Model Prescription Accountability Act

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Policy Statement

This Act is intended to provide new technological solutions to the problem of preventing and controlling the diversion and abuse of prescription drugs whose therapeutic benefits are accompanied by psychoactive effects. While the vast majority of these medications are used for important medical purposes and contribute to a better quality of life for persons suffering from debilitating or lifethreatening disorders, there also are a small but significant number of cases in which these drugs are diverted for the purpose of sustaining abuse and dependence. For example, a survey by the National Institute on Drug Abuse (NIDA) found that, in 1990, 8.5 million persons reported that they had used a pharmaceutical analgesic, stimulant, sedative or tranquilizer for other than medical reasons at some time in the preceding year[1]. The economic dimensions of such diversion suggest a major criminal enterprise: with a single tablet sold in a pharmacy for $1 or less and sold on the "street" for $20-50 each, the federal Drug Enforcement Administration (DEA) estimates that prescription drug diversion constitutes a $25 billion annual market.

Governments and health professionals share a responsibility for promoting the appropriate use of prescription drugs, while preventing their misuse, abuse and diversion to non-medical purposes. This responsibility poses challenges very different from those of the so-called "war" on illicit drugs, because this control must be achieved without impeding the access of patients to needed medical care.

In response to this challenge, governments at all levels have adopted various acts to govern the manufacture, distribution, sale, possession and use of controlled drugs.

For example, international drug control treaties require governments to restrict the production, trade and consumption of certain drugs. While these treaties create stringent control mechanisms, they also require international organizations to work with national governments to assure that restrictions on these drugs are not so rigid as to negatively affect patients' access to them[2].

Federally, the Congress has enacted a number of statutes to regulate the manufacture, importation, distribution, and use of pharmaceutical products that have any degree of potential for abuse [21 CFR]. The Comprehensive Drug Abuse Prevention and Control Act, adopted in l970, consolidated more than 50 federal drug laws into one comprehensive vehicle. The federal Controlled Substances Act (CSA), enacted a year later, created a system for classifying prescription drugs according to their importance in medical use and their potential for abuse. The CSA also required written prescriptions for Schedule II drugs, regulated record-keeping and refills, created information systems to detect diversion, and established a system of criminal penalties for violations[3]. The Congress designated the U.S. DEA as the authority to register practitioners and assure compliance with the CSA and related rules.

The federal CSA also explicitly recognizes that the drugs in Schedules II through V are "necessary to maintain the health and general welfare of the American people[4]."

It is in the states, however, that most of the power to regulate medical and pharmacy practice is vested. Through rules governing the licensure and discipline of health professionals, as well as requirements for registration and inspection of distributors of prescription medications, state governments have acquired the most direct control over prescription drug use and the most effective tools for halting prescription drug abuse.

To this end, almost every state has adopted its own Controlled Substances Act (CSAs). While most of the state CSAs are very similar to the federal CSA, states have the option of adopting additional regulations, and may even classify drugs more restrictively than the federal CSA.

CONTEMPORARY APPROACHES TO DRUG CONTROL

Exercising this authority, the states have experimented with a number of aproaches to prescription drug control:

FORMULARY RESTRICTIONS AND OTHER REIMBURSEMENT RULES

Over the years, most states have experimented with restricting Medicaid formularies (lists of drugs approved for reimbursement) as a diversion control method, with somewhat mixed results[5]. This authority is provided under federal law to limit government's obligation to subsidize medication prescribed for uses that are not essential to treat a diagnosed medical condition. Recently, however, this authority was invoked in an amendment to the Omnibus Budget Reconciliation Act of l990 (OBRA) to add an entire class of drugs —- the benzodiazepines — to the list of drugs that states can exclude from Medicaid reimbursement. Medical groups have argued that this "sweeping exclusion" of benzodiazepines is overly broad since it precludes payment for a variety of medically appropriate uses, including the treatment of epilepsy, panic disorder, generalized anxiety disorder, insomnia, and movement disorder[6].

EXPANDED ARCOS

The DEA's Automated Reports and Consolidated Orders System (ARCOS) tracks sales of all Schedule II drugs and the Schedule III narcotics from the point of original manufacture or importation to the ultimate sale to a retail distributor (typically, a physician, hospital or community pharmacy). Federal law requires that DEA compile and analyze these data, which are provided to selected state agencies at no charge. A subset of ARCOS, the Diversion Analysis and Detection System, tracks direct sales for the wholesale to the retail level.

The DEA recently proposed that the ARCOS system be expanded to cover all controlled substances in federal Schedules II-V, to impose new refill restrictions on drugs in Schedule III, and to change the report categories and distribution.

MEDICAID ABUSE DRUG AUDIT SYSTEM

The Office of the Inspector General of the U.S. Department of Health and Human Services has devised the Medicaid Abuse Drug Audit System (MADAS), a computer software program that

uses Medicaid data specifically for the purposes of diversion control. The MADAS software, offered to the states at no cost, already is being used in a number of jurisdictions with considerable success. In New York, for example, MADAS identifies about 800 potential "doctor shopping" patients each month and drastically curtails their inappropriate drug consumption by restricting them to a single physician and pharmacy[7].

DRUG USE REVIEW

Medicaid, Blue Cross/Blue Shield, and other health insurors conduct drug use review (DUR) — which is defined as "a formal program for assessing data on drug use against explicit, prospective standards, and, as necessary, introducing remedial strategies to achieve some desired end[8] — to determine whether drugs are being prescribed appropriately and cost-effectively. By l993, all state Medicaid programs will be required to perform such reviews, using the same data as MADAS[9]. An important difference is that DUR traditionally has been an educational rather than a regulatory program[10]. For example, physicians with outdated prescribing knowledge typically have been offered an opportunity to update their knowledge without interrupting patient care. However, utilization review is now more frequently linked to physician reimbursement, with insurors reducing or refusing benefit payments for services that are deemed medically unnecessary. In such an environment, it seems certain that DUR will evolve into an increasingly powerful regulatory tool.

