

2013 DRAFTING REQUEST

Senate Substitute Amendment (SSA-SB352)

Received: 1/9/2014 Received By: mduchek
 Wanted: As time permits Same as LRB: s0207
 For: Sheila Harsdorf (608) 266-7745 By/Representing: Harsdorf
 May Contact: Drafter: mduchek
 Subject: Health - emergency med services Addl. Drafters:
 Occupational Reg. - misc Extra Copies:

Submit via email: YES
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Pre Topic:

No specific pre topic given

Topic:

Sub combining AB 446 with changes and LRB-3360/P2 to allow physicians and others to prescribe naloxone to unspecified 3rd parties via a standing order ✓

Instructions:

See attached

Drafting History:

| <u>Vers.</u> | <u>Drafted</u> | <u>Reviewed</u> | <u>Typed</u> | <u>Proofed</u> | <u>Submitted</u> | <u>Jacketed</u> | <u>Required</u> |
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| /1 | mduchek | h e e u 1/9/14 | h e e u 1/9/14 | _____ | _____ | | |
| | | | | _____ | _____ | | |

FE Sent For:

<END>



State of Wisconsin
2013 - 2014 LEGISLATURE



50227/1

LRE:2074
MED:eev&wlj:jm

~~ASSEMBLY~~ SUBSTITUTE AMENDMENT ~~X~~,
TO ASSEMBLY BILL 446 *oe 352*

Senate

January 8, 2014 - Offered by Representative NYGREN.

nygren

1 AN ACT *nygren* to renumber and amend 448.015 (4) (bm); to amend 256.15 (8) (e),
2 441.07 (1g) (d), 450.10 (1) (a) (intro.), 450.11 (1), 450.11 (3), 450.11 (4) (a) 5. a.,
3 450.11 (7) (h) and 895.48 (1); and to create 256.01 (13), 256.40, 441.07 (1g) (d)
4 2., 441.18, 448.015 (4) (bm) 2., 448.037, 450.01 (1) (d), 450.01 (13v), 450.11 (1i)
5 and 450.11 (4) (a) 5. c. of the statutes; relating to: prescription, possession,
6 dispensing, delivery, and administration of opioid antagonists; training and
7 agreements for administering opioid antagonists; requiring emergency medical
8 technicians to carry opioid antagonists; and immunity for certain individuals
9 who prescribe, dispense, deliver, or administer opioid antagonists.

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Analysis by the Legislative Reference Bureau

Prescriptions for opioid antagonists written to third parties; possession, delivery, and dispensing of opioid antagonists

Under current law, no person may dispense any prescribed drug or device, except upon the prescription order of a person who is authorized to prescribe drugs

(practitioner). Prescription orders must contain certain information and must generally specify the name and address of the patient to whom the drug or device is prescribed (patient). In addition, under current law, no prescribed drug or device may be dispensed unless there is a label attached to the container that includes certain information, including the name of the patient. Also under current law, no person may possess a prescription drug unless the prescription drug is obtained in compliance with certain requirements for prescriptions and prescription orders, and no person may possess a prescription drug with intent to deliver.

This substitute amendment specifically provides that any person may possess an opioid antagonist, as defined in the substitute amendment, and provides that, with certain qualifications, any person may deliver (transfer) or dispense an opioid antagonist to another person. Opioid antagonists are prescription drugs, such as the drug naloxone, some of which can, when administered to a person undergoing an overdose on drugs such as heroin or prescription narcotics, have the effect of countering the effects of the overdose.

Also under this substitute amendment, a licensed physician, a licensed physician assistant, or an advanced practice nurse certified to issue prescription orders (APRN prescriber) may, directly or by the use of a standing order, prescribe an opioid antagonist to a person in a position to assist an individual at risk of undergoing an opioid-related drug overdose. The substitute amendment requires a physician, physician assistant, or APRN prescriber who prescribes an opioid antagonist in this manner to ensure that the person to whom the opioid antagonist will be delivered has the knowledge and training necessary to safely administer the opioid antagonist to an individual undergoing an opioid-related overdose and that the person demonstrates the capacity to ensure that any individual to whom the person further delivers or dispenses the opioid antagonist has or receives that knowledge and training. A physician, physician assistant, or APRN prescriber may only dispense or deliver an opioid antagonist in accordance with these provisions or his or her other lawful authority to dispense prescription drugs.

