State of the States

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1. Implementation of the Drug Quality and Security Act – H.R. 3204, Public Law 113-54

2. Prescription Drug Abuse and Controlled Substances
H.R. 3204, The Drug Quality & Security Act

• More than just compounding!
  – Title I – Compounding Quality Act
  – Title II – Drug Supply Chain Security Act
Title II – Drug Supply Chain Security Act

• State pedigree requirements were immediately preempted by the new federal law on **November 27, 2013**, the day it was signed by the President.

• Most states are focused on Title I, the compounding section of H.R. 3204 and are unaware of the immediate preemption.
HDMA State Education Efforts

• HDMA sent a memo to all 50 state regulatory authorities (Board of Pharmacy, Dept. of Health, etc.) regarding the passage of H.R. 3204 and the preemption provisions.

• Follow-up conversations with individual states have confirmed there’s a lot of confusion out there regarding new requirements, preemption, etc.
Title II – Drug Supply Chain Security Act

• Current federal PDMA pedigree requirements until January 1, 2015.
  • Preempts all state “normal distribution” pedigree requirements, etc.

• Phased-in approach starts with first requirements on January 1, 2015.

• End result is unit-level traceability in 10 years.
Title II – Drug Supply Chain Security Act

• Strengthens distributor licensure standards with national uniform requirements in the following areas:
  – Storage, handling and facility requirements;
  – Surety bonds;
  – Background checks for key personnel; and,
  – Stronger penalties for felons, repeat violations, etc.
Title II – Drug Supply Chain Security Act

• Timeline:
  – New FDA requirements must be final by November 2015
  – Effective two years later (November 2017)
  – Gives states those two years to adopt

• Until these new federal licensure standards are promulgated by FDA, the status quo will be maintained with respect to existing state distributor licensure requirements.
Title II – Drug Supply Chain Security Act

• Must we reinvent the wheel... again?
  – HDMA is recommending that because 29 states have been active in stronger licensing requirements in the last 10 years, a lot of good work has already been done in this area that FDA should consider when developing new federal requirements.
Title II – Drug Supply Chain Security Act

• States can continue to regulate in other unrelated areas of licensure such as controlled substances...
Florida

• Department of Business and Professional Regulation (DBPR) agrees that Florida pedigree requirements were immediately preempted on November 27, 2013.

• DBPR will issue individual Declaratory Statements to answer specific questions regarding Florida Chapter 499 pedigree requirements.
Florida

• DBPR is not planning to introduce any legislation in 2014 to clean-up preempted pedigree requirements in Chapter 499.
• Legislation may be introduced in 2015.
California

• Last month the California Board of Pharmacy approved the following three recommended action items related to H.R. 3204:
  – Provide and publish a notice of preemption to the public;
  – Seek a legislative repeal of California’s provisions via 2014 proposed legislation;
  – Stop the adoption of and withdraw pending regulations to implement California’s e-pedigree requirements.
Oklahoma

• The Board of Pharmacy recently sent a notice seeking volunteers for a new Pedigree Rules Review Committee.
• First meeting will be held April 2, 2014.
• The committee is charged with “reviewing the Board’s rules for compliance with H.R. 3204 and recommending proposed changes to the Board’s rules consistent with the enforcement of federal statutes.”
Other States

• Process of Review
  – Arizona board staff conducting complete review of their current regulations on pedigree
  – Minnesota will be reviewing within the year, including their current state licensing requirements
  – Nevada was not aware of preemption so decided to review their current requirements

• Agreed on preemption
  – North Dakota
Title II Continued Work

• HDMA has convened members to address issues - Traceability Implementation Work Group (TIWG)
  – Meet in person once a month
  – Weekly calls
• Coordinating with other associations
  – HIDA, NACDS, NCPA, PDSA, etc.
• Process is evolving
Controlled Substances and Prescription Drug Abuse
Nationwide Prescription Drug Abuse

• 52 million people in the US, over age 12, have used prescription drugs non-medically in their lifetime (NIDA 2011)

• In 2012, 6.8 million Americans aged 12 or older reported nonmedical use of prescription drugs in the past month (NIDA, revised January 2014)

• The US is 5% of the world’s population and consumes 75% of the world’s prescription drugs (UNODC 2011)

• Unintentional overdose deaths involving prescription drugs have quadrupled since 1999 and outnumber heroin and cocaine (NIDA, 2011)
Nationwide Prescription Drug Abuse

Where are the prescription drugs obtained?