TRIPLICATE PRESCRIPTION PROGRAMS

In an effort to deal with prescription drug diversion, seven states (California, Idaho, Illinois, Indiana, Michigan, New York, Texas) have enacted triplicate prescription programs. Two other states (Hawaii, Rhode Island) have duplicate prescription programs, and Washington State imposes a triplicate requirement on a case-by-case basis. Under these systems, physicians are required to use special state-issued, serially numbered, three-part prescription order forms to prescribe all Schedule II drugs. (In l989, New York expanded its triplicate program to include Schedule IV anti-anxiety agents.) The physician retains a copy of each completed prescription and gives the remaining copies to the patient. The patient surrenders the copies to the pharmacist, who retains a file copy and forwards a copy to the designated state agency[11].

Critics of triplicate programs — often including physicians and patient-advocacy groups — point to recently published research associating triplicate programs with significant reductions in use of psychoactive drugs for legitimate medical purposes[12]. The significant data entry and processing costs associated with such systems (variously reported as $0.70 to $1.15 per prescription) have slowed the rate of adoption of triplicate programs by additional states, and have led some states with in-place triplicate programs to look toward electronic data transfer programs as a less-expensive alternative.

ELECTRONIC DATA TRANSFER

Already in use in Oklahoma and Massachusetts, and under study in several other states, electronic data transfer (EDT) systems apply new technological resources to state collection of prescription information. In such a system, the sequence of events in preparing and cashing a prescription order might be as follows:

1. A physician writes an order on a customary prescription order form (no special form is required) and gives it to the patient.
2. The patient presents the prescription form to the pharmacist, who dispenses the prescription and then transmits specified data about the prescription (identifying the physician, the patient, and the drug) via a point-of-sale computer terminal to a central mainframe.
3. At the mainframe (perhaps operated by a state agency, but more likely by a contract vendor), the prescription data are compared to pre-established program criteria. These might include (a) whether the physician is registered with DEA and the state to prescribe a controlled drug; (b) whether the drug prescribed is outside the scope of practice (a dentist prescribing amphetamines, for example); (c) whether the drug is prescribed in appropriate amounts or for customary periods of time; and (d) whether the patient has cashed similar prescriptions from other physicians or at other pharmacies.
4. Prescriptions that fail any of these criteria are excepted out for further (manual) review, and possible referral to a licensing board or enforcement agency for follow-up action.
5. Periodically, data in the mainframe are compiled into summary reports, showing the range of prescription activity by geographic region; by physician, pharmacist or patient; and by drug group and specific drug product. "Outliers" in any of these categories (such as the l0% of physicians who prescribed the largest amount of a given drug) are flagged for investigation. System data also can be accessed to answer investigators' questions at any time.

SUMMARIZING THE ARGUMENTS FOR EDT

The essential elements of EDT systems are in use today. Triplicate prescription programs compile data to generate overview reports and flag "outliers." Pharmacists use point-of-sale computer terminals to verify customers' eligibility for prescription drug insurance benefits. (The point-of-sale data transmission technology is universally recognizable in credit approval of charge card purchases.) Drug utilization review (DUR) programs employ therapeutic criteria to assess the appropriateness of prescribing decisions. *EDT programs essentially merge these existing systems to achieve a new level of technology.* (In fact, the federal Omnibus Budget Reconciliation Act of l990 mandates adoption of a similar system for Medicaid beneficiaries.)

Further, EDT systems appear to protect patient privacy, in that most data exist only in computer-encoded form, and access to information is limited to officials directly involved in investigations. Because it does not require use of special prescription order forms (as does triplicate), EDT is "invisible" to both the physician and patient, and thus has no negative effect on drug therapy.

EDT can provide data to state officials in hours, rather than months, because data are entered electronically at the time each prescription is dispensed, and can be accessed electronically on request.

Because it is computer-based, EDT is flexible, and can accommodate adjustments to program criteria and even the addition or deletion of specific drugs as the diversion problem changes.

Finally, EDT costs significantly less to operate than triplicate programs: in Oklahoma, officials estimate that EDT costs $250,000 per year, as compared with projected costs of up to $600,000 annually for a triplicate program.

[1] National Institute on Drug Abuse, 1990.

[2] Angarola, R., *The Effect of National and International Drug Control Laws on Patient Care, in* BALANCING THE RESPONSE TO PRESCRIPTION DRUG ABUSE: REPORT OF A NATIONAL SYMPOSIUM ON MEDICINE & PUBLIC POLICY (Wilford, B.B. ed. 1990).

[3] *Id.*

[4] *Id.*

[5] Kreling, C., *The Effect of an International Analgesic Formulary Restriction on Medicaid Drug Expenditures in Wisconsin*, 27 MEDICAL CARE 34-44 (1989).

[6] American College of Neuropsychiatry, 1991.

[7] Office of the Inspector General, INITIATIVE TO IMPROVE STATES' INTERNAL CONTROLS OVER PRESCRIPTION DRUGS PURCHASED UNDER THE MEDICAID PROGRAM (Publication No. A-03-90-000204, 1990).

[8] Rucker, T.D., *Drug Utilization Review: Moving Toward an Effective and Safe Model*, in SOCIETY AND MEDICATION: CONFLICTING SIGNALS FOR PRESCRIBERS AND PATIENTS (Morgan, J.P., Kagan, D.C. ,ed. 1983).

[9] Office of the Inspector General, *supra* note 7.

[10] Rucker, T.D., *supra* note 8.

[11] Drug Enforcement Administration, MULTIPLE COPY PRESCRIPTION RESOURCE GUIDE (1987).

[12] The Gallup Organization, Inc., *Physicians' Attitudes Toward the New York Triplicate Prescription Legislation*, (1991); Wientraub, M., Singh, S., Byrne, L., Muharaj, K., Guttmacher, L., *Consequences of the 1989 New York State Triplicate Benzodiazepine Prescription Regulations*, 266(17) J.A.M.A. 2392-2397 (1991).

