



Legal/Policy Toolkit for Adoption and Implementation of Expedited Partner Therapy

*Prepared by the Arizona State University, Sandra Day O'Connor College of Law
in Collaboration with The Centers for Disease Control and Prevention*

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of STD Prevention



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Prepared by:

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Disclaimer- *The information in this Toolkit does not represent the official legal positions of the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention/HHS, or state and local governments, and is not meant to provide specific legal advice. Users of this Toolkit should consult with their official state and local legal counsel for specific legal advice and guidance.*

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I. Introduction

Expedited partner therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with a sexually transmitted disease without clinical assessment of the partners. This is typically accomplished by clinicians providing prescriptions or medications to the patient to give to his/her sex partners. In August 2006, the Centers for Disease Control and Prevention (CDC) in its [Sexually Transmitted Diseases Treatment Guidelines, 2006](#), recommended EPT as an evidenced-based option to manage chlamydial infection and gonorrhea by treating index patients' sex partners to prevent reinfection and curtail further transmission. EPT is also recommended in the updated guidelines, [Sexually Transmitted Diseases Treatment Guidelines, 2010](#). Since CDC's 2006 recommendation, other organizations have supported EPT, including the American Bar Association, the American Medical Association, the Society for Adolescent Health and Medicine, the American Academy of Pediatrics, and the American Congress of Obstetricians and Gynecologists.

In discussions of EPT, the legal status of the practice remained an area of uncertainty in many states. From 2005 to 2007, to assist state and local STD programs in their efforts to implement EPT as an additional partner services tool, CDC collaborated with the *Centers for Law and the Public's Health at Georgetown and Johns Hopkins Universities (Center)* on the first phase of an EPT law project to assess the legal framework concerning EPT across all 50 states and other jurisdictions (the District of Columbia and Puerto Rico). The primary research objective was to conceptualize, frame, and identify legal provisions that impact a clinician's ability to provide a prescription for a patient's sex partner, without prior evaluation of that partner, for purposes of treating an STD (specifically chlamydia or gonorrhea). This project led to the (1) analysis of statutes, regulations, judicial decisions and administrative opinions concerning EPT; and (2) posting of these data on [CDC's EPT website](#), which is updated monthly. The information presented on the website is not legal advice, nor is it a comprehensive analysis of all of the legal provisions that could implicate the legality of EPT in a given jurisdiction.

The original analysis of state laws by the *Center* and CDC concluded that only 10 states expressly permitted EPT in 2006. Subsequent CDC analysis suggests that this number has increased to 27 states as of November 2010.

The purpose of the second phase of the EPT law project was to assist states that are interested in adopting laws supportive of EPT as well as to assist states that had adopted such laws with addressing barriers to their full implementation. Accordingly, the CDC engaged the Public Health Law and Policy Program at the Sandra Day O'Connor College of Law, Arizona State University (ASU), to research and prepare legal and policy tools to assist states at various stages of EPT adoption and implementation.

On May 13, 2010, the CDC, in collaboration with ASU, convened a consultation of subject-matter experts to identify, characterize, and assess the barriers to adoption and implementation of laws and policies that authorize the practice of EPT. A follow-up webinar on June 10, 2010 provided an additional opportunity for discussion of these issues. Through these efforts, stakeholders identified and prioritized specific tools that would be helpful to inform

policymakers and practitioners about key issues related to EPT authorization and implementation.

This Toolkit is the principal outcome of the second phase of the EPT law project. It is intended as a resource for voluntary use by government officials at the state and local levels, their public and private sector partners, and others who are interested in adopting or facilitating the implementation of statutes or regulations that permit EPT in clinical practice. ***This Toolkit is not designed to provide specific legal guidance or advice and does not represent the official legal positions of federal, state, or local governments. The contents of the Toolkit should be discussed with the assistance of official state and local legal counsel.***

This Toolkit includes the following four tools: (1) Sample State Legislative Language on Liability Issues Related to Expedited Partner Therapy; (2) Discussion of Selected Issues Related to Practitioners' Liability for Harms to Partners Through Expedited Partner Therapy; (3) Frequently Asked Questions: Health Information Privacy for Physicians, Pharmacists, and Other Healthcare Practitioners Concerning Expedited Partner Therapy; and (4) Considerations for Drafting and Implementing Legislation and Regulations Concerning Expedited Partner Therapy.

This Toolkit is accessible at <http://www.cdc.gov/std/ept>.

II. Sample State Legislative Language on Liability Issues Related to Expedited Partner Therapy

Purpose

This tool is intended as a resource for voluntary use by government officials at the state and local levels, their public and private sector partners, and others who are interested in adopting or facilitating the implementation of statutes or regulations that permit expedited partner therapy (EPT) in clinical practice. The practice of EPT raises questions as to whether a healthcare practitioner may be liable for harms incurred by the sex partners of index patients. Thus, practitioners' liability concerns related to partner injuries may impede the practice of EPT in some jurisdictions. To address these concerns, several states have included specific language on liability in legislation that authorizes EPT.

The Table of sample legislative language provides specific language from nine states that introduced or passed legislation, as of Sept. 24, 2010, which (1) authorizes EPT to treat sexually transmitted diseases, primarily chlamydia and/or gonorrhea; and (2) protects physicians or other healthcare practitioners from liability. The nine states reviewed below were selected following a review of all states' laws expressly authorizing EPT. Hypertext links provide ready access to specific legislative sources. A brief analysis of these provisions is also provided in the final column of the table. Further analysis of physician and other healthcare practitioners' liability is available in the corresponding tool, "Discussion of Selected Issues Related to Practitioners' Liability for Harms to Partners Through Expedited Partner Therapy," on p.10.

State/Citation	Adopted Legislative Language	Commentary
Illinois, 410 ILL. COMP. STAT. 325/6(e)(5) (2010)	<p>"A health care professional prescribing, dispensing, furnishing, or otherwise providing in good faith without fee or compensation prescription antibiotics to partners under this subsection (e) and providing counseling and written materials as required by item (3) of this subsection (e) shall not be subject to civil or professional liability, except for willful or wanton misconduct. A health care professional shall not be subject to civil or professional liability for choosing not to provide expedited partner therapy."</p>	<p>Illinois law allows healthcare professionals to participate in EPT without being subject to liability, except for acts that constitute willful or wanton misconduct, so long as the healthcare professional provides counseling and written materials to the index patient, including warnings of potential allergies, side effects, and dangers to pregnant women who take the prescribed antibiotics.</p>

State/Citation	Adopted Legislative Language	Commentary
<p>Illinois, 410 ILL. COMP. STAT. 325/6(e)(6) (2010)</p>	<p>“A pharmacist or pharmacy shall not be subject to civil or professional liability for choosing not to fill a prescription that would cause the pharmacist or pharmacy to violate any provision of the Pharmacy Practice Act, including the definition of ‘prescription’ set forth in subsection (e) of Section 3 of the Pharmacy Practice Act or the definition of ‘drug regimen review’ set forth in subsection (y) of Section 3 of the Pharmacy Practice Act.”</p>	<p>While this language does not directly refer to EPT, it allows pharmacists in Illinois to opt out of participating in EPT without being subject to liability.</p>
<p>Maine, 22 ME. REV. STAT. ANN. tit. 22, § 1242(3) (2010)</p>	<p>“A health care professional who provides expedited partner therapy in good faith without fee or compensation under this section and provides counseling and written materials as required in subsection 1 is not subject to civil or professional liability in connection with the provision of the therapy, counseling and materials, except in the case of willful and wanton misconduct. A health care professional is not subject to civil or professional liability for choosing not to provide expedited partner therapy.”</p>	<p>Maine’s provision largely resembles Illinois’s provision. This statutory provision offers a clear legislative statement about the limits of liability for healthcare professionals, except for acts that constitute willful or wanton misconduct.</p>
<p>Missouri, S.B. 982, 95th Gen. Assem., 2nd Reg. Sess., (Mo. 2010)</p>	<p>“Any licensed physician may, but shall not be required to, utilize expedited partner therapy for the management of the partners of persons with chlamydia or gonorrhea... Any licensed physician utilizing expedited partner therapy for the management of partners of persons with chlamydia or gonorrhea under this section shall have immunity from any civil liability that may otherwise result by reason of such actions, unless such physician acts negligently, recklessly, in bad faith, or with malicious purpose.”</p>	<p>Missouri law explicitly states that physicians are not required to use EPT. The liability provision explicitly applies only to physicians, thus offering no direct protection to other healthcare practitioners. Even so, Missouri’s legislative language offers questionable liability protections for physicians since it exempts physicians’ acts of “negligence,” as well as reckless or malicious acts. Since no physician is arguably liable for acts which do not constitute negligence, the substantive value of this language may be limited to direct claims from partners who may not be able to successfully sue a physician for acts of negligence because of a lack of a doctor-patient relationship.</p>

