INDEPENDENT PHARMACY COOPERATIVE
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Capitol Agenda
THE INDEPENDENT FORUM

DEA Issues Final Rules Impacting Community Pharmacy

Controlled Substance Take-Back Program

Effective October 9, 2014 the Drug Enforcement Administration (DEA) will allow certain authorized registrants, including: manufacturers, distributors, reverse distributors and retail pharmacies to voluntarily administer controlled drug mail-back programs and maintain collection receptacles. The new rule expands the authority of authorized retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.

The DEA regulation also makes clear that registrants cannot use the collection receptacles to dispose of unused controlled substances in their inventory or stock. Additional recordkeeping and security requirements can be found at the Federal Register. Independent pharmacies can review the new rule and several allowable disposal options at www.justice.gov/dea/.

Hydrocodone Combination Products (HCPs) will be Schedule II Substances

Effective October 6, 2014, Hydrocodone Combination Products (HCPs) will be Schedule II substances under the Controlled Substances Act (CSA). For prescribers, the change primarily means that they may not authorize refills for any HCP prescriptions. However, they may issue multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of HCPs (if state law permits). The Drug Enforcement Administration (DEA) is allowing HCP prescriptions issued before October 6, 2014 that authorize refills to be refilled until April 8, 2015.

For pharmacies, the primary change is that they will need to utilize a DEA Form 222 in order to obtain HCPs from a distributor, and they must keep HCP records separate or readily retrievable. Security and inventory requirements will be the same as for other Schedule II items.

The packaging and labeling requirement changes for manufacturers and distributors do not apply to pharmacies. Pharmacies with HCPs in commercial containers labeled as Schedule III may continue to dispense these HCPs after the implementation of the final rule.

For more information and links to the Federal Register rule, go to www.ipcrx.com.

IPC Achieves Unprecedented Success in State Legislative Sessions

MAC Reform Efforts by IPC

IPC enjoys unprecedented success in its state legislative efforts. In 2014, IPC was actively engaged with Maximum Allowable Cost (MAC) legislation in Utah [HB 113], Minnesota [H.F. 1872], Colorado [HB 1213] and Iowa [HF 2297]. These states passed meaningful MAC reporting and appeal requirements that require PBMs change their egregious reimbursement practices. These efforts set important precedent for MAC reform nationwide.

IPC Focus on Fair Audit Legislation

IPC continues to work in Ohio on pharmacy fair audit legislation. The bill is set to be moved in early November 2014, IPC will be there to ensure its passage. Of critical importance, audit legislation was also passed in Florida which seemed unlikely of gaining traction at the beginning of the legislative session. IPC worked closely with community pharmacy stakeholders on this much needed law.

A Seat at the Table

IPC's long-time goal is to go beyond simply reporting legislative/regulatory news; and more importantly, be responsible for shaping it:

"IPC has established itself as one of the leading advocacy organizations for community pharmacy," said Sr. Vice President of Government Relations, Mark Kinney. "We have strategically taken the bipartisan approach to issues which has strengthened our ability to develop positive working relationships with members on both sides of the aisle. I see us only continuing these efforts in the months and years to come."

Drug Supply Chain Security Act of 2013

Effective July 1, 2015, the Drug Supply Chain Security Act of 2013 will require pharmacies (dispensers) to pass, capture and maintain certain types of information with respect to each drug transaction (or change in ownership). The Act addresses three types of "information": (1) transaction information (TI) that includes name of product, strength and dosage form, NDC, container size, shipment date and name and address of sender and recipient; (2) transaction history (TH), a list of all prior transactions; and (3) transaction statement (TS) an attestation by the prior business that is transferring ownership that they have complied with the Act. Pharmacies will receive this information from their respective wholesaler(s).

Definition of "transaction" exceptions include: (1) The dispensing of a medication by a pharmacist to a patient as well as the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies; and, (2) The transfer of a product from one pharmacy to fill a prescription for an identified patient.

For updates regarding returns, recordkeeping requirements, treatment of "suspect" and "illegitimate" product, and more go to www.ipcrx.com.

Pharmaceutical Care Management Association (PCMA) Files Lawsuit Against the State of Iowa

On September 2nd, the Pharmaceutical Care Management Association (PCMA), on behalf of its members, filed a lawsuit against the State of Iowa to enjoin HF 2297 that provides authority to the Insurance Commissioner to address PBM MAC reimbursement problems. The lawsuit seeks a declaration that the federal Employee Retirement Income Security Act (ERISA) of 1974, 29 U.S.C. § 1144 preempts HF 2297. This lawsuit also seeks a further declaration that HF 2297 violates the Takings Clauses of both the United States Constitution and the Iowa Constitution; as well as the Dormant Commerce Clause of the United States Constitution.

HF 2297 passed unanimously through the Iowa legislature. IPC worked diligently with the Iowa Pharmacy Association (IPA) and other stakeholders to help educate legislators on the importance of this much needed legislation. IPC will continue to expend resources and work tireless to challenge unfair PBM practices.

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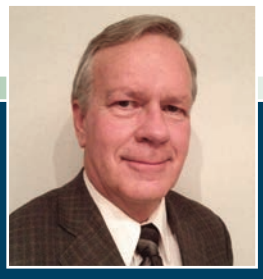
IPC at Work for You!

For more Government Relations info go to www.ipcrx.com.

Meet the Government Relations TEAM

Mark Kinney
Mark Kinney is the Senior Vice President of Government Relations at IPC. With more than 15 years of state and federal legislative experience, Kinney represents independent pharmacy nationwide. He has participated in numerous legislative conferences and committees and is a noted speaker for state and national pharmacy events.

John Covello
Director of Government Relations John Covello brings more than 20 years of rich background in governmental relations at the local, state and federal level. John directs IPC's legislative and regulatory initiatives in key states as well as assists on IPC's federal efforts for community pharmacy.



Brad Young
Brad Young brings extensive government affairs experience to IPC having served 11 years in the Colorado House of Representatives. Young has participated in effective lobbying efforts on issues such as Medicaid Reimbursement rates, pharmacy audits, drug substitution, drug discount cards, and many others.

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Email us at governmentrelations@ipcrx.com or call 800.755.1531.