The substitute amendment allows a licensed pharmacist to, upon the prescription order of a physician, physician assistant, or APRN prescriber that is in accordance with the provisions described above, deliver or dispense the opioid antagonist to the person specified in the prescription order. Under the substitute amendment, a pharmacist may only deliver or dispense an opioid antagonist in accordance with those provisions or in accordance with his or her other legal authority to dispense prescription drugs.

The substitute amendment specifically provides that actions taken by a licensed physician, licensed physician assistant, certified APRN prescriber, or licensed pharmacist in accordance with the provisions described above do not constitute unprofessional conduct and are therefore not grounds for professional discipline.

Administration of opioid antagonists by emergency medical services personnel

Under current law, the Department of Health Services (DHS) serves as the lead state agency for emergency medical services and has various duties relating to the provision of emergency medical services, including:

1. Certifying first responders, who are individuals that, as a condition of employment or as members of an organization that provides emergency medical care before hospitalization, provide emergency medical care to sick, disabled, or injured individuals before the arrival of an ambulance. In order to become certified as a first responder, an individual must satisfy certain criteria, including completing a first responder course that meets certain specified criteria. Certified first responders may undertake only certain actions specified under current law, including administering medications that are specified by DHS by rule.

2. Licensing emergency medical technicians (EMTs), who are individuals that may provide emergency medical services ranging from basic life support and patient handling and transportation to emergency cardiac, trauma, and other lifesaving or emergency procedures, depending on the level of EMT licensure. Current law specifies three levels of EMT licensure, known as EMT – basic, EMT – intermediate, and EMT – paramedic (advanced). In order to become licensed as an EMT, an individual must satisfy certain criteria, including obtaining training commensurate with the level of EMT licensure that is sought. EMTs may, under current law, undertake only those actions that are authorized in rules promulgated by DHS for their level of licensure.

3. Licensing ambulance service providers, who are persons engaged in the business of transporting sick, disabled, or injured individuals by ambulance to or from facilities or institutions providing health services. Ambulance service providers must satisfy certain requirements to be licensed and use EMTs and first responders for the provision of emergency medical services.

This substitute amendment provides that certified first responders may administer naloxone or another opioid antagonist if they have received training necessary to safely administer naloxone or the other opioid antagonist, as determined by DHS. The substitute amendment also requires that DHS permit EMTs at all levels of licensure to administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose. DHS must, under the substitute amendment, require EMTs to undergo any training necessary to safely and properly administer naloxone or the other opioid antagonist.

The substitute amendment also requires every ambulance service provider to ensure that every EMT under the provider's supervision who has obtained the training necessary to safely and properly administer the drug naloxone or another opioid antagonist has a supply of naloxone or the other opioid antagonist available for administration when he or she is performing his or her duties as an EMT, to the extent that naloxone or the other opioid antagonist is available to the ambulance service provider. Finally, the substitute amendment requires every ambulance service provider to ensure that every EMT and certified first responder under the

provider's supervision keeps a record of the administration of naloxone and other opioid antagonists in the case of a suspected opioid-related overdose, and to submit those records to DHS, in the manner prescribed by DHS.

In addition, the substitute amendment allows a law enforcement agency or fire department to enter into a written agreement to affiliate with an ambulance service provider or a physician for the purposes of 1) obtaining a supply of naloxone or another opioid antagonist; and 2) allowing law enforcement officers and fire fighters to obtain the training necessary to safely and properly administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose.

Immunity

The substitute amendment provides that any person who delivers an opioid antagonist to another person is immune from civil or criminal liability for any outcomes resulting from delivering or dispensing the opioid antagonist, subject to the qualifications that 1) a physician, a physician assistant, or an APRN prescriber is immune from any criminal or civil liability for any outcomes resulting from prescribing, delivering, or dispensing an opioid antagonist if he or she acts in accordance with the procedures in the substitute amendment or otherwise lawfully prescribes or dispenses an opioid antagonist, and if he or she acts in good faith; and 2) a pharmacist is immune from any criminal or civil liability for any outcomes resulting from delivering or dispensing the opioid antagonist if he or she acts in accordance with the procedures in the substitute amendment or otherwise lawfully dispenses an opioid antagonist, and if he or she acts in good faith. The substitute amendment also provides that a physician, physician assistant, APRN prescriber, or pharmacist who has the immunity described above may not be subject to professional discipline by the relevant credentialing board.