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Cohen, S., *Drug Abuse and the Prescribing Physician*, in FREQUENTLY PRESCRIBED AND ABUSED DRUGS: THEIR INDICATIONS, EFFICACY AND RATIONAL PRESCRIBING (Buchwald, C., Cohen, S., Katz, D., ed. 1980).

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Highlights of the Model Prescription Accountability Act

ASSUMPTIONS AND REMEDIAL GOALS

- Recognizes that the diversion and abuse of prescription drugs is a serious public health concern, involving an estimated 8.5 million people 12 years or older in nonmedical use of controlled sedatives, tranquilizers, stimulants, or analgesics.
- Simultaneously acknowledges that controlled substances are essential to the effective care of patients suffering a variety of medical conditions, and that access to these drugs for legitimate purposes must be preserved.
- Improves the state's ability to stop illegal diversion of prescription drugs in an efficient and cost effective manner, without impeding the appropriate prescribing of pain-killing and other prescription drugs or compromising patients' interests in confidentiality.
- Provides assistance to many thousands of individuals who are addicted to prescription drugs and who presently are receiving no professional attention by using the electronic monitoring system to identify such persons and refer to treatment. The benefits to those individuals, and the resulting social and economic benefits to society, will far outweigh the costs of detection and treatment.

PROCEDURES AND REMEDIES

- Creates a process for the collection, analysis and use of essential information on the prescribers, dispensers and recipients of controlled substances in order to prevent the harm to patients and the public that ensues from such drug diversion and abuse.
- Employs an electronic network for rapid and reliable transmission of data from dispensing pharmacies to a central data repository.
- Acknowledges that the value of information in preventing drug diversion depends on its being rapidly and readily available to authorized personnel under appropriate circumstances.
- Requires the designated state agency to use its administrative procedures to determine which substances are being misused and abused, and are therefore subject to monitoring. This approach increases the likelihood that the list of monitored controlled substances will be kept up to date, since it is less cumbersome to administratively identify newly misused or abused substances than to pass another law every time a Schedule II-IV controlled substance starts to be misused or abused in the state; and provides greater governmental flexibility for each state to respond to its particular prescription drug abuse problems.
- Minimizes the financial impact on pharmacies by developing an electronic network that is compatible with (and supportable by) other electronic pharmacy communications equipment and systems already in use.
- Appoints a broadly representative Prescription Accountability and Patient Care Improvement Board to oversee the data collection process and make preliminary determinations as to the ultimate disposition of cases involving questionable drug prescribing, dispensing or use.
- Provides for the establishment of general criteria to determine which cases will be brought to the attention of the Board. These criteria are to be programmed into the electronic monitoring system to automatically detect cases in which "an identified controlled substance has been dispensed for a period of time or in a quantity or manner outside the established norms or standards." Requires that the standards for exception and referral be consistent with

well established and respected guidelines and research in the field.

- Facilitates the sharing of case information among relevant state agencies and between state and federal officials. This reflects the intent to encourage state / federal cooperation and coordination.
- Imposes coding requirements, stringent limitations on access to the data, and other safeguards on sensitive patient information to protect the confidentiality of the physician-patient encounter. Establishes a process for consultation with state medical and other health professional societies or their representatives, recognized patient advocacy groups, and individuals knowledgeable regarding privacy protection issues.

Model Prescription Accountability Act

Section 1. Short Title.

This [Act] shall be known and may be cited as the "Model Prescription Accountability Act."*

Section 2. Legislative Findings.

(a) The inappropriate non-medical use of licit prescribed drugs is a serious public health concern.

(b) According to the 1990 National Household Survey on Drug Abuse, an estimated 8.5 million people 12 years or older used controlled sedatives, tranquilizers, stimulants, or analgesics for nonmedical reasons at least once during the preceding year.

(c) According to the NIDA sponsored Drug Abuse Research Survey of drug treatment facilities around the country, approximately 10% of the patients' principal drugs of abuse were drugs that may be prescribed.

(d) The federal Drug Enforcement Administration (DEA) has estimated that the illegal diversion of legal controlled substances constitutes a $25 billion market.

(e) A federal Health and Human Services Inspector General has reported that roughly one out of sixteen seniors — between 1.5 and 2 million — are addicted or at risk of addiction to benzodiazapenes (tranquilizers such as Valium, Librium, Xanax, and Halcion). Such addiction has been referred to as "America's 'other' drug problem."

(e) It is the policy of this state that any retail monitoring system, in order not to impede the appropriate prescribing and use of prescription drugs, must not be unduly burdensome to prescribing physicians and must fully protect the legitimate confidentiality concerns of patients.

(f) A controlled substance electronic accountable prescription system will efficiently and effectively detect and reduce the use of retail prescription practices to obtain prescription drugs for improper purposes.

Section 3. Purpose.

This [Act] is intended to improve the state's ability to stop illegal diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate prescribing of pain killing and other prescription drugs and that will ensure the full protection of patients' interests in preserving the confidentiality of sensitive medical information.

COMMENT

Each year, millions of patients in the U.S. are treated for a variety of serious medical problems with prescription drugs whose therapeutic benefits are accompanied by some potential for abuse and addiction. Federal and state governments and health professionals share a responsibility for promoting the appropriate use of these drugs, while preventing their misuse, abuse and diversion to non-medical purposes. In pursuit of this goal, a number of states have implemented "triplicate prescription" programs to monitor the prescribing and use of pharmaceutical drugs that also have the potential for abuse. In most of them, the triplicate programs were at least initially opposed by organizations of patients, physicians and pharmaceutical manufacturers, on the grounds that such programs are costly, inefficient, and an intrusion into the confidentiality of the doctor-patient relationship.

