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1 AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Right to Try Act.

Section 5. Findings. The General Assembly finds that the process of approval for investigational drugs, biological products, and devices in the United States often takes many years, and a patient with a terminal illness does not have the luxury of waiting until such drug, product, or device receives United States Food and final approval from the Administration. As a result, the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to terminally ill patients. A patient with a terminal illness has a fundamental right to attempt to preserve his or her own life by accessing investigational drugs, biological products, and devices. Whether to use available investigational drugs, biological products, and devices is a decision that rightfully should be made by the patient with a terminal illness in consultation with his or her physician and is not a decision to be made by the government.

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- Section 10. Definitions. For the purposes of this Act: 1
- 2 "Accident and health insurer" has the meaning given to that
- 3 term in Section 126.2 of the Illinois Insurance Code.
- "Eligible patient" means a person who: 4
 - (1) has a terminal illness;
 - (2) has considered all other treatment approved by the United States Food and Drug Administration;
 - (3) has received a prescription or recommendation from his or her physician for an investigational drug, biological product, or device;
 - (4) has given his or her informed consent in writing the use of the investigational drug, biological product, or device or, if he or she is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given informed consent on his or her behalf; and
 - (5) has documentation from his or her physician indicating that he or she has met the requirements of this Act.
 - "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase I of a clinical trial, but has not been approved for general use by the United States Food and Drug Administration.
- 25 "Phase I of a clinical trial" means the stage of a clinical

- 1 trial where an investigational drug, biological product, or
- device has been tested in a small group for the first time to
- 3 evaluate its safety, determine a safe dosage range, and
- 4 identify side effects.
- 5 "Terminal illness" means a disease that, without
- 6 life-sustaining measures, can reasonably be expected to result
- 7 in death in 24 months or less.
- 8 Section 15. Availability of drugs, biological products,
- 9 and devices.
- 10 (a) A manufacturer of an investigational drug, biological
- 11 product, or device may make available such drug, product, or
- 12 device to eligible patients. Nothing in this Act shall be
- 13 construed to require a manufacturer to make available any drug,
- 14 product, or device.
- 15 (b) A manufacturer may:
- 16 (1) provide an investigational drug, biological
- 17 product, or device to an eliquible patient without receiving
- 18 compensation; or
- 19 (2) require an eligible patient to pay the costs of or
- 20 associated with the manufacture of the investigational
- 21 drug, biological product, or device.
- 22 Section 20. Insurance coverage. An accident and health
- insurer may choose to provide coverage for the cost of an
- 24 investigational drug, biological product, or device. Nothing

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- 1 in this Act shall be construed to require an accident and
- 2 health insurer to provide coverage for the cost of any
- 3 investigational drug, biological product, or device.
- 4 Section 80. The Nursing Home Care Act is amended by
- 5 changing Section 2-104 as follows:
- 6 (210 ILCS 45/2-104) (from Ch. 111 1/2, par. 4152-104)

Sec. 2-104. (a) A resident shall be permitted to retain the services of his own personal physician at his own expense or under an individual or group plan of health insurance, or under any public or private assistance program providing such coverage. However, the facility is not liable for negligence of any such personal physician. Every resident shall be permitted to obtain from his own physician or the physician attached to the facility complete and current information concerning his medical diagnosis, treatment and prognosis in terms and language the resident can reasonably be expected to understand. Every resident shall be permitted to participate in the planning of his total care and medical treatment to the extent that his condition permits. No resident shall be subjected to experimental research or treatment without first obtaining his informed, written consent. The conduct of any experimental research or treatment shall be authorized and monitored by an institutional review board appointed by the Director. The membership, operating procedures and review

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criteria for the institutional review board shall be prescribed under rules and regulations of the Department and shall comply the requirements for institutional review established by the federal Food and Drug Administration. No person who has received compensation in the prior 3 years from manufactures, that distributes, pharmaceuticals, biologics, or medical devices may serve on the institutional review board.