1. 54.2%: FREE from friend or relative
2. 18.1%: One doctor
3. 16.6% Bought/took from friend or relative
4. 3.9%: Drug dealer or stranger
5. 2.2%: Other
6. 1.9%: More than one doctor
7. 0.3%: Bought on the internet
State Activity

- Prescription Drug Abuse/ Controlled Substances
  - Thresholds/Suspicious Ordering
  - Pain Clinics/Pill Mills
  - Pseudoephedrine and Hydrocodone Rescheduling
  - PDMPs

- Disposal/Product Stewardship Programs

- State Initiatives
  - NGA Report
  - State-specific legislation and/or programs

- HDMA Initiative
  - Public Relations Firm
Controlled Substances State Activity

• Distributor/Pharmacy Threshold
  ➢ Maryland legislation would require distributors to notify pharmacy customers before limiting distribution of all prescription drugs and devices
  ➢ Tennessee Board of Pharmacy expected to address issues related to distributors limiting shipments of controlled substances

• Suspicious Orders
  ➢ Tennessee proposal would set arbitrary number of 5,000 dosage units as suspicious; identical to Florida 2011 legislation. Sponsor open to our suggested amendments.

• Study Bills
  ➢ Pennsylvania AG Study Commission on Drug Abuse – AG Kane focused on recent increase in heroin use
  ➢ New Jersey Statewide Opioid Law Enforcement Coordinating Task Force
Controlled Substances State Activity

• Distributor/Pharmacy Threshold and Suspicious Ordering
  ➢ Possible conflict or counter to the Federal Controlled Substances Act, Title 21.1301.74(b)
  ➢ Concerns on DEA enforcement
  ➢ Federal does not require specific amounts
Pain Clinic or “Pill Mill”

Pill Mills:
- No physical exam required
- Cash only
- Walk-ins vs. appointments
- High volume
- Customers travel long distances
State Pain Clinic Legislation

Components of Pain Clinic Legislation

- Requires licensure with the state
- Facility must be owned by a physician
- Ban on dispensing certain controlled substances
- New criminal penalties for overprescribing

State Pain Clinic Licensing

- The following states have adopted pain care clinic laws/regulations: Florida, Georgia, Louisiana, Kentucky, Mississippi, Ohio, Tennessee, Texas, and West Virginia.
- So far in 2014, one pain clinic bill has been introduced in Oklahoma. Iowa and New York have holdover bills.
State Pseudoephedrine Laws & Regulations

• This year, there are four states (WV, IL, TN, IN) that have introduced bills proposing to list PSE in Schedule III.

• Twelve states have enacted PSE as a Schedule V controlled substance in the past nine years.

• Two (OR and MS) have enacted PSE as a Schedule III controlled substance, requiring a prescription.
Hydrocodone Laws & Regulations

• New York is the only state to pass legislation rescheduling hydrocodone combination products.

• On 2/27, the DEA announced a Notice of Proposed Rule Making to reschedule hydrocodone combination products to Schedule II.
  - May file request for hearing on or before 3/31/14
  - Comments must be filed on or before 4/28/14
  - Rule expected to be final by year end
Storage and Handling Exemption

Fourteen states have made pseudoephedrine or hydrocodone a controlled substance. All but one have included language exempting appropriately licensed wholesalers from further storage and recordkeeping requirements.

- Kansas did not include
- Working on pending legislation in three states to include
Federal Legislation


• Introduced by Reps. Blackburn (R-Tenn.) and Marino (R-Pa.)
• Clarifies terminology - Clarifies terminology in the Controlled Substances Act - “consistent with public health and safety” and “imminent danger.”
• Requirements for DEA registrants - Requires registrants to obtain criminal background checks and drug tests on employees who have access to controlled substances. Dispensers are exempt from this requirement.
• Corrective Action Plans - Requires Attorney General to give registrants the opportunity to correct the grounds for revocation or suspension.
• Working Group – Establishes a Working Group of supply chain representatives, public policy experts, DEA, FDA, ONDCP, law enforcement and patient groups.
Prescription Drug Monitoring Programs

• PDMPs collect, monitor, and analyze prescribing and dispensing data submitted by pharmacies and practitioners.

• Most PDMPs collect controlled substances listed under Schedules II-IV.

