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A BILL FOR AN ACT

RELATING TO HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 The legislature finds that many patients who SECTION 1. 2 have been diagnosed with sexually transmitted diseases, 3 including chlamydia and gonorrhea, have sexual partners who 4 refuse to seek treatment. To prevent reinfection, adequate 5 treatment of sexually transmitted diseases should include 6 treatment of sexual partners. Expedited partner therapy is a 7 partner treatment approach where partners of patients who test 8 positive for certain sexually transmitted diseases are provided 9 medication without previous medical evaluation. 10 The legislature further finds that because of expedited 11 partner therapy's effectiveness in reducing reinfection rates, 12 the Centers for Disease Control and Prevention has recommended 13 its use since 2006 among heterosexual partners of patients 14 diagnosed with chlamydia or gonorrhea when it is unlikely the 15 partners will seek timely evaluation and treatment. 16 legislature additionally finds that Hawaii has high reported rates of chlamydia. The most recent Centers for Disease Control 17 18 and Prevention data ranks Hawaii twenty-second in the nation for

- 1 reported chlamydia infection rates, with the disease peaking in
- 2 the age group between fifteen and twenty-four years.
- 3 The legislature also finds that primary care providers,
- 4 including persons licensed under chapter 453, Hawaii Revised
- 5 Statutes, and advanced practice registered nurses with
- 6 prescriptive authority under chapter 457, Hawaii Revised
- 7 Statutes, currently diagnose and treat persons with sexually
- 8 transmitted diseases. Expedited partner therapy will permit
- 9 these health professionals to adequately treat sexually
- 10 transmitted diseases and prevent reinfection through the
- 11 treatment of sexual partners.
- 12 The purpose of this Act is to allow health professionals to
- 13 provide expedited partner therapy, in accordance with Centers
- 14 for Disease Control and Prevention guidelines and
- 15 recommendations, to the heterosexual partners of a patient who
- 16 has been diagnosed as having chlamydia or gonorrhea.
- 17 SECTION 2. Chapter 453, Hawaii Revised Statutes, is
- 18 amended by adding a new part to be appropriately designated and
- 19 to read as follows:
- 20 "PART . EXPEDITED PARTNER THERAPY
- 21 §453-A Definitions. As used in this part:

1	"Exp	edited partner therapy" means the indirect treatment of				
2	heterosexual partners of a patient who has been diagnosed as					
3	having a sexually transmitted disease through the dispensing or					
4	prescribi	ng of antibiotic therapy for the treatment of the				
5	heterosex	ual partners to the patient without the physical				
6	examinati	on of the heterosexual partners by a health				
7	professio	nal.				
8	"Hea	lth professional" means any of the following:				
9	(1)	A person licensed or otherwise authorized by law to				
10		practice medicine or surgery under this chapter and				
11		whose scope of practice includes the diagnosis and				
12		treatment of sexually transmitted diseases;				
13	(2)	An advanced practice registered nurse with				
14		prescriptive authority under chapter 457 and duly				
15		licensed in the State; or				
16	(3)	For the purpose of dispensing antibiotic therapy under				
17		this section, a pharmacist who is licensed or				
18		otherwise authorized to engage in the practice of				
19		pharmacy under chapter 461.				
20	"Sex	ual activity" means sexual intercourse, cunnilingus,				
21	fellatio,	anal intercourse, or any other intrusion, however				
22	slight, o	f any part of a person's body or of any object into the				
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- 1 genital or anal openings of another person's body, but emission
- 2 of semen is not required.
- 3 "Sexually transmitted disease" means chlamydia or
- 4 gonorrhea, as recommended by the Centers for Disease Control and
- 5 Prevention for expedited partner therapy.
- 6 §453-B Expedited partner therapy. (a) A health
- 7 professional may in addition to treating a patient, provide
- 8 expedited partner therapy to the partners of the patient if all
- 9 of the following requirements are met:
- 10 (1) The patient has a laboratory-confirmed or suspected
- 11 clinical diagnosis of a sexually transmitted disease;
- 12 (2) The patient indicates that the patient has partners
- with whom the patient has engaged in sexual activity
- 14 within the sixty-day period immediately preceding the
- diagnosis of a sexually transmitted disease; and
- 16 (3) The patient indicates that the patient's partners are
- 17 unable or unlikely to seek clinical services in a
- timely manner.
- (b) A health professional who provides expedited partner
- 20 therapy as authorized in this section shall do all of the
- 21 following:

1	(1)	Dispense or prescribe antibiotic therapy in the name
2		of the partners, if known, without the physical
3		examination of the partners by the health
4		professional. Notwithstanding any law to the
5		contrary, if the name of the partners are not known,
6		the health professional shall dispense or prescribe
7		the antibiotic therapy in the name of "Expedited
8		Partner Therapy";
9	(2)	Convey to the patient that it is important to notify
10		the patient's partners of the patient's diagnosis and
11		that it is important for the partners to obtain
12		medical care for a complete evaluation, testing for
13		sexually transmitted diseases, counseling, and
14		treatment;
15	(3)	Distribute to the patient the information sheet
16		developed pursuant to section 453-C; and
17	(4)	Follow all Centers for Disease Control and Prevention
18		guidelines related to the practices and
19		recommendations for expedited partner therapy.
20	§453	-C Information sheet. The department of health shall
21	develop a	nd, upon request, distribute to health professionals

1	subject t	o this part an information sheet that includes all of
2	the follo	wing:
3	(1)	A description of expedited partner therapy and its
4		purpose;
5	(2)	A notice that an individual who has been treated for a
6		sexually transmitted disease should be retested after
7		treatment to detect possible persistent or recurrent
8		infection, including information on the timing of
9		retesting, as recommended by the Centers for Disease
10		Control and Prevention;
11	(3)	A warning about the possible dangers of administering
12		antibiotic therapy to a pregnant individual;
13	(4)	Information about antibiotics dispensed or prescribed
14		and dosages of those antibiotics dispensed or
15		prescribed, as recommended by the Centers for Disease
16		Control and Prevention;
17	(5)	A warning about the risk of allergies to and drug
18		interactions with the antibiotics described in
19		paragraph (4);
20	(6)	Information about sexually transmitted diseases, the
21		treatment of sexually transmitted diseases, and the
22		prevention of sexually transmitted diseases;

1	(7)	A notice that the patient and the patient's partners
2		should abstain from sexual activity for seven days
3		after the patient and the partners have completed the
4		antibiotic therapy;
5	(8)	A notice that the partners should be tested for
6		sexually transmitted diseases;
7	(9)	A notice of the risk to the patient, the partners, and
8		others, including the public health, if a sexually
9		transmitted disease is not completely treated;
10	(10)	A notice of the responsibility of the patient to
11		notify sexual partners of the risk of sexually
12		transmitted diseases and the importance of examination
13		and treatment for sexually transmitted diseases; and
14	(11)	A statement advising any individual who has any
15		questions regarding anything in the information sheet
16		to contact a health professional or the department of
17		health.
18	§ 453	-D Limitation of liability. A health professional who
19	provides	expedited partner therapy as authorized under section
20	453-B, in	cluding a person licensed or otherwise authorized by
21	law to pra	actice medicine or surgery under this chapter, an
22	advanced]	practice registered nurse with prescriptive authority
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- 1 under chapter 457, or a pharmacist who is licensed or otherwise
- 2 authorized to engage in the practice of pharmacy under chapter
- 3 461, shall not be subject to prosecution in a criminal
- 4 proceeding, liable for damages in a civil action, or subject to
- 5 disciplinary action under sections 453-8 and 453-8.2 for
- 6 personal injury, death, or other consequences arising from or
- 7 related in any way to the provision of expedited partner therapy
- 8 by the health professional; provided that this section shall not
- 9 apply if the action of the health professional in providing
- 10 expedited partner therapy is gross negligence."
- 11 SECTION 3. Section 328-16, Hawaii Revised Statutes, is
- 12 amended as follows:
- 1. By amending subsections (a), (b), and (c) to read:
- "(a) A prescription drug shall be dispensed only if its
- 15 label bears the following:
- 16 (1) The name, business address, and telephone number of
- 17 the seller. The business address shall be the
- physical location of the pharmacy or the dispensing
- 19 practitioner's office;
- 20 (2) [The] Except as otherwise authorized for expedited
- 21 partner therapy in section 453-B, the name of the
- 22 person for whom the drug was prescribed or the name of