The institutional review board may approve only research or treatment that meets the standards of the federal Food and Drug Administration with respect to (i) the protection of human and (ii) financial disclosure subjects by clinical investigators. The Office of State Long Term Care Ombudsman and the State Protection and Advocacy organization shall be given an opportunity to comment on any request for approval before the board makes a decision. Those entities shall not be provided information that would allow a potential human subject to be individually identified, unless the board asks the Ombudsman for help in securing information from or about the resident. The board shall require frequent reporting of the progress of the approved research or treatment and its impact on residents, including immediate reporting of any adverse impact to the resident, the resident's representative, the Office of the State Long Term Care Ombudsman, and the State Protection and Advocacy organization. The board may not approve any retrospective study of the records of any resident about

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the safety or efficacy of any care or treatment if the resident was under the care of the proposed researcher or a business associate when the care or treatment was given, unless the study is under the control of a researcher without any business relationship to any person or entity who could benefit from the findings of the study.

No facility shall permit experimental research treatment to be conducted on a resident, or give access to any person or person's records for a retrospective study about the safety or efficacy of any care or treatment, without the prior written approval of the institutional review board. No nursing home administrator, or person licensed by the State to provide medical care or treatment to any person, may assist or participate in any experimental research on or treatment of a resident, including a retrospective study, that does not have the prior written approval of the board. Such conduct shall be grounds for professional discipline by the Department of Financial and Professional Regulation.

The institutional review board may exempt from ongoing review research or treatment initiated on a resident before the individual's admission to a facility and for which the board determines there is adequate ongoing oversight by another institutional review board. Nothing in this Section shall prevent a facility, any facility employee, or any other person from assisting or participating in any experimental research on or treatment of a resident, if the research or treatment began

- 1 before the person's admission to a facility, until the board
- 2 has reviewed the research or treatment and decided to grant or
- 3 deny approval or to exempt the research or treatment from
- 4 ongoing review.
- 5 The institutional review board requirements of this
- 6 <u>subsection</u> (a) do not apply to investigational drugs,
- 7 <u>biological products, or devices used by a resident with a</u>
- 8 <u>terminal illness as set forth in the Right to Try Act.</u>
- 9 (b) All medical treatment and procedures shall be 10 administered as ordered by a physician. All new physician
- orders shall be reviewed by the facility's director of nursing
- or charge nurse designee within 24 hours after such orders have
- been issued to assure facility compliance with such orders.
- 14 All physician's orders and plans of treatment shall have
- 15 the authentication of the physician. For the purposes of this
- 16 subsection (b), "authentication" means an original written
- 17 signature or an electronic signature system that allows for the
- 18 verification of a signer's credentials. A stamp signature, with
- or without initials, is not sufficient.
- 20 According to rules adopted by the Department, every woman
- 21 resident of child-bearing age shall receive routine
- 22 obstetrical and gynecological evaluations as well as necessary
- 23 prenatal care.
- 24 (c) Every resident shall be permitted to refuse medical
- 25 treatment and to know the consequences of such action, unless
- 26 such refusal would be harmful to the health and safety of

- others and such harm is documented by a physician in the 1
- 2 resident's clinical record. The resident's refusal shall free
- 3 the facility from the obligation to provide the treatment.
- (d) Every resident, resident's quardian, or parent if the 4
- 5 resident is a minor shall be permitted to inspect and copy all
- 6 his clinical and other records concerning his care
- 7 maintenance kept by the facility or by his physician. The
- 8 facility may charge a reasonable fee for duplication of a
- 9 record.
- 10 (Source: P.A. 96-1372, eff. 7-29-10; 97-179, eff. 1-1-12.)
- 11 Section 90. The Medical Practice Act of 1987 is amended by
- 12 changing Section 22 as follows:
- (225 ILCS 60/22) (from Ch. 111, par. 4400-22) 13
- 14 (Section scheduled to be repealed on December 31, 2015)
- 15 Sec. 22. Disciplinary action.
- (A) The Department may revoke, suspend, place on probation, 16
- 17 reprimand, refuse to issue or renew, or take any other
- 18 disciplinary or non-disciplinary action as the Department may
- deem proper with regard to the license or permit of any person 19
- 20 issued under this Act, including imposing fines not to exceed
- 21 \$10,000 for each violation, upon any of the following grounds:
- (1) Performance of an elective abortion in any place, 22
- 23 locale, facility, or institution other than:
- 24 (a) a facility licensed pursuant to the Ambulatory

