Legal and Policy Issues Concerning Expedited Partner Therapy (EPT)

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Public Health Law Network

- Funded by the Robert Wood Johnson Foundation
- The Network works with public health lawyers, practitioners, and others to improve the public's health through law
- The Western Region connects and serves individuals and organizations through technical assistance, training, and other efforts
- www.publichealthlawnetwork.org

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Disclaimer

- *Please note that information provided during this session does not constitute legal advice.*

- *Please seek guidance from your legal counsel for specific, legal advice.*

Overview

- Brief assessment of the public health impacts of Chlamydia and Gonorrhea
- Expedited Partner Therapy (EPT)
  - CDC and other organizations' support and guidance
- Legal barriers/facilitators project
  - **Stage 1**: Legal landscape of EPT
  - **Stage 2**: Identify and assess legal and policy barriers to the practice of EPT and adoption of laws and policies authorizing EPT

Public Health Impacts

Chlamydia (CT)

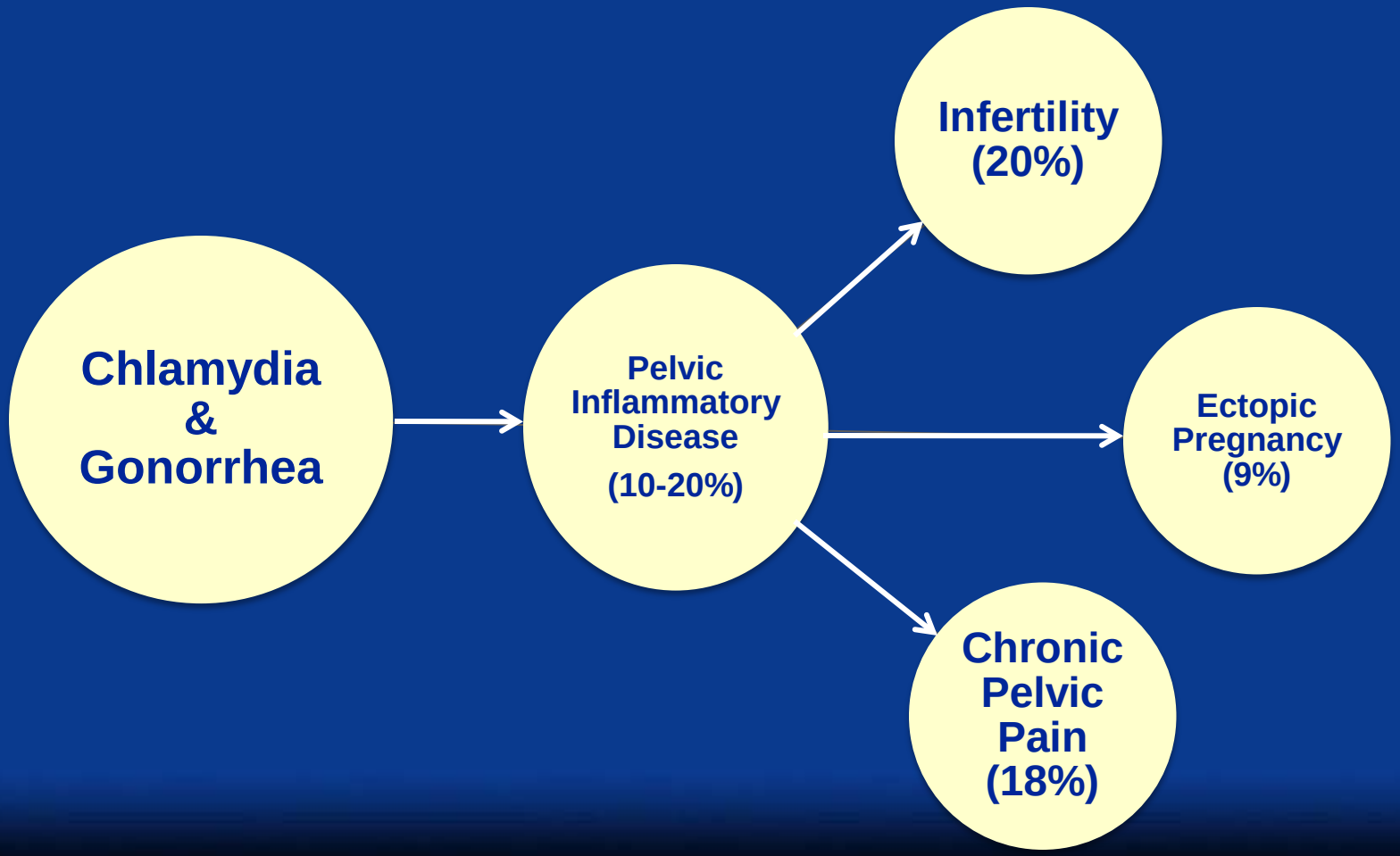
- 1,244,180 new cases reported to CDC (2009) (actual cases are >)
- Most commonly-reported infectious disease in the U.S.
- Bacterial infection, easily transmitted via sexual contact, asymptomatic
- Women are frequently re-infected if their partners are not treated