More recently, several states have moved to convert to "electronic data transfer" systems, which they see as offering important advantages: (1) the functions of trip-

* This [Act] is based in part on H.R. 5051, "Prescription Accountability and Patient Care Improvement Act", introduced by U.S. Representative Pete Stark in 1992.

licate prescription procedures can be fully met by electronic data transfer systems, with no additional time consuming burdens placed on prescribing physicians and with very little additional burden on pharmacies; (2) whereas triplicate programs have been widely criticized as so cumbersome as to cause physicians to substantially reduce even medically appropriate prescribing, early data show no similar untoward effect with electronic systems; (3) electronic systems can be programmed to identify suspect prescribing, dispensing, or receiving practices more rapidly, more reliably and more cost effectively than triplicate programs, resulting in better enforcement and substantial savings to the taxpayer; (4) electronic data transfer systems can be integrated with existing electronic pharmacy inventory systems, minimizing hardware acquisition and data processing costs to pharmacies and, ultimately, to their customers.

Section 4. Definitions.

As used in this [Act]:

(a) "Board" means a Prescription Accountability and Patient Care Improvement Board established under Section 6(b).

(b) "Central repository" means a central repository established under Section 5(c).

(c) "Controlled substance" has the meaning given such term in [section of the state controlled substances act].

(d) [Designated state agency] means the state agency responsible for the functions listed in Section 5(e).

(e) [Director] means the director of the [designated state agency].

(f) "Dispenser" means a person who distributes a Schedule II-IV controlled substance (as defined in subsection (l)), but does not include:

(1) a licensed hospital pharmacy that distributes such substances for the purposes of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility;

(2) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician; or

(3) a wholesale distributor of a Schedule II-IV controlled substance.

(g) "Identification card" means a valid driver's license, valid military identification card, other valid photo identification card issued pursuant to state law.

(h) "Identification number" means, with respect to an individual:

(1) Social Security account number or the unique number contained on the individual's identification card (as defined in subsection (g)); or

(2) If the controlled substance is obtained for an animal, a number described in paragraph (1) of the animal's owner.

(i) "Patient Panel" means a Patient Care Advisory Panel established under Section 6(e)(2).

(j) "Registration number" means, with respect to a dispensing physician, the dispenser's registration number with [the state narcotics control agency] or, in the case of a pharmacist, the National Association of Board of Pharmacy number for the pharmacy where the dispensation is made.

(k) "Practice Panel" means a Drug Utilization Review Board's Practice Parameter Advisory Panel established under Section 6(d)(2).

(l) "Schedule II-IV controlled substance" means a controlled substance which is listed in Schedule II, III, or IV of the Schedules provided under Section 202 of the [state controlled substances act] or the Federal Controlled Substances Act (21 U.S.C.812).

(m) "System" means an electronic prescription accountability and patient care improvement program, as described in Section 5(a).

COMMENT

The definition of "controlled substance" is made by reference to the state controlled substances act in order to incorporate existing state law. This is intended to provide guidance and certainty as to what is, and what is not, a controlled substance and thus to avoid the unnecessary additional uncertainty and litigation that may be occasioned by using a new definition.

Hospital pharmacies are excluded from the definition of "dispensers" to the extent that they are dispensing drugs on an inpatient basis or to patients being discharged, because these systems — when appropriately supervised — present only limited opportunities for drug diversion. However, to the extent that a hospital pharmacy fills prescriptions for individuals who come from outside the hospital, it would be covered under the

definition of "dispenser" and would be subject to the requirements of the [Act].

Similarly, situations where nurses or medication aides administering drugs to patients at the direction of a physician are excluded because they do not present significant opportunities for diversion.

Wholesale distributors already are monitored and regulated by the federal Drug Enforcement Administration and are required to have special registrations and/or permits by a majority of the states. Therefore, wholesaler distributors are also excluded from the definition of "dispensers."

"Identification cards" and "identification numbers" are defined with sufficient flexibility to provide for those individuals (such as children) who do not have driver's licenses or military identification cards. Most states will find it practical to use Social Security numbers as "identification numbers" since *all* individuals are now required by federal law to have a Social Security number.

Section 5. Requirements for Controlled Substances Electronic Accountable Prescription System; Central Repository; Designation of State Agency.

(a) System Requirements. A controlled substances electronic accountable prescription system shall be established within six months of the effective date of this [Act], which includes the following:

(1) Reporting of Information Required. The [designated state agency] shall determine those schedules of controlled substances, classes of controlled substances, and/or specific controlled substances which, according to federal drug abuse data collection systems and generally accepted medical standards, are being misused and abused in the state. No identified controlled substance may be dispensed unless information relevant to the dispensation of the substance is reported electronically or by universal claim form to the central repository (established under subsection (c), in accordance with state regulations made by the [state agency responsible for scheduling controlled substances].

(2) Information to be Transmitted. Effective not later than nine months after the effective date of this [Act], the information to be transmitted under paragraph (1) shall include at least the following for each dispensation:

(A) The recipient's identification number (as defined in subsection (e)(2));

(B) The recipient's date of birth;

(C) The 8-digit National Drug Code number of the substance dispensed;

(D) The date of dispensation;

(E) The quantity of substance dispensed;

(F) The number of refills authorized;

(G) The prescriber's United States Drug Enforcement Administration (DEA) registration number and other numbers as defined in subparagraph (3)(B);

(H) The dispenser's DEA registration number and other numbers as defined in subsection (e)(3); and

(I) The prescriber's practice specialty and subspecialties, as determined by the state's medical licensure board or the Physician Masterfile of the American Medical Association.

(3) Collection Procedures.

(A) Procedures. Under the system:

(i) information shall be reported in numerical format, not less than once every 14 days, on the filling of prescriptions for designated controlled substances and the dispensing of drug samples by a licensed practitioner; and

(ii) each dispenser shall maintain a record of such filled prescriptions (including all information described in paragraph (2)) for a period of two years, shall keep such records separately from other prescription records, and shall make such records available for inspection and copying by authorized appropriate state regulatory agency personnel, and by law enforcement officers conducting a criminal investigation.

(B) Prescriber Information. Effective not later than six months after the effective date of this [Act], the [designated state agency] in consultation with the state's medical licensure board, shall develop procedures to provide information on the state's licensed prescribers and their respective recognized practice specialties (or specialties), as well as their federal DEA [and

state] registration numbers, with the schedules of controlled substances they are registered to prescribe, to the central data repository designated under this [Act]. Through the repository, the state shall make this information available to dispensers in an electronic format compatible with the dispenser's existing electronic transmission system. The state shall update this information on a regular basis.

