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2011-2012 Regular Sessions

IN ASSEMBLY

January 27, 2011

Introduced by M. of A. CUSICK -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing a prescription monitoring program

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEM-BLY, DO ENACT AS FOLLOWS:

Section 1. Article 33 of the public health law is amended by adding a new title 5-A to read as follows:

## TITLE V-A

PRESCRIPTION MONITORING PROGRAM

5 SECTION 3355. SHORT TITLE. б

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- 3356. DEFINITIONS.
  - 3357. ESTABLISHMENT OF A PRESCRIPTION MONITORING PROGRAM.
  - 3358. ADVISORY BOARD.
    - 3359. REPORTING OF PRESCRIPTION MONITORING INFORMATION.
  - 3360. ACCESS TO THE PRESCRIPTION MONITORING INFORMATION; CONFI-DENTIALITY.
  - 3361. EDUCATION AND TREATMENT.
  - 3362. UNLAWFUL ACTS AND PENALTIES.
- 3363. EVALUATION, DATA ANALYSIS AND REPORTING.
  - 3364. RULES AND REGULATIONS.
    - 3365. SEVERABILITY.

17 S 3355. SHORT TITLE. THIS ACT SHALL BE KNOWN AND MAY BE CITED AS THE "PRESCRIPTION MONITORING ACT". 18

19 S 3356. DEFINITIONS. 1. "BOARD" MEANS THE ADVISORY BOARD ESTABLISHED 20 UNDER SECTION THIRTY-THREE HUNDRED FIFTY-EIGHT OF THIS TITLE.

21 2. "DISPENSER" MEANS A PERSON AUTHORIZED IN THIS STATE TO DISTRIBUTE 22 TO THE ULTIMATE USER A SUBSTANCE MONITORED BY THE PRESCRIPTION MONITOR-23 ING PROGRAM, BUT DOES NOT INCLUDE:

24 (A) A LICENSED HOSPITAL PHARMACY THAT DISTRIBUTES SUCH SUBSTANCES FOR 25 THE INPATIENT HOSPITAL CARE OR PURPOSES OF THE DISPENSING OF

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [] is old law to be omitted.

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PRESCRIPTIONS FOR CONTROLLED SUBSTANCES AT THE TIME OF DISCHARGE FROM 1 2 SUCH A FACILITY; 3 (B) A LICENSED NURSE OR MEDICATION AIDE WHO ADMINISTERS SUCH A 4 SUBSTANCE AT THE DIRECTION OF A LICENSED PHYSICIAN; OR 5 (C) A WHOLESALE DISTRIBUTOR OF A SUBSTANCE MONITORED BY THE 6 PRESCRIPTION MONITORING PROGRAM. 7 "PRESCRIBER" MEANS A LICENSED HEALTH CARE PROFESSIONAL WITH PRES-3. 8 CRIPTIVE AUTHORITY. 9 4. "PRESCRIPTION MONITORING INFORMATION" MEANS INFORMATION SUBMITTED 10 TO AND MAINTAINED BY THE PRESCRIPTION MONITORING PROGRAM. 11 5. "PRESCRIPTION MONITORING PROGRAM" MEANS A PROGRAM ESTABLISHED UNDER 12 SECTION THIRTY-THREE HUNDRED FIFTY-SEVEN OF THIS TITLE. 3357. ESTABLISHMENT OF A PRESCRIPTION MONITORING PROGRAM. 1. THE 13 S 14 DEPARTMENT SHALL ESTABLISH AND MAINTAIN, WITH THE CONSULTATION OF THE 15 BOARD, AN ELECTRONIC SYSTEM FOR MONITORING THE FOLLOWING SUBSTANCES DISPENSED IN THE STATE: FEDERALLY CONTROLLED SUBSTANCES, ADDITIONAL 16 STATE SPECIFIED CONTROLLED SUBSTANCES, AND DRUGS OF CONCERN DOCUMENTED 17 TO DEMONSTRATE A POTENTIAL FOR ABUSE, PARTICULARLY THOSE IDENTIFIED BY 18 19 LAW ENFORCEMENT AND ADDICTION TREATMENT PROFESSIONALS. 2. THE DEPARTMENT MAY CONTRACT WITH A VENDOR TO ESTABLISH AND MAINTAIN 20 21 ELECTRONIC MONITORING SYSTEM PURSUANT TO GUIDELINES WHICH THE THE 22 DEPARTMENT SHALL PROMULGATE. 23 S 3358. ADVISORY BOARD. 1. THERE IS HEREBY ESTABLISHED AN ADVISORY 24 BOARD TO ASSIST THE DEPARTMENT IN CARRYING OUT THE DUTIES OF THIS ARTI-25 CLE. THE ADVISORY BOARD SHALL CONSIST OF THE FOLLOWING MEMBERS: 26 (A) A REPRESENTATIVE OF THE STATE BOARD OF MEDICINE, APPOINTED BY THE 27 BOARD. 28 (B) A REPRESENTATIVE OF THE STATE BOARD OF PHARMACY, APPOINTED BY THE 29 BOARD. (C) A REPRESENTATIVE OF THE STATE BOARD OF DENTAL EXAMINERS, APPOINTED 30 31 BY THE BOARD. 32 (D) A REPRESENTATIVE OF THE STATE BOARD OF NURSING, APPOINTED BY THE 33 BOARD. 34 (E) THE ATTORNEY GENERAL OR HIS OR HER DESIGNEE. 35 (F) A REPRESENTATIVE OF THE DEPARTMENT, APPOINTED BY THE COMMISSIONER. (G) A REPRESENTATIVE OF THE NEW YORK STATE MEDICAL SOCIETY, APPOINTED 36 37 BY THE SOCIETY. 38 (H) A REPRESENTATIVE OF THE NEW YORK STATE DENTAL ASSOCIATION, 39 APPOINTED BY THE ASSOCIATION. 40 (I) A REPRESENTATIVE OF THE NEW YORK STATE ASSOCIATION OF CHIEFS OF 41 POLICE, APPOINTED BY THE ASSOCIATION. 42 (J) A REPRESENTATIVE OF RETAIL PHARMACY, APPOINTED BY THE NEW YORK 43 STATE PHARMACISTS ASSOCIATION. 44 THE DEPARTMENT SHALL SEEK AND THE BOARD SHALL PROVIDE INPUT AND 2. 45 ADVICE REGARDING THE DEVELOPMENT AND OPERATION OF THE ELECTRONIC MONI-TORING SYSTEM, INCLUDING BUT NOT LIMITED TO: 46 47 (A) WHICH STATE CONTROLLED SUBSTANCES SHOULD BE MONITORED; 48 (B) WHICH DRUGS OF CONCERN DEMONSTRATE A POTENTIAL FOR ABUSE AND 49 SHOULD BE MONITORED; 50 (C) DESIGN AND IMPLEMENTATION OF EDUCATIONAL COURSES IDENTIFIED IN SECTION THIRTY-THREE HUNDRED SIXTY-ONE OF THIS TITLE; 51 52 (D) PROPER ANALYSIS AND INTERPRETATION OF PRESCRIPTION MONITORING 53 INFORMATION; 54 (E) DESIGN AND IMPLEMENTATION OF AN EVALUATION COMPONENT; AND 55 (F) POTENTIAL NOMINEES TO THE BOARD.

S 3359. REPORTING OF PRESCRIPTION MONITORING INFORMATION. 1. EACH 1 2 DISPENSER SHALL SUBMIT TO THE DEPARTMENT, BY ELECTRONIC MEANS, OR OTHER 3 FORMAT SPECIFIED IN A WAIVER GRANTED BY THE DEPARTMENT, INFORMATION 4 SPECIFIED BY THE DEPARTMENT, INCLUDING: 5 (A) A PATIENT IDENTIFIER, 6 (B) THE DRUG PRESCRIBED OR DISPENSED, 7 (C) THE DATE OF THE PRESCRIPTION OR DISPENSING, 8 (D) THE QUANTITY PRESCRIBED OR DISPENSED, (E) THE PRESCRIBER, AND 9 10 (F) THE DISPENSER. EACH DISPENSER SHALL SUBMIT THE REQUIRED INFORMATION AS FREQUENTLY 11 2. 12 AS SPECIFIED BY THE DEPARTMENT. 13 3. THE DEPARTMENT MAY GRANT A WAIVER OF ELECTRONIC SUBMISSION TO ANY 14 DISPENSER FOR GOOD CAUSE, INCLUDING FINANCIAL HARDSHIP, AS DETERMINED BY 15 THE DEPARTMENT. THE WAIVER SHALL STATE THE FORMAT AND FREQUENCY WITH WHICH THE DISPENSER SHALL SUBMIT THE REQUIRED INFORMATION. 16 S 3360. ACCESS TO THE PRESCRIPTION MONITORING INFORMATION; CONFIDEN-17 18 TIALITY. 1. EXCEPT AS INDICATED IN SUBDIVISIONS TWO, THREE, AND FOUR OF 19 THIS SECTION, PRESCRIPTION MONITORING INFORMATION SUBMITTED TO THE 20 DEPARTMENT SHALL BE CONFIDENTIAL AND NOT SUBJECT TO PUBLIC OR OPEN 21 RECORDS LAWS. 22 2. THE DEPARTMENT SHALL REVIEW THE PRESCRIPTION MONITORING INFORMA-IF THERE IS REASONABLE CAUSE TO BELIEVE A VIOLATION OF LAW OR 23 TION. BREACH OF OCCUPATIONAL STANDARDS MAY HAVE OCCURRED, THE DEPARTMENT SHALL 24 25 NOTIFY THE APPROPRIATE LAW ENFORCEMENT AND OCCUPATIONAL LICENSING, CERTIFICATION OR REGULATORY AGENCY OR ENTITY, AND PROVIDE PRESCRIPTION 26 27 MONITORING INFORMATION REQUIRED FOR AN INVESTIGATION. 3. THE DEPARTMENT MAY PROVIDE PRESCRIPTION MONITORING INFORMATION FOR 28 PUBLIC RESEARCH, POLICY OR EDUCATION PURPOSES, TO THE EXTENT ALL INFOR-29 MATION REASONABLY LIKELY TO REVEAL THE PATIENT OR OTHER PERSON WHO IS 30 THE SUBJECT OF THE INFORMATION HAS BEEN REMOVED. 31 32 THE FOLLOWING PERSONS, AFTER SUCCESSFUL COMPLETION OF THE EDUCA-4. 33 TIONAL COURSES IDENTIFIED IN SUBDIVISION ONE OF SECTION THIRTY-THREE HUNDRED SIXTY-ONE OF THIS TITLE, MAY ACCESS THE PRESCRIPTION MONITORING 34 35 INFORMATION IN THE SAME OR SIMILAR MANNER, AND FOR THE SAME OR SIMILAR PURPOSES, AS THOSE PERSONS ARE AUTHORIZED TO ACCESS SIMILAR CONFIDENTIAL 36 INFORMATION UNDER FEDERAL AND STATE LAW AND REGULATION. 37 38 (A) A CRIMINAL JUSTICE AGENCY WHICH ENFORCES THE LAWS OF THIS STATE OR 39 THE UNITED STATES RELATING TO CONTROLLED SUBSTANCES AND WHICH HAS INITI-40 ATED AN ACTIVE INVESTIGATION INVOLVING A SPECIFIC VIOLATION OF LAW. (B) A PRACTITIONER, AS DEFINED IN SECTION THIRTY-THREE HUNDRED TWO OF 41 THIS ARTICLE, OR AN EMPLOYEE OF THE PRACTITIONER WHO IS ACTING ON BEHALF 42 43 OF AND AT THE DIRECTION OF THE PRACTITIONER, WHO REQUESTS SUCH INFORMA-TION AND CERTIFIES THAT THE INFORMATION IS NECESSARY TO PROVIDE MEDICAL 44 45 TREATMENT TO A CURRENT PATIENT. (C) A PHARMACIST, AS DEFINED IN SECTION THIRTY-THREE HUNDRED TWO OF 46 47 ARTICLE, OR A PHARMACY INTERN OR PHARMACY TECHNICIAN WHO IS ACTING THIS ON BEHALF OF AND AT THE DIRECTION OF THE PHARMACIST, WHO REQUESTS 48 SUCH INFORMATION AND CERTIFIES THAT THE REQUESTED INFORMATION WILL BE USED TO 49 50 DISPENSE CONTROLLED SUBSTANCES TO A CURRENT PATIENT. (D) A PATIENT WHO IS IDENTIFIED IN THE RECORD UPON A WRITTEN REQUEST 51 52 FOR THE PURPOSE OF VERIFYING THAT INFORMATION. 5. A PERSON WHO HAS KNOWLEDGE BY VIRTUE OF HIS OR HER OFFICE OF THE

53 5. A PERSON WHO HAS KNOWLEDGE BY VIRTUE OF HIS OR HER OFFICE OF THE 54 CONTROLLED SUBSTANCES PRESCRIBED TO OR OBTAINED BY A PARTICULAR PERSON 55 SHALL DISCLOSE SUCH KNOWLEDGE TO A PHARMACY TO INFORM THE PHARMACY THAT 56 SUCH PERSON WHO PRESENTS OR HAS PRESENTED A PRESCRIPTION FOR ONE OR MORE

CONTROLLED SUBSTANCES AT THE PHARMACY MAY HAVE ALSO OBTAINED ONE OR MORE 1 2 CONTROLLED SUBSTANCES AT ANOTHER PHARMACY WHERE THE CIRCUMSTANCES INDI-3 CATE A POSSIBILITY OF DRUG ABUSE OR DIVERSION, POTENTIAL HARM TO THE 4 PERSON, OR SIMILAR GROUNDS UNDER REGULATIONS OF THE COMMISSIONER. 5 6. THE DEPARTMENT SHALL BE IMMUNE FROM CIVIL LIABILITY ARISING FROM 6 INACCURACY OF ANY OF THE INFORMATION SUBMITTED TO THE DEPARTMENT PURSU-7 ANT TO THIS TITLE. 8 S 3361. EDUCATION AND TREATMENT. 1. THE DEPARTMENT OF HEALTH SHALL, IN CONSULTATION WITH THE BOARD, IMPLEMENT THE FOLLOWING EDUCATION COURSES: 9 10 (A) AN ORIENTATION COURSE DURING THE IMPLEMENTATION PHASE OF THE PRESCRIPTION MONITORING PROGRAM. 11 12 (B) A COURSE FOR PERSONS WHO ARE AUTHORIZED TO ACCESS THE PRESCRIPTION MONITORING INFORMATION BUT WHO DID NOT PARTICIPATE IN THE ORIENTATION 13 14 COURSE. 15 (C) A COURSE FOR PERSONS WHO ARE AUTHORIZED TO ACCESS THE PRESCRIPTION 16 MONITORING INFORMATION BUT WHO HAVE VIOLATED LAWS OR BREACHED OCCUPA-TIONAL STANDARDS INVOLVING DISPENSING, PRESCRIBING AND USE OF SUBSTANCES 17 MONITORED BY THE PRESCRIPTION MONITORING PROGRAM. 18 19 (D) A CONTINUING EDUCATION COURSE FOR HEALTH CARE PROFESSIONALS DEVEL-OPED BY THE AMERICAN SOCIETY OF ADDICTION MEDICINE AND THE STATE MEDICAL 20 SOCIETY ON PRESCRIBING PRACTICES, PHARMACOLOGY AND IDENTIFICATION, 21 TREATMENT AND REFERRAL OF PATIENTS ADDICTED TO OR ABUSING SUBSTANCES 22 23 MONITORED BY THE PRESCRIPTION MONITORING PROGRAM. WHEN APPROPRIATE, THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, 24 25 SHALL DEVELOP THE CONTENT OF THE EDUCATION COURSES DESCRIBED IN PARA-26 GRAPHS (A), (B) AND (C) OF THIS SUBDIVISION. 27 2. THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL STRONGLY 28 RECOMMEND THE APPLICATION OF A COURSE TO INFORM THE PUBLIC ABOUT USE, 29 DIVERSION AND ABUSE OF, AND ADDICTION TO, SUBSTANCES MONITORED BY THE PRESCRIPTION MONITORING PROGRAM. 30 3. THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL, WHEN APPRO-31 32 PRIATE: 33 (A) WORK WITH ASSOCIATIONS FOR IMPAIRED PROFESSIONALS TO ENSURE INTER-VENTION, TREATMENT AND ONGOING MONITORING AND FOLLOW-UP; AND 34 (B) ENSURE THAT INDIVIDUAL PATIENTS WHO ARE IDENTIFIED AND WHO HAVE 35 BECOME ADDICTED TO SUBSTANCES MONITORED BY THE PRESCRIPTION MONITORING 36 37 PROGRAM RECEIVE ADDICTION TREATMENT. 38 S 3362. UNLAWFUL ACTS AND PENALTIES. 1. A DISPENSER WHO KNOWINGLY 39 FAILS TO SUBMIT PRESCRIPTION MONITORING INFORMATION TO THE DEPARTMENT AS 40 REOUIRED BY THIS TITLE SHALL BE SUBJECT TO A FINE OF ONE THOUSAND FIVE 41 HUNDRED DOLLARS. 2. A PERSON AUTHORIZED TO HAVE PRESCRIPTION MONITORING INFORMATION 42 43 PURSUANT TO THIS TITLE WHO KNOWINGLY DISCLOSES SUCH INFORMATION IN 44 VIOLATION OF THIS TITLE SHALL BE SUBJECT TO A FINE OF ONE THOUSAND 45 DOLLARS. 3. A PERSON AUTHORIZED TO HAVE PRESCRIPTION MONITORING INFORMATION 46 47 PURSUANT TO THIS TITLE WHO USES SUCH INFORMATION IN A MANNER OR FOR A 48 PURPOSE IN VIOLATION OF THIS TITLE SHALL BE SUBJECT TO A FINE OF FIVE 49 HUNDRED DOLLARS. 50 S 3363. EVALUATION, DATA ANALYSIS AND REPORTING. 1. THE DEPARTMENT SHALL, IN CONSULTATION WITH THE BOARD, DESIGN AND IMPLEMENT AN EVALU-51 ATION COMPONENT TO IDENTIFY COST-BENEFITS OF THE PRESCRIPTION MONITORING 52 PROGRAM, AND OTHER INFORMATION RELEVANT TO POLICY, RESEARCH AND EDUCA-53 54 TION INVOLVING SUBSTANCES MONITORED BY THE PRESCRIPTION MONITORING 55 PROGRAM.

1 2. THE DEPARTMENT SHALL REPORT TO THE LEGISLATURE ON A PERIODIC BASIS, 2 NO LESS THAN ANNUALLY, ABOUT THE COST-BENEFITS AND OTHER INFORMATION 3 NOTED IN SUBDIVISION ONE OF THIS SECTION.

4 S 3364. RULES AND REGULATIONS. THE DEPARTMENT SHALL PROMULGATE RULES 5 AND REGULATIONS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS TITLE.

6 S 3365. SEVERABILITY. IF ANY PROVISION OF THIS TITLE OR APPLICATION 7 THEREOF TO ANY PERSON OR CIRCUMSTANCE IS HELD INVALID, THE INVALIDITY 8 SHALL NOT AFFECT OTHER PROVISIONS OR APPLICATIONS OF THE TITLE WHICH CAN 9 BE GIVEN EFFECT WITHOUT THE INVALID PROVISIONS OR APPLICATIONS, AND TO 10 THIS END THE PROVISIONS OF THIS TITLE ARE SEVERABLE.

11 S 2. The department of health shall, within 180 days after the effec-12 tive date of this act, and after consultation with the Prescription 13 Monitoring Program Advisory Board, establish regulations requiring phar-14 macists to access the prescription monitoring program before filling a 15 prescription for a controlled substance. The department of health shall 16 also establish protocols to be followed by pharmacists after accessing 17 such information.

18 S 3. The Prescription Monitoring Program Advisory Board shall, within 19 180 days after the effective date of this act, make recommendations and 20 submit a written report to the legislature concerning integrating pres-21 cribers into the electronic submission requirements of the prescription 22 monitoring program as well as any possible changes to the official New 23 York state prescription form for controlled substances to include more 24 information concerning a patient's controlled substance use.

25 S 4. This act shall take effect on the ninetieth day after it shall 26 have become a law.