Gonorrhea (GC)

- 301,174 new cases reported to CDC (2009) (actual cases are >)
- Second most commonly-reported infectious disease
- Bacterial infection, easily transmitted via sexual contact, asymptomatic
- Persons infected may be more likely to transmit or contract HIV

http://www.cdc.gov/std/chlamydia/STDFact-Chlamydia.htm
http://www.cdc.gov/std/Gonorrhea/STDFact-gonorrhea.htm

Womens' Health Consequences



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Breaking the CT and GC Chain

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Expedited Partner Therapy

- EPT is a component of comprehensive partner services for STI treatment recommended by CDC
- Partners are provided treatment through the patient without an intervening clinical assessment of the partner
- Patients typically deliver either medications or prescriptions to their partners

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Expedited Partner Therapy - Illustrated

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Expedited Partner Therapy in the Management of Sexually Transmitted Diseases

Review and Guidance

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Disease Control and Prevention
National Center for HIV, STD, and TB Prevention

CDC

http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf

CDC EPT Guidance 2006

"[E]vidence indicates that EPT should be available to clinicians as an **option for partner management. . .** that **does not replace** other strategies, such as standard patient referral or provider-assisted referral . . . ."

Centers for Disease Control and Prevention. Expedited partner therapy in the management of sexually transmitted diseases. Atlanta, GA: US Department of Health and Human Services, 2006

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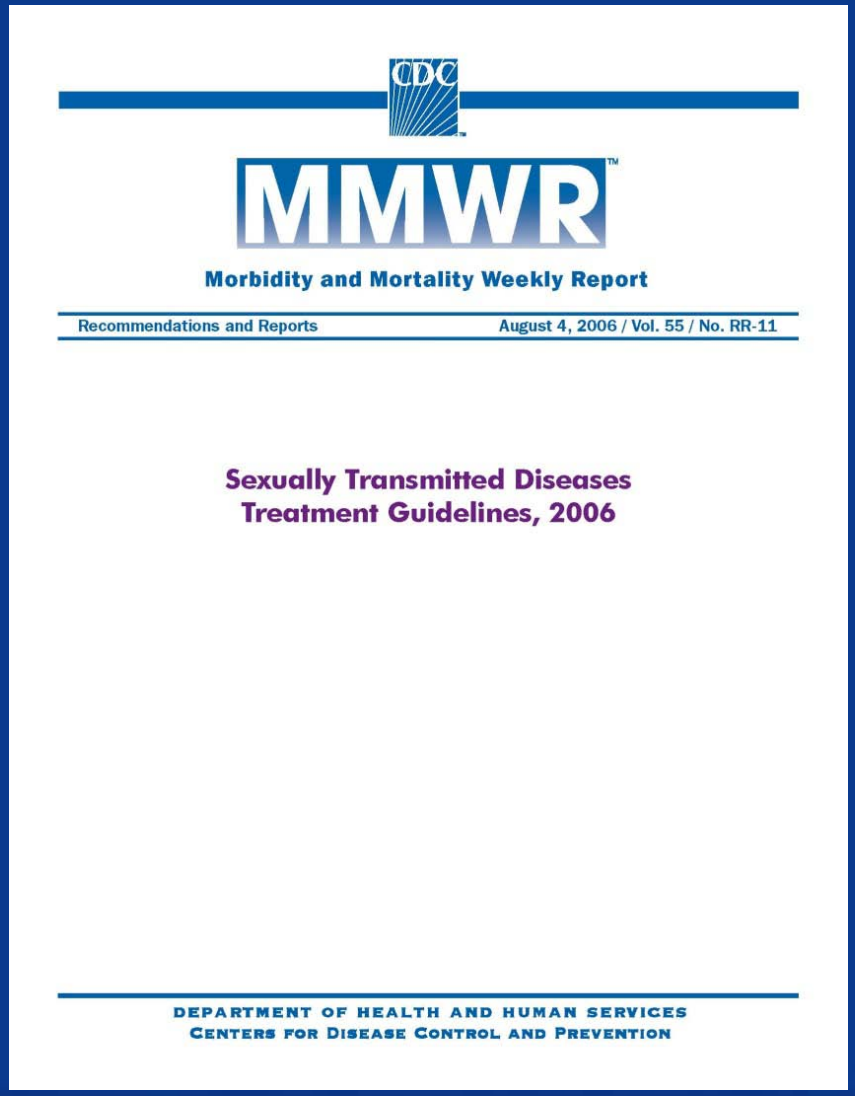