State/Citation	Adopted Legislative Language	Commentary
<p>New York, N.Y. PUB. HEALTH LAW, Art. 23, tit.1, § 2312 (2010).</p>	<p>“A health care practitioner who reasonably and in good faith renders expedited partner therapy in accordance with this section and following the rules and regulations promulgated by the commissioner shall not be subject to civil or criminal liability or be deemed to have engaged in unprofessional conduct.”</p>	<p>New York law allows treatment of STDs by licensed physicians only (N.Y. PUB. HEALTH LAW, Art. 23, tit.1. §2305 (2010)). Correspondingly, its legislative liability protections may extend solely to physicians.</p>
<p>Rhode Island, R.I. Gen. Laws § 23-11-20 (2010)</p>	<p>“Neither a licensed physician, licensed physician assistant or certified registered nurse practitioner who, in good faith, prescribes prescription drugs to a patient's sexual partner or partners for the treatment of a sexually transmitted chlamydia or gonorrhea infection in accordance with this section, nor the group or healthcare facility for which they work, shall be subject to civil or criminal liability and shall not be deemed to have engaged in unprofessional conduct.”</p>	<p>Rhode Island law provides broad liability protection. It (1) specifically identifies those healthcare practitioners who are entitled to protection; (2) uniquely extends liability protections to physicians' groups or healthcare facilities where EPT is practiced; and (3) does not specifically exempt practitioners' acts of willful, reckless, or wanton conduct (although other state liability laws may exempt these acts from liability protection).</p>
<p>Utah, Utah Code Ann. § 58-1-501.3 (2009)</p>	<p>“This section does not require a practitioner or a licensee under this chapter to prescribe or dispense a drug to treat a sexually transmitted disease for patient delivered expedited partner therapy... A practitioner or licensee under this chapter is not liable for a medical malpractice action if the use of expedited partner therapy is in compliance with this section, except for those acts which are grossly negligent or willful and wanton.”</p>	<p>Utah law explicitly states that a practitioner or a licensee may, but is not required to, use EPT. Its liability language specifically addresses claims in medical malpractice, thus potentially allowing claims against healthcare practitioners on other legal grounds (e.g., a claim against a practitioner may arise under breach of contract where the practitioner is contractually bound to provide specific services, but fails to do so).</p>
<p>Wisconsin, WIS. STAT. § 448.035(4)(a) (2009)</p>	<p>“(a) Except as provided in par. (b), a physician, physician assistant, or certified advanced practice nurse prescriber is immune from civil liability for injury to or the death of a person who takes any antimicrobial drug if the antimicrobial drug is prescribed, dispensed, or furnished under this section and if expedited partner therapy is provided as specified under this section. (b) The immunity under par. (a) does not extend to the donation, distribution, furnishing, or dispensing of an antimicrobial drug by a physician, physician assistant, or certified advanced practice nurse prescriber whose act or omission involves reckless, wanton, or intentional misconduct.”</p>	<p>Wisconsin law distinctly protects healthcare practitioners from liability resulting from “injury to or death of a person who takes any antimicrobial drug” when given through EPT. This offers considerable latitude to healthcare practitioners who prescribe differing treatments through EPT.</p>

State/Citation	Proposed Language	Commentary
<p>Connecticut, H.B. 5450 § 1(e), 2010 Reg. Sess. (Conn. 2010)</p>	<p>“A prescribing practitioner who prescribes or dispenses oral antibiotic drugs to the sexual partner or partners of a patient diagnosed with an infection of chlamydia or gonorrhea, in accordance with the provisions of this subsection, shall not be deemed to have violated the prescribing practitioner's standard of care for such prescribing or dispensing.”</p>	<p>The proposed language identifies EPT as not in violation of the standard of care. While this provision does not directly address liability like several of the provisions above, it affirms that EPT practices are consistent with the standard of care. This may offer some liability protection for healthcare practitioners against claims grounded in medical malpractice. Since the practice of EPT is consistent with the standard of care, liability claims cannot suggest a practitioner acted outside the standard in using EPT.</p>
<p>Nebraska, L.B. 992, 101st Leg., 2nd Sess. (Neb. 2010)</p>	<p>“Any medical practitioner, any official health department, the Department of Health and Human Services, or any other person making such reports or notifications or providing such prescription drugs pursuant to section 1 of this act shall be immune from suit for slander or libel or breach of privileged communication based on any statements contained in such reports and notifications or pursuant to provision of such prescription drugs.”</p>	<p>The proposed language protects physicians from liability claims relating to breaches of confidentiality which may arise through EPT.</p>

III. Discussion of Select Issues Related to Practitioners' Liability for Harms to Partners Through Expedited Partner Therapy

Purpose

This tool is intended as a resource for voluntary use by government officials at the state and local levels, their public and private sector partners, and others who are interested in facilitating the implementation of statutes or regulations that permit expedited partner therapy (EPT) in clinical practice.

Users should view this tool as a guide to identifying and understanding healthcare liability and related legal issues that should be discussed with the assistance of official legal counsel. It is intended to provide an overview and explanation of pertinent legal issues, not an exhaustive analysis of all facets of legal issues underlying civil liability claims.

Overview

In general, physicians or other healthcare practitioners may be liable for a patient's injuries or death resulting from medical care, including treatment through prescription drugs, under several legal theories. Practitioners' acts may, for example, (1) be inconsistent with the prevailing standard of care;¹ (2) fall outside specific contractual obligations; (3) contravene medical or pharmacy board guidance; or (4) constitute negligence or intentional acts which lead directly to harms to patients or others. In each of these examples, a healthcare practitioner may be held legally responsible for injuries or other harms to a patient.

Potential liability of healthcare practitioners for their patients' resulting injuries is a constant concern in most healthcare settings. The practice of EPT raises questions as to whether a practitioner may be liable for harms incurred by the sex partners of index patients. Thus, practitioners' liability concerns related to partner injuries may impede the practice of EPT in some jurisdictions. However, our research found no reported cases in which courts have specifically addressed the liability of physicians, pharmacists, or other healthcare practitioners or entities for partner injuries through the practice of EPT. A few cases involve judicial review of a medical or pharmaceutical board's decision to revoke a practitioner's license based on unlawful prescription practices or other licensing violations, which has indirect implications for EPT.²

Claims of medical malpractice against physicians using EPT to treat chlamydia and gonorrhea are theoretically possible. However, since the risk of adverse reactions to the antibiotics used in EPT to treat these infections is minimal and can be managed with reasonable care and precautions, the threat of medical malpractice claims is comparably low. A lack of reported judicial decisions, however, does not mean that liability claims have not arisen or that they have not been settled out of court.

Addressing potential liability claims underlying EPT requires jurisdiction-specific analyses due to variations in state and local laws in areas such as: (1) whether EPT is legally permissible;³ (2) whether EPT constitutes an appropriate standard of care; (3) whether a doctor-patient relationship with the partner arises; and (4) the extent of liability protections⁴ for practitioners. Without attempting to provide legal guidance for any specific jurisdiction, this document lays out

essential legal and policy issues concerning potential liability claims arising through the practice of EPT, including

- whether a professional relationship (e.g., physician-patient relationship) is established between a healthcare practitioner and their patient's sex partner through EPT;
- the extent of a healthcare practitioner's duty to a patient's partner outside a formal, professional relationship;
- whether EPT constitutes the standard of care; and
- whether a healthcare practitioner owes a patient's partner a "duty to warn" regarding treatments offered via EPT.

Existence of a Professional Relationship Between Healthcare Practitioners and Sex Partners

Liability claims based on medical malpractice typically arise between patients and practitioners who share a recognized medical relationship.⁵ From this formal relationship (e.g. a physician-patient relationship) specific legal duties arise, such as the physician's duty to provide minimally competent care. Failure to provide such care due to negligence or other acts or omissions may lead to claims of medical malpractice.

