HOUSE AMENDED

PRIOR PRINTER'S NOS. 2075, 2094, 2158 PRINTER'S NO. 2190

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1368 Session of 2015

INTRODUCED BY KILLION, YAW, SCARNATI, CORMAN, AUMENT, BROWNE, BARTOLOTTA, FOLMER, RAFFERTY, RESCHENTHALER, VULAKOVICH, FONTANA, TEPLITZ, COSTA, HUTCHINSON, YUDICHAK, STEFANO, MENSCH AND ARGALL, SEPTEMBER 23, 2016

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, OCTOBER 24, 2016

AN ACT

Amending Title 35 (Health and Safety) of the Pennsylvania Consolidated Statutes, in public safety, providing for safe opioid prescription AND FOR PATIENT VOLUNTARY NONOPIOID DIRECTIVE and imposing powers and duties on certain Commonwealth agencies. <--

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Title 35 of the Pennsylvania Consolidated Statutes is amended by adding ~~a chapter~~ CHAPTERS in Part III to read: <--

CHAPTER 51

SAFE OPIOID PRESCRIPTION

Sec.

§ 5101. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"College." Any of the following:

(1) A medical college.

(2) A medical training facility, including a school of nursing and a school of optometry.

(3) A dental school.

(4) An osteopathic medical college or osteopathic medical training facility.

"Controlled substance." A drug, substance or immediate precursor included in Schedules II through V of section 4 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Licensing boards." The following:

(1) The State Board of Dentistry.

(2) The State Board of Medicine.

(3) The State Board of Nursing.

(4) The State Board of Optometry.

(5) The State Board of Osteopathic Medicine.

(6) The State Board of Podiatry.

"Opioid." Any of the following:

(1) A preparation or derivative of opium.

(2) A synthetic narcotic that has opiate-like effects but is not derived from opium.

(3) A group of naturally occurring peptides that bind at or otherwise influence opiate receptors, including opioid agonist.

§ 5102. Safe opioid prescription education.

(a) Curriculum.--Beginning August 1, 2017, the licensing

boards shall, by joint regulation, implement a safe prescription of a controlled substance containing an opioid curriculum. The curriculum may be offered in colleges or by providers approved by the licensing boards and shall include all of the following:

(1) Current, age-appropriate information relating to pain management.

(2) Multimodal treatments for chronic pain that minimize the use of a controlled substance containing an opioid.

(3) If a controlled substance containing an opioid is indicated, instruction on safe methods of prescribing a controlled substance containing an opioid that follow guideline-based care.

(4) Identification of patients who have risk factors for developing problems with prescription of a controlled substance containing an opioid.

(5) Training on managing substance ~~abuse~~ USE disorders as a chronic disease. <--

(b) Separation from standardized curriculum.--~~The education required under this chapter shall not be considered part of the college's curriculum necessary for graduation.~~ THE EDUCATION REQUIRED UNDER THIS CHAPTER SHALL NOT BE CONSIDERED TO BE A MANDATE OF THE CURRICULUM NECESSARY FOR GRADUATION. NOTHING IN THIS CHAPTER SHALL BE CONSTRUED TO PROHIBIT A COLLEGE FROM REQUIRING SUCH CURRICULUM TO BE NECESSARY TO GRADUATE AFTER AUGUST 1, 2017. <--

§ 5103. Temporary regulations.

In order to facilitate the prompt implementation of this chapter, each licensing board may issue temporary regulations. The following shall apply:

(1) The temporary regulations shall expire no later than

two years after their issuance.

(2) The temporary regulations issued by each licensing board shall not be subject to:

(i) Sections 201, 202 and 203 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(ii) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

CHAPTER 52 <--

PATIENT VOLUNTARY NONOPIOID DIRECTIVE

SEC.

§ 5201. SCOPE OF CHAPTER.

THIS CHAPTER RELATES TO PATIENT VOLUNTARY NONOPIOID DIRECTIVES.

§ 5202. DEFINITIONS.

THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS CHAPTER SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

"CONTROLLED SUBSTANCE." AS DEFINED IN THE ACT OF APRIL 14, 1972 (P.L.233, NO.64), KNOWN AS THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT.

"DEPARTMENT." THE DEPARTMENT OF HEALTH OF THE COMMONWEALTH.

"HEALTH CARE FACILITY." A HEALTH CARE FACILITY AS DEFINED IN SECTION 103 OF THE ACT OF JULY 19, 1979 (P.L.130, NO.48), KNOWN

AS THE HEALTH CARE FACILITIES ACT, OR ANY OTHER FACILITY OR INSTITUTION LICENSED, REGISTERED OR OTHERWISE PERMITTED TO DISTRIBUTE, DISPENSE, CONDUCT RESEARCH WITH OR PRESCRIBE OR ADMINISTER A CONTROLLED SUBSTANCE CONTAINING AN OPIOID OR OTHER CONTROLLED SUBSTANCE IN THE COURSE OF PROFESSIONAL PRACTICE OR RESEARCH IN THIS COMMONWEALTH.

