


**Council on Licensure,
Enforcement and Regulation**



DENVER
2009 Annual Conference
September 10 - 12

**Challenges of Regulating
Internet Professional
Practices**

Presenters: Steve Hart, RPH, Kentucky Board
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Promoting Regulatory Excellence

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Regulating Internet Professional Practices...

- The Realities...
- The Challenges...
- The Opportunities...


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The Realities...

- Technology here to stay!
- Internet: mode or tool?
- Protecting the public

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Technology...

- A “mutual” embrace
- Challenges existing norms, ways
- Benefits vs. risks

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The Challenges...


- Changing rules to accommodate vs. technology accommodating rules
- Regulated vs. non-regulated practices
- Cannot regulate the internet
- Protecting the public against themselves*

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In Ontario...

- Jurisdiction only over “members”
 - registered students, interns, pharmacists, pharmacy technicians (2010)
 - accredited pharmacies (owners/operators)
- Non-members must be prosecuted in provincial/federal courts

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Ontario College of Pharmacists...

- Enable vs. prohibit
- Embrace technology and innovative practice
...BUT
*only where appropriate safeguards are in place
- Do NOT create different rules to accommodate emerging technologies

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Internet Pharmacies

- The *Drug and Pharmacies Regulation Act (DPRA)* does not contemplate "virtual" pharmacies therefore, any internet site must be operated by an accredited "bricks and mortar" pharmacy and must display clearly:
 - pharmacy's name and physical location
 - accreditation #
 - owner/operator's name
 - pharmacy's telephone #
 - designated manager
 - hours a licensed pharmacist available
 - the green Point of Care symbol

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Point of Care Symbol




www.ocpinfo.com 1-800-220-1921

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Policy – Ontario pharmacies operating internet sites

- Must be operated as part of accredited site
- Designated manager responsible for all aspects of pharmacy operation, including internet site

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Policy – Ontario pharmacies operating internet sites (continued)

- Same expectations, requirements re:
 - authenticity, verification
 - pharmacist participation in “decision to sell”, availability for consultation
 - deliveries policy
 - tracking, temperature control, breakage, etc.
 - transmission (two way) in accordance with federal, provincial rules, standards of practice
 - all prescriptions recorded, filed, entered in same system
 - website must be in compliance with all laws and standards (including advertising)


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Pharmacies vs. Non-Pharmacies

- Unlicensed sites main concern
- Canadian flag ≠ Canada!
- 2002-2003 thecanadiadrugstore.com
 - not a drug store
 - selling only to U.S. market
- Extensive investigation

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- May 2002 – 15 charges laid under
 - *Regulated Health Professions Act (RHPA)*
 - *Pharmacy Act (PA)*
 - *Drug & Pharmacies Regulation Act (DPRA)*against The Canadian Drugstore Inc., one of its directors, an Ontario pharmacist, an Ontario pharmacy, an Ontario physician, and a Canadian drug wholesaler
- July 2003 – successful prosecution of all

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Key challenge?


- Protecting the Public against themselves!
- www.ocpinfo.com → public site
 - urge public to verify legitimacy
 - POC symbol/accreditation # in Canada
 - VIPPS symbol in U.S.
 - includes Q&A's
- Partnerships are key to getting the message out!

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Opportunities

- To dispel belief that regulators are barriers to change, innovation!
- "lead" vs. "be led"
- "pro-act" vs. "re-act"
- To highlight public protection mandate by resisting pressures that are not in sync
 - competition fears
 - resistance to change
 - economic concerns

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Yesterday...

- Computers in pharmacies (1970's)
- Mail order (1980's – early '90's)
- Internet (2000 – present)

Coming soon...

- Remote dispensing machines!

So...

- EMBRACE technology/innovative practice
- EXPECT - innovative practices to accommodate the same rules, principles and standards of practice
- ENSURE - safeguards and accountabilities in place to protect the public

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Today's Discussion

- Prescription Drug Abuse
- Rogue Internet Pharmacies
- NABP (National Association of Boards of Pharmacy) VIPPS certification
- Kentucky Pharmacy Practice Act Changes
- Ryan Haight Act
- Kentucky Case

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Prescription Drug Abuse

- Nearly 7 million Americans are abusing prescription drugs
- Prescription pain relievers are drug user's drug of choice vs marijuana and cocaine
- Nearly 1 in 10 high school seniors admits to abusing powerful prescription painkillers. A shocking 40 percent of teens and an almost equal number of their parents think abusing prescription painkillers is safer than abusing "street" drugs.