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Surgical	Treatment	Center	Act;
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- (b) an institution licensed under the Hospital Licensing Act;
- (c) an ambulatory surgical treatment center or hospitalization or care facility maintained by the State or any agency thereof, where such department or agency has authority under law to establish and enforce standards for the ambulatory surgical treatment centers, hospitalization, or care facilities under its management and control;
- (d) ambulatory surgical treatment centers, hospitalization or care facilities maintained by the Federal Government; or
- ambulatory surgical treatment centers, hospitalization or care facilities maintained by any university or college established under the laws of this State and supported principally by public funds raised by taxation.
- (2) Performance of an abortion procedure in a wilful and wanton manner on a woman who was not pregnant at the time the abortion procedure was performed.
- (3) A plea of guilty or nolo contendere, finding of guilt, jury verdict, or entry of judgment or sentencing, including, but not limited to, convictions, preceding sentences of supervision, conditional discharge, or first offender probation, under the laws of any jurisdiction of

- the United States of any crime that is a felony.
- (4) Gross negligence in practice under this Act.
 - (5) Engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public.
 - (6) Obtaining any fee by fraud, deceit, or misrepresentation.
 - (7) Habitual or excessive use or abuse of drugs defined in law as controlled substances, of alcohol, or of any other substances which results in the inability to practice with reasonable judgment, skill or safety.
 - (8) Practicing under a false or, except as provided by law, an assumed name.
 - (9) Fraud or misrepresentation in applying for, or procuring, a license under this Act or in connection with applying for renewal of a license under this Act.
 - (10) Making a false or misleading statement regarding their skill or the efficacy or value of the medicine, treatment, or remedy prescribed by them at their direction in the treatment of any disease or other condition of the body or mind.
 - (11) Allowing another person or organization to use their license, procured under this Act, to practice.
 - (12) Adverse action taken by another state or jurisdiction against a license or other authorization to practice as a medical doctor, doctor of osteopathy, doctor

of osteopathic medicine or doctor of chiropractic, a certified copy of the record of the action taken by the other state or jurisdiction being prima facie evidence thereof. This includes any adverse action taken by a State or federal agency that prohibits a medical doctor, doctor of osteopathy, doctor of osteopathic medicine, or doctor of chiropractic from providing services to the agency's participants.

- (13) Violation of any provision of this Act or of the Medical Practice Act prior to the repeal of that Act, or violation of the rules, or a final administrative action of the Secretary, after consideration of the recommendation of the Disciplinary Board.
- (14) Violation of the prohibition against fee splitting in Section 22.2 of this Act.
- (15) A finding by the Disciplinary Board that the registrant after having his or her license placed on probationary status or subjected to conditions or restrictions violated the terms of the probation or failed to comply with such terms or conditions.
 - (16) Abandonment of a patient.
- (17) Prescribing, selling, administering, distributing, giving or self-administering any drug classified as a controlled substance (designated product) or narcotic for other than medically accepted therapeutic purposes.

- (18) Promotion of the sale of drugs, devices, appliances or goods provided for a patient in such manner as to exploit the patient for financial gain of the physician.
- (19) Offering, undertaking or agreeing to cure or treat disease by a secret method, procedure, treatment or medicine, or the treating, operating or prescribing for any human condition by a method, means or procedure which the licensee refuses to divulge upon demand of the Department.
- (20) Immoral conduct in the commission of any act including, but not limited to, commission of an act of sexual misconduct related to the licensee's practice.
- (21) Wilfully making or filing false records or reports in his or her practice as a physician, including, but not limited to, false records to support claims against the medical assistance program of the Department of Healthcare and Family Services (formerly Department of Public Aid) under the Illinois Public Aid Code.
- (22) Wilful omission to file or record, or wilfully impeding the filing or recording, or inducing another person to omit to file or record, medical reports as required by law, or wilfully failing to report an instance of suspected abuse or neglect as required by law.
- (23) Being named as a perpetrator in an indicated report by the Department of Children and Family Services under the Abused and Neglected Child Reporting Act, and

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upon proof by clear and convincing evidence that the licensee has caused a child to be an abused child or neglected child as defined in the Abused and Neglected Child Reporting Act.