CDC

MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports | August 4, 2006 / Vol. 55 / No. RR-11

Sexually Transmitted Diseases
Treatment Guidelines, 2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

http://www.cdc.gov/std/treatment/default.htm

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CDC STD Treatment Guidance 2006

1. "When medical evaluation, counseling, and treatment of partners cannot be done because of the particular circumstances of a patient or partner or because of resource limitations, **other partner management options can be considered**….

Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2006. MMWR 2006;55 (no. RR-11):6

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CDC STD Treatment Guidance 2006

2. Patient-delivered therapy (i.e., via medications or prescriptions) can prevent re-infection of index cases and has been associated with a higher likelihood of partner notification, compared with unassisted patient referral of partners.

Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2006. MMWR 2006;55 (no. RR-11):6

CDC STD Treatment Guidance 2006

3. Medications and prescriptions for patient-delivered therapy should be **accompanied** by treatment instructions, appropriate warnings about taking medications if pregnant, general health counseling, and advice that partners should seek personal medical evaluations, ...”

Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2006. MMWR 2006;55 (no. RR-11):6

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National Support for EPT

- **AMA Council on Science and Public Health** adopted by the AMA House of Delegates in 2006 [http://www.ama-assn.org/ama/pub/category/16410.html]
- **Society for Adolescent Medicine & American Academy of Pediatrics**
  - Endorses use of EPT as an option for STI care among partners exposed within 60 days to heterosexual males/females with CT or GC when other partner management strategies are impractical/unsuccessful
  - Supports modifying existing laws impeding EPT implementation
- **American Bar Association 2008 Recommendation**
  - Urges jurisdictions to support the removal of legal barriers to the appropriate use of EPT by HCWs

Legal Barriers to EPT

Matthew Golden et al. suggests in 2005 based on their survey study of representatives of state boards of medicine and pharmacy that **88%** of participants perceived EPT as either "**illegal**" or of "**uncertain illegality**."

Golden MR, et al. The legal status of patient delivered partner therapy for sexually transmitted infections in the U.S., STD 2005; 32: 112-114.

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Legal Barriers to EPT

- Specific legal authorization
- Scope of practice limits
- Drug dispensing and labeling issues
- Liability concerns
- Health insurance limitations

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Assessing Legal and Policy Issues Concerning EPT for Sexually Transmitted Infections

Stage 1 - Legal Assessment

- Initial assessment of the legal environment underlying the practice of EPT across states
  - **Identify major legal issues**
  - **Clarify relevant laws, ethics, and policies** that facilitate or impede EPT
  - **Offer legal interpretations, strategies, or proposals** for reform to facilitate EPT across jurisdictions consistent with public health laws and policies

Stage 1 - Methodology

- Examine statutes, bills, regulations, cases, opinions, and other laws and policies in all states in 4 key areas:

1. Laws concerning the ability of physicians to provide a prescription to a patient's partner without prior evaluation of the partner

2. Laws concerning the ability of other health care personnel (nurses, physicians' assistants, pharmacists) to provide a prescription to a patient's partner without prior evaluation