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Prescription Drug Abuse

- Opioid painkillers now cause more drug overdose deaths than cocaine and heroin combined.
- Twenty-five percent of drug-related emergency department visits are associated with abuse of prescription drugs.
- Methods of acquiring prescription drugs for abuse include "doctor-shopping," traditional drug-dealing, theft from pharmacies or homes, illicitly **acquiring prescription drugs via the Internet**, and from friends or relatives.


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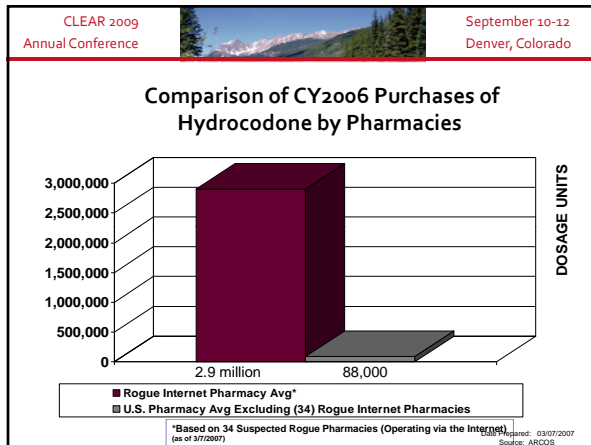
Rogue Internet Pharmacies

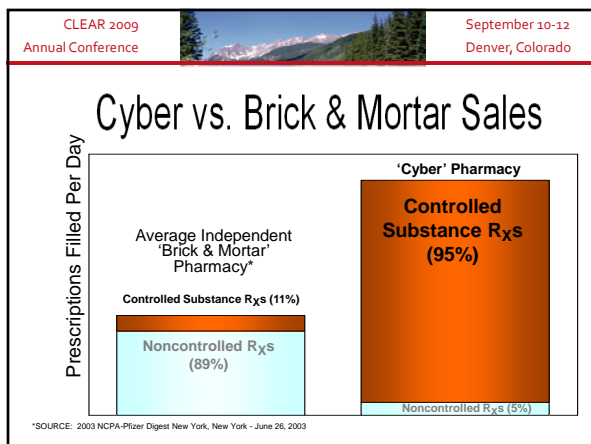
- Characteristics of questionable internet drug outlets
 - No prescription required
 - Prescription based upon an on-line questionnaire
 - No contact phone numbers or street address
 - No pharmacist consultation


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Rogue Internet Pharmacies

- Characteristics of questionable internet drug outlets (continued)
 - Waivers
 - Limited medications
 - International web sites
 - Spam solicitations






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Rogue Internet Pharmacies

- Dangers in obtaining a prescription over the internet
 - Harmful effects
 - Drug interactions
 - Questionable professional practices
 - Risk to personal, medical, or financial information
 - Counterfeit drugs

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NABP Efforts

- Verified Internet Pharmacy Practice Sites (VIPPS)
 - In response to public concern of the safety of pharmacy practices on the Internet, NABP developed the VIPPS accreditation program in the spring of 1999. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria that VIPPS-accredited pharmacies follow

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NABP Efforts

- Verified Internet Pharmacy Practice Sites (VIPPS)
 - A pharmacy practice site must comply with the licensing and survey requirements of the states in which it does business, and must demonstrate to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, maintenance of a quality assurance and improvement program, and provision of meaningful consultation between patients and pharmacists.