"LICENSING BOARD." THE TERM SHALL INCLUDE THE FOLLOWING:

(1) THE STATE BOARD OF MEDICINE AS SET FORTH IN THE ACT OF DECEMBER 20, 1985 (P.L.457, NO.112), KNOWN AS THE MEDICAL PRACTICE ACT OF 1985.

(2) THE STATE BOARD OF OSTEOPATHIC MEDICINE AS SET FORTH IN THE ACT OF OCTOBER 5, 1978 (P.L.1109, NO.261), KNOWN AS THE OSTEOPATHIC MEDICAL PRACTICE ACT.

(3) THE STATE BOARD OF NURSING AS SET FORTH IN THE ACT OF MAY 22, 1951 (P.L.317, NO.69), KNOWN AS THE PROFESSIONAL NURSING LAW.

(4) THE STATE BOARD OF PODIATRY AS SET FORTH IN THE ACT OF MARCH 2, 1956 (1955 P.L.1206, NO.375), KNOWN AS THE PODIATRY PRACTICE ACT.

(5) THE STATE BOARD OF DENTISTRY AS SET FORTH IN THE ACT OF MAY 1, 1933 (P.L.216, NO.76), KNOWN AS THE DENTAL LAW.

"OPIOID." ANY OF THE FOLLOWING:

(1) A PREPARATION OR DERIVATIVE OF OPIUM.

(2) A SYNTHETIC NARCOTIC THAT HAS OPIATE-LIKE EFFECTS BUT IS NOT DERIVED FROM OPIUM.

(3) A GROUP OF NATURALLY OCCURRING PEPTIDES THAT BIND AT OR OTHERWISE INFLUENCE OPIATE RECEPTORS, INCLUDING OPIOID AGONIST.

"PATIENT." AN INDIVIDUAL WHO IS UNDER THE MEDICAL CARE OF A PRACTITIONER.

"PRACTITIONER." A HEALTH CARE PRACTITIONER AS DEFINED IN SECTION 103 OF THE ACT OF JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE HEALTH CARE FACILITIES ACT.

"SECRETARY." THE SECRETARY OF HEALTH OF THE COMMONWEALTH.

"SYSTEM." THE ACHIEVING BETTER CARE BY MONITORING ALL PRESCRIPTIONS PROGRAM ELECTRONIC PRESCRIPTION MONITORING SYSTEM WITH A DATABASE COMPONENT AS ESTABLISHED UNDER THE ACT OF OCTOBER 27, 2014 (P.L.2911, NO.191), KNOWN AS THE ACHIEVING BETTER CARE BY MONITORING ALL PRESCRIPTIONS PROGRAM (ABC-MAP) ACT.

"VOLUNTARY NONOPIOID DIRECTIVE." A WRITTEN INSTRUCTION FORM EXECUTED BY A PATIENT EVIDENCING THE NAMED PATIENT'S REQUEST NOT TO HAVE A CONTROLLED SUBSTANCE CONTAINING AN OPIOID OFFERED, SUPPLIED, PRESCRIBED OR OTHERWISE ADMINISTERED TO THE NAMED PATIENT BY A PRACTITIONER.

§ 5203. VOLUNTARY NONOPIOID DIRECTIVE.

(A) DUTY OF DEPARTMENT.--

(1) IN CONSULTATION WITH A STATEWIDE PROFESSIONAL ORGANIZATION REPRESENTING PHYSICIANS LICENSED TO PRACTICE MEDICINE IN ALL ITS BRANCHES, STATEWIDE ORGANIZATIONS REPRESENTING NURSING HOMES, REGISTERED PROFESSIONAL NURSES, EMERGENCY MEDICAL SYSTEMS AND A STATEWIDE ORGANIZATION REPRESENTING HEALTH CARE FACILITIES, THE DEPARTMENT SHALL DEVELOP AND PUBLISH A UNIFORM VOLUNTARY NONOPIOID DIRECTIVE FORM WHICH MAY BE USED BY A PATIENT TO DENY OR REFUSE THE ADMINISTRATION OR PRESCRIBING OF A CONTROLLED SUBSTANCE CONTAINING AN OPIOID BY A PRACTITIONER.

(2) THE VOLUNTARY NONOPIOID DIRECTIVE FORM DEVELOPED BY THE DEPARTMENT IN ACCORDANCE WITH PARAGRAPH (1) SHALL INDICATE TO ALL PRESCRIBING PRACTITIONERS AND HEALTH CARE

FACILITIES THAT THE NAMED PATIENT SHALL NOT BE OFFERED, PRESCRIBED, SUPPLIED WITH OR OTHERWISE ADMINISTERED A CONTROLLED SUBSTANCE CONTAINING AN OPIOID.

