

What's on the Horizon? Licensure Concerns for Pharmaceutical Companies

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Current Landscape

- D.C. detailer licensing requirement (SafeRx Act)
- Detailer payment disclosure laws
- Academic detailing



Current Landscape: Detailer Licensing

- D.C. SafeRx Act – only current licensure law
 - License required to engage in “the practice of pharmaceutical detailing”
 - Education, examination, and “fitness” requirement to obtain license; continuing education requirement to renew
 - Criminal, civil, and administrative penalties against individual detailers for non-compliance
 - Board of Pharmacy authorized to regulate detailing and to collect information from detailers re: communications with health professionals in the District
 - Prohibition on deceptive or misleading marketing by detailers



Current Landscape: Disclosure Laws

- Detailer disclosure requirements are frequently proposed in the states, and are likely source of new legislation at the state level going forward
 - In 2008, ~ 20 states proposed such legislation
 - General characteristics
 - Reporting threshold of \$25-\$100
 - Food/travel/honoraria/consulting fees fall within disclosure requirement
 - Research/Educational benefits and patient samples generally excluded from disclosure requirements
 - States with disclosure laws – California, D.C., Maine, Massachusetts, Minnesota, Vermont, West Virginia

Source: Nat'l Conference of State Legislatures, 2008 Prescription Drug State Legislation



Current Landscape: Academic Detailing

- State-sponsored “counter-detailing” – provide information and research to health professionals
 - Instead of banning or restricting drug industry marketing, states provide objective information about effective treatment strategies
- States with academic detailing laws – Pennsylvania, Vermont, Mississippi, Massachusetts, North Carolina, Oregon, New Hampshire, D.C.



On the Horizon: Licensure

- D.C. SafeRx Act is the only currently enacted licensure regime
- Expectation that 15 or more states will propose licensure requirements in 2009
 - Early version of new Massachusetts detailing law required licensure—enacted version does not (S. 2660)
- Licensure regimes create significant administrative burden on companies and individuals
 - Standards for obtaining license and conduct permitted may vary from state to state



D.C. SafeRx Act – Implementation

- Board of Pharmacy
 - Rulemaking/Administrative Procedure Concerns
 - Burdensome application process
 - 5 different forms to fill out, with conflicting and sometimes illogical requirements (e.g., U.S. government issued ID)
 - Required disclosure of personal information (SS#, criminal convictions, medical conditions) with no apparent safeguards to protect privacy or guard against improper use
 - Current efforts to clarify Act to address convention speakers, conference attendees, other overbreadth concerns



D.C. SafeRx Act – Substance

■ Licensure Requirement

- Imposes requirements on individuals, rather than companies
 - Carries with it threat of administrative, civil, and even criminal sanctions for violations
- Ability of Board of Pharmacy to collect information concerning detailers' communications risks disclosure of proprietary or confidential information (e.g. call records)
- Act provides for academic detailing but excludes academic detailers from licensure and other requirements (which apply only to “representatives of a pharmaceutical manufacturer or labeler”)



D.C. SafeRx Act – Substance

- Prohibition on Deceptive or Misleading Marketing
 - Possible conflict between D.C. interpretation and enforcement and federal standard (FDA's prohibition on false or misleading labeling)
 - Unclear how D.C. intends to enforce this prohibition
 - Likely availability of administrative, civil, and criminal sanctions for violations
 - Possible applicability to OTC drugs



D.C. SafeRx Act – Substance

- Code of Ethics
 - “A pharmaceutical detailer shall not willfully harass, intimidate, or coerce a licensed health professional, or an employee or representative of a licensed health professional through any form of communication. . . .” D.C. Municipal Regs for Pharmaceutical Detailers § 8305.4
 - “Reasonable person” standard employed to determine whether conduct constitutes willful harassment, intimidation, or coercion. § 8305.5
 - “A pharmaceutical detailer shall provide information to healthcare professionals that is accurate, fairly balanced, and consistent with FDA approved labeling.” § 8305



Licensure: Possible Legal Challenges

- Administrative law – D.C. SafeRx Act
 - Board of Pharmacy failure to consider comments, failure to follow administrative procedure requirements (*i.e.*, minutes) possibly actionable under D.C. Administrative Procedures Act
 - Privacy and confidentiality concerns in connection with license application—form requires SS#, requests arrest and conviction information, requests information about physical or mental conditions, substance abuse
 - Pharmaceutical companies cannot ask these questions in considering whether to employ a detailer



Licensure: Possible Legal Challenges

- First Amendment viewpoint discrimination
 - Licensure and deceptive or misleading marketing requirements in SafeRx Act apply only to “representatives of a pharmaceutical manufacturer or labeler,” and not to academic “counter-detailers”
 - Requiring licensing and exposing to administrative, civil, or criminal sanctions for pharmaceutical detailers, but not academic detailers discriminates on the basis of the speaker and viewpoint



Licensure: Possible Legal Challenges

- First Amendment commercial speech
 - Licensure requirement as impermissible restriction or burden on commercial speech (*Central Hudson*)
 - Requiring person to obtain permit or license before speaking generally viewed as burdening First Amendment freedoms
 - Restrictions on commercial speech are permitted, so long as government has substantial interest in regulating speech and regulation is no broader than necessary to directly advance that substantial interest
 - Education and examination requirements in SafeRx Act may be broader than necessary to advance government interest in protecting public health (as detailers do not have contact with patients)



Licensure: Possible Legal Challenges

- First Amendment compelled speech
 - D.C. Code of Conduct requires detailers provide “fairly balanced” information
 - To the extent this requirement is interpreted to require provision of information about alternative products or therapies (and therefore to require promotion of competitor products by detailers), strong arguments that this violates First Amendment freedom to choose content of own speech
 - Even if regulation is interpreted only to require disclosure of factual information (e.g. existence of generic alternative), possible argument that this interferes with speech



Licensure: Possible Legal Challenges

■ Preemption

- SafeRx act prohibits deceptive or misleading marketing
- FDA labeling and promotional labeling judgments strike balance between adequately warning of potential dangers and not unnecessarily deterring beneficial use
- Preemption argument strengthened if D.C.'s enforcement of this requirement is inconsistent with FDA judgments
- Supreme Court decision in *Wyeth v. Levine* may strengthen or weaken any such argument



Licensure: Possible Legal Challenges

- Void for vagueness
 - SafeRx Act Code of Conduct “harassment” provision
 - “A pharmaceutical detailer shall not willfully harass, intimidate, or coerce a licensed health professional, or an employee or representative of a licensed health professional through any form of communication, including through the sending of messages of disappointment for the failure to prescribe certain medications”
 - “the Board shall use a reasonable person standard to determine whether the conduct constitutes willful harassment, intimidation, or coercion”



Conclusion

- Licensure requirements, similar to the D.C. SafeRx Act, are the next big wave in state attempts to regulate detailing
- Problems with D.C. SafeRx likely not unique to that Act—most licensure regimes will implicate commercial speech and possibly be vulnerable to as-applied preemption and compelled speech challenge
- Agencies tasked with implementing these new licensure regimes may be ill-equipped to do so, and highlighting breadth of application (and possible legal infirmities) to agencies will be key in obtaining sensible implementing regulations