1		the owner of the animal for which the drug was
2		prescribed;
3	(3)	The serial number of the prescription;
4	(4)	The date the prescription was prepared;
5	(5)	The name of the practitioner if the seller is not the
6		practitioner;
7	(6)	The name, strength, and quantity of the drug;
8	(7)	The "use by" date for the drug, which shall be:
9		(A) The expiration date on the manufacturer's
10		container; or
11		(B) One year from the date the drug is dispensed,
12		whichever is earlier;
13	(8)	The number of refills available, if any;
14	(9)	In the case of the dispensing of an equivalent generic
15		drug product, the statement "same as (brand name of
16		the drug product prescribed or the referenced listed
17		drug name)", or words of similar meaning; and
18	(10)	Specific directions for the drug's use; provided that
19		if the specific directions for use are too lengthy for
20		inclusion on the label, the notation "take according
21		to written instructions" may be used if separate
22		written instructions for use are actually issued with

1	the drug by the practitioner or the pharmacist, but in
2	no event shall the notation "take as directed",
3	referring to oral instructions, be considered
4	acceptable.
5	If any prescription for a drug does not indicate the number of
6	times it may be refilled, if any, the pharmacist shall not
7	refill that prescription unless subsequently authorized to do so
8	by the practitioner. The act of dispensing a prescription drug
9	other than a professional sample or medical oxygen contrary to
10	this subsection shall be deemed to be an act that results in a
11	drug being misbranded while held for sale.
12	(b) In addition to the requirements enumerated in
13	subsection (a), a prescription drug shall be dispensed only:
14	(1) By a pharmacist pursuant to a valid prescription $[\Theta r]_{\underline{r}}$
15	section 461-1[+], or section 453-B;
16	(2) By a medical oxygen distributor pursuant to a
17	prescription or certificate of medical necessity;
18	provided that the drug to be dispensed is medical
19	oxygen; or
20	(3) By a practitioner to an ultimate user; provided that:
21	(A) [The] Except as otherwise authorized for
22	expedited partner therapy in section 453-B, the

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1		pract	citioner shall inform the patient, prior to
2		dispe	ensing any drug other than a professional
3		samp	le, that the patient may have a written,
4		oral	ly ordered, or electronically transmitted or
5		conve	eyed prescription directed to a pharmacy or a
6		medio	cal oxygen distributor of the patient's own
7		choi	ce;
8	(B)	The p	practitioner shall promptly record in the
9		pract	titioner's records:
10		(i)	The prescription in full;
11		(ii)	The name, strength, and quantity of the
12			drug, and specific directions for the drug's
13			use;
14	(iii)	The date the drug was dispensed; [and]
15		(iv)	[The] Except as otherwise authorized for
16			expedited partner therapy in section 453-B,
17			the name and address of the person for whom
18			the drug was prescribed or the name of the
19			owner of the animal for which the drug was
20			prescribed; and

1			(V) Prescription drugs dispensed or prescribed
. 2			for expedited partner therapy as authorized
3			under section 453-B.
4		(C)	The records described in subparagraph (B) shall
5			be subject to the inspection of the department or
6			its agents at all times; and
7		(D)	No undisclosed rebate, refund, commission,
8			preference, discount, or other consideration,
9			whether in the form of money or otherwise, has
10			been offered to the practitioner as compensation
11			or inducement to dispense or prescribe any
12			specific drug in preference to other drugs that
13			might be used for the identical therapeutic
14			indication.
15	(c) Z	A pr	escription may be communicated in writing, orally,
16	or by elect	tron	ic transmission, and shall include the following
17	information	n:	
18	(1)	Гhе	authorization of the practitioner noted as
19	=	foll	ows:
20	·	(A)	Written prescriptions shall include the original
21			signature of the practitioner;

1		(B)	Orai	prescriptions shall be promptly recorded by
2			the	pharmacist or medical oxygen distributor and
3			shal	l include the practitioner's oral code
4			desi	gnation; and
5		(C)	Elec	tronic prescriptions shall be irrefutably
6			trac	eable to the prescribing practitioner by a
7			reco	gnizable and unique practitioner identifier
8			such	as:
9			(i)	A bitmap or graphic image of the
10			i e	prescriber's handwritten signature and the
11				prescriber's oral code designation (or
12				license number or other identifier if the
13				prescriber is an out-of-state practitioner);
14			(ii)	An electronic signature;
15		(iii)	A digital signature; or
16			(iv)	By other means as approved by the director;
17	(2)	The	date	of issuance;
18	(3)	The	pract	itioner's name, business telephone number,
19		and	busin	ess address, unless the practitioner is
20		othe	rwise	uniquely identified and the pharmacy or
21		medi	cal o	xygen distributor dispensing the prescription