Traditionally a physician-patient relationship is established when an individual seeks a physician's medical expertise and assistance and the physician knowingly accepts the individual as a patient.⁶ Some states clarify that a physician-patient relationship is established only where the physician personally examines the patient.⁷ In several states, however, the mere acceptance or initial undertaking of patient treatment by a physician is sufficient to establish a legally-recognized relationship from which liability may arise.⁸

Whether a practitioner may be liable for harms to the sex partner of a patient through EPT depends upon a court's determination of whether a formal relationship exists between the partner and the patient's healthcare practitioner. The relationship between a physician and the patient's partner via EPT is distinct because

- the physician will generally not consult with, or examine, the partner (even after treatment is provided); and
- the partner has not sought out treatment from the physician even though the partner may be accepting treatment by taking antibiotics at the physician's instruction.

Some states have specifically acknowledged a lack of a physician-patient relationship through legislation authorizing EPT.⁹ In other states, however, the act of providing treatment through EPT that will knowingly be used by an identified partner may be sufficient to establish a formal relationship. For example, a formal relationship may be established where a physician writes a prescription for the partner using the partner's name or identifying information. In these states, physicians and other healthcare practitioners may owe the partner some duty of care. Failure to fulfill this duty could result in a medical malpractice claim.

Healthcare Practitioners' Duties to a Partner Outside a Formal Relationship

Even if there is no formal relationship with a patient's partner, a practitioner may also owe a special duty to non-patients when there is a foreseeable risk to these persons.¹⁰ For example, physicians have been found liable for failing to provide a patient with proper information to protect an intimate partner from contracting a communicable disease, including a sexually transmitted disease (STD).¹¹ In some circumstances a physician may be liable where a partner contracts an STD from the physician's patient.

Concerning EPT, a physician may be liable for failing to

- properly instruct the patient on the risks of transmitting the disease to their partner;
- inform the patient how to prevent the transmission; or
- properly diagnose and treat the STD.

A patient's partner may be at risk where a physician uses EPT and fails to properly instruct the patient to provide the partner with warnings or written materials related to the use of the prescribed or dispensed medications. States that have adopted legislation protecting healthcare practitioners from liability for EPT generally require practitioners to provide written materials for the partner.¹² If a physician provides the patient with the requisite information,¹³ the practitioner will have likely fulfilled his or her legal duty to the partner. Furthermore, where a practitioner counsels a patient about the risks of transmitting an STD to the patient's partner, regardless of whether the practitioner elects to use EPT, the practitioner may be released from liability. In such cases, the patient is obligated to properly inform his or her partner or take steps to prevent transmission of the STD.¹⁴

Based on our review of relevant law, it appears unlikely that a physician will be found liable to a partner for failing to practice EPT (even though the patient and partner may ultimately be harmed through infection or reinfection of an STD). While multiple states have established EPT as a permissible or recommended practice, none have mandated it. In states where EPT is permitted, a physician may determine whether EPT is appropriate. Additionally, many states have issued guidance limiting the use of EPT to specific circumstances consistent with CDC recommendations. EPT, for example, is not currently recommended for men who have sex with men or women who have sex with women.¹⁵

EPT as the Standard of Care

Civil liability in a medical malpractice case is largely determined by the standard of care in the state in which a healthcare practitioner is licensed to practice. The standard of care is the minimum level of competency a healthcare practitioner must meet while providing medical services.¹⁶ What constitutes the standard of care varies across states and depends on numerous factors, including the legality of a medical practice.

In general, states follow one of two forms of standard of care: (1) a standard established by the "custom of practice," which requires a practitioner's actions to be within the custom of his or her practice area by jurisdiction and area of specialty;¹⁷ or (2) the "reasonable physician" standard which requires a physician's actions be reasonable regardless of custom.¹⁸ In each circumstance, expert testimony may be required to help determine what the custom of practice is or what is reasonable.

The legality of EPT in a state may directly impact practitioners' liability. A healthcare practitioner practicing in a state where EPT is explicitly prohibited¹⁹ may be liable for harms caused as a result of the use of EPT through what is known as "negligence per se." According to this legal theory, a practitioner's negligence may be established by his or her failure to meet specific legal duties set by law.²⁰ Thus, if a practitioner offers EPT in a state that has prohibited it, liability may arise for resulting harms to patients or others, regardless of whether the practitioner's actions were reasonable.²¹

In states where EPT is either legally permissible or potentially legally permissible, a healthcare practitioner may be liable for harm resulting from the clinical use of EPT if the practice is determined to be outside of the standard of care. Whether EPT is within the standard of care is determined based on (1) the customary practices in the state and (2) whether the practitioner's actions are viewed as reasonable based on expert testimony and jury findings.²² Evidence of whether EPT constitutes the standard of care may include guidance issued by CDC or state medical or pharmacy boards, as well as a state's adoption of EPT by statute or regulation.²³ Upon consideration of expert testimony and evidence of the standard of care, the jury will determine whether a practitioner's decision to use EPT was within the standard of care. If EPT is determined not to fall within the standard of care, the healthcare practitioner may be found liable for injuries resulting from treatment.

Transposing a Practitioner's Duty to Warn Partners to Drug Manufacturers

A physician or pharmacist owes a special duty to patients when prescribing or dispensing prescription drugs²⁴ to warn them of any potential complications, side-effects, or adverse reactions under what is known as the "learned intermediary doctrine."²⁵ This duty may potentially extend to partners of patients. State laws permitting EPT may require a treating physician to provide counseling and written information to the patient regarding potential risks of the prescribed treatment.²⁶

However, if a drug manufacturer has reason to know that practitioners may not have the opportunity to reduce the risks of harm, the drug manufacturer may be required to provide adequate warnings directly to partners regarding potential side effects.²⁷ A drug manufacturer, in effect, assumes the duty to warn of various harms through prescription label requirements or other communications.²⁸

This transfer of liability from practitioners to manufacturers may potentially occur when a practitioner issues a "double dose" prescription through EPT to the patient for the patient to dispense equally to his or her partner. Where the manufacturer is aware of this practice, it likely has reason to know that the practitioner may not have an opportunity to warn the partner of potential risks through counseling. Conversely, the transfer of liability may not apply where a practitioner writes a specific prescription for the partner. In such a case, the practitioner may be found to have directly provided treatment to the partner, and thus has a duty to warn.

Conclusion

A physician or other practitioner may be held liable for harms to partners through EPT depending on whether (1) a formal practitioner relationship is established; (2) the partner has a foreseeable risk outside such a relationship; (3) EPT is consistent with the standard of care; and/or (4) potential liability transfers to a drug manufacturer who has reason to know the practitioner is not positioned to reduce the risks of harm to the partner. State-specific legal analyses and consideration of the facts of individual cases are also important in determining whether liability for harms to partners may arise.

Generally, healthcare practitioners who use EPT in their practice may be able to mitigate liability through the following practices:

- Review information regarding options for partner treatment when determining whether to implement EPT;
- Provide the patient with sufficient information, including written materials, to provide to the partner regarding potential risks; and
- Consult with legal counsel as to the legality of EPT and the standard of care within the state.

References

¹ *Burke v. Skaggs*, 867 A.2d 213, 220-21 (D.C. 2005).

² *See* *Carloni v. De Buono*, 245 A.D.2d 970, 972, 667 N.Y.S.2d 109 (N.Y. App. Div. 1997) (upholding revocation of physician's license for misconduct, including issuing a prescription without prior examination); *Balmir v. De Buono*, 237 A.D.2d 648, 649, 655 N.Y.S.2d 113 (N.Y. App. Div. 1997) (upholding revocation of physician's license for refilling prescriptions that were inconsistent with physical finding where patients produced empty medication bottles); *Jones v. N.D. State Bd. of Med. Examrs.*, 691 N.W.2d 251, 258 (N.D. 2005) (upholding revocation of physician's license for prescribing over the Internet without prior examination or physician-patient relationship); *Reed v. State Med. Bd. of Ohio*, 833 N.E.2d 814, 825 n.4 (Ohio Ct. App. 2005) (upholding revocation of physician's license when she prescribed extra doses of antibiotic to a patient who insisted on giving extra doses to her husband); *Royder v. State Med. Bd. of Ohio*, 2002 WL 31867888 (Ohio Ct. App. 2002) (upholding revocation of physician's license for failing to evaluate new patients before giving a prescription, and instead delegating to a physician assistant); *State ex rel. Okla. Bd. of Med. Licensure and Supervision v. Litchfield*, 103 P.3d 1111 (Okla. Civ. App. 2004) (upholding suspension of physician's license and finding of misconduct when physician prescribed to patients without establishing a physician-patient relationship or prior examination); *State v. Ray*, 848 P.2d 46, 47 (Okla. Civ. App. 1992) (upholding disciplinary action against physician for filling prescription without establishing "doctor/patient relationship and/or examination"); *Gale v. State Bd. of Med. Examrs.*, 282 S.C. 474, 320 S.E.2d 35 (S.C. Ct. App. 1984) (upholding revocation of physician's license when physician wrote prescriptions outside of physician-patient relationship).