3. Laws concerning prescription requirements (e.g., patient-specific information requirements)

4. Laws concerning public health authorization for EPT (via incorporation by reference or other techniques)

Stage 1 - Limitations

- Reviews are systematic and comprehensive, but not exhaustive
- Interpreting non-binding legal sources, such as policy guidance documents or administrative decisions, is complicated
- Comparative snapshot of legal provisions that may highlight laws concerning EPT in a given jurisdiction based on currently available information
- Jurisdiction-specific feedback can clarify specific legal issues

Stage 1 - Products

- Comprehensive table of state and territorial legal authorities to assist law and policy-makers, STD prevention professionals, and HCWs assess the legality of EPT available at: http://www.cdc.gov/std/ept/legal/default.htm

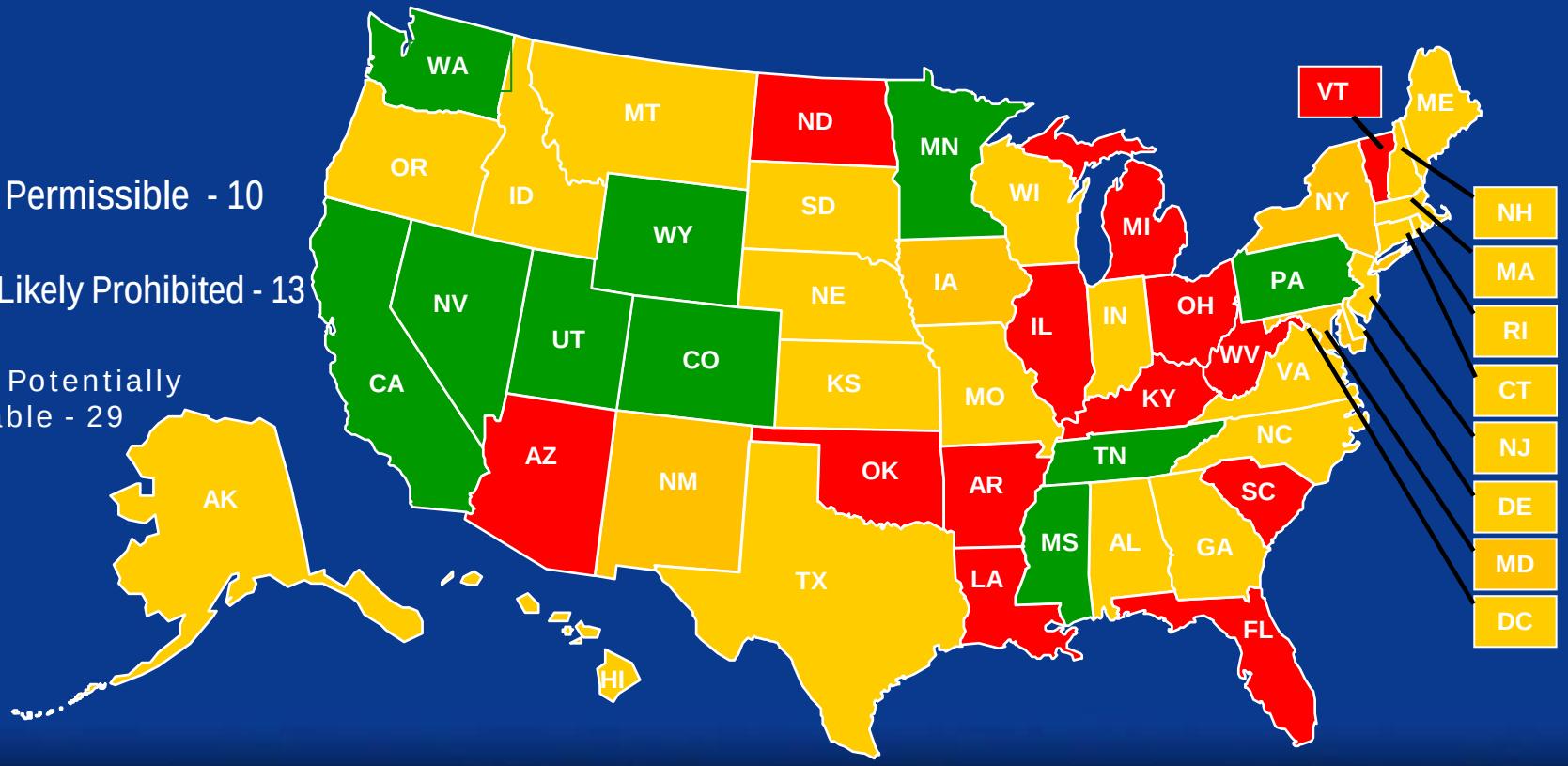
- James G. Hodge, Jr., Amy Pulver, et al., Expedited Partner Therapy for Sexually Transmitted Diseases: Assessing the Legal Environment, *American Journal of Public Health* (February 2008)