(3) THE VOLUNTARY NONOPIOID DIRECTIVE FORM SHALL BE POSTED IN A DOWNLOADABLE FORMAT ON THE DEPARTMENT'S PUBLICLY ACCESSIBLE INTERNET WEBSITE.

(B) EXECUTION OF FORM.--THE FOLLOWING SHALL APPLY:

(1) A PATIENT MAY EXECUTE AND FILE A VOLUNTARY NONOPIOID DIRECTIVE FORM WITH A PRACTITIONER OR OTHER AUTHORITY AUTHORIZED BY THE SECRETARY TO ACCEPT THE VOLUNTARY NONOPIOID DIRECTIVE FORM FOR FILING. EACH PRACTITIONER OR OTHER PERSON AUTHORIZED BY THE SECRETARY TO ACCEPT A VOLUNTARY NONOPIOID DIRECTIVE FORM FOR FILING SHALL DATE AND AFFIX HIS SIGNATURE TO THE FORM IN THE PRESENCE OF THE PATIENT AS EVIDENCE OF ACCEPTANCE AND SHALL PROVIDE A SIGNED COPY OF THE FORM TO THE PATIENT.

(2) THE PATIENT EXECUTING AND FILING A VOLUNTARY NONOPIOID DIRECTIVE FORM WITH A PRACTITIONER SHALL SIGN AND DATE THE FORM IN THE PRESENCE OF THE PRACTITIONER, A DESIGNEE OF THE PRACTITIONER OR OTHER PERSON AUTHORIZED BY THE SECRETARY TO ACCEPT A VOLUNTARY NONOPIOID DIRECTIVE FORM FOR FILING. IN THE CASE OF A PATIENT WHO IS UNABLE TO EXECUTE AND FILE A VOLUNTARY NONOPIOID FORM, THE PATIENT MAY DESIGNATE A DULY AUTHORIZED GUARDIAN OR HEALTH CARE PROXY TO EXECUTE AND FILE THE FORM IN ACCORDANCE WITH PARAGRAPH (1).

(3) A PATIENT MAY REVOKE THE VOLUNTARY NONOPIOID DIRECTIVE FORM FOR ANY REASON AND MAY DO SO BY WRITTEN OR ORAL MEANS.

(4) NOTWITHSTANDING PARAGRAPH (1), BEFORE SIGNING A VOLUNTARY NONOPIOID DIRECTIVE FORM A PRACTITIONER MAY, IF

DEEMED APPROPRIATE, ASSESS THE PATIENT'S PERSONAL AND FAMILY HISTORY OF ALCOHOL OR DRUG ABUSE AND EVALUATE THE PATIENT'S RISK FOR MEDICATION MISUSE OR ABUSE. IN EVALUATING SUCH RISKS, THE PRACTITIONER SHALL ACCESS THE SYSTEM TO DETERMINE WHETHER AN UNUSUAL OR SUSPECT PATTERN FOR THE PRESCRIBING OF CONTROLLED SUBSTANCES CONTAINING OPIOIDS TO THE PATIENT HAS BEEN REPORTED TO THE SYSTEM. IF A PRACTITIONER REASONABLY BELIEVES THAT A PATIENT IS AT RISK FOR SUBSTANCE MISUSE OR ABUSE OR A PRACTITIONER BELIEVES IN THE PRACTITIONER'S EXPERT MEDICAL OPINION THAT FOR ANY OTHER REASON THE NONOPIOID DIRECTIVE IS APPROPRIATE, THE PRACTITIONER SHALL SIGN THE FORM. THE PRACTITIONER SIGNING THE NONOPIOID DIRECTIVE FORM SHALL NOTE DOING SO IN THE PATIENT'S MEDICAL RECORD.

§ 5204. GUIDELINES.

(A) ADOPTION OF GUIDELINES.--THE DEPARTMENT SHALL ADOPT AND PUBLISH GUIDELINES FOR THE IMPLEMENTATION OF THE VOLUNTARY NONOPIOID DIRECTIVE FORM. THE GUIDELINES SHALL INCLUDE, BUT NOT BE LIMITED TO:

(1) A STANDARD FORM FOR THE RECORDING AND TRANSMISSION OF THE VOLUNTARY NONOPIOID DIRECTIVE FORM, WHICH SHALL INCLUDE VERIFICATION BY THE PATIENT'S PRACTITIONER AND WHICH SHALL COMPLY WITH THE WRITTEN CONSENT REQUIREMENTS OF THE PUBLIC HEALTH SERVICE ACT (58 STAT. 682, 42 U.S.C. § 290DD-2(B)) AND 42 CFR PT. 2 (RELATING TO CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS), PROVIDED THAT THE VOLUNTARY NONOPIOID DIRECTIVE FORM SHALL ALSO PROVIDE THE BASIC PROCEDURES NECESSARY TO REVOKE THE VOLUNTARY NONOPIOID DIRECTIVE FORM.