³ A review of the current status of state EPT laws is available at <http://cdc.gov/std/ept>.

⁴ *See* 410 ILL. COMP. STAT. 325/6(e)(5) (2010); 22 ME. REV. STAT. ANN. c. 251, sub-c. 3, art. 5 § 1242 (2010); S.B. 982, 95th Gen. Assem., 2nd Reg. Sess., (Mo. 2010); N.Y. PUB. HEALTH LAW, Art. 23, tit.1, § 2312 (2010); R.I. GEN. LAWS § 23-11-20 (2010); UTAH CODE ANN. § 58-1-501.3 (2009); WIS. STAT. § 448.035(4)(a) (2009); H.B. 5450 § 1(e), 2010 Reg. Sess. (Ct. 2010); L.B. 992, 101st Leg., 2nd Sess. (Neb. 2010); *see also* the corresponding EPT Tool: "Best Practices" Table: *Sample State Legislative Language on Liability Issues Related to EPT* for additional information on states that have adopted or have introduced liability protections within EPT legislation.

⁵ *Castillo v. Emergency Med. Assocs., P.A.*, 372 F.3d 643 (4th Cir. 2004); *Lyons v. Grether*, 218 Va. 630, 239 S.E.2d 103, 105 (Va. 1977) (noting that Virginia courts have found that a "physician's duty arises only upon the creation of a physician-patient relationship; that relationship springs from a consensual transaction, a contract, express or implied, general or special").

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- ⁶ *Oliver v. Brock*, 342 So.2d 1 (Ala. 1976); *see also* *St. John v. Pope*, 901 S.W.2d 420 (Tex.1995) (although a physician does not need to directly deal with a patient to establish a relationship, a physician has the right to decline to treat a patient and thus decline the physician-patient relationship).
- ⁷ *Irvin v. Smith*, 31 P.3d 934, 941 (Kan. 2001).
- ⁸ *Calhoun v. U.S.*, 539 F.Supp.2d 500 (D.Mass. 2008) (the “essence” of the physician-patient relationship commences when a physician undertakes to diagnose or treat a patient, including beginning to diagnose and treatment of a baby for post-birth complications); *Gillespie v. Univ. of Chicago Hosps.*, 900 N.E.2d 737 (App. Ct. 1st Dist. 2008) (acknowledging that a physician-patient relationship may exist even in the absence of any meetings between the physician and the patient, where the physician performs services for the patient).
- ⁹ *See* UTAH CODE ANN. § 58-1-501.3(1)(b)(i) (“with whom a practitioner does not have a bonafide practitioner-patient relationship”).
- ¹⁰ *Tarasoff v. Regents of Univ. of Cal.*, 17 Cal.3d 425 (1976) (extending a physician’s special relationship and duty of care with a patient to a third party when the physician had knowledge that the patient was going to harm the third party).
- ¹¹ *DiMarco v. Lynch Homes-Chester County, Inc.*, 583 A.2d 422 (Pa. 1990); Restatement (Second) of Torts § 324A.
- ¹² *See* 410 ILL. COMP. STAT. 325/6(e)(3) (requiring healthcare professionals to provide counseling and written materials).
- ¹³ Often established by state laws or by state-issued guidance. *See supra* note 12.
- ¹⁴ *See* *Endres v. Endres*, 968 A.2d 336, 338 (Vt. 2008); *Duke v. Housen*, 589 P.2d 334 (Wyo. 1979); *De Vall v. Strunk*, 96 S.W.2d 245 (Tex. Civ. App. 1936) (finding individuals liable for transmitting a communicable disease where the individual knew or should have known of the infection and risk of transmission).
- ¹⁵ Centers for Disease Control, *Legal Status of EPT – Summary Totals*, <http://www.cdc.gov/std/ept/legal/totals.htm> (last visited July 30, 2010) (“27 states feature one or more laws that may limit the ability of some healthcare practitioners to conduct EPT”).
- ¹⁶ *McCarty v. Mladineo*, 636 So.2d 377, 380 (Miss. 1994).
- ¹⁷ Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164-70 (2000).
- ¹⁸ *Helling v. Carey*, 519 P.2d 981, 983 (1974) (establishing the rule that a physician is liable where he fails to use reasonable care in treating a patient).
- ¹⁹ *See e.g.*, FLA. ADMIN. CODE ANN. R. 64B8-9.014 (requires examination and diagnoses for a healthcare provider to provide treatment); MICH. COMP. LAWS § 333.17745 (a practitioner can only prescribe for the practitioner’s own patient); OHIO REV. CODE ANN. § 4730.21 (practitioner cannot provide treatment without prior examination).
- ²⁰ W. Keeton, D. Dobbs, R. Keeton & D. Owen, *Prosser and Keeton on the Law of Torts* 220, 230 (5th ed. 1984).
- ²¹ *Law v. Camp*, 116 F.Supp.2d 295, 303 (D.Conn. 2000), *aff’d* 15 Fed.Appx. 24 (2nd Cir. 2001).
- ²² *Supra* note 1 at 219.
- ²³ *See* *Decker v. St. Mary’s Hosp.* 249 Ill.App.3d 802 (1993) (finding that various forms of evidence, including state statutes, are admissible to demonstrate the standard of care in medical malpractice cases against a hospital); *Walski v. Tiesenga*, 72 Ill.2d 249, 257 (1978).
- ²⁴ The learned intermediary doctrine is a concept of products liability tort law that traditionally absolves the manufacturer from liability to the consumer as long as the manufacturer has provided adequate warning to the patient’s physician.
- ²⁵ *Sterling Drug v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).
- ²⁶ *See supra* note 13 (Illinois’ EPT law requires healthcare professionals to provide index patients counseling and written materials, including warnings of potential allergies and side effects and potential dangers to pregnant women who take the prescribed antibiotics).
- ²⁷ *Davis v. Wyeth Lab. Inc.*, 399 F.2d 121 (9th Cir. 1968) (manufacturer was liable and had a duty to warn potential patients of the dangers inherent in using the prescription drug, a polio vaccine, which was administered to the general public).
- ²⁸ *Id.* at 131.

IV. Frequently Asked Questions About Health Information Privacy for Physicians, Pharmacists, and Other Healthcare Practitioners Concerning Expedited Partner Therapy

Purpose

This tool is intended as a resource for voluntary use by healthcare practitioners, government officials at the state and local levels, their public and private sector partners, and others who are interested in facilitating the implementation of statutes or regulations that permit expedited partner therapy (EPT) in clinical practice and who have specific interest in legal issues related to health information privacy in that context. This tool contains information regarding concerns of physicians, pharmacists, and other healthcare practitioners in the public or private sectors related to EPT patient and partner information privacy. The content focuses primarily on relevant federal laws but emphasizes that practitioners, in all cases, should consult with their legal counsel to understand the implications of federal laws in more detail and to understand the implications of pertinent state privacy laws.

This tool has four sections: 1) general privacy concerns, 2) healthcare practitioner communications, 3) privacy issues specific to minors, and 4) prescription labeling requirements.

A. GENERAL PRIVACY CONCERNS

1. Do the protections of the HIPAA Privacy Rule¹ apply to the practice of EPT?

Yes. The HIPAA Privacy Rule applies to covered entities (and their business associates) that electronically transmit individually identifiable health information as part of standard health transactions. Covered entities include healthcare practitioners, health plans, and healthcare clearinghouses, as well as any other persons or entities engaged in covered functions (i.e., those activities which assimilate the healthcare services that covered entities provide).² To the extent that EPT is part of the continuum of healthcare services, the HIPAA Privacy Rule applies to healthcare practitioners, including physicians, nurses, pharmacists, and even public health workers, who treat patients or their sex partners through EPT.³ Considerable additional privacy protections may be required by state laws.