(C) Consultation. In developing reporting procedures, the [designated state agency] shall seek the counsel of the state health professions licensure boards, state and federal law enforcement agencies, state medical and other health professional societies or their representatives, recognized patient advocacy groups, and individuals and other state agencies involved in and knowledgeable regarding privacy protection issues, and any other interested persons.

(4) Use of Central Repository. The system shall provide for the use of a central repository in accordance with subsection (c).

(5) Designation of State Agency. The operation of the system shall be overseen by the [designated state agency].

(6) Confidentiality. The system shall provide for confidentiality of information in the system, in accordance with Section 6.

(b) Electronic Transmittal Requirement.

(1) In General. Except as provided in paragraph (2), the transmittal of information under this section shall be made:

(A) through an electronic transmitting device which is compatible with the receiving device of the central repository; or

(B) by computer diskette, magnetic tape, or other appropriate electronic means which meets the specifications provided by rules of the [designated state agency]. The [designated state agency] shall pay the direct costs of such transmittal, such as telephone charges.

(2) Temporary Exemption. The [director] may exempt individual dispensing entities from the electronic information reporting requirements of this subsection if:

(A) the imposition of such requirement would result in financial hardship for a particular pharmacist; and

(B) the pharmacist agrees to provide the information to the agency by use of a pharmacy universal claim form.

No individual dispensing entity filing an average of more than 20 universal claim forms per month, over a six month period, shall be exempted from the electronic information reporting requirements of this subsection.

(c) Use of Central Repository.

(1) In General. The system shall provide for the maintenance of information collected in a central repository which meets the requirements of this subsection.

(2) Requirements for Central Repositories.

(A) Information Retrieval Capabilities. The central repository shall be a data processing system maintained by (or under contract with) the [designated state agency]. Such system shall be capable of aggregating and displaying the collected information in formats required by the [designated state agency], including reports showing controlled substances by:

(i) prescriber name and identifying number(s) as specified by the [designated state agency] but including at least the prescriber's federal DEA registration number;

(ii) dispenser name, location, and registration number;

(iii) recipient identification number and date of birth; and

(iv) 8-digit National Drug Code number, frequency, quantity, number of refills, and whether new or refill prescription.

(B) On-Line Access. The central repository shall provide the [designated state agency] with [___hours] per day, on-line access to information. The repository shall be capable of electronic receipt of practitioner disciplinary data from the Federation of State Medical Boards, National Association of Boards of Pharmacy, other national associations of health professional boards, the Health Care Financing Administration, and the National Practitioner Databank.

(C) Security. The central repository shall

secure the information against access by unauthorized persons and shall be subject to review and oversight by the [director] of the [designated state agency] or the [director's] designee to ensure the security of the information and the system.

(D) Information to Board. If the central repository is not operated by the Board or the [designated state agency], the vendor-repository shall provide information in response to Board inquiries within [24] hours, and shall provide routine reports on a regular schedule to be specified by the [director] of the [designated state agency].

(E) Provision of Information to Board Within 30 Days of Termination of Relationship Between Board and Central Repository. If the relationship between the Board and the vendor-repository is terminated, the vendor-repository shall provide to the Board within 30 days all collected information, the database maintained by the vendor-repository, and such software as is needed to access the information and the database.

(3) Selection of Repository. The establishment of the central repository under this paragraph shall be conducted through a competitive bidding process or amendment of a preexisting competitively bid contract. However, the [director] of the [designated state agency] shall select the most overall cost effective and efficient computerization system and automatic data processing services and equipment to ensure the successful implementation of the system. The [director] may enter into a contract with the selected vendor to serve as the central repository under this subsection.

(d) Out-of-State Prescriptions. A prescription from an out-of-state physician may be dispensed: 1) if it conforms in every way to all state requirements; and 2) if the pharmacist enters the required information into the controlled substances electronic accountable prescription system.

(e) Responsibilities of the [Designated State Agency].

(1) In General. The [designated state agency] shall:

(A) oversee and administer the collection of information under the system;

(B) control access to the information in the system; and

(C) produce exception reports described in paragraph (2) for purposes of subsections (c) through (e) of Section 6.

(2) Exception Report Defined. In this subsection, the term "exception report" means a report of aggregated data and information indicating that an identified controlled substance has been dispensed for a period of time or in a quantity or manner outside the established norms or standards, consistent with guidelines established by the Agency for Health Care Policy and Research, peer-reviewed medical literature, printed patient inserts included with prescriptions that are controlled substances, the American Hospital Formulary Service Drug Information, USP-Drug Information, and Drug Evaluations of the American Medical Association, or other established drug utilization review principles, for a prescriber practicing a particular specialty or field of health care, for a dispenser doing business in a particular location, or for other criteria determined by the Board to be reasonable and necessary to carry out the purposes of this [Act].

COMMENT

Section 5 establishes the requirements and mechanisms for the state electronic accountability system.

Subsection (a) sets forth the general system requirements and provides a generous period of time — six months — for the [designated state agency] to establish the system.

Paragraph (a)(1) of the [Act] sets up the mechanism for determining *which substances* must be monitored. Rather than statutorily specifying which controlled substances are subject to monitoring, the [Act] requires the [designated state agency] to use its administrative procedures to determine which substances are being misused and abused, and are therefore subject to monitoring. This approach has several advantages: 1) it increases the likelihood that the list of monitored controlled substances will be kept up to date, since it is less cumbersome to administratively identify newly misused or abused substances than to pass another law every time a Schedule II-IV controlled substance starts to be misused or abused in the state; 2) it provides greater governmental flexibility for each state to respond to its particular prescription drug abuse problems; and 3) it ensures, through the notice and hearing requirements of the state administrative procedures law, well-informed decision-making by the [designated state agency]. Once a controlled substance has been admin-

istratively identified as a substance being abused or misused in the state, *all dispensations must be reported to the central repository*.