- (24) Solicitation of professional patronage by any corporation, agents or persons, or profiting from those representing themselves to be agents of the licensee.
- (25) Gross and wilful and continued overcharging for professional services, including filing false statements for collection of fees for which services are not rendered, including, but not limited to, filing such false statements for collection of monies for services not rendered from the medical assistance program of the Department of Healthcare and Family Services (formerly Department of Public Aid) under the Illinois Public Aid Code.
- (26) A pattern of practice or other behavior which demonstrates incapacity or incompetence to practice under this Act.
- (27) Mental illness or disability which results in the inability to practice under this Act with reasonable judgment, skill or safety.
- (28) Physical illness, including, but not limited to, deterioration through the aging process, or loss of motor skill which results in a physician's inability to practice under this Act with reasonable judgment, skill or safety.
 - (29) Cheating on or attempt to subvert the licensing

- examinations administered under this Act.
- (30) Wilfully or negligently violating the confidentiality between physician and patient except as required by law.
 - (31) The use of any false, fraudulent, or deceptive statement in any document connected with practice under this Act.
 - (32) Aiding and abetting an individual not licensed under this Act in the practice of a profession licensed under this Act.
 - (33) Violating state or federal laws or regulations relating to controlled substances, legend drugs, or ephedra as defined in the Ephedra Prohibition Act.
 - (34) Failure to report to the Department any adverse final action taken against them by another licensing jurisdiction (any other state or any territory of the United States or any foreign state or country), by any peer review body, by any health care institution, by any professional society or association related to practice under this Act, by any governmental agency, by any law enforcement agency, or by any court for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this Section.
 - (35) Failure to report to the Department surrender of a license or authorization to practice as a medical doctor, a doctor of osteopathy, a doctor of osteopathic medicine, or

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doctor of chiropractic in another state or jurisdiction, or surrender of membership on any medical staff or in any medical or professional association or society, while disciplinary investigation by anv of authorities or bodies, for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this Section.

- (36) Failure to report to the Department any adverse judgment, settlement, or award arising from a liability claim related to acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this Section.
- (37) Failure to provide copies of medical records as required by law.
- (38)Failure to furnish the Department, investigators or representatives, relevant information, legally requested by the Department after consultation with the Chief Medical Coordinator or the Deputy Medical Coordinator.
- (39) Violating the Health Care Worker Self-Referral Act.
- (40) Willful failure to provide notice when notice is required under the Parental Notice of Abortion Act of 1995.
- (41) Failure to establish and maintain records of patient care and treatment as required by this law.
 - (42) Entering into an excessive number of written

- collaborative agreements with licensed advanced practice
 nurses resulting in an inability to adequately
 collaborate.
 - (43) Repeated failure to adequately collaborate with a licensed advanced practice nurse.
 - (44) Violating the Compassionate Use of Medical Cannabis Pilot Program Act.
 - (45) Entering into an excessive number of written collaborative agreements with licensed prescribing psychologists resulting in an inability to adequately collaborate.
 - (46) Repeated failure to adequately collaborate with a licensed prescribing psychologist.