2. What types of health data are entitled to legal privacy protections?

The HIPAA Privacy Rule (and most state health information privacy laws) protects individually identifiable health information retained or transmitted by physicians, pharmacists, and other healthcare practitioners. These data are known as “protected health information” (PHI) in the HIPAA Privacy Rule.⁴ PHI includes any identifiable data that relates to the individual’s past, present, or future physical or mental health condition, any information indicating that they have been treated, and payment information.⁵ In addition, other information that could be used to

easily identify the individual (e.g., name, address, date of birth, Social Security number, etc.) is protected.⁶

3. Is a partner's identifiable health information entitled to privacy protections?

Yes. A partner treated through EPT is entitled to the same privacy protections as an index patient. Most privacy laws do not distinguish between a patient's PHI and a sex partner's PHI. Generally, a healthcare practitioner or other covered entity must apply the same privacy standards to partners' identifiable data as they would apply to patients.⁷

4. Under the HIPAA Privacy Rule am I legally required or permitted to gather and report information about partners receiving EPT?

In general, PHI may not be used or disclosed without written authorization from the individual, unless disclosure is expressly required or permitted under the HIPAA Privacy Rule.⁸ If individual authorization is provided, use and disclosure of PHI must be consistent with the terms of the individual's written authorization agreement. Under the Privacy Rule, disclosures are required when 1) the individual requests access to his or her PHI; or 2) the federal Department of Health and Human Services requests PHI for narrowly defined purposes, including privacy investigations by the Department.⁹

Disclosures without individual authorization are permitted under several circumstances, including 1) where a disclosure to others is requested by the individual for any purpose; 2) in connection with treatment, billing, and other operational activities; 3) when lawfully requested by law enforcement authorities; and 4) when requested by public health agencies.¹⁰ Concerning EPT, for example, if a state reporting requirement mandates a healthcare practitioner to report the names of index patients and partners to state public health authorities, the HIPAA Privacy Rule allows this disclosure even without individual authorization in the interest of protecting the public's health. The Privacy Rule requires that healthcare practitioners disclose only the "minimum necessary" amount of identifiable data to accomplish the intended purpose of the disclosure.¹¹ A healthcare practitioner is entitled to rely on the determination of a public health agency as to what constitutes the minimum amount of information necessary for specific disclosures.

B. HEALTHCARE PRACTITIONER COMMUNICATIONS

5. How do I protect myself from claims of breach of the duty of confidentiality concerning communications related to providing EPT for patients and their partner(s)?

Generally under state law, healthcare practitioners owe their patients a duty of confidentiality concerning the patients' identifiable health data. Under this legal duty, practitioners should not disclose their patients' health data to others without patient authorization. However, the duty of confidentiality is subject to several exceptions, including disclosures required under public health reporting laws or necessary disclosures to prevent the spread of communicable diseases. Consistent with the HIPAA Privacy Rule, courts have specifically recognized that prevention of the spread of a communicable disease may justify limited sharing of patient health information.

Even so, written policies and procedures¹² for disclosures of PHI without patient authorization¹³ should be maintained by healthcare practitioners, and the PHI disclosed should be limited to the minimum necessary to accomplish the objective underlying the disclosure.¹⁴

6. Am I legally permitted or required to answer questions from a parent, spouse, significant other, or family member regarding an EPT prescription I wrote or dispensed?

Information regarding a patient, or a patient's sex partner, may be disclosed to a family member, relative, or personal friend of the patient or partner in limited circumstances.¹⁵ Disclosure can be made where 1) the patient or partner agrees in advance to the disclosure; 2) in specific cases involving patients or partners who are minors (subject to each state's laws); or 3) where necessary to protect the health or safety of another person.¹⁶ Consistent with the HIPAA Privacy Rule, a healthcare practitioner may use professional judgment to disclose information in the individual's best interest when the individual is not present and has not had an opportunity to agree to the disclosure.¹⁷ Disclosures are limited to the PHI that is directly relevant to the outside person's involvement with the individual's healthcare,¹⁸ or needed to properly notify an individual who is directly at risk of exposure to a communicable disease in accordance with partner notification laws.

7. What information may be reported to a payor or insurer for a patient and their partner(s) receiving EPT without violating health information privacy laws?

Patient authorization is not required for the disclosure of PHI in connection with billing and healthcare operations under the HIPAA Privacy Rule.¹⁹ The information required by a specific payor or insurer may vary, but any information required to obtain payment or reimbursement may be disclosed without specific patient authorization. State insurance and privacy laws may necessitate specific information be disclosed to a payor with additional protections. However, as noted above, reasonable efforts must be made to disclose only the minimum amount of identifiable information necessary to receive payment or reimbursement.²⁰

8. Am I legally required to report specific uses of EPT to state or local public health agencies, including identifiable information about the patient and partner?

Yes, if state or local laws require the reporting of cases of the disease you are treating via EPT. State or local public health reporting requirements are not waived by the HIPAA Privacy Rule.²¹ While state and local laws vary, many require reporting of confirmed cases of specific communicable diseases (including chlamydia and gonorrhea). Some laws require reporting of suspected cases of these diseases, which in the context of EPT, may include partners of index patients receiving treatment through EPT.²² Some states require reporting of all instances of examination, prescription, or provision of treatment for these diseases, which would also apply to both the patient and partners.²³ The specific information required to be reported varies by state.

9. Can the patient legally demand that I keep private his or her information concerning the use of EPT?

According to the HIPAA Privacy Rule, patients are permitted to request lawful restrictions of the disclosure of their identifiable health information.²⁴ For example, an adult patient may ask her physician not to disclose information to her partner(s) due to privacy concerns. A practitioner may agree to such requests, although the Privacy Rule does not require the practitioner to do so.²⁵ However, if the patient asks the physician not to disclose her diagnoses of an STD to local or state public health authorities (despite a reporting requirement under state or local law), the physician may not legally agree to this request because the protections of the Privacy Rule do not supersede state or local public health reporting requirements.

C. PRIVACY ISSUES SPECIFIC TO MINORS²⁶

10. As a healthcare practitioner am I required or permitted to share information about a minor who receives treatment through EPT with the partner's parent or guardian?

State law largely controls the treatment of minors and whether the disclosure of a minor's health information to a parent or guardian is permitted or required. In many contexts, a minor needs parental consent to most healthcare services, although most states have specific exceptions for certain services (as discussed below).²⁷ As a result, under the HIPAA Privacy Rule, parents or guardians are often allowed to access a minor's health data.²⁸ State laws vary as to who constitutes a minor for the purposes of healthcare services. While many states define a minor as anyone under age eighteen,²⁹ some states have established higher or lower age thresholds.³⁰ Some minors are considered "emancipated" when they serve in the military or become married, pregnant, or a parent. Healthcare practitioners are not generally permitted to share information about an emancipated minor with a parent or guardian,³¹ including information about treatment received via EPT. Most states have laws allowing unemancipated minors to consent to and receive certain services without parental involvement, such as testing and treatment for sexually transmitted diseases (STDs).³² In some cases, healthcare practitioners are not permitted to share information about a minor receiving treatment for an STD with a parent or guardian; other states allow healthcare practitioners to share information with the minor's parent at their discretion.³³ Finally, if a healthcare practitioner reasonably believes that a minor is experiencing abuse or neglect due to knowledge acquired while providing treatment through EPT, the practitioner must report this to the appropriate government authority.³⁴

11. Am I legally required to report information to law enforcement or other authorities about individuals treated through EPT which may involve a sexual relationship between an adult and a minor?

A healthcare practitioner may be required to report sexual relationships involving minors under certain circumstances. There is significant variation among states regarding the age at which a person can legally consent to sex.³⁵ Additionally, many states' laws may refer to a combination of factors, such as the age difference between the minor and the adult or the actual ages of the minor and the adult, to determine whether a crime, commonly known as statutory rape, has

occurred.³⁶ A healthcare practitioner may be required to report the relationship to either law enforcement or other government authorities if the relationship constitutes child abuse, as defined by state law.³⁷ For example, in all states, a healthcare practitioner who offers EPT must report the case to the proper authorities as child abuse if he/she knows the adult sex partner is legally responsible for the minor (e.g., a parent or guardian).³⁸ In addition, some states classify all instances of statutory rape as child abuse and require these cases to be reported; other states classify statutory rape as child abuse only for minors below a specified age.³⁹

D. PRESCRIPTION LABELING REQUIREMENTS

12. As a healthcare practitioner, how do my state's prescription labeling requirements relating to health information privacy impact my ability to practice EPT?