1		has the prescriber's contact information on fife
2		accessible within the dispensing area;
3	(4)	The name, strength, and quantity of the drug to be
4		dispensed, and specific directions for the drug's use;
5	(5)	[The] Except as otherwise authorized for expedited
6		partner therapy in section 453-B, the name and address
7		of the person for whom the prescription was written or
8		the name of the owner of the animal for which the drug
9		was prescribed, unless the pharmacy or medical oxygen
10		distributor dispensing the prescription has the
11		address on file accessible within the dispensing area;
12	(6)	The room number and route of administration, if the
13		patient is in an institutional facility; and
14	(7)	The number of allowable refills, if the prescription
15		is refillable. If the number of refills authorized by
16		the practitioner is indicated using the terms "as
17		needed" or "prn", the prescription may be refilled up
18		to twelve months from the date the original
19		prescription was written. After the twelve-month
20		period, the "as needed" or "prn" prescription may be
21		refilled for a subsequent three-month period;
22		provided:

I	(A)	The prescription is refilled only once during the
2		three-month period;
3	(B)	The refill does not exceed a thirty-day supply of
4		the drug;
5	(C)	The refill does not provide any amount of the
6		drug fifteen months beyond the date the original
7		prescription was written;
8	(D)	In the case of medical oxygen, the duration of
9		therapy indicated on a certificate of medical
10		necessity shall supersede any limitations or
11		restrictions on refilling; and
12	(E)	Subparagraphs (A) to (D) shall apply only to
13		pharmacies and medical oxygen distributors
14		practicing in the State."
15	2. By am	ending subsection (g) to read:
16	"(g) Any	drug other than medical oxygen dispensed pursuant
17	to a prescript	ion shall be exempt from the requirements of
18	section 328-15	(except paragraphs (1), (9), (11), and (12), and
19	the packaging	requirements of paragraphs (7) and (8)), if the
20	drug bears a l	abel containing:
2.1	(1) The	name and address of the pharmacy.

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The serial number and the date of the prescription or
1
         (2)
2
              of its filling;
3
         (3)
              The name of the practitioner;
              [The] Except as otherwise authorized for expedited
         (4)
4
5
              partner therapy in section 453-B, the name of the
6
              patient;
7
         (5) The directions for use; and
8
              Any cautionary statements contained in the
         (6)
              prescription.
9
10
    This exemption shall not apply to any drug dispensed in the
11
    course of the conduct of a business of dispensing drugs pursuant
12
    to diagnosis by mail, or to a drug dispensed in violation of
    subsection (a), (b), (c), or (d)."
13
         SECTION 4. Section 328-17.6, Hawaii Revised Statutes, is
14
15
    amended as follows:
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         1. By amending subsections (c) and (d) to read:
17
         "(c) Any pharmacist or medical oxygen distributor who
    fills or refills a prescription from an out-of-state
18
19
    practitioner shall:
20
              Note the following on the prescription record:
21
              out-of-state practitioner's full name, address, and
22
              telephone number;
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1	(2)	Be responsible for validating and verifying the
2		practitioner's prescriptive authority by virtue of a
3		valid out-of-state license, a Drug Enforcement
4		Administration registration number, or other measures
5		as appropriate; and
6	(3)	[Demand] Except as otherwise authorized for expedited
7		partner therapy in section 453-B, demand proper
8		identification from the person whose name appears on
9		the prescription prior to filling the prescription, in
10		addition to complying with any identification
11		procedures established by the department for filling
12		and refilling an out-of-state prescription.
13	(d)	Before refilling a transferred out-of-state
14	prescript	ion, a pharmacist or medical oxygen distributor shall:
15	(1)	[Advise] Except as otherwise authorized for expedited
16		partner therapy in section 453-B, advise the person
17		whose name appears on the prescription that the
18		prescription on file at the originating out-of-state
19		pharmacy or medical oxygen distributor may be
20		canceled; and
21	(2)	Record all information required to be on a
22		prescription, including:

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1	(A)	The date of issuance of the original
2		prescription;
3	(B)	The number of refills authorized on the original
4		prescription;
5	(C)	The date the original prescription was dispensed;
6	(D)	The number of valid refills remaining and the
7		date of the last refill;
8	(E)	The out-of-state pharmacy's or out-of-state
9		medical oxygen distributor's name, telephone
10		number, and address, and the original
11		prescription number or control number from which
12		the prescription information was transferred; and
13	(F)	The name of the transferor pharmacist or the
14		medical oxygen distributor's agent."
15	2. By am	ending subsection (f) to read:
16	"(f) An	out-of-state prescription record shall state the
17	date of fillin	g or refilling and, except as otherwise authorized
18	for expedited	partner therapy in section 453-B, the local
19	address of the	person whose name appears on the prescription."
20	SECTION 5	. Section 328-17.7, Hawaii Revised Statutes, is
21	amended by ame	nding subsection (a) to read as follows:

1	"(a)	Every practitioner, pharmacist, or medical oxygen
2	distribute	or who compounds, sells, or delivers any prescribed
3	drug to a	patient or a patient's agent shall maintain records
4	that ident	tify:
5	(1)	The specific drug product dispensed, including:
6		(A) The product's national drug code (NDC) number; or
7		(B) The brand name or the established name and the
8		name or commonly accepted abbreviation of the
9		principal labeler of the drug product dispensed,
10		the product strength, and the dosage form;
11	(2)	The quantity of the drug;
12	(3)	Directions for use;
13	(4)	The number of allowable refills;
14	(5)	The date of initial dispensing and the dates of all
15		refilling;
16	(6)	The date of any transfer of the prescription;
17	(7)	The name, business address, and telephone number of
18		the recipient pharmacist or medical oxygen distributor
19		for any transfer of prescription;
20	(8)	The prescribing practitioner, including name, business
21		address, and telephone number;

1,	(9)	The format (oral, written, or electronic) in which the	
2		prescription was received;	
3	(10)	[The] Except as otherwise authorized for expedited	
4		partner therapy in section 453-B, the patient,	
5		including name, address, and telephone number;	
6	(11)	The date of prescribing; and	
7	(12)	The name of the practitioner, pharmacist, or medical	
8		oxygen distributor dispensing the drug.	
9	Every prescription dispensed shall have the name of the		
10	pharmacist, dispensing practitioner, or medical oxygen		
11	distributor responsible for the dispensing appended to the		
12	prescription record, and every prescription record shall be		
13	preserved and legible for a period of not less than five years		
14	The prescription records shall be subject at all times to the		
15	inspection of the director of health or the director's agent."		
16	SECTION 6. Chapter 457, Hawaii Revised Statutes, is		
17	amended by adding a new section to be appropriately designated		
18	and to read as follows:		
19	"§457- Advanced practice registered nurses; expedited		
20	partner therapy. Advanced practice registered nurses who meet		
21	the definition of a health professional as defined in section		

- 1 453-A, shall be authorized to provide expedited partner therapy
- 2 in accordance with part of chapter 453."
- 3 SECTION 7. In codifying the new sections added by section
- 4 2 of this Act, the revisor of statutes shall substitute
- 5 appropriate section numbers for the letters used in designating
- 6 the new sections in this Act.
- 7 SECTION 8. Statutory material to be repealed is bracketed
- 8 and stricken. New statutory material is underscored.
- 9 SECTION 9. This Act shall take effect upon its approval.

10

Report Title:

Sexually Transmitted Diseases; Expedited Partner Therapy; Health Professionals; Prescription Drugs; Labeling; Record Keeping

Description:

Allows health professionals, subject to certain requirements, to treat the heterosexual partners of patients diagnosed as having chlamydia or gonorrhea, the sexually transmitted diseases recommended by the Centers for Disease Control and Prevention for expedited partner therapy, by dispensing or prescribing medication to the heterosexual partners without examining the partners. Provides protection from criminal liability, legal liability, and disciplinary action for health professionals who provide expedited partner therapy as authorized. Requires the department of health to develop an information sheet about sexually transmitted diseases for use by health professionals who provide expedited partner therapy. Creates exceptions to prescription drug labeling and reporting requirements for expedited partner therapy. (SD2)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.