EPT Legal Status 2006

EPT is Permissible - 10

EPT is Likely Prohibited - 13

EPT is Potentially Allowable - 29



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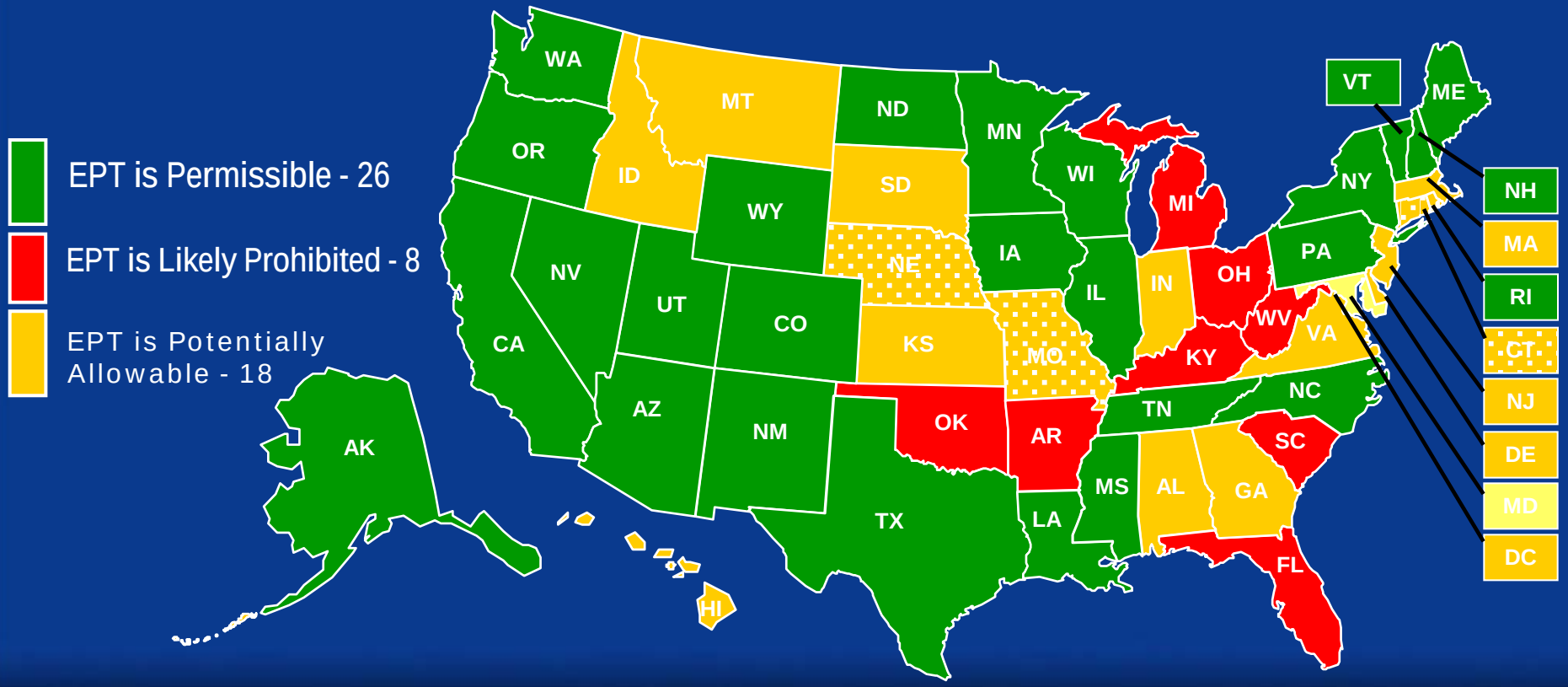
EPT Legal Status 2010



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EPT – AZ Statutory Authorization
September 2008

"Prescribing, dispensing or furnishing a prescription medication or a prescription-only device (as defined in § 32-1901) to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. This subdivision does not apply to:

(v) Prescriptions written or antimicrobials dispensed to a contact (as defined in § 36-661) who is believed to have had significant exposure risk with another person who has been diagnosed with a communicable disease by the prescribing or dispensing physician."