Except for actions involving the ground numbered (26), all proceedings to suspend, revoke, place on probationary status, or take any other disciplinary action as the Department may deem proper, with regard to a license on any of the foregoing grounds, must be commenced within 5 years next after receipt by the Department of a complaint alleging the commission of or notice of the conviction order for any of the acts described herein. Except for the grounds numbered (8), (9), (26), and (29), no action shall be commenced more than 10 years after the date of the incident or act alleged to have violated this Section. For actions involving the ground numbered (26), a pattern of practice or other behavior includes all incidents alleged to be part of the pattern of practice or other behavior

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The entry of an order or judgment by any circuit court establishing that any person holding a license under this Act is a person in need of mental treatment operates as a suspension of that license. That person may resume their practice only upon the entry of a Departmental order based upon a finding by the Disciplinary Board that they have been determined to be recovered from mental illness by the court and upon the Disciplinary Board's recommendation that they be permitted to resume their practice.

of the license was outside the State of Illinois shall not be

included within any period of time limiting the commencement of

disciplinary action by the Department.

The Department may refuse to issue or take disciplinary

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- action concerning the license of any person who fails to file a 1 2 return, or to pay the tax, penalty or interest shown in a filed 3 return, or to pay any final assessment of tax, penalty or interest, as required by any tax Act administered by the 5 Illinois Department of Revenue, until such time as
- requirements of any such tax Act are satisfied as determined by 6
- 7 the Illinois Department of Revenue.
- of 8 The recommendation t.he Department, upon the 9 Disciplinary Board, shall adopt rules which set forth standards 10 to be used in determining:
- 11 (a) when person will be deemed sufficiently 12 rehabilitated to warrant the public trust;
 - what constitutes dishonorable, unethical (b) unprofessional conduct of a character likely to deceive, defraud, or harm the public;
 - (c) what constitutes immoral conduct in the commission of any act, including, but not limited to, commission of an of sexual misconduct related to the licensee's act practice; and
- 20 (d) what constitutes gross negligence in the practice of medicine. 21
- 22 However, no such rule shall be admissible into evidence in 23 any civil action except for review of a licensing or other 24 disciplinary action under this Act.
- 25 In enforcing this Section, the Disciplinary Board or the 26 Licensing Board, upon a showing of a possible violation, may

compel, in the case of the Disciplinary Board, any individual 1 2 who is licensed to practice under this Act or holds a permit to 3 practice under this Act, or, in the case of the Licensing Board, any individual who has applied for licensure or a permit 4 5 pursuant to this Act, to submit to a mental or physical 6 examination and evaluation, or both, which may include a 7 substance abuse or sexual offender evaluation, as required by 8 the Licensing Board or Disciplinary Board and at the expense of 9 the Department. The Disciplinary Board or Licensing Board shall 10 specifically designate the examining physician licensed to 11 practice medicine in all of its branches or, if applicable, the 12 multidisciplinary team involved in providing the mental or 13 physical examination and evaluation, or both. The multidisciplinary team shall be led by a physician licensed to 14 15 practice medicine in all of its branches and may consist of one 16 or more or a combination of physicians licensed to practice 17 medicine in all of its branches, licensed chiropractic physicians, licensed clinical psychologists, licensed clinical 18 social workers, licensed clinical professional counselors, and 19 20 other professional and administrative staff. Any examining physician or member of the multidisciplinary team may require 21 22 any person ordered to submit to an examination and evaluation 23 pursuant to this Section to submit to any additional testing deemed necessary to 24 supplemental complete 25 examination or evaluation process, including, but not limited to, blood testing, urinalysis, psychological testing, or 26

neuropsychological testing. The Disciplinary Board, 1 2 Licensing Board, or the Department may order the examining physician or any member of the multidisciplinary team to 3 provide to the Department, the Disciplinary Board, or the 4 5 Licensing Board any and all records, including business 6 records, that relate to the examination and evaluation, 7 including any supplemental testing performed. The Disciplinary 8 Board, the Licensing Board, or the Department may order the 9 examining physician or any member of the multidisciplinary team 10 present testimony concerning this examination 11 evaluation of the licensee, permit holder, or applicant, 12 including testimony concerning any supplemental testing or 13 documents relating to the examination and evaluation. No 14 information, report, record, or other documents in any way 15 related to the examination and evaluation shall be excluded by 16 reason of any common law or statutory privilege relating to 17 between the licensee, permit holder, communication applicant and the examining physician or any member of the 18 19 multidisciplinary team. No authorization is necessary from the 20 licensee, permit holder, or applicant ordered to undergo an evaluation and examination for the examining physician or any 21 22 member of the multidisciplinary team to provide information, 23 reports, records, or other documents or to provide anv 24 testimony regarding the examination and evaluation. The 25 individual to be examined may have, at his or her own expense, another physician of his or her choice present during all 26

