   d) Anesthetics; or
   e) Anticoagulants

The exemptions do not apply to convenience kits containing any controlled substances.

Tacked onto the bill on the last day of the session was an unrelated issue on abortion ultrasounds. The bill (if not vetoed by Governor Crist) would require physicians to perform an ultrasound prior to performing the abortion and to share the results with the patient. There is also a section that restricts the use of state or federal funds to pay for elective abortions. This is shared with FPA members not to stir debate but to inform the members that this controversial issue may be the reason why the Governor may consider a veto. If vetoed the other pharmacy provisions would not become law.

The bill also grants permission for insurance entities to offer rewards or incentives for participating in voluntary wellness programs. These awards or incentives could include, but not limited to merchandise, gifts, debit card, modifications to copayments etc.

Included in this bill is a declaration that it is state policy that federal, state or local governments could not compel a person to purchase health insurance or services under certain circumstances. This is likely in response to the federal health care reform measures passed by Congress in 2009 requiring insurance coverage for everyone including those in public service and high risk occupations. The bill also takes away a requirement for the Agency for Health Care Administration to use certified mail to notify licensees under the Agency banner when the expiration date is nearing.

HB5001 – General Appropriations Bill (Medicaid Mail Order)

Included in this bill is a provision that creates a mail order service for chronically ill patients. The language in this bill reads as follows:

The agency shall issue an invitation to negotiate with a pharmacy or pharmacies to provide mail order delivery services at no cost to the patients who elect to receive their drugs in this manner for patients with chronic disease states including but not limited to congestive heart failure, diabetes, HIV/AIDS, patients suffering from end stage renal disease or cancer in order to assist Medicaid patients in securing prescriptions and to reduce program costs. The agency shall select patients appropriate for this mail order project and shall limit the number of participants to 20,000 patients statewide.

This issue presented itself in the last week of the legislative session with no committee review. The Florida Pharmacy Association began an immediate campaign to oppose the

language including a call to Governor Crist to veto the item. It is very possible that the 20,000 patient population of chronically diseased represents a significant majority of the Medicaid prescription drug spend.

Members need to also note that the Florida House had proposed a significant reimbursement reduction for pharmacy providers. Prior to the beginning of the legislative session Medicaid pharmacy reimbursement was the lower of:

WAC + 4.75%
AWP – 16.4%
Usual and Customary

State maximum allowable cost (SMAC) or
Federal upper limit (FUL)

While the current pharmacy reimbursement formula did not change the legislature did not alter the effect of the First Databank settlement resulting in what was published as AWP. This means that Florida Pharmacy providers will continue to suffer through the 4% dollar reduction since the republishing of AWP back in September of 2009.

Also found in the budget is a provision on page 402 where state employees can get their first 3 fills of certain maintenance drugs through a community pharmacy with the remainder required to be dispensed from mail order.

The Governor has signed the bill but also has vetoed certain sections including the funding for the USF Pharmacy school program. The mail order section was not vetoed.

HB5003 – Implementing Appropriations Bill (State Employee Prescription Benefit)

We found in this bill a revision to the state employee prescription benefit plan copays. The new formulas are as follows:

	New copay	Old copay
For generic drug with card	$7	$10
For preferred brand name drug with card	$30	$25
For nonpreferred brand name drug with card	$50	$40
For generic mail order drug	$14	$20
For preferred brand name mail order drug	$60	$50
For nonpreferred brand name mail order drug	$100	$80

The governor has signed the bill but vetoed specific portions.

HB5201 – Doctor of Pharmacy Degree Program at USF

House bill 5201 (budget conference report) authorized a doctor of pharmacy degree program at the University of South Florida. The bill requires that the program be physically located on the new campus of the University of South Florida Polytechnic. The university is authorized to develop and implement the program within existing facilities only until the construction of a pharmacy facility on the new campus of the University of South Florida Polytechnic is completed. This proposal was also introduced in S838 and HB101. While the governor has signed this bill the funding on the section associated with USF program was vetoed.

HB5311 – Defining Medical Convenience Kits in F.S. 499 – Transfer of Wholesaling to DBPR

This bill eliminates the need for a pedigree for the wholesale distribution of a medical convenience kit if the following conditions are met[4]:

1) The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a medical device manufacturer.
2) The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer
3) The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit
4) The drugs contained in the medical kit are:
   a) a. Intravenous solutions intended for the replenishment of fluids and electrolytes; 1294
   b) b. Products intended to maintain the equilibrium of water and minerals in the body;
   c) c. Products intended for irrigation or reconstitution;
   d) d. Anesthetics; or
   e) e. Anticoagulants.