Prescription labeling requirements related to health information privacy vary among states, with significant implications for practitioners seeking to practice EPT. Some states require prescription labels to contain patient identifying information, such as an individual's name and address.⁴⁰ In these states, if a patient cannot provide, or chooses not to provide, identifying information about his or her partner, the healthcare practitioner will not have access to the legally required identifying information for the partner's prescription. Thus, the healthcare practitioner would not be able to issue a legally valid prescription for the partner. States that require identifying information for prescription labels may prohibit practitioners from issuing blank prescriptions for partners. Other states, however, have amended or passed laws to enable practitioners to issue valid prescriptions for EPT without the partner's identifying information.

Some states do not require identifying information to appear on prescription labels.⁴¹ In these states, healthcare practitioners may issue a blank prescription for a partner that complies with their state's requirements for prescription labeling and identifying information.

13. Can I write a prescription for a partner (without the partner's identifiable information) when the patient will not share any identifying information about his or her partner?

A healthcare practitioner's ability to write a prescription for an unidentified partner depends greatly on the laws of the state. In many states, it is illegal for healthcare practitioners to prescribe medication for individuals they have not examined.⁴² Other states prohibit healthcare practitioners from prescribing medications for individuals if there is no practitioner/patient relationship.⁴³ In these states, practitioners cannot write a prescription for an unidentified partner. Some states, however, have amended or passed laws to facilitate the practice of EPT by allowing a practitioner to write a prescription for a partner they have not examined⁴⁴ or a partner with whom they have not established a practitioner/patient relationship.⁴⁵ Among these states, some explicitly allow a prescription to be written for an unidentified partner for EPT purposes.⁴⁶

14. As a pharmacist, can I dispense a prescription drug when the prescription was made out to an unnamed individual?

States vary in the extent to which they allow pharmacists to dispense a prescription drug when the prescription is made out to an unnamed person. Some states only allow pharmacists to dispense a prescription drug to an “ultimate user”⁴⁷ or an identified patient.⁴⁸ In these states, a pharmacist is not allowed to dispense an additional dose of medication, intended for an unnamed partner, to a patient. The pharmacist may, however, dispense the additional dose directly to the unnamed partner. In addition, several states do not permit a pharmacist to dispense a prescription drug if the pharmacist believes that the prescription was written in the absence of a practitioner/patient relationship.⁴⁹ In these states, a lack of identifying information may lead pharmacists to believe a practitioner/patient relationship does not exist; thus, they cannot legally dispense prescription medications. To facilitate the provision of EPT, some states have amended or passed laws to allow pharmacists to dispense drugs to an unnamed patient or “other individual entitled to receive the prescription drug.”⁵⁰

For information on prescription requirements by state, *see* www.cdc.gov/std/ept/legal/default.htm.

References:

¹ The HIPAA Privacy Rule is federal regulation issued by DHHS which seeks to protect individuals’ health information privacy rights. Additional information can be found at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html>.

² 45 C.F.R. §§ 160.102 and 160.103.

³ <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

⁴ 45 C.F.R. § 160.103.

⁵ <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

⁶ *Id.*

⁷ 45 C.F.R. § 160.103 (an “individual” is any person who is the subject of protected health information).

⁸ 45 C.F.R. § 164.502(a).

⁹ 45 C.F.R. § 164.502(a)(2).

¹⁰ <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

¹¹ 45 C.F.R. §§ 164.502(b) and 164.514(d).

¹² 45 C.F.R. § 164.530(i).

¹³ 45 C.F.R. §§ 164.502(b) and 164.514(d).

¹⁴ *Id.*

¹⁵ 45 C.F.R. § 164.510 (b).

¹⁶ 45 C.F.R. § 164.510 (b)(2).

¹⁷ *Id.*

¹⁸ *Id.* (a covered entity may disclosure information according to inferences drawn from allowing a person to act on behalf of the individual, e.g. picking up a prescription).

¹⁹ 45 C.F.R. §§ 164.501, 164.502(a)(1)(ii), and 164.506.

²⁰ 45 C.F.R. § 164.502(b).

²¹ 45 C.F.R. § 160.203(c).

²² E.g., N.Y. Comp. Codes R. & Regs. tit. 10, § 2.10 (2010); Or. Admin. R. 333-018-0015 (2010).

²³ E.g., La. Rev. Stat. Ann. § 40:1065 (2010).

²⁴ 45 C.F.R. § 164.522 (a)(1)(i).

²⁵ *Id.* (However, where a covered entity agrees to the restriction, information may not be disclosed in violation of the agreement).

²⁶ Please note: All references to specific state statutes are provided as examples. These references are not intended to include information about all 50 states.

²⁷ Heather Boonstra & Elizabeth Nash, Guttmacher Inst., *Minors and the Right to Consent to Healthcare* (2000), available at <http://www.guttmacher.org/pubs/tgr/03/4/gr030404.html> (last visited August 20, 2010).

²⁸ 45 C.F.R. § 164.502(e)(3) (2010).

²⁹ E.g., Ariz. Rev. Stat. Ann. § 8-201 (2010); Mich. Comp. Laws § 722.4 (2010); Tenn. Code Ann. § 37-1-102 (2010).

³⁰ Legal Information Inst., Cornell Univ. Law Sch., *Emancipation of minors – laws*, available at http://topics.law.cornell.edu/wex/table_emancipation (last visited Aug. 20, 2010).

³¹ Comm. on Bioethics, Am. Acad. of Pediatrics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 *Pediatrics* 314, 315 (1995).

³² Heather Boonstra & Elizabeth Nash, Guttmacher Inst., *Minors and the Right to Consent to Healthcare* (2000), available at <http://www.guttmacher.org/pubs/tgr/03/4/gr030404.html> (last visited August 20, 2010).

³³ *Id.*

³⁴ E.g., Nat'l Ctr. for Youth Law, *Minor Consent, Confidentiality, and Child Abuse Reporting in California* (2006), available at http://www.youthlaw.org/fileadmin/ncyl/youthlaw/publications/minor_consent/Minor_Consent_Report_Download.pdf (Aug. 20, 2010).

³⁵ Legal Information Inst., Cornell Univ. Law Sch., *Emancipation of minors – laws*, available at http://topics.law.cornell.edu/wex/table_emancipation (last visited Aug. 20, 2010).

³⁶ Sharon G. Elstein, Noy Davis, ABA Ctr. on Children & the Law, *Sexual Relationships Between Adult Males and Young Teen Girls: Exploring the Legal and Social Responses* (1997), available at http://new.abanet.org/child/PublicDocuments/statutory_rape.pdf (last visited Aug. 20, 2010).

³⁷ *Id.*

³⁸ Asaph Glosser, Karen Gardiner & Mike Fishman, Lewin Group, *Statutory Rape: A Guide to State Laws and Reporting Requirements* (2004), available at <http://www.lewin.com/content/publications/3068.pdf> (last visited August 20, 2010).

³⁹ *Id.*

⁴⁰ E.g., Alaska Admin. Code tit. 12, § 52.460 (2010); Fla. Stat. § 465.186 (2010); N.J. Stat. Ann. § 24:21-17 (2010); S.C. Code Ann. § 40-43-86 (2010).

⁴¹ E.g., Ala. Admin. Code r. 680-X-2.13 (2010); Ind. Code § 16-42-3-6 (2010); Neb. Rev. Stat. § 71-5404.

⁴² E.g., Ala. Admin. Code r. 540-X-9.11 (2010); Fla. Admin. Code Ann. r. 64B8-9.014 (2010); 844 Ind. Admin. Code 5-4-1 (2010); 902 Ky. Admin. Regs. 2:080 (2010).

⁴³ E.g., Okla. Stat. tit. 59 § 59-509(12) (2010).

⁴⁴ E.g., Iowa Code § 139A.41 (2010); Md. Code Regs. 10.06.01.17-1 (2010); N.M. Code R. § 16.10.8.8 (2010); N.Y. Pub. Health Law § 2312 (2010).

