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# 2014

## HDMA DISTRIBUTION MANAGEMENT CONFERENCE AND TECHNOLOGY EXPO

Co-hosted with IFPW (International Federation of Pharmaceutical Wholesalers)  
Supported by CAPDM (Canadian Association for Pharmacy Distribution Management)

# State of the States

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# State of the States

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

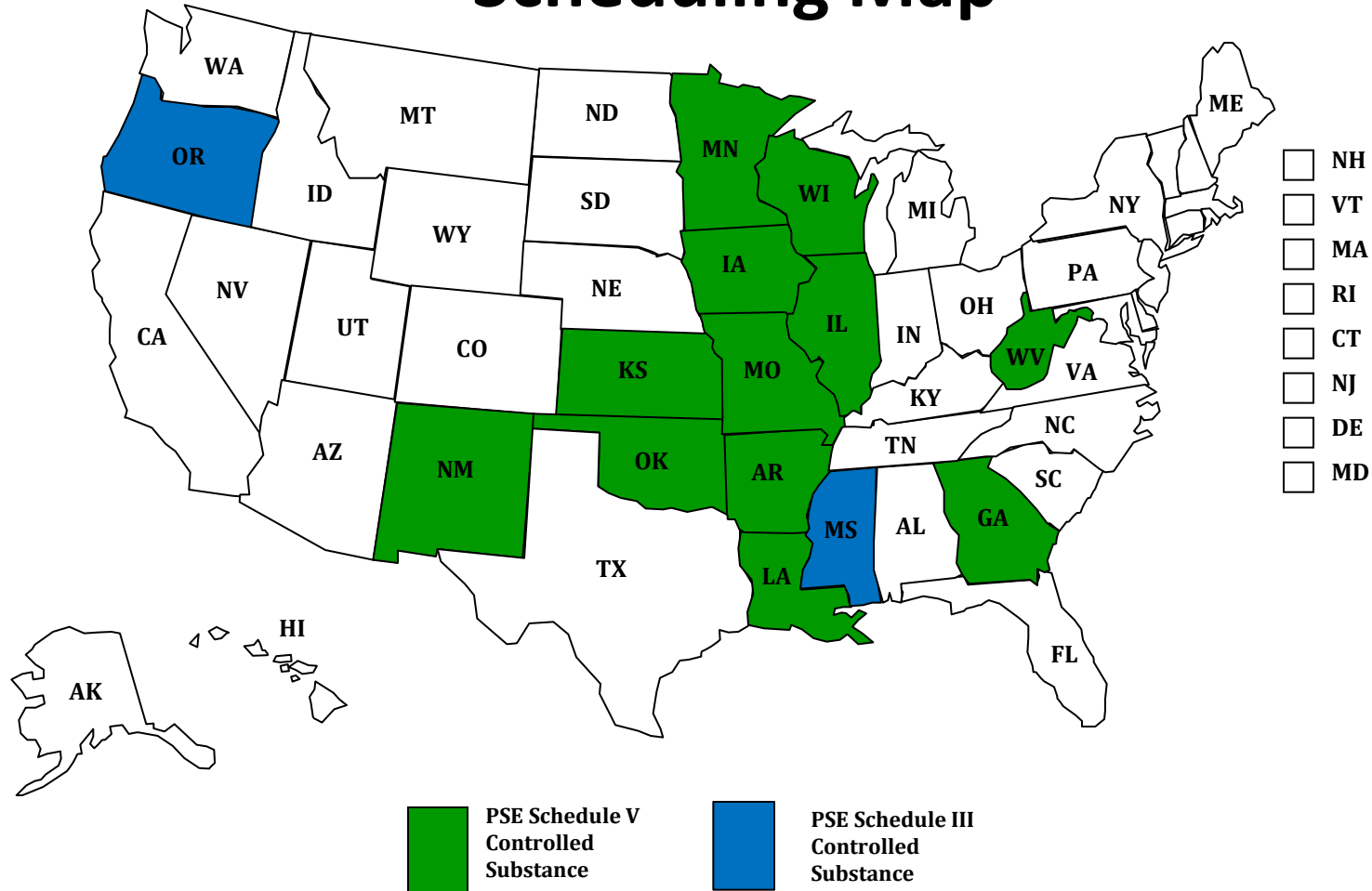
- The following states have adopted pain care clinic laws/regulations: Florida, Georgia, Louisiana, Kentucky, Mississippi, Ohio, Tennessee, Texas, and West Virginia.
- So far in 2014, one pain clinic bill has been introduced in Oklahoma. Iowa and New York have holdover bills.



# 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.

# HDMA Enacted PSE Controlled Substances Scheduling Map



# 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

## H.R. 4069 – Ensuring Patient Access and Effective Drug Enforcement Act of 2014

- 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](http://dmc.hdma.net))
  - HDMA website