(2) PROCEDURES TO RECORD THE VOLUNTARY NONOPIOID DIRECTIVE FORM IN THE PATIENT'S MEDICAL RECORD OR, IF

AVAILABLE, THE PATIENT'S INTEROPERABLE ELECTRONIC MEDICAL RECORD AND IN THE SYSTEM.

(3) REQUIREMENTS AND PROCEDURES FOR A PATIENT TO APPOINT A DULY AUTHORIZED GUARDIAN OR HEALTH CARE PROXY TO OVERRIDE A PREVIOUSLY FILED VOLUNTARY NONOPIOID DIRECTIVE FORM AND CIRCUMSTANCES UNDER WHICH AN ATTENDING PRACTITIONER MAY OVERRIDE A PREVIOUSLY FILED VOLUNTARY NONOPIOID DIRECTIVE FORM BASED ON DOCUMENTED MEDICAL JUDGMENT WHICH SHALL BE RECORDED IN THE PATIENT'S MEDICAL RECORD.

(4) PROCEDURES TO ENSURE THAT ANY RECORDING, SHARING OR DISTRIBUTING OF DATA RELATIVE TO THE VOLUNTARY NONOPIOID DIRECTIVE FORM COMPLIES WITH ALL FEDERAL AND STATE CONFIDENTIALITY LAWS.

(5) APPROPRIATE EXEMPTIONS FOR PRACTITIONERS AND OTHER HEALTH CARE PROVIDERS AND EMERGENCY MEDICAL PERSONNEL TO PRESCRIBE OR ADMINISTER A CONTROLLED SUBSTANCE CONTAINING AN OPIOID WHEN, IN THEIR PROFESSIONAL MEDICAL JUDGMENT, A CONTROLLED SUBSTANCE CONTAINING AN OPIOID IS NECESSARY.

(B) PUBLICATION.--THE DEPARTMENT SHALL PUBLISH THE GUIDELINES IN THE PENNSYLVANIA BULLETIN AND ON ITS PUBLICLY ACCESSIBLE INTERNET WEBSITE.

(C) WRITTEN PRESCRIPTIONS.--A WRITTEN PRESCRIPTION THAT IS PRESENTED AT AN OUTPATIENT PHARMACY OR A PRESCRIPTION THAT IS ELECTRONICALLY TRANSMITTED TO AN OUTPATIENT PHARMACY SHALL BE PRESUMED TO BE VALID FOR THE PURPOSES OF THIS SECTION AND A PHARMACIST IN AN OUTPATIENT SETTING SHALL NOT BE HELD IN VIOLATION OF THIS SECTION FOR DISPENSING A CONTROLLED SUBSTANCE CONTAINING AN OPIOID OR OTHER CONTROLLED SUBSTANCE IN CONTRADICTION TO A VOLUNTARY NONOPIOID DIRECTIVE FORM, EXCEPT UPON EVIDENCE THAT THE PHARMACIST ACTED KNOWINGLY AGAINST THE

VOLUNTARY NONOPIOID DIRECTIVE FORM.

§ 5205. EXEMPTION FROM LIABILITY.

(A) PRACTITIONER EXEMPTION.--NO PRACTITIONER OR EMPLOYEE OF A PRACTITIONER ACTING IN GOOD FAITH SHALL BE SUBJECT TO CRIMINAL OR CIVIL LIABILITY OR BE CONSIDERED TO HAVE ENGAGED IN UNPROFESSIONAL CONDUCT FOR FAILING TO OFFER OR ADMINISTER A PRESCRIPTION OR MEDICATION ORDER FOR A CONTROLLED SUBSTANCE CONTAINING AN OPIOID UNDER THE VOLUNTARY NONOPIOID DIRECTIVE FORM.

(B) REPRESENTATIVE EXEMPTION.--NO PERSON ACTING AS A REPRESENTATIVE OR AN AGENT UNDER A HEALTH CARE PROXY SHALL BE SUBJECT TO CRIMINAL OR CIVIL LIABILITY FOR MAKING A DECISION UNDER SECTION 5204(A)(3) (RELATING TO GUIDELINES) IN GOOD FAITH.

§ 5206. LICENSING BOARDS.

NOTWITHSTANDING ANY OTHER PROVISION OF LAW OR REGULATION, A LICENSING BOARD MAY LIMIT, CONDITION OR SUSPEND THE LICENSE OF OR ASSESS A FINE AGAINST A PRACTITIONER WHO RECKLESSLY OR NEGLIGENTLY FAILS TO COMPLY WITH A PATIENT'S VOLUNTARY NONOPIOID DIRECTIVE FORM.

Section 2. This act shall take effect immediately.