⁴⁵ E.g., Mo. Rev. Stat. § 191.648 (2010).

⁴⁶ E.g., Utah Code Ann. § 58-1-501.3 (2010).

⁴⁷ E.g., Kan. Stat. Ann. § 65-1626(k) (2010); 247 Mass. Code Regs. 2.00 (2010).

⁴⁸ E.g., W. Va. Code § 16-4-24 (2010).

⁴⁹ E.g., Fla. Stat. § 465.023 (2010); Tex. Occ. Code § 562.056 (2010).

⁵⁰ E.g., Ky. Rev. Stat. Ann. § 315.010 (2010)

V. Considerations for Drafting and Implementing Legislation and Regulations Concerning Expedited Partner Therapy

Purpose

This tool is intended as a resource for voluntary use by government officials at the state and local levels, their public and private sector partners, and others who are interested in adopting or facilitating the implementation of statutes or regulations that permit expedited partner therapy (EPT) in clinical practice.

This tool consists of three flowcharts, each corresponding to the legal status of EPT within a jurisdiction. With the assistance of their legal counsel, users should determine in advance whether EPT is legally permissible, potentially allowable, or prohibited in their jurisdiction, and then consult the appropriate flowchart.

Each flowchart presents a series of legal and policy considerations that may arise during the drafting and implementing of EPT-related statutes or regulations. These considerations should guide discussions between users and their legal counsel and may highlight potential issues of law and policy that may need to be addressed to adopt or implement EPT-related statutes or regulations.

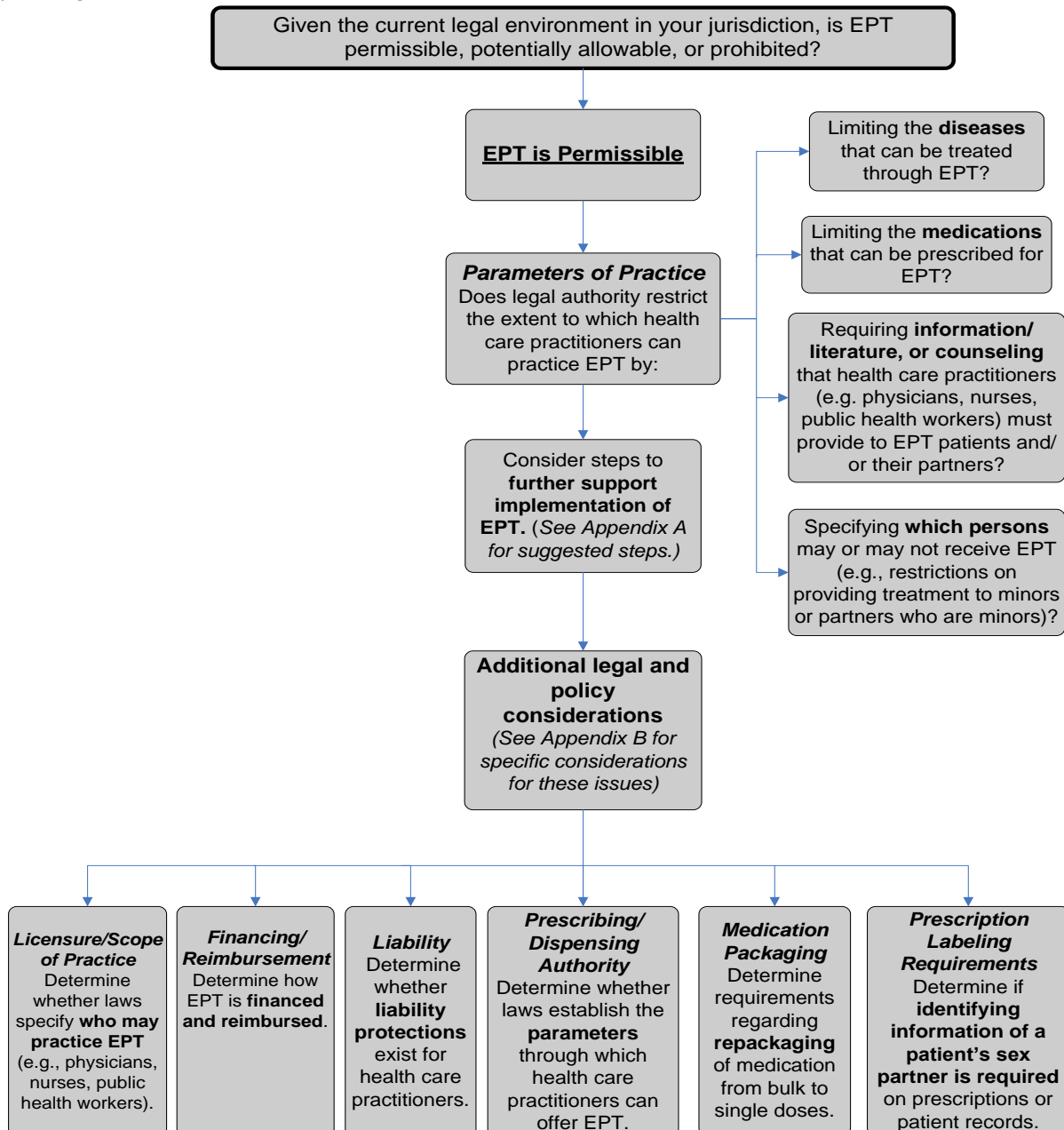
Following these flowcharts are a series of three appendices that users and their legal counsel may want to consider as part of their planning efforts. **Appendix A** identifies relevant questions in addition to those included in the flowchart that a public health practitioner may want to discuss with legal counsel. These issues for consideration may relate to changing the legality of EPT or supporting EPT implementation. **Appendix B** categorizes specific issues for consideration related to EPT implementation in five common areas from a legislative perspective. **Appendix C** provides information for public health practitioners who want to enhance understanding of the legal authorities underlying various statutory and regulatory provisions related to EPT. A review of this flowchart and accompanying appendices may assist public health practitioners to better understand issues of law and policy related to EPT prior to seeking guidance from his or her legal counsel.

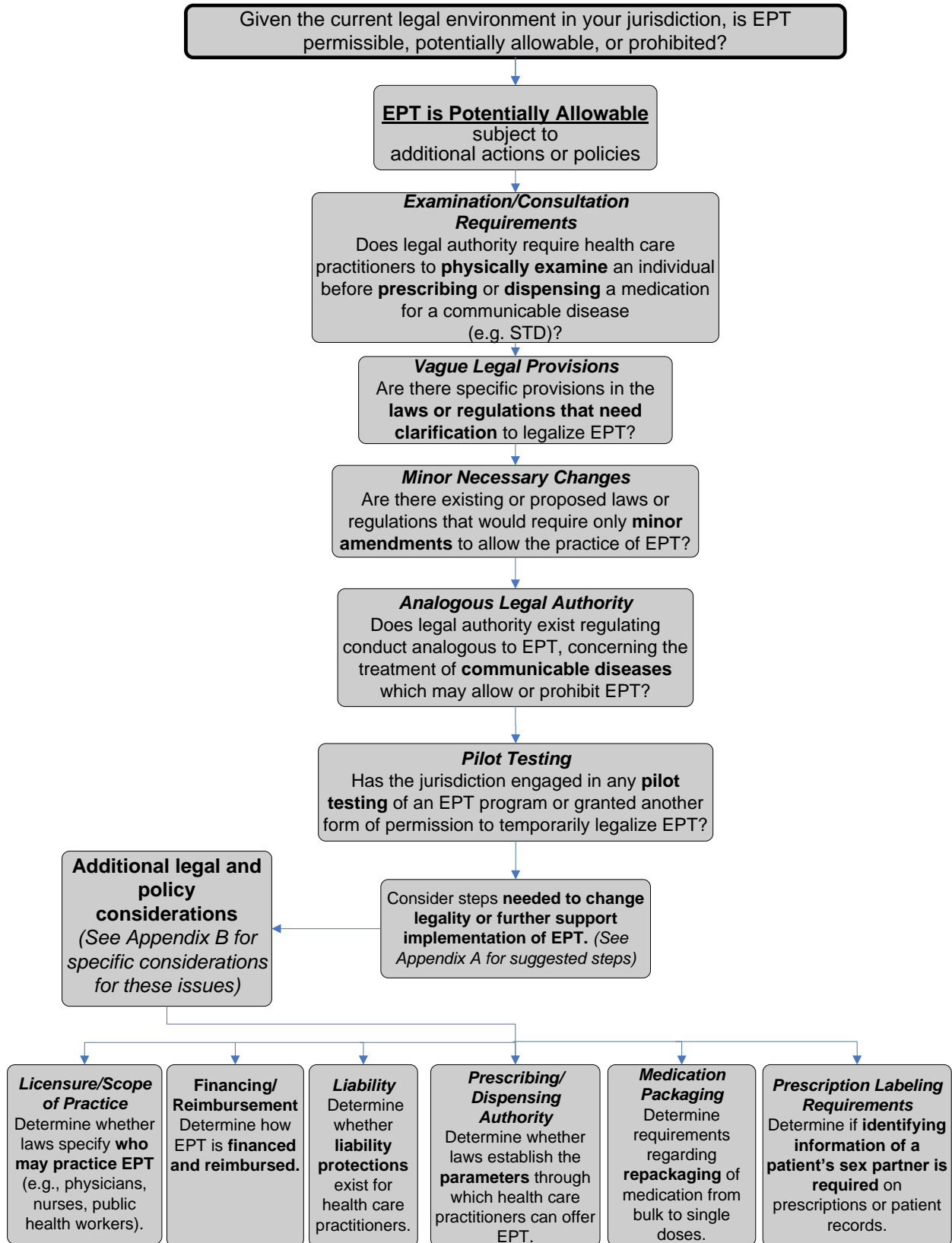
Additional information on EPT and pertinent laws is accessible at <http://www.cdc.gov/std/ept>.