aspects of the examination. Failure of any individual to submit 1 2 to mental or physical examination and evaluation, or both, when directed, shall result in an automatic suspension, without 3 hearing, until such time as the individual submits to the 5 examination. If the Disciplinary Board or Licensing Board finds a physician unable to practice following an examination and 6 evaluation because of the reasons set forth in this Section, 7 8 the Disciplinary Board or Licensing Board shall require such 9 physician to submit to care, counseling, or treatment by 10 physicians, or other health care professionals, approved or 11 designated by the Disciplinary Board, as a condition for 12 issued, continued, reinstated, or renewed licensure practice. Any physician, whose license was granted pursuant to 13 14 Sections 9, 17, or 19 of this Act, or, continued, reinstated, renewed, disciplined or supervised, subject to such terms, 15 16 conditions or restrictions who shall fail to comply with such 17 terms, conditions or restrictions, or to complete a required program of care, counseling, or treatment, as determined by the 18 Chief Medical Coordinator or Deputy Medical Coordinators, 19 20 shall be referred to the Secretary for a determination as to whether the licensee shall have their license suspended 21 22 immediately, pending a hearing by the Disciplinary Board. In 23 instances in which the Secretary immediately suspends a license under this Section, a hearing upon such person's license must 24 25 be convened by the Disciplinary Board within 15 days after such 26 suspension and completed without appreciable delay.

Disciplinary Board shall have the authority to review the subject physician's record of treatment and counseling regarding the impairment, to the extent permitted by applicable federal statutes and regulations safeguarding the

confidentiality of medical records.

An individual licensed under this Act, affected under this Section, shall be afforded an opportunity to demonstrate to the Disciplinary Board that they can resume practice in compliance with acceptable and prevailing standards under the provisions of their license.

The Department may promulgate rules for the imposition of fines in disciplinary cases, not to exceed \$10,000 for each violation of this Act. Fines may be imposed in conjunction with other forms of disciplinary action, but shall not be the exclusive disposition of any disciplinary action arising out of conduct resulting in death or injury to a patient. Any funds collected from such fines shall be deposited in the Medical Disciplinary Fund.

All fines imposed under this Section shall be paid within 60 days after the effective date of the order imposing the fine or in accordance with the terms set forth in the order imposing the fine.

(B) The Department shall revoke the license or permit issued under this Act to practice medicine or a chiropractic physician who has been convicted a second time of committing any felony under the Illinois Controlled Substances Act or the

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Methamphetamine Control and Community Protection Act, or who has been convicted a second time of committing a Class 1 felony under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A person whose license or permit is revoked under this subsection B shall be prohibited from practicing medicine or treating human ailments without the use of drugs and without operative surgery.

(C) The Department shall not revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action against the license or permit issued under this Act to practice medicine to a physician based solely upon the recommendation of the physician to an eligible patient, as defined under Section 10 of the Right to Try Act, regarding, or prescription for, or treatment with, an investigational drug, biological product, or device.

(D) (C) The Disciplinary Board shall recommend to the civil penalties Department and any other appropriate discipline in disciplinary cases when the Board finds that a willfully performed physician an abortion with actual knowledge that the person upon whom the abortion has been performed is a minor or an incompetent person without notice as required under the Parental Notice of Abortion Act of 1995. Upon the Board's recommendation, the Department shall impose, for the first violation, a civil penalty of \$1,000 and for a second or subsequent violation, a civil penalty of \$5,000.

- (Source: P.A. 97-622, eff. 11-23-11; 98-601, eff. 12-30-13; 1
- 98-668, eff. 6-25-14; 98-1140, eff. 12-30-14.) 2