Paragraph (a)(2) sets forth *what information* must be transmitted to the central repository. It is designed to provide sufficient identifying information about the patient, the controlled substance, the physician, and the pharmacist. The physician's specialty and sub-specialties are useful in determining whether a controlled substance is generally within a physician's scope of practice, so this information is also required. Later in the [Act], Section 6(a) establishes strict and rigorous mechanisms to ensure full confidentiality of all patient information transmitted under paragraph (a)(2).

It is anticipated that the data collection procedures established in paragraph (a)(3) can be efficiently integrated with the computerized inventory systems already in place with the vast majority of pharmacies. Most pharmacies will transmit the required information by simply "downloading" *via* telephone modem to the central repository. Clause (a)(3)(A)(i) requires that this occur every 14 days, although it is more likely that most pharmacies will do this between each business day. Clause (a)(3)(A)(ii) requires the pharmacies to maintain records of filled prescriptions for two years in the event that they are necessary for purposes of verification, routine inspections or other investigations.

Subparagraph (a)(3)(B) simply requires that the [designated state agency] provides pharmacies information they need about licensed prescribers in order to fulfill their reporting requirements under the [Act]. Subparagraph (a)(3)(C) ensures comprehensive input from a wide variety of interested groups in the development of reporting procedures.

Subsection (b) establishes the general requirement that the information be stored and transmitted to the central repository electronically. It has been established in Oklahoma, Massachusetts, and other locations that this method of storage and transmittal is much more efficient and inexpensive for pharmacies than handling multi-part paper (e.g., triplicate) prescription forms. Such electronic systems also lend themselves to greater confidentiality safeguards and to more rapid and reliable detection of inappropriate prescribing, dispensing or receiving of prescription drugs.

In recognition of the different circumstances faced by a relatively few pharmacies that handle a very small volume of prescriptions, paragraph (b)(2) provides that pharmacies filling twenty or fewer controlled substance prescriptions per month may be permitted to file *paper* "pharmacy universal forms" (rather than storing and transmitting the information *electronically*) if necessary to avoid financial hardship. The vast majority of pharmacies will find it easier and less expensive to handle the information electronically.

Subsection (c) sets forth the requirements for the central repository. Subparagraph (c)(2)(A)'s requirement that the information be retrievable by prescriber, by dispenser, by recipient, or by drug, is critical to the information's value in detecting potential problems.

Similarly, the value of the information depends on its being readily available under appropriate circumstances. It is intended that the [designated state agency] have on-line access to this information pursuant to subparagraph (c)(2)(B), at least during business hours. States may wish to consider making the information accessible around the clock to maximize its utility to all enforcement agencies.

In addition to Section 6(c)'s extensive confidentiality protections, subparagraph (c)(2)(C) requires the central repository to secure the information against unauthorized access, and requires the additional protection of placing responsibility squarely on the [director] of the [designated state agency] to "ensure the security of the information and the system."

Subparagraphs (c)(2)(D) and (E) apply where the central repository is operated by a private vendor (a "vendor-repository"). These subparagraphs ensure, by force of state law, that the vendor will cooperate fully with the Prescription Accountability and Patient Care Improvement Board, and that the availability of the information in the repository in no way be jeopardized because the vendor's contract to maintain the central repository has been terminated.

Paragraph (c)(3) provides that the normal government bidding process be used to select a central repository. However, the system that provides the most cost effective and efficient services to the taxpayer is not necessarily the one with the lowest price tag. For example, a "less expensive" system may actually be more costly if it provides services of significantly lower quality or in a much slower time frame. In recognition of this, the [director] is mandated by this paragraph to "select the most overall cost effective and efficient" system.

Although prescription drug abusers living near state borders may be able, to some degree, to exploit nearby out-of-state pharmacies, a prohibition against filling

out-of-state prescriptions may seriously inconvenience large number of law-abiding citizens and thus is too extreme a response. Subsection (d) represents a reasonable balancing of the need to address this problem with the legitimate need of travelers in our mobile society to occasionally have their home physician's prescriptions filled. Under this subsection, such prescriptions can be filled, but the required information still must be entered into the system. Thus, a prescription drug abuser who obtains drugs through out-of-state prescriptions might delay but would not escape detection.

Because of the strong concerns about confidentiality and about access to information collected under this system, it is critical that the lines of authority and responsibility for oversight, administration and control of the entire system be absolutely clear. Paregraph (e)(1) is intended to accomplish this. Each state legislature will need to determine the most appropriate state agency, under the state's bureaucratic structure, to designate for this responsibility.

Paragraph (e)(2) provides for the establishment of general criteria that are used to determine which cases will be brought to the attention of the Board. These criteria will be programmed into the electronic monitoring system to automatically detect cases in which "an identified controlled substance has been dispensed for a period of time or in a quantity or manner outside the established norms or standards." These cases will be referred to the Board for further review and, if necessary, investigation and action. This subsection requires that the standards for exception and referral be consistent with well-established and respected guidelines and research in the field.

Section 6. Confidentiality of Information; Disclosure of Information.

(a) Confidentiality.

(1) In General. The information collected under this [Act] shall not be available to the public or used for any commercial purpose. Ownership of all data collected shall reside with the state. Data collected pursuant to this [Act] shall not be co-mingled with or used to augment or validate any other database.

(2) Limitations on Access and Use. Responsibility for limiting access to information in the system is vested in the [director] of the [designated state agency]. Information in the system shall be administered by the Board established under subsection (b) and shall only be disclosed:

(A) to the Prescription Accountability and Patient Care Improvement Board (established under subsection (b));

(B) for the purposes of utilizing exception reports established in Section 5(e)(1)(C);

(C) pursuant to subsection (c) (relating to possible violations of controlled substances acts);

(D) pursuant to subsection (d) relating to practice counseling); and

(E) pursuant to subsection (e) (relating to patient counseling).

Nothing in this section shall be construed to preclude the use of information that does not identify specific patients or health professionals, for purposes of reporting pursuant to subsection (b)(4).