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NABP Efforts

- WWW.NABP.NET Buying prescriptions on-line
 - Approved Pharmacies 18 sites
 - VIPPS Certified
 - Non-approved Pharmacies
 - Non-recommended (NABP site >3075)
 - Legitscript

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VIPPS Webpage




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VIPPS Accredited Pharmacies




Default	Web Business Name	Web Site Address
	Amber Direct, LLC	www.amberdirect.com
	Central.com	www.central.com
	DrugSource, Inc.	www.drugsource.com
	Empire.com	www.empire.com
	FamilyMedx	www.familymedx.com
	HealthSource	www.healthsource.com
	MAJOR SUPPLY, INC. dba	www.ma.com
	OTCPharmacy	
	Liberty Medical Supply, Inc.	www.libertymedical.com
	Medix Health Systems, Inc.	www.medix.com
	Prescription Solutions	www.prescriptionsolutions.com
	Priora Therapeutics, LLC	www.prioratherapeutics.com
	Ro-Choice, Inc.	www.rochoice.com
	Salvo.com	www.salvo.com
	Tan Drug, Inc/CDPH	www.tandrug.com
	Thompson Dr.	www.thompson.com
	WebPharmacy	www.webpharmacy.com
	WebPharm Health	www.webpharm.com

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**Kentucky Pharmacy Practice Act
Changed June 2005**

- **315.035 Permit required for operation of a pharmacy**
 - (8) Any pharmacy within the Commonwealth that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall, prior to obtaining a permit, receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS accreditation shall remain current.

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**Kentucky Pharmacy Practice Act
changed June 2005**

- **315.035 Permit required for operation of a pharmacy**
 - (9) Any pharmacy within the Commonwealth doing business by use of the Internet shall certify the percentage of its annual business conducted via the Internet and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.

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**Kentucky Pharmacy Practice Act
changed June 2005**

- **315.0351 Out-of-state pharmacy**
 - (9) Any out-of-state pharmacy that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar accreditation, shall be maintained and remain current.

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Kentucky Pharmacy Practice Act
June 2005

- 315.035 Permit required for operation of a pharmacy
 - (10) Any out-of-state pharmacy doing business in the Commonwealth of Kentucky shall certify the percentage of its annual business conducted via the Internet and electronic mail and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.

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Kentucky Pharmacy Practice Act
June 2005

- **218A.140 Prohibited acts relating to controlled substances -- Penalties.**
 - (3) No person shall knowingly obtain or attempt to obtain a prescription for a controlled substance without having formed a valid practitioner-patient relationship with the practitioner or his or her designee from whom the person seeks to obtain the prescription.

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Kentucky Pharmacy Practice Act
June 2005

- **218A.140 Prohibited acts relating to controlled substances -- Penalties.**
 - (5) Any person who violates any subsection of this section shall be guilty of a Class D felony for a first offense and a Class C felony for subsequent offenses.
 - **Effective:** June 26, 2007

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State Level Program

- Prescription Drug Monitoring Programs
 - Individual State Programs
 - 38 states have enacted legislation
 - 33 states have operational programs
 - No uniformity among states
 - Boards of Pharmacy monitor
 - State Drug Enforcement
 - State Police
 - State Board of Health

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Ryan Haight Bill

- Effective April 19, 2009
- Named after a California teenager who overdosed on a painkiller he purchased on-line from doctor he never saw
- This law mandates at least one face to face meeting with a patient.
- This has always been a requirement for VIPPS certified pharmacies (18)

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Kentucky Internet Pharmacy Cases

- Pharmacy Group, Inc
 - Louisville, Ky (urban area)
 - No Controlled Substances
 - Questionnaire based
 - MD was located in New Jersey
 - Fioricet, Tramadol, Viagra, Cialis were top sellers

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Kentucky Internet Pharmacy Cases

- Meat Market Pharmacy
 - Louisville, Ky (urban area)
 - Non-pharmacist owner
 - Financial difficulties owed wholesaler >\$100K
 - Approached by A.T. from Florida with a promise to fix his financial woes
 - Two MDs in Tampa area
 - Pharmacist notified Board, confiscated 235 electronically transmitted controlled prescriptions

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Kentucky Internet Pharmacy Cases

- Advanced Pharmacy
 - Louisville, Ky (office complex)
 - Falsified application (infusion pharmacy)
 - Non pharmacist owner (Florida)
 - Pharmacist (unemployed)
 - Used broker sites to generate prescriptions
 - Seized over 300 prescription records filled in first four days (average price to customer \$108.00)

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Advanced Pharmacy Case



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Advanced Pharmacy Case



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Advanced Pharmacy Case



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Advanced Pharmacy Case



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Questions?

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