HDMA
Healthcare Distribution Management Association

LATE TESTIMONY

Healthcare Distribution Management Association (HDMA)
Testimony on S.B. 40 SD2
Classifying Pseudoephedrine as a Schedule V Controlled Substance
Hawaii House Health Committee
March 22, 2011

My name is Sergio Santiviago, Associate Director for State Government Affairs with the Healthcare Distribution Management Association (HDMA), and on behalf of our four full-service wholesale drug distributor members with facilities located in Hawaii I am respectfully submitting the following written testimony on S.B.40 SD2.

As a strong advocate for the safe, reliable, and efficient distribution of the nation's healthcare products, HDMA applauds the goal of preventing precursor chemicals used for manufacturing methamphetamine and other illegal substances—such as pseudoephedrine (PSE)—from being purchased in large quantities or stolen at the pharmacy level for such purposes. However, without additional clarifying language, S.B. 40 SD2 will have a significant, negative impact on legitimate drug distribution that we believe may be unintended.

Specifically, classifying products containing PSE as Schedule V controlled substances would substantially change current inventory practices and safeguards for distributors in Hawaii by triggering federal Drug Enforcement Administration (DEA) regulations requiring that, in effect, the large volume of over-the-counter (OTC) products containing pseudoephedrine be stored in smaller cages and/or vaults located within already-secure warehouses (see 21 C.F.R. §1301.72(b)). These DEA requirements were created with the intent of securing the typically much smaller quantities of controlled substances that are commonly stored within it.

Whether storing controlled substances, prescription or OTC drugs—or typically all of them—licensed and registered drug distribution centers are highly regulated and secure facilities that must comply with strict federal and state regulatory requirements, and pass regular DEA and Hawaii Board of Pharmacy inspections. If a facility is—as most are—licensed to distribute controlled substances, prescription and OTC drugs, it must comply with federal requirements for storing controlled substances—even while appropriately storing non-controlled substance drugs within the facility, but outside of the vaults or cages reserved for controlled substances.

Federal regulations concerning storage of controlled substances mandate multiple and specific security procedures, such as (1) employee screening; (2) restricted access; (3) alarm systems; (4) self-locking and closing doors; (5) detailed, tamper-protected, recordkeeping; and (6) inventory control systems. Thus, DEA-registered wholesale drug distributors already meet the objectives of S.B. 40—storing drug products in highly secure facilities with limited opportunities for access, even if not all drug products being warehoused are schedule I–V controlled substances. As a result of these strict requirements, these facilities have not been a source of pseudoephedrine diversion.

Therefore, HDMA respectfully asks you to consider adding the following language as a new subsection to the bill, exempting distributors from the additional (and unnecessary) storage and handling burdens triggered by S.B. 40 SD2:

"This section does not apply to wholesale drug distributors licensed and regulated by the Hawaii Board of Pharmacy and registered with, and regulated by, the United States Drug Enforcement Administration, and exempts such wholesale drug distributors from storage, reporting, recordkeeping or physical security control requirements for controlled substances containing pseudoephedrine."

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Twelve states passing similar legislation or regulations classifying pseudoephedrine as either a Schedule III-V controlled substance have included this specific exemption from the additional storage and handling requirements as described above for wholesale drug distributors. These states recognize that to require DEA-registered wholesale distributors' compliance with unnecessary, expensive, and otherwise inapplicable security burdens fails to contribute towards the goal of reducing illegal access to PSEs.

Thank you in advance for your consideration of our comments, and if you have any questions, need additional information, or are interested in touring the operations at an in-state distribution facility, please do not hesitate to contact me at 703.885.0231

HDMA respectfully recommends adding the following language to Section 1 of S.B.40 SD 2—as reported out by the Senate and referred to the House Health Committee on 3/14/11—amending HRS 329.22 by creating a new subsection "(f):"

(f) Section 329-22 does not apply to wholesale drug distributors licensed and regulated by the Hawaii Board of Pharmacy and registered with, and regulated by, the United States Drug Enforcement Administration, and exempts such wholesale drug distributors from storage, reporting, recordkeeping or physical security control requirements only for controlled substances containing pseudoephedrine.

Enacted PSE Controlled Substance Scheduling Requirements
2/2/2011

State/Bill No.	Status	Exemption Summary
Arkansas SB 109	Signed by Governor 2/22/05	Places PSE products under Sch. V. **In-state distributors selling only to pharmacy are exempt.**
Illinois HB 4300	Signed by governor 5/25/06	Places PSE products under Sch. V. **Allows that persons registered with the DEA shall not be required to meet the physical security control requirements (such as cage or vault) for Sch. V controlled substances containing PSE.**
Iowa SF 169	Signed by governor 3/22/05	Places PSE products under Sch V. Distributors included in exemption list: **A vendor who holds a permit issued by the board and who sells, transfers, or otherwise furnishes a precursor substance to a practitioner or a pharmacy as defined in section 155A.3.**
Louisiana HB 890	Effective 8/15/09	Places PSE products under Sch V. Wholesalers licensed by the state and DEA are **exempt** from the storage, reporting, record keeping, and physical security requirements for controlled dangerous substances for nonprescription products containing ephedrine, pseudoephedrine, and phenylpropanolamine which are not listed in another schedule.
Minnesota HF 1	Signed by governor 6/02/05, SF 51 provisions incorporated into HF 1 (*Omnibus public safety finance bill*.)	Places PSE products under Sch. V. **Includes distributor storage exemption.**

Enacted PSE Controlled Substance Scheduling Requirements
2/2/2011

State/Bill No.	Status	Exemption Summary
Missouri SB 10	Signed by governor 6/15/05	Places PSE products under Sch. V. **Requires Board to promulgate rules regarding distributor storage exemption.** Emergency rule mirrored the federal List 1 Chemical requirements
Mississippi HB 512	Signed by the governor 2/2010, Effective 7/1/2010	Places PSE products under Sch. III. **Includes storage/handling exemption for wholesalers.**
New Mexico HB 211	Signed by governor 3/1/06	Places PSE products under Sch. V. Excludes liquids and liquid gel caps. **Sec 16.19.20.49 allows for distributors who meet DEA security requirements to be exempt from any additional storage/security requirements.**
Oklahoma HB 2176	Final regulations signed 7/11/2004	Places PSE products under Sch. V. **Distributors may apply for a special registration and be exempt from additional security and storage requirements.**
Oregon HB 2485	Signed by governor 8/16/05	Places PSE products under Sch. III, requiring a prescription. Does not exempt liquids. **Board of Pharmacy included distributor storage exemption in regulation**.
West Virginia SB 147	Signed by Governor 5/11/05	Places single ingredient PSE products under Sch V, excluding pediatrics. Does not exempt liquids. **Board of Pharmacy clarified that no additional storage/security or recordkeeping requirements would be placed on distributors.**

Enacted PSE Controlled Substance Scheduling Requirements
2/2/2011

State/Bill No.	Status	Exemption Summary
Wisconsin AB 183	Signed by Governor 6/7/07	Places PSE products under Sch. V. **Includes amendment prohibiting the Board from proposing additional storage requirements for distributors.**