Ariz. Rev. Stat. Ann. § 32-1401.27(ss)(v)

http://www.azdhs.gov/phs/oids/std/pdf/Prevention%20Bulletin%20Jan%202009%20draft%20STD%20only.pdf

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Stage 2 - EPT Legal Consultation

Goal: identify legal barriers and develop responsive tools

Consultation on May 13, 2010 at CDC, Atlanta:

1. Barriers to Implementing EPT in Practice: **Liability**
2. Barriers to Implementing EPT in Practice: **Regulatory and Licensure Provisions**
3. Legal and Political Barriers to **Adoption of Laws and Policies Authorizing EPT**
4. Identification and Development of **Tools to Address Identified Barriers**

I. Barriers to Implementing EPT: Liability

- **General**: Liability concerns vary among states
- **Providers**: lost opportunity to test; risks and adverse reactions; loss of control over distributed drug; partner violence
- **Entities**: sovereign immunity may apply to governmental public health agencies, but not private entities; insurers reluctant to cover partners
- **Patients**: confidentiality concerns and partner violence

II. Barriers to Implementing EPT: Regulatory and Licensure Provisions

- **Financing**
  - Double prescription vs. separate prescription for partners
  - Insurance coverage
  - Federal and state payments via Medicaid programs
- **Minors**
  - Distribution to a minor whose partner is also a minor
  - Involvement of state agencies that oversee child services
  - Health concerns relating to infertility in young women or HIV
- **Medical Licensure**
  - Collaborative practice agreements; administrative rules; scope of practice limitations; medical board interpretations
- **Privacy Concerns**

III. Barriers Impeding EPT Authorization

What has worked:

- **Explicit statutory authorization**
- **Programs** initiated at the local level
- **Support** from organizations/partners
- **Advisory committees** (Medical Director)
- **Rule changes** at the administrative level including medical boards

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III. Barriers Impeding EPT Authorization

- **What has not worked:**
  - **Lack of support** from key players (medical boards, insurers)
  - **Conflicts** with pharmacy laws
  - **Misinformation** on efficacy of EPT
  - **Lack of involvement** of outside organizations
  - **Redefining** key legal terms (e.g., “dispense”)
  - **Local idiosyncrasies**

IV. Tools to Address Legal Barriers

Following the consultation at CDC, we sought guidance from state and local practitioners as to the types of practical, applied tools they needed to facilitate the implementation or authorization of EPT in their jurisdictions

Menu of Potential Tools

- Model legislation
- Legal best practices
- Adoption guides
- Models notices/guidelines
- Sample legal guidance letters
- Memorandum of Understanding
- Training guides
- Specific legal memoranda
- Tailored legal outlines
- Direct legal support
- Legal fact sheets
- FAQs
- Legal snapshots
- Legal decision trees
- Legal hotline
- Translational documents

CDC EPT Legal Toolkit

1) Sample State Legislative Language on Liability Issues Related to EPT
2) Discussion of Selected Issues Related to Practitioners' Liability for Harms to Partners Through EPT
3) Frequently Asked Questions: Health Information Privacy for Physicians, Pharmacists, and Other Healthcare Practitioners Concerning EPT
4) Considerations for Drafting and Implementing Legislation and Regulations Concerning EPT

Conclusion and Acknowledgements

- *Special thanks to Lexi White and Chase Millea for their research and contributions to this presentation*

- CDC's EPT Legal Status

http://www.cdc.gov/std/ept/legal/default.htm

- ASU's Public Health Law and Policy

http://www.law.asu.edu/publichealthlaw/PublicHealthLaw/Projects.aspx#EPT

- *Questions, comments, thoughts?*

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