In addition, the substitute amendment provides that any person who, reasonably believing another person to be undergoing an opioid-related drug overdose, administers an opioid antagonist to that person is immune from civil or criminal liability for any outcomes resulting from the administration of the opioid antagonist to that person. However, the substitute amendment qualifies this immunity granted for administering opioid antagonists by providing that 1) consistent with Wisconsin's Good Samaritan law, the immunity does not extend when employees trained in health care or health care professionals render emergency care for compensation and within the scope of their usual and customary employment or practice under certain circumstances; and 2) a law enforcement officer or fire fighter only has the immunity granted in the substitute amendment for administering an opioid antagonist if acting pursuant to an agreement described above to affiliate with an ambulance service provider or a physician.

1

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

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SECTION 1. 256.01 (13) of the statutes is created to read:

1 256.01 (13) "Opioid antagonist" has the meaning given in s. 450.01 (13v).

2 **SECTION 2.** 256.15 (8) (e) of the statutes is amended to read:

3 256.15 (8) (e) A certified first responder is authorized to use an automated
4 external defibrillator, as prescribed for first responders in rules promulgated by the
5 department. The rules shall set forth authorization for the use of an automated
6 external defibrillator or, for a defibrillator that may be operated in more than one
7 mode, use as an automated external defibrillator only. A certified first responder is
8 authorized to administer naloxone or another opioid antagonist if the first responder
9 has received training necessary to safely administer naloxone or the other opioid
10 antagonist, as determined by the department. A certified first responder is also
11 authorized to employ other techniques, including the administration of
12 nonvisualized advanced airways, and the administration of medications that are
13 specified by the department by rule. In promulgating the rules under this
14 paragraph, the department shall consult with the state medical director for
15 emergency medical services and the emergency medical services board. The rule
16 shall include those techniques that are specified in the most current guidelines
17 issued by the National Highway Traffic Safety Administration under 23 CFR 1205.3
18 (a) (5).

19 **SECTION 3.** 256.40 of the statutes is created to read:

20 **256.40 Opioid antagonists.** (1) In this section:

21 (a) "Fire fighter" means any person employed by the state or any political
22 subdivision as a member or officer of a fire department or a member of a volunteer
23 fire department, including the state fire marshal and deputies.

1 (b) “Law enforcement agency” means an agency of a federally recognized Indian
2 tribe or band or a state or political subdivision of a state, whose purpose is the
3 detection and prevention of crime and enforcement of laws or ordinances.

4 (c) “Law enforcement officer” means any person employed by a law enforcement
5 agency who is authorized to make arrests for violations of the laws or ordinances that
6 the person is employed to enforce.

7 (d) “Opioid–related drug overdose” means a condition including extreme
8 physical illness, decreased level of consciousness, respiratory depression, coma, or
9 the ceasing of respiratory or circulatory function resulting from the consumption or
10 use of an opioid, or another substance with which an opioid was combined.

11 (2) (a) Subject to par. (b), the department shall permit all emergency medical
12 technicians to administer naloxone or another opioid antagonist to individuals who
13 are undergoing or who are believed to be undergoing an opioid–related drug
14 overdose.

15 (b) The department shall require emergency medical technicians to undergo
16 any training necessary to safely and properly administer naloxone or another opioid
17 antagonist as specified under par. (a).

18 (c) Every ambulance service provider shall do all of the following:

19 1. Ensure that every emergency medical technician under the ambulance
20 service provider’s supervision who has obtained the training necessary to safely and
21 properly administer naloxone or another opioid antagonist has a supply of naloxone
22 or the other opioid antagonist available for administration when he or she is
23 performing his or her duties as an emergency medical technician, to the extent that
24 naloxone or the other opioid antagonist is available to the ambulance service
25 provider.