Included in this bill is language that transfers all of the statutory powers, duties and functions, records, personnel etc related to the administration and management of Florida Statutes from the Department of Health to the Department of Business and Professional Regulation (DBPR). This means that DBPR will be regulating prescription drug wholesaling and everything association with 499 rather than the Department of Health. It is likely that pharmacies that are holding active wholesaling licenses will renew through DBPR. The bill was signed into law by Governor Crist with the effective date of the transfer being October 1, 2011.

FPA Monitored Bills that Did Not Pass

H1503 – Revisions to General Health Care Regulation

FPA advocates monitored this proposed bill very carefully during the closing moments of the 2010 legislative session. This 119 page bill as originally filed appeared to focus on a number of health regulation issues such as but not limited to changes to the requirements for licensing facilities, redefining the term "Joint Commission on the Accreditation of Hospitals" and further defining the role of the Division of Medical Quality Assurance within the Florida Department of Health. As the session continued a number of amendments were tacked on or tossed at this bill that could have some impact to pharmacy. For example there was language that created a pilot "full service" health and wellness program for state employees through a single vendor. Other amendments seemed to define who could own a health care clinic and pharmacists were not listed.

S1064 - Resolution on Sales Tax Exemption on DMEPOS Products

This bill proposed an amendment to the State Constitution to permanently prohibit the state from imposing a sales tax on the sale of food and medical products and supplies. This bill was never heard in Committee.

S1260 – Revision of the Florida Controlled Substance Act

The bill schedules a number of chemicals as controlled substances. The proposed scheduling of these chemicals in S1260 would have moved F.S. 893 to be more consistent with federal scheduling of these chemicals. This bill was never heard in Committee.

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[4] This exemption does not apply to convenience kits containing any controlled substances listed in F.S. 893 or the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

S2194, H1149 – Audits of Pharmacy Records

These bills were designed to expand auditing standards in Florida Medicaid as published in 465.188 to make them applicable to all third party administrators. These FPA supported provisions were never heard in committee due to our redirected efforts to fight against Medicaid cuts and mandatory mail order.

H911, S958 – Electronic Health Records

These bills as originally filed were designed to future facilitate the use of electronic health records by health care practitioners. While these bills ultimately died the FPA was successful in getting licensees under Florida Statutes 465 listed as "health care practitioners" for purposes of unquestionable access to the electronic health records. These bills unfortunately died on the calendar.

S652, H517 – Requirement for Pharmacies to Dispensed Contraceptive Products without Delay

As anticipated this year 2 bills were filed to require pharmacies to dispense contractive products. The bill defined the duties of the pharmacy and required that its employees do not:
1) Intimidate, threaten, or harass a patient in the delivery of services relating to a request for contraception;
2) Interfere with or obstruct the delivery of services relating to a request for contraception;
3) Intentionally misrepresent or deceive a patient about the availability of contraception or its mechanism of action;
4) Breach medical confidentiality with respect to a request for contraception or threaten to breach such confidentiality; or
5) Refuse to return a valid, lawful prescription for contraception upon a patient's or patient representative's request.

These bills included language negotiated by the FPA during the 2008 legislative session that allowed for a basis for refusing to provide a contraceptive such as patient's inability to pay, lack of a valid prescription and also on the basis of a professional or clinical judgment of the pharmacists. Additional language was also included to allow for refusal under religions reasons so long as the patient is accommodated by the pharmacy. These bills were never heard in committee.

H275, S516 – Required Insurance Coverage for Prescription Drugs

These bills required coverage for prescription drugs once started at the beginning of a plan year to be consistent to the end of the plan year for patients with preexisting conditions. It appears that the language would prohibit plans from revising their covered formularies and implementing prior authorization program revisions after a patient has enrolled in a prescription drug plan. Neither of these bills was heard in committee.

S330, H135 – Expansion of Optometrist Prescribing Authority.

The bill authorizes certified optometrists to administer and prescribe certain oral ocular pharmaceutical agents in addition to topical agents. The bill revises requirements for the existing formulary of topical ocular pharmaceutical agents that certified optometrists may administer and prescribe to include those topical pharmaceutical agents appropriate to treat and diagnose ocular disease or disorders within the scope of optometric practice. There also appears to be some language that would permit optometrists to prescribe certain controlled substances. The bill passed one committee in the Senate but was never heard in the House. Both bills died.