• Used by states as a tool to identify and prevent prescription drug abuse and diversion.
Prescription Drug Monitoring Programs

• Currently 49 states and one territory have legislation authorizing the creation and operation of a PDMP
  ➢ Forty-eight states have a PDMP that is operational

• Interstate sharing of data is important
  ➢ Twenty-four states engaged in interstate data sharing
  ➢ States are utilizing InterConnect through NABP

• There are two federal sources of funding
  ➢ The Harold Rogers Prescription Drug Monitoring Program (HRPDMP)
  ➢ The National All Schedules Prescription Electronic Reporting Act (NASPER)
Prescription Drug Monitoring Programs

Missouri is the only state that does not authorize a PDMP
• 2014 legislation has been introduced (again) in Missouri to establish a PMP

Virginia is working to integrate their PDMP to interface with ConnectVirginia, the Commonwealth’s health exchange
• PDMP registration is tied to license renewal for providers

Funding Issues
• California SB 809/CURES requires a $6 annual fee for licensees
• Florida has formed a foundation and advisory Board to raise funds to support their PMP
Disposal

• Support convenient, safe and cost-effective options

• State
  - Kentucky increased number of permanent drug take-back sites to 170
  - Arkansas’ “Monitor Secure and Dispose” Drop Box Project has awarded 60 new collection units to law enforcement agencies

• DEA Tack-Back Initiatives
  - Held seven times throughout the past three years
Product Stewardship

• State
  ➢ California introduced SB1014, the Home Generated Pharmaceutical Waste Collection Disposal Act, based on Alameda County
    ➢ “Producers” must submit a product stewardship plan
    ➢ Based on Alameda County – intent was not to include distributors

• Local
  ➢ Alameda passed the Safe Drug Disposal Ordinance
  ➢ King County Secure Medicine Return Regulations
  ➢ Illinois allows counties to establish disposal programs
NGA Issue Brief: Six Strategies for Reducing Prescription Drug Abuse

1. Make better use of prescription drug monitoring programs
   • Use as real-time
   • More effective as an analytic tool

2. Enhance enforcement
   • Coordinated approach and key partnerships
   • Provide education and training to law enforcement and licensing boards

3. Ensure proper disposal
   • Patient education
   • Take-back initiatives
NGA Issue Brief: Six Strategies for Reducing Prescription Drug Abuse

4. Leverage state’s role as regulator and purchaser
   • Educational opportunities
   • Requirements for healthcare providers
   • Adopt guidelines on appropriate prescribing practices
   • Restrict how and when patients access prescription drugs

5. Build Partnerships
   • Interagency collaboration
   • Stakeholder and non-traditional collaborations to develop strategy

6. Use the bully pulpit to promote public education
   • Public awareness campaigns
   • Utah’s “Use Only As Directed” media and education campaign
NGA launched the “Prescription Drug Abuse Reduction Policy Academy”

- White paper: Reducing Prescription Drug Abuse: Lessons Learned from an NGA Policy Academy
  - Leadership Matters
  - Prescribing behavior needs to change
  - Disposal options should be convenient and cost-effective
  - Prescription drug monitoring programs (PDMPs) are underused
  - Public education is critical
  - Treatment is essential
  - Data, metrics, and evaluation must drive policy and practice
State Initiatives

• Arkansas developed prescribing guidelines for emergency physicians and pain medicine specialists

• Kentucky developed training courses for providers to meet CMEs as a result of legislation

• Oregon and Oregon Medical Association partnered with Boston University and Case Western Reserve to train prescribers

• Alabama developed provider training with a focus on treatment for addicts
  ➢ Alabama Pain Management Act – increased regulations on pain clinics
  ➢ Alabama Doctor Shopping Act establishes criminal penalties for doctor shoppers
HDMA Initiatives

• HDMA hired a public relations firm – APCO Worldwide
  ➢ Conducted quantitative research and held focus groups in Philadelphia, Orlando, and Washington, DC
  ➢ Found most people don’t know about wholesalers; need to educate audiences of “who we are” and “what we do”

• Create education and awareness of industry efforts surrounding controlled substance abuse

• Industry Toolkit – Fact Sheets, State of Principles on Combating Drug Abuse and Diversion; infographic and video
  ➢ Drug abuse and diversion
  ➢ Supply chain security
  ➢ The role of distributors
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Session Wrap-up

- **Speakers Engage!**
  - New to the Expo Hall this year
  - Located in the RIGHT back corner
  - Let’s continue the conversation

- **Session Evaluation**
  - Two easy ways!
    - Mobile App (dmc.hdma.net)
    - HDMA website