1 2. Require each certified first responder and emergency medical technician
2 under the supervision of the ambulance service provider to, in the manner prescribed
3 by the department, keep a record of each instance in which the certified first
4 responder or emergency medical technician administers naloxone or another opioid
5 antagonist to an individual who is undergoing or who is believed to be undergoing
6 an opioid–related drug overdose.

7 3. Submit records under subd. 2. to the department in the manner prescribed
8 by the department.

9 **(3)** (a) A law enforcement agency or fire department may enter into a written
10 agreement to affiliate with an ambulance service provider or a physician for all of the
11 following purposes:

12 1. Obtaining a supply of naloxone or another opioid antagonist.

13 2. Allowing law enforcement officers and fire fighters to obtain the training
14 necessary to safely and properly administer naloxone or another opioid antagonist
15 to individuals who are undergoing or who are believed to be undergoing an
16 opioid–related drug overdose.

17 (b) A law enforcement officer or fire fighter who, reasonably believing another
18 person to be undergoing an opioid–related drug overdose, administers naloxone or
19 another opioid antagonist to that person shall be immune from civil or criminal
20 liability for any outcomes resulting from the administration of the opioid antagonist
21 to that person, if the law enforcement officer or fire fighter is acting pursuant to an
22 agreement and any training obtained under par. (a).

23 **SECTION 4.** 441.07 (1g) (d) of the statutes, as affected by 2013 Wisconsin Act 114,
24 is amended to read:

1 441.07 (1g) (d) Misconduct or unprofessional conduct. In this paragraph,
2 “misconduct” and “unprofessional conduct” do not include providing any of the
3 following:

4 1. Providing expedited partner therapy as described in s. 448.035.

5 **SECTION 5.** 441.07 (1g) (d) 2. of the statutes is created to read:

6 441.07 (1g) (d) 2. Prescribing or delivering an opioid antagonist in accordance
7 with s. 441.18 (2).

8 **SECTION 6.** 441.18 of the statutes is created to read:

9 **441.18 Prescriptions for and delivery of opioid antagonists.** (1) In this
10 section:

11 (a) “Administer” has the meaning given in s. 450.01 (1).

12 (b) “Deliver” has the meaning given in s. 450.01 (5).

13 (c) “Dispense” has the meaning given in s. 450.01 (7).

14 (d) “Opioid antagonist” has the meaning given in s. 450.01 (13v).

15 (e) “Opioid-related drug overdose” has the meaning given in s. 256.40 (1) (d).

16 (2) (a) An advanced practice nurse certified to issue prescription orders under
17 s. 441.16 may, directly or by the use of a standing order, prescribe an opioid
18 antagonist to a person in a position to assist an individual at risk of undergoing an
19 opioid-related drug overdose and may deliver the opioid antagonist to that person.
20 A prescription order under this paragraph need not specify the name and address of
21 the individual to whom the opioid antagonist will be administered, but shall instead
22 specify the name of the person to whom the opioid antagonist will be delivered.

23 (b) An advanced practice nurse who prescribes or delivers an opioid antagonist
24 under par. (a) shall ensure that the person to whom the opioid antagonist will be
25 delivered has the knowledge and training necessary to safely administer the opioid

1 antagonist to an individual undergoing an opioid-related overdose and that the
2 person demonstrates the capacity to ensure that any individual to whom the person
3 further delivers the opioid antagonist has or receives that knowledge and training.

4 (3) An advanced practice nurse who, acting in good faith, prescribes or delivers
5 an opioid antagonist in accordance with sub. (2), or who, acting in good faith,
6 otherwise lawfully prescribes or dispenses an opioid antagonist, shall be immune
7 from criminal or civil liability and may not be subject to professional discipline under
8 s. 441.07 for any outcomes resulting from prescribing, delivering, or dispensing the
9 opioid antagonist.

10 **SECTION 7.** 448.015 (4) (bm) of the statutes is renumbered 448.015 (4) (bm)
11 (intro.) and amended to read:

12 448.015 (4) (bm) (intro.) “Unprofessional conduct” does not include providing
13 any of the following:

14 1. Providing expedited partner therapy as described in s. 448.035.

15 **SECTION 8.** 448.015 (4) (bm) 2. of the statutes is created to read:

16 448.015 (4) (bm) 2. Prescribing or delivering an opioid antagonist in accordance
17 with s. 448.037 (2).

18 **SECTION 9.** 448.037 of the statutes is created to read:

19 **448.037 Prescriptions for and delivery of opioid antagonists.** (1) In this
20 section:

21 (a) “Administer” has the meaning given in s. 450.01 (1).

22 (b) “Deliver” has the meaning given in s. 450.01 (5).

23 (c) “Dispense” has the meaning given in s. 450.01 (7).

24 (d) “Opioid antagonist” has the meaning given in s. 450.01 (13v).

25 (e) “Opioid-related drug overdose” has the meaning given in s. 256.40 (1) (d).

1 **(2)** (a) A physician or physician assistant may, directly or by the use of a
2 standing order, prescribe an opioid antagonist to a person in a position to assist an
3 individual at risk of undergoing an opioid-related drug overdose and may deliver the
4 opioid antagonist to that person. A prescription order under this paragraph need not
5 specify the name and address of the individual to whom the opioid antagonist will
6 be administered, but shall instead specify the name of the person to whom the opioid
7 antagonist will be delivered.

8 (b) A physician or physician assistant who prescribes or delivers an opioid
9 antagonist under par. (a) shall ensure that the person to whom the opioid antagonist
10 will be delivered has the knowledge and training necessary to safely administer the
11 opioid antagonist to an individual undergoing an opioid-related overdose and that
12 the person demonstrates the capacity to ensure that any individual to whom the
13 person further delivers the opioid antagonist has or receives that knowledge and
14 training.

15 **(3)** A physician or physician assistant who, acting in good faith, prescribes or
16 delivers an opioid antagonist in accordance with sub. (2), or who, acting in good faith,
17 otherwise lawfully prescribes or dispenses an opioid antagonist, shall be immune
18 from criminal or civil liability and may not be subject to professional discipline under
19 s. 448.02 for any outcomes resulting from prescribing, delivering, or dispensing the
20 opioid antagonist.

21 **SECTION 10.** 450.01 (1) (d) of the statutes is created to read:

22 450.01 (1) (d) In the case of an opioid antagonist, any person.

23 **SECTION 11.** 450.01 (13v) of the statutes is created to read:

24 450.01 **(13v)** “Opioid antagonist” means a drug, such as naloxone, that satisfies
25 all of the following:

1 (a) The drug binds to the opioid receptors and competes with or displaces opioid
2 agonists at the opioid receptor site but does not activate the receptors, effectively
3 blocking the receptor and preventing or reversing the effect of an opioid agonist.

4 (b) The drug is not a controlled substance.

5 **SECTION 12.** 450.10 (1) (a) (intro.) of the statutes is amended to read:

6 450.10 (1) (a) (intro.) In this subsection, “unprofessional conduct” includes any
7 of the following, but does not include the dispensing of an antimicrobial drug for
8 expedited partner therapy as described in s. 450.11 (1g) or the delivery of an opioid
9 antagonist as described in s. 450.11 (1i):

10 **SECTION 13.** 450.11 (1) of the statutes is amended to read:

11 450.11 (1) DISPENSING. ~~No~~ Except as provided in sub. (1i) (b) 2., no person may
12 dispense any prescribed drug or device except upon the prescription order of a
13 practitioner. All prescription orders shall specify the date of issue, the name and
14 address of the practitioner, the name and quantity of the drug product or device
15 prescribed, directions for the use of the drug product or device, the symptom or
16 purpose for which the drug is being prescribed if required under sub. (4) (a) 8., and,
17 if the order is written by the practitioner, the signature of the practitioner. Except
18 as provided in s. ss. 441.18 (2), 448.035 (2), and 448.037 (2), all prescription orders
19 shall also specify the name and address of the patient. Any oral prescription order
20 shall be immediately reduced to writing by the pharmacist and filed according to sub.
21 (2).

22 **SECTION 14.** 450.11 (1i) of the statutes is created to read:

23 450.11 (1i) OPIOID ANTAGONISTS. (a) *Prescription and liability.* 1. A pharmacist
24 may, upon the prescription order of an advanced practice nurse prescriber under s.
25 441.18 (2), or of a physician or physician assistant under s. 448.037 (2), that complies

1 with the requirements of sub. (1), deliver an opioid antagonist to the person specified
2 in the prescription order. The pharmacist shall provide a consultation in accordance
3 with rules promulgated by the board for the delivery of a prescription to the person
4 to whom the opioid antagonist is delivered.

5 2. A pharmacist who, acting in good faith, delivers an opioid antagonist in
6 accordance with subd. 1., or who, acting in good faith, otherwise lawfully dispenses
7 an opioid antagonist, shall be immune from criminal or civil liability and may not be
8 subject to professional discipline under s. 450.10 for any outcomes resulting from
9 delivering or dispensing the opioid antagonist.

10 (b) *Possession, dispensing, and delivery.* 1. Any person may possess an opioid
11 antagonist.

12 2. a. Subject to subd. 2. b. to d., any person may deliver or dispense an opioid
13 antagonist.

14 b. An advanced practice nurse prescriber may only deliver or dispense an opioid
15 antagonist in accordance with s. 441.18 (2) or in accordance with his or her other legal
16 authority to dispense prescription drugs.

17 c. A physician or physician assistant may only deliver or dispense an opioid
18 antagonist in accordance with s. 448.037 (2) or in accordance with his or her other
19 legal authority to dispense prescription drugs.

20 d. A pharmacist may only deliver or dispense an opioid antagonist in
21 accordance with par. (a) 1. or in accordance with his or her other legal authority to
22 dispense prescription drugs.

23 (c) *Immunity.* 1. In this paragraph, “opioid-related drug overdose” has the
24 meaning given in s. 256.40 (1) (d).

1 2. Subject to par. (a) 2. and ss. 441.18 (3) and 448.037 (3), any person who, acting
2 in good faith, delivers or dispenses an opioid antagonist to another person shall be
3 immune from civil or criminal liability for any outcomes resulting from delivering or
4 dispensing the opioid antagonist.

5 3. Subject to ss. 256.40 (3) (b) and 895.48 (1g), any person who, reasonably
6 believing another person to be undergoing an opioid-related drug overdose,
7 administers an opioid antagonist to that person shall be immune from civil or
8 criminal liability for any outcomes resulting from the administration of the opioid
9 antagonist to that person.

10 **SECTION 15.** 450.11 (3) of the statutes is amended to read:

11 450.11 (3) PREPARATION OF PRESCRIPTION DRUGS. ~~No~~ Except as provided in sub.
12 (1i) (b), no person other than a pharmacist or practitioner or their agents and
13 employees as directed, supervised, and inspected by the pharmacist or practitioner
14 may prepare, compound, dispense, or prepare for delivery for a patient any
15 prescription drug.

16 **SECTION 16.** 450.11 (4) (a) 5. a. of the statutes is amended to read:

17 450.11 (4) (a) 5. a. Except as provided in subd. 5. b. and c., the full name of the
18 patient.

19 **SECTION 17.** 450.11 (4) (a) 5. c. of the statutes is created to read:

20 450.11 (4) (a) 5. c. For an opioid antagonist when delivered under sub. (1i) (a),
21 the name of the person to whom the opioid antagonist will be delivered as specified
22 in s. 441.18 (2) (a) or 448.037 (2) (a).

23 **SECTION 18.** 450.11 (7) (h) of the statutes is amended to read:

1 450.11 (7) (h) No Except as provided in sub. (1i) (b), no person may possess a
2 prescription drug unless the prescription drug is obtained in compliance with this
3 section.

4 **SECTION 19.** 895.48 (1) of the statutes is amended to read:

5 895.48 (1) Any Except as provided in sub. (1g), any person who renders
6 emergency care at the scene of any emergency or accident in good faith shall be
7 immune from civil liability for his or her acts or omissions in rendering such
8 emergency care. This

9 **(1g)** The immunity described in sub. (1) and s. 450.11 (1i) (c) 3. does not extend
10 when employees trained in health care or health care professionals render
11 emergency care for compensation and within the scope of their usual and customary
12 employment or practice at a hospital or other institution equipped with hospital
13 facilities, at the scene of any emergency or accident, enroute to a hospital or other
14 institution equipped with hospital facilities, or at a physician's office.

15

(END)