HB225 – Controlled Substance Dispensing Restrictions for Practitioners

This bill as originally filed would have restricted practitioners registered under 465.0276 (dispensing practitioners) from dispensing more than a 72 hour supply of controlled substances. During various committee stops language was added that required pharmacies to connect to a multistate electronic prescribing network as a condition of obtaining or renewing a pharmacy permit. The Florida Pharmacy Association prepared 4 pages of written comment to the staff director of the House Health Regulation Committee and met several times with the House sponsor and his aid explaining the challenges to this part of the bill's amended language. Additional language was added in an attempt to further regulate pain clinics. At some point during the legislative debate the 72 hour restriction was removed against the objections of the FPA. The FPA was successful in getting a version of that language amended onto SB2272. This bill ultimately died on the calendar.

Federal Health Care Reform Legislation Monitored by the FPA

IMPACT ON COMMUNITY PHARMACY (See Stat News, March 22, 2010)[5]

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 Manufactures 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 mean 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.

[5] Provided to the FPA from the National Community Pharmacists Association

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.

Proposed Board of Pharmacy Rule Changes

Two issues that the Florida Pharmacy Association is monitoring at the Board of Pharmacy include further development of the Board's technician training program rules and a request to consider modification of the rule requiring Florida permitted community pharmacies to be open 4 hours per week.

Technician Training Rules

The Florida Board of Pharmacy has been in rule development since passage of Senate bill 1360 during the 2008 legislative session. This bill required pharmacy technicians to register with the Florida Department of Health. Rule drafts have been exchanged at a number of Board of Pharmacy meetings along with requests for workshops and hearings by interested stakeholders. All individuals who are presenting as pharmacy technicians in Florida must wear a name badge with the words "Registered Pharmacy Technician" on it. These individuals must also have registered with the Florida Department of Health by December 31, 2009. Registered Florida technicians will have until December 31, 2010 to do one of the following three things:

- Completed a Board approved training program or

- Have completed a certification program approved by NCCA or
- Have worked a minimum of 1,500 under a licensed pharmacist

Beginning January 1, 2011 the only way that an individual can function as a pharmacy technician in Florida is to complete a Board approved technician training program and register with the Department of Health or be currently enrolled in a Florida Department of Health approved technician training program. After January 1, 2011 the option to use certification or work experience to become eligible for registration will cease to exist as the grandfather period would have ended December 31, 2010. Members need to be aware that the slowing of the technician training program rule development may create some problems with technician registration eligibility. It is our hope that the Board will be able to complete its work before the end of this year. A copy of the current rule draft has been published on the FPA web site.

Requirement for Community Pharmacies to be Open 40 Hours

The Florida Pharmacy Association filed a request before the Florida Board of Pharmacy for consideration and review of rule 64B16-28.1081 which requires community pharmacy permits to be open a minimum of 40 hours and 5 days per week with certain exceptions. The Florida Pharmacy Association through the House of Delegates has since 1995 been supportive of removing regulations that dictate the operating hours of pharmacies. We are not aware of any regulations that define the hourly operating standards for other critical health care providers such as physicians or dentists. The Board agreed to agenda this issue at meetings of the rules committee. A review was discussed at their meeting in Jacksonville and also in Ft. Lauderdale. The FPA also presented results of a survey where 71% of 28 states that responded indicated that they had no regulations that govern the number of hours that a pharmacy should be open.

Summary

Members need to be aware of the need for an ever watchful eye on the policy making process. In many cases a policy decision may have a positive or negative effect on our ability to care for our patients. Many decisions are also made that could adversely (or positively) affect a pharmacy's financial posture. Members who know who their state and federal legislators can have a significant impact on health care rules and regulations.

We are also very excited about the new opportunities for services that our profession can get into. With the need for medication therapy management, adherence and disease management the Florida pharmacist is key to a healthier population. Members networking with other members can build lasting relationships with the entire industry through collaborative care.

The Florida Pharmacy Association is proud to be the catalyst behind the development of state and national leaders. Running for APhA trustee is Merritt Island pharmacist **Mark Hobbs,** past president FPA. Also in the leadership pipeline for the National Community Pharmacists Association is Lynn Haven pharmacist **DeAnn Mullins** who is serving as secretary treasurer. Your current Chair of the FPA Board of Directors was honored by APhA with the Good Government of the Year award. Past FPA President **Kathy Petsos** received her fellow status with APhA.

Finally we all witnessed history this year with our own **Ed Hamilton**, FPA past president, concluding his term as president of the American Pharmacists Association. Ed is only the second Floridian to ever reach that goal. During Dr. Hamilton's leadership APhA facilitated the renovation and move into its new building. Congratulations Ed from your FPA family.