Note: In this document “legal authority” refers to statutes, judicial decisions, and rules, regulations, and disciplinary opinions of health professional regulatory boards (such as state medical or pharmacy boards). Advisory opinions and position statements of health professional regulatory boards and state attorneys general may also be considered, although such opinions do not carry the same force of law as do statutes, regulations, or judicial decisions.

Considerations for Drafting and Implementing Legislation and Regulations Concerning Expedited Partner Therapy

Users should discuss the contents of this tool with the assistance of official state and local legal counsel and may find it useful to consult [CDC's website](#) as a resource, which contains a comparative snapshot of legal provisions concerning EPT. Appendix C provides additional sources that may be useful to consult along with official legal counsel.





Given the current legal environment in your jurisdiction, is EPT permissible, potentially allowable, or prohibited?

EPT is Prohibited

Minor Necessary Changes
Are there existing or proposed laws or regulations that would require only **minor amendments** to allow the practice of EPT?

Analogous Legal Authority
Does legal authority exist regulating conduct analogous to EPT, concerning the treatment of **communicable diseases** which may allow or prohibit EPT?

Pilot Testing
Has the jurisdiction engaged in any **pilot testing** of an EPT program or granted another form of permission to temporarily legalize EPT?

Consider steps to **advocate for changing legality of EPT**. (See *Appendix A* for suggested steps.)

When drafting legislation, **consider issues noted** in the “Permissible” and “Potentially Allowable” sections.

Appendix A: Additional considerations to change the legality of, or to further support the implementation of, EPT:

- Have stakeholders and/or advocates been encouraged to work with legislators and other elected officials to draft and introduce legislation to make EPT legally permissible?
- Have state or local public health authorities been encouraged to work with state medical groups to draft resolutions supporting EPT or incorporate by reference CDC's STD guidelines or comparable national guidance recommending EPT?
- Have regulations been developed to support implementation of laws relevant to EPT?
- Are statements available from policymakers in support of legalizing EPT?
- Has the Attorney General, or comparable official, issued an opinion about EPT's legality?
- What are physician groups', medical boards', pharmacy boards', or licensing authorities' policies toward EPT?
- Has outreach to local professional organizations (e.g., AMA chapter, pharmacists' association) been attempted to educate them about the legality or implementation status of EPT?
- Are resources available to disseminate information about permitted EPT practices to healthcare practitioners to raise their awareness?
- Has information about liability or liability protections for healthcare practitioners who provide EPT or entities that allow or support EPT been disseminated to local practitioners or professional associations?
- Has outreach to the state Medicaid office or state health quality improvement coalition* been attempted to discuss the possibility of including EPT as a reimbursable service?
- Do written policy guidelines concerning EPT implementation need to be developed and distributed to key stakeholders?
- Do model clinical/facility guidelines concerning EPT implementation need to be developed and distributed to key stakeholders?

*State health quality improvement coalition refers to a coalition of healthcare stakeholders such as physicians, hospitals, health plans, purchasers, consumers, academics, and government agencies, who work together to promote improvement in the quality of healthcare services and provide a forum to discuss cost-effective services.

Appendix B: Additional considerations regarding implementing EPT in jurisdictions where EPT is permissible or potentially allowable:

- Licensure and Scope of Practice
 - For healthcare practitioners (e.g., nurse practitioners) whose licensure requires a collaborative practice agreement with a physician, hospital, or other healthcare entity, can the provision of EPT be prohibited by the physician, hospital, or other entity?
 - Are certain healthcare practitioners prohibited from distributing sample medications to patients?

- Financing and Reimbursement
 - Do laws, regulations, or other policies
 - require health insurance plans to cover the costs of the antibiotics or dispensing fees for a patient's sex partner?
 - prohibit dispensing drugs to a person who is not a registered patient in the clinic or medical practice?
 - allow insurers to prohibit reimbursement for a partner's prescriptions?
 - prohibit treatment coverage of persons who are not enrolled in the health plan (including Medicaid)?

- Liability
 - Are civil or criminal liability protections explicit in laws for public or private healthcare practitioners who practice EPT or entities that support or allow EPT?
 - Do sovereign immunity protections (laws that protect government from being sued) apply to the actions of public health agents or healthcare practitioners/entities that contract with government to provide EPT?
 - Do Good Samaritan laws (i.e., laws that protect individuals who volunteer to assist someone in need) apply to the actions of healthcare practitioners implementing EPT?
 - Does the practice of EPT constitute the standard of care in the jurisdiction according to courts, medical boards, or other licensing authorities?
 - Does a legally recognized relationship exist in the jurisdiction between the EPT practitioner and the patient's sex partner according to the terms of the jurisdiction's laws?

- Prescribing and Dispensing Authority
 - Are healthcare practitioners allowed to prescribe or dispense a double dose of a prescription medicine?
 - Are healthcare practitioners allowed to prescribe or dispense a prescription without a name and/or address?
 - Are public health workers allowed to issue prescriptions for EPT?

- Medication Packaging (Only applicable if practitioner is writing the prescription and legally permitted to dispense medication)
 - Is the repackaging of medication from bulk to single doses regimens prohibited?

Appendix C: General Guidance on Locating Selected Legal Authority Sources

EPT-related legal authorities may reside in a variety of statutory and regulatory provisions. This table provides guidance on locating selected sources in general terms. Always consult with your official legal counsel to identify and interpret the sources and laws relevant to your jurisdiction. Users also may find it useful to consult [CDC's website](#), which contains a comparative snapshot of legal provisions.

Issue	Locating Selected Legal Authority Sources
Licensure and Scope of Practice	Legal provisions limiting the practice of EPT may be fragmented and can be based on healthcare practitioner type, diseases that EPT should be used to treat, specific medications, patient information requirements, and/or other prohibitions. Both state statutes and regulatory boards governing the health professions generally give guidance on these matters.
Liability	See, “Discussion of Selected Issues Related to Practitioners’ Liability for Harms to Partners Through Expedited Partner Therapy,” p. 10
Prescribing Authority	State medical boards, other professional board regulations, and state statutes generally regulate the authority of healthcare practitioners to prescribe medications.
Dispensing Authority	<p>State pharmacy board regulations or state statutes generally regulate the conduct of pharmacists, including the authority to dispense.</p> <p>Physician dispensing will generally be regulated by state medical board regulations, though such conduct may be alternatively or concurrently regulated by a state pharmacy board or by statute.</p>
Medication Packaging	State pharmacy board regulations or state statutes generally regulate the conduct of pharmacists, including requirements regarding medication packaging.
Prescription Labeling Requirements	<p>State pharmacy board regulations or state statutes generally regulate the conduct of pharmacists, including labeling requirements.</p> <p>FDA regulates the labeling and repackaging of drugs.</p>