(3) Encoding Information.

(A) In General. Information collected under the system shall be formatted through data encryption standard codes or electronic coding techniques so as to fully protect the individual privacy of all patients.

(B) Secrecy of Codes. Under the system:

(i) half of the data encryption standard code shall be known to the two members of the Board described in subsection (b)(1)(B); and

(ii) the other half of the data encryption standard code shall be known to the two members of the Board described in subsection (b)(1)(C).

Only the [director] of the [designated state agency] (or the [director's] designee) shall know the full data encryption standard code.

(C) Consultation. In establishing the confidentiality of the data encryption standard code and any information collected under the system, the [director]:

(i) shall be available to consult regularly with representatives of patient membership organizations and representatives of civil liberties organizations; and

(ii) shall take such steps (in addition to

encryption) as may be appropriate, including the use of public and private key encryption and cryptographic techniques, to ensure the protection of the information.

(4) Violations of Confidentiality.

(A) In General. If the information in a system is disclosed in violation of this section or other applicable state and federal law, the [director] of the [designated state agency], in consultation with state law enforcement officials, shall change the data encryption standard code and take such other immediate steps as are necessary to secure the system, and shall take all steps necessary to enforce subparagraph (B) or any other state or federal privacy statute.

(B) Criminal Punishment. It is a felony to knowingly disclose or attempt to disclose, or to use or attempt to use, information in the system in violation of this section. Violators are subject to a term of imprisonment of not more than [___] years and a fine of not more than [$___].

(5) Purging of Patient Data. The [designated state agency] shall cause to be purged from the central repository system, no later than three years after the date an individual's prescription is made available to the Board, the identification number of the individual unless the information is part of an active investigation.

(b) Establishment of Prescription Accountability and Patient Care Improvement Board.

(1) Board Membership. The [director] of the [designated state agency] shall appoint a Prescription Accountability and Patient Care Improvement Board(Board) consisting of:

(A) the [director] (or the [director's] designee);

(B) two officials or employees of the [designated state agency]; or other health care provider experts — one a pharmacologist and one a specialist in addiction medicine — who have knowledge of and experience in appropriate prescribing of controlled substances for legitimate medical purposes;

(C) two state law enforcement officials or employees with knowledge of and experience with cases involving illegal diversion of controlled substances and the illegal or inappropriate prescribing of controlled substances;

(D) one representative recommended to the Director by the State Medical Association; and

(E) one representative recommended to the Director by the State Pharmacy Association.

A DEA diversion control officer may be invited to attend any or all of the meetings of the Board.

(2) Referral by the Board. If, based on information in the system, the Board determines that there is a reasonable cause for further inquiry into a possible violation of the state or federal controlled substances acts, the Board shall direct the [director] of the [designated state agency]:

(A) in cases involving the inappropriate practices of practitioners or pharmacists, to seek the advice and counsel of the Director of the Practice Parameter Advisory Panel (established under subsection (d)(2)) and recognized medical peer review organizations; or

(B) in cases involving individual recipients of controlled substances, to seek the advice and counsel of the Director of the Patient Care Advisory Panel (established under subsection (e)(2)).

(3) General Trend Reports.

(A) The Board shall regularly prepare and make available to the [single state authority on alcohol and other drugs], and other state and local regulatory, licensing, and law enforcement agencies, a statistical report on patterns and trends of controlled substances distribution, diversion, and abuse.

(B) The Board shall report to the governor and to the presiding officer of each house of the legislature on the outcome of this program with respect to its impact on legitimate distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances in the state.

(C) The Board shall convene periodic meetings to coordinate a state diversion prevention and control program, and shall oversee cooperation activities (including exchange of information) among state agencies and with officials of neighboring states and the federal government.

(4) Board Access to Information. Access to information in the system may be provided to members of the Board, other than the [director] or the [director's] designees, only when at least three of the members are present.

(5) Meetings. The Board shall meet regularly at the call of the [director].

(6) Board Appointments. In case of a vacancy, the [director] shall appoint a replacement within 30 days.

(c) Referral to [State Narcotics Control Agency] and Medical Board or Licensing Agencies.

(1) In General. After consultation with the other members of the Board, the [director] shall refer to the [state narcotics control agency] and medical board or other licensing agencies case any information in the system for which, based on the practice parameters established by the Drug Utilization Review Board and after consultation with recognized state medical peer review organizations, there is reasonable cause for further inquiry into the illegal diversion of, or the illegal prescribing of, controlled substances. Identities of the patients involved in such cases shall be encoded except where the [director] makes a finding that disclosure of the patient's identity is of material importance to the investigation.

(2) Uses of Information Disclosed. Responsibility for the use of information disclosed under this subsection to the state narcotics control agency shall be vested in the [director] of the [designated state agency] (or to the [director's] designee). The [director] shall limit the disclosure and use of such information to:

(A) officials authorized under state law who are employed as investigative agents of the [state narcotics control agency];

(B) the United States DEA Group supervisor (or such supervisor's designee) and appropriate officials of the federal Health Care Financing Administration;

(C) the executive director or chief investigator, as designated by each board, of the state health professional licensure boards, but only with respect to information relevant to licensees of their respective boards; and

(D) federal or state grand juries.

(3) Certain Additional Disclosure Authorized. In case of illegal diversion or prescribing activity, this section shall not prevent the disclosure, at the discretion of the [director] of the [designated state agency], in cooperation with the [state narcotics control agency], of investigative information to police officers and investigative agents of federal, state, county or municipal law enforcement agencies, district attorneys and attorneys general in furtherance of criminal investigations or prosecutions within their respective jurisdictions.

(d) Improving Physician Prescribing Practices.

(1) In General. After consultation with the other members of the Board, the [director] of the [designated state agency] shall make available to the state medical board and other licensing agencies, statistical data or encoded case information in the system where, based on the practice parameters established by the state's drug review board established under Section 1927(g)(3) of the Social Security Act (each such board in this section referred to as the DUR Board), there is reasonable cause for further inquiry and investigation of a medically inappropriate prescribing of controlled substances, for the purposes of further inquiry and investigation and taking additional appropriate measures. Information also may be disclosed to the state medical and other health professions societies or their representatives for the purposes of developing rules, procedures and educational initiatives to improve physician prescribing practices and patient care.

(2) Drug Utilization Review Board's Practice Parameter Advisory Panel.

(A) Establishment. The [director] of the [designated state agency], in cooperation with the state DUR Board, shall appoint a Practice Parameter Advisory Panel consisting of the DUR Board and physician specialist organizations representing addiction medicine, oncologist, oncology nurses, psychiatry, podiatrists, dentists, pharmacists, neurologists, specialists in sleep disorders, medical licensure and supervisors, osteopathic examiners, and veterinary medical examiners, and any other representative of a physician group or other health profession designated by the [director] as serving the interests of physicians who treat patients requiring the prescribing of controlled substances.

(B) Duties. Within one year of the effective date of this [Act], the DUR Practice Parameter Advisory Panel shall:

(i) develop practice parameters based on standards consistent with guidelines established by the Agency for Health Care Policy and Research, peer-reviewed medical literature, printed patient inserts included with prescriptions that are controlled substances, the American Hospital Formulary Service Drug Information, USP-Drug Information, and Drug Evaluations of American Medical Association, or other established drug utilization review principles which will serve as advisory guidelines for the Board and health professionals practicing in the state with regard to the prescribing of controlled substances;

(ii) notify and share relevant information on the established practice parameters with the state medical board, licensure agencies, and representatives of the state medical and other health professional societies for the purposes of improving physician prescribing practices, of addressing the undertreatment of cancer pain, AIDS-related pain, mental health-related care, and other medical needs relating to controlled substances, and of addressing the needs of individuals in need of addiction or substance abuse treatment; and

(iii) notify and share relevant information on the established practice parameters with appropriate state agencies for the purposes of identifying and addressing illegal activity and illegal prescribing practices, and informing such agencies of acceptable forms of medical and prescriptive practices.

(e) Improvements in Patient Care.

(1) In General. After consultation with the other members of the Board, the state medical board and other state licensure boards, representatives of the state medical society and other health professions organizations, and specialists in Addiction Medicine, the [director] of the [designated state agency] shall develop procedures, based on the practice parameters developed by the DUR Board, to address the needs of individuals who require substance abuse treatment. These procedures may include physician notification by a certified medical professional within the [designated state agency] of cases of individual patients who, based on the established practice parameters, may be addicted to controlled substances and, at the discretion of the physician, may involve notification of the individual patient by the physician solely for the purposes of facilitating entry into substance abuse treatment or other means of improving patient care.

(2) Patient Care Advisory Panel.

(A) Establishment. The [director] shall establish and seek the advice and counsel of representatives of patient membership organizations, so as to take into account cancer pain, AIDS-related pain, narcolepsy, epilepsy, attention deficit disorder, sickle cell anemia, arachnoiditis, mental health-related care, chronic intractable pain of other organic causes, or any other medical need deemed necessary.

(B) Duties. Within one year of the effective date of this [Act], the Patient Panel shall:

(i) develop standards which will serve as advisory guidelines for the Board; and

(ii) notify and share relevant information in a timely manner with the [director] of the [state narcotics control agency] (or the [director's] designee).

COMMENT

Subsection 6(a) is intended to give effect to a strong policy of maintaining patient confidentiality to the greatest extent possible. Paragraph 6(a)(1) unequivocally prohibits any public or commercial use of the data, as well as any co-mingling of the data to enhance the accuracy or commercial value of any other database.

Responsibility for ensuring confidentiality is placed squarely on the [director] by paragraph 6(a)(2), which also strictly enumerates the ways in which the information may be used. The legislative intent is clear: this information should not be used in any way that does not clearly fall within the scope of this paragraph.

Confidentiality is further assured by the requirements of paragraph (a)(3), which specify that all information be formatted in code. Only *one* individual, the [director], is permitted to be in possession of the full encryption standard code. Additionally, two Board members

with health care backgrounds may possess *half* of the encryption code, while two Board members with law enforcement backgrounds may possess the *other half* of the encryption code. These confidentiality protections are stringent, and they are intended to be. Moreover, the [director] is required to be available to meet with patient membership and civil liberties organizations about the encryption mechanisms to provide additional assurances that confidentiality will be vigorously maintained.

The [Act] deals harshly with knowing violations of the confidentiality requirements. Subparagraph (a)(4)(B) makes any knowing violation a *felony* offense.

Finally, paragraph (a)(5) imposes the general requirement that the patient's identification number be *purged* no later than three years after it is made available to the Board. Obviously, if the information is being used in an active investigation, it should not be purged until it is no longer needed.

Subsection (b) governs the makeup and functioning of the Board. Paragraph (b)(1) ensures that the medical, pharmacological, treatment, and law enforcement perspectives are well represented on the Board. Subparagraph (B) makes clear that the [director] is not *required* to appoint Agency employees or officials, but rather is free to appoint a pharmacological expert and addiction medicine expert from the private sector. Finally, the Board is specifically authorized to invite the DEA diversion control officer. This reflects the legislature's intent to encourage state/federal cooperation and coordination.

Under the [Act], the designated state agency refers exception reports to the Board for review. *See* Section 5(e)(1)(C). Where the Board finds reasonable cause for further inquiry into possible controlled substance act violations, paragraph (b)(2) directs the Board to have the [director] consult with the Practice Parameter Advisory Panel and recognized medical peer review organizations (in cases involving possible violations by physicians or pharmacists) or with the Patient Care Advisory Panel (in cases involving possible violations by recipients). It is, of course, intended that neither the actual identity of the individuals in question nor any information that might compromise a future investigation would be disclosed during this advice and counsel process.

Subsections (c)-(e) provide further guidance on how the Board should pursue a case if it finds reasonable cause for further inquiry into inappropriate or illegal conduct. Where there is reasonable cