8320

2011-2012 Regular Sessions

IN ASSEMBLY

June 13, 2011

Introduced by M. of A. CUSICK -- (at request of the Department of Law) -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to creating an on-line real time controlled substance reporting system to monitor the prescribing and dispensing of certain controlled substances

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

1 Section 1. This act shall be known and may be cited as the "Internet 2 System for Tracking Over-Prescribing (I-STOP) Act".

3 S 2. The public health law is amended by adding a new section 3343-a 4 to read as follows:

5 S 3343-A. ON-LINE REAL-TIME CONTROLLED SUBSTANCE REPORTING SYSTEM. 1. 6 ESTABLISHMENT OF SYSTEM. THE COMMISSIONER SHALL, IN ACCORDANCE WITH THE 7 PROVISIONS OF THIS SECTION, ESTABLISH AND MAINTAIN A SYSTEM FOR COLLECT-8 ING, MONITORING AND REPORTING DATA CONCERNING THE PRESCRIBING AND DISPENSING OF SCHEDULE II, III, IV, OR V CONTROLLED SUBSTANCES, OR ANY 9 OTHER SUBSTANCES SPECIFIED BY THE COMMISSIONER, THAT ARE PRESCRIBED OR 10 DISPENSED. SUCH SYSTEM SHALL ALLOW PRACTITIONERS AND PHARMACISTS TO 11 MONITOR AND REPORT SUCH DATA BY MEANS 12 OF AN INTERNET PORTAL AND A WEBSITE AND ANY OTHER ELECTRONIC MEANS DEEMED APPROPRIATE BY THE COMMIS-13 SUCH SYSTEM SHALL ENABLE PRACTITIONERS AND PHARMACISTS TO MONI-14 SIONER. TOR AND REPORT SUCH DATA AT THE TIME A PRESCRIPTION IS 15 ISSUED OR SUCH 16 SUBSTANCE IS DISPENSED. THE COMMISSIONER SHALL ADOPT AND SUCH SYSTEM 17 SHALL MAINTAIN PROCEDURES AND SAFEGUARDS TO ENSURE THE PRIVACY AND 18 CONFIDENTIALITY OF PATIENT INFORMATION AND TO ENSURE THAT ANY DATA 19 COLLECTED OR REPORTED IS NOT UNLAWFULLY ACCESSED OR DISCLOSED. THE SHALL ALSO ESTABLISH ACCEPTABLE ERROR TOLERANCE RATES FOR 20 COMMISSIONER DATA AND PROCEDURES FOR PRACTITIONERS AND PHARMACISTS TO FOLLOW 21 IN THE 22 EVENT OF A TECHNOLOGICAL FAILURE.

23 2. REPORTING OBLIGATIONS. EVERY PRACTITIONER OR PHARMACIST WITHIN THE 24 STATE OR ANY OTHER DISPENSER WHO HAS OBTAINED A LICENSE, PERMIT OR OTHER

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

LBD11782-01-1

AUTHORIZATION TO OPERATE FROM THE COMMISSIONER OF EDUCATION, OR ANY 1 2 AGENT THEREOF, SHALL REPORT TO THE COMMISSIONER THE DATA SPECIFIED IN 3 PARAGRAPH A OR B OF THIS SUBDIVISION THROUGH AN INTERNET PORTAL AND 4 WEBSITE MAINTAINED BY THE COMMISSIONER AND ANY OTHER METHOD DEEMED 5 APPROPRIATE BY THE COMMISSIONER, UPON ISSUING A PRESCRIPTION OR DISPENS-6 ING A SCHEDULE II, III, IV, OR V CONTROLLED SUBSTANCE OR ANY OTHER 7 SUBSTANCE SPECIFIED BY THE COMMISSIONER; PROVIDED THAT SUCH REPORTING SHALL NOT BE REQUIRED FOR ANY SUCH SUBSTANCE ADMINISTERED DIRECTLY TO A 8 PATIENT, OR FOR SUCH SUBSTANCE DISPENSED PURSUANT TO SECTION THREE THOU-9 10 SAND THREE HUNDRED THIRTY-FOUR, THREE THOUSAND THREE HUNDRED THIRTY-SEV-11 EN OR THREE THOUSAND THREE HUNDRED FORTY-TWO OF THIS CHAPTER OR ANY RULE 12 OR REGULATION PROMULGATED UNDER THOSE SECTIONS.

13 A. DATA TO BE REPORTED BY PRACTITIONERS. DATA CONCERNING SCHEDULE II, 14 III, IV, OR V CONTROLLED SUBSTANCES OR ANY OTHER SUBSTANCES SPECIFIED BY THE COMMISSIONER THAT ARE PRESCRIBED SHALL INCLUDE BUT NOT BE LIMITED TO 15 THE FOLLOWING: PRACTITIONER PRESCRIPTION NUMBER; PRACTITIONER NATIONAL 16 IDENTIFICATION NUMBER; PATIENT NAME; PATIENT ADDRESS, INCLUDING STREET, 17 18 CITY, STATE, ZIP CODE; PATIENT DATE OF BIRTH; PATIENT'S SEX; DATE 19 PRESCRIPTION ISSUED; METRIC QUANTITY; NATIONAL DRUG CODE NUMBER OF THE DRUG; NUMBER OF DAYS SUPPLY; PRACTITIONER DRUG ENFORCEMENT ADMINIS-20 TRATION NUMBER; DATE PRESCRIPTION WRITTEN; SERIAL NUMBER OF OFFICIAL 21 22 PRESCRIPTION FORM, OR AN IDENTIFIER DESIGNATED BY THE DEPARTMENT; 23 PAYMENT METHOD, AND NUMBER OF REFILLS AUTHORIZED.

24 B. DATA TO BE REPORTED BY PHARMACISTS. DATA CONCERNING SCHEDULE II, 25 III, IV, OR V CONTROLLED SUBSTANCES OR ANY OTHER SUBSTANCES SPECIFIED BY THE COMMISSIONER THAT ARE DISPENSED SHALL INCLUDE BUT NOT BE LIMITED TO 26 27 THE FOLLOWING: PHARMACY PRESCRIPTION NUMBER; PHARMACY'S NATIONAL IDEN-28 TIFICATION NUMBER; PATIENT NAME; PATIENT ADDRESS, INCLUDING STREET, 29 CITY, STATE, ZIP CODE; PATIENT DATE OF BIRTH; PATIENT'S SEX; DATE PRESCRIPTION FILLED; METRIC QUANTITY; NATIONAL DRUG CODE NUMBER OF THE 30 DRUG; NUMBER OF DAYS SUPPLY; PRACTITIONER DRUG ENFORCEMENT ADMINIS-31 32 TRATION NUMBER; DATE PRESCRIPTION WRITTEN; SERIAL NUMBER OF OFFICIAL 33 PRESCRIPTION FORM, OR AN IDENTIFIER DESIGNATED BY THE COMMISSIONER; 34 PAYMENT METHOD; NUMBER OF REFILLS AUTHORIZED; AND REFILL NUMBER.

35 DUTY TO CONSULT DATABASE; PROHIBITIONS. EVERY PRACTITIONER OR 3. PHARMACIST WITHIN THE STATE, INCLUDING ANY OTHER DISPENSER WHO HAS 36 37 OBTAINED A LICENSE, PERMIT, OR OTHER AUTHORIZATION TO OPERATE FROM THE 38 COMMISSIONER OF EDUCATION, SHALL MAKE INQUIRY TO THE ON-LINE CONTROLLED 39 SUBSTANCE REPORTING SYSTEM ESTABLISHED PURSUANT TO SUBDIVISION ONE OF 40 THIS SECTION PRIOR TO PRESCRIBING OR DISPENSING ANY SCHEDULE II, III, IV, OR V CONTROLLED SUBSTANCE OR ANY OTHER SUBSTANCE SPECIFIED BY THE 41 COMMISSIONER; PROVIDED THAT THIS SUBDIVISION AND PARAGRAPHS (A) AND (B) 42 43 HEREOF, SHALL NOT APPLY TO ANY SUCH SUBSTANCE ADMINISTERED DIRECTLY TO A PATIENT OR FOR ANY SUCH SUBSTANCE DISPENSED PURSUANT TO SECTIONS THREE 44 45 THOUSAND THREE HUNDRED THIRTY-FOUR, THREE THOUSAND THREE HUNDRED THIR-TY-SEVEN OR THREE THOUSAND THREE HUNDRED FORTY-TWO OF THIS CHAPTER AND 46 47 ANY RULE PROMULGATED THEREUNDER.

48 A. NO PRACTITIONER SHALL PRESCRIBE ANY SCHEDULE II, III, IV, OR V 49 CONTROLLED SUBSTANCE OR ANY OTHER SUBSTANCE SPECIFIED BY THE COMMISSION-50 ER WITHOUT REVIEWING A PATIENT'S CONTROLLED SUBSTANCE PRESCRIPTION HISTORY AS SET FORTH IN THE ON-LINE CONTROLLED SUBSTANCE REPORTING 51 SYSTEM TO DETERMINE THAT SUCH PRESCRIPTION IS MEDICALLY NECESSARY AND 52 WOULD NOT OTHERWISE VIOLATE SECTION THREE THOUSAND THREE HUNDRED FIFTY 53 54 OF THIS ARTICLE, OR, FOR PRESCRIPTIONS ELIGIBLE FOR REIMBURSEMENT BY THE 55 MEDICAID PROGRAM, SECTION ONE HUNDRED FORTY-FIVE-B OF THE SOCIAL 56 SERVICES LAW.

1 B. NO PHARMACIST SHALL DISPENSE ANY SCHEDULE II, III, IV, OR V 2 CONTROLLED SUBSTANCE OR ANY OTHER SUBSTANCE SPECIFIED BY THE COMMISSION-3 ER WITHOUT CONFIRMING THE EXISTENCE OF A MATCHING REPORT PROVIDED BY A 4 PRACTITIONER THROUGH THE ON-LINE CONTROLLED SUBSTANCE REPORTING SYSTEM.

5 LIMITATIONS ON USE; DISCLOSURE RESTRICTIONS. A. NO PRACTITIONER OR 4. 6 PHARMACIST SHALL DISCLOSE OR BE REQUIRED TO DISCLOSE ANY DATA VIEWED OR 7 RECEIVED THROUGH THE ON-LINE CONTROLLED SUBSTANCE REPORTING SYSTEM 8 UNLESS SO REQUIRED BY A PROVISION OF LAW SPECIFICALLY RELATING TO THE 9 TREATMENT OF A PATIENT OR RELATING TO THE MANDATORY REPORTING OF AN 10 ILLEGAL USE OR ABUSE OF A CONTROLLED SCHEDULE II, III, IV OR V SUBSTANCE OR ANY OTHER SUBSTANCE SPECIFIED BY THE COMMISSIONER. DISCLOSURE BY A 11 12 PRACTITIONER OR PHARMACIST TO ANY OTHER PERSON OR ENTITY, INCLUDING DISCLOSURE IN THE CONTEXT OF A CIVIL ACTION WHERE THE DISCLOSURE IS 13 14 SOUGHT EITHER FOR THE PURPOSE OF DISCOVERY OR FOR EVIDENCE, IS PROHIBIT-15 ED.

16 B. THE COMMISSIONER MAY NOT DISCLOSE DATA COLLECTED FOR THE ON-LINE 17 CONTROLLED SUBSTANCE REPORTING SYSTEM UNLESS SPECIFICALLY SO AUTHORIZED 18 BY LAW.

19 C. THE COMMISSIONER SHALL BE AUTHORIZED TO REVIEW BY ELECTRONIC MEANS 20 OR OTHERWISE THE DATE COLLECTED OR PUBLISHED FOR THE ON-LINE CONTROLLED 21 SUBSTANCE REPORTING SYSTEM. THE COMMISSIONER SHALL BE AUTHORIZED TO 22 DISCLOSE DATA COLLECTED FOR OR PUBLISHED ON THE ON-LINE CONTROLLED SUBSTANCE REPORTING SYSTEM, WITHOUT NECESSITY OF SUBPOENA, TO: (I) THE 23 DIRECTOR OF THE OFFICE OF THE PROFESSIONS OF THE DEPARTMENT OF EDUCATION 24 25 OR HIS OR HER DESIGNEE WHO IS RESPONSIBLE FOR THE LICENSURE, REGULATION, OR DISCIPLINE OF PRACTITIONERS OR PHARMACISTS; (II) THE DEPUTY ATTORNEY 26 27 GENERAL FOR MEDICAID FRAUD CONTROL OR HIS OR HER DESIGNEE; (III) THE 28 MEDICAID INSPECTOR GENERAL OR HIS OR HER DESIGNEE; (IV) A JUDGE OR A 29 PROBATION OR PAROLE OFFICER ADMINISTERING A DIVERSION OR PROBATION PROGRAM OF A CRIMINAL DEFENDANT WHO IS ELIGIBLE TO PARTICIPATE 30 IN A COURT-ORDERED DRUG DIVERSION OR PROBATION PROGRAM; OR (V) A PRACTITIONER 31 32 OR PHARMACIST, OR THEIR AGENT, WHO REQUESTS INFORMATION AND CERTIFIES THAT THE REQUESTED INFORMATION IS FOR THE PURPOSE OF PROVIDING MEDICAL 33 OR PHARMACEUTICAL TREATMENT TO A CURRENT PATIENT. ANY PERSON TO WHOM THE 34 35 COMMISSIONER DISCLOSES SUCH DATA PURSUANT TO THIS PARAGRAPH SHALL NOT PROVIDE SUCH DATA TO ANY OTHER PERSON OR ENTITY EXCEPT BY COURT ORDER, 36 37 WHICH SHALL BE GRANTED ONLY UPON APPLICATION BY SUCH PERSON AND ONLY 38 UPON A SHOWING THAT SUCH AN ORDER IS NECESSARY FOR SUCH PERSON TO CARRY 39 OUT HIS OR HER DUTIES AS A PUBLIC OFFICER OR AS A PRACTITIONER OR PHAR-40 MACIST; PROVIDED THAT THE COMMISSIONER OF THE DEPARTMENT OF EDUCATION MAY SUBMIT THE DATA AS EVIDENCE IN ANY ADMINISTRATIVE HEARING AS AUTHOR-41 42 IZED BY LAW.

D. THE COMMISSIONER SHALL BE AUTHORIZED TO PROVIDE THE DATA REPORTED
TO OR COLLECTED FOR THE ON-LINE CONTROLLED SUBSTANCE REPORTING SYSTEM
UPON RECEIPT OF A SUBPOENA ISSUED TO A POLICE OFFICER, DISTRICT ATTORNEY, OR GRAND JURY, OR ANY FEDERAL OR STATE LAW ENFORCEMENT AGENCY.

47 E. THE COMMISSIONER MAY USE ANY DATA OR REPORTS COLLECTED FOR OR 48 REPORTED TO THE ON-LINE CONTROLLED SUBSTANCE REPORTING SYSTEM FOR THE 49 PURPOSE OF IDENTIFYING MEDICAID RECIPIENTS WHOSE USAGE OF CONTROLLED 50 SUBSTANCES MAY BE APPROPRIATELY MANAGED BY A SINGLE OUTPATIENT PHARMACY 51 OR PRIMARY CARE PRACTITIONER.

52 F. NOTHING IN THIS SUBDIVISION SHALL BE INTERPRETED TO ALLOW A DISCLO-53 SURE OF INFORMATION OTHERWISE PROHIBITED BY FEDERAL LAW.

54 5. IMMUNITY. NO PUBLIC OFFICER ACTING IN GOOD FAITH NOR THE STATE OF 55 NEW YORK NOR ANY DEPARTMENT, BUREAU, BOARD OR POLITICAL SUBDIVISION 56 THEREOF SHALL BE SUBJECT TO CIVIL LIABILITY ARISING FROM ANY FALSE 1 INFORMATION OF ANY DATA SUBMITTED TO OR REPORTED BY THE ON-LINE 2 CONTROLLED SUBSTANCE REPORTING SYSTEM; OR ANY FAILURE OF THE SYSTEM TO 3 ACCURATELY OR TIMELY REPORT SUCH DATA; OR FOR DISCLOSURE OF ANY DATA 4 MAINTAINED BY THE SYSTEM RESULTING FROM SUCH OFFICER ACTING IN GOOD 5 FAITH IN THE DISCHARGE OF HIS OR HER DUTIES.

6 6. CIVIL PENALTIES. NOTWITHSTANDING ANY OTHER PROVISION OF THIS ARTI-7 CLE RELATING TO VIOLATIONS OF THIS ARTICLE:

8 A. ANY PRACTITIONER OR PHARMACIST WHO KNOWINGLY FAILS TO TRANSMIT DATA 9 TO THE COMMISSIONER AS REQUIRED BY SUBDIVISION TWO OF THIS SECTION SHALL 10 BE LIABLE TO THE STATE FOR A CIVIL PENALTY OF FIVE HUNDRED DOLLARS FOR THE FIRST PRESCRIPTION ISSUED WHICH IS NOT PROPERLY REPORTED; ONE THOU-11 SAND DOLLARS FOR THE SECOND PRESCRIPTION NOT PROPERLY REPORTED; AND FIVE 12 THOUSAND DOLLARS FOR EACH PRESCRIPTION NOT PROPERLY REPORTED THEREAFTER. 13 14 B. ANY PRACTITIONER OR PHARMACIST WHO KNOWINGLY FAILS TO REVIEW DATA 15 PRIOR TO PRESCRIBING OR DISPENSING ANY SUBSTANCE IN VIOLATION OF SUBDI-16 VISION THREE OF THIS SECTION SHALL BE LIABLE TO THE STATE FOR A CIVIL 17 PENALTY OF FIVE HUNDRED DOLLARS FOR THE FIRST PRESCRIPTION SO ISSUED; 18 THOUSAND DOLLARS FOR THE SECOND PRESCRIPTION SO ISSUED; AND FIVE ONE 19 THOUSAND DOLLARS FOR EACH PRESCRIPTION ISSUED IN VIOLATION OF SUBDIVI-20 SION THREE OF THIS SECTION THEREAFTER.

C. ANY PRACTITIONER OR PHARMACIST WHO KNOWINGLY DISCLOSES INFORMATION
IN VIOLATION OF SUBDIVISION FOUR OF THIS SECTION SHALL BE LIABLE FOR A
PENALTY OF NOT MORE THAN FIVE HUNDRED DOLLARS FOR THE FIRST SUCH DISCLOSURE; ONE THOUSAND DOLLARS FOR THE SECOND SUCH DISCLOSURE; AND FIVE
THOUSAND DOLLARS FOR EACH SUCH DISCLOSURE ISSUED IN VIOLATION OF SUBDIVISION THREE THEREAFTER.

D. NOTHING IN THIS SECTION SHALL BE INTERPRETED TO PREEMPT OR RESTRICT ANY CIVIL ACTION BY ANY INDIVIDUAL FOR DAMAGES RESULTING FROM AN ILLEGAL DISCLOSURE OF INFORMATION IN VIOLATION OF SUBDIVISION FOUR OF THIS SECTION, OR ANY OTHER CIVIL OR CRIMINAL ACTION BY THE COMMISSIONER OR ANY LAW ENFORCEMENT AGENCY.

32 7. EDUCATION AND OUTREACH. THE COMMISSIONER SHALL WORK WITH THE STATE 33 EDUCATION DEPARTMENT AND ANY OTHER GOVERNMENTAL OR PRIVATE PROFESSIONAL ORGANIZATION RESPONSIBLE FOR THE LICENSURE, REGULATION, OR DISCIPLINE OF 34 35 PRACTITIONERS, PHARMACISTS, AND OTHER PERSONS WHO ARE AUTHORIZED TO PRESCRIBE, ADMINISTER, OR DISPENSE CONTROLLED SUBSTANCES, FOR THE DEVEL-36 OPMENT OF A CONTINUING EDUCATION PROGRAM ABOUT THE PURPOSES AND USES OF 37 38 THE ON-LINE CONTROLLED SUBSTANCE REPORTING SYSTEM ESTABLISHED BY THIS 39 SECTION. THE ATTORNEY GENERAL SHALL WORK WITH THE DEPARTMENT OF CRIMINAL 40 JUSTICE SERVICES FOR THE DEVELOPMENT OF A CONTINUING EDUCATION PROGRAM FOR LAW ENFORCEMENT OFFICERS ABOUT THE PURPOSES AND USES OF THE ELEC-41 TRONIC SYSTEM FOR MONITORING ESTABLISHED IN THIS SECTION. 42

8. RULES AND REGULATIONS. THE COMMISSIONER SHALL PROMULGATE RULES AND
REGULATIONS NECESSARY TO EFFECTUATE THE PROVISIONS OF THIS SECTION;
PROVIDED HOWEVER, THE COMMISSIONER SHALL NOT PROMULGATE ANY RULE OR
REGULATION THAT REQUIRES ANY PRACTITIONER OR PHARMACIST TO PAY A FEE OR
TAX SPECIFICALLY DEDICATED TO THE OPERATION OF THE SYSTEM.

S 3. This act shall take effect immediately; provided, however, that subdivisions 2, 3, 4, 5, 6 and 7 of section 3343-a of the public health law as added by section two of this act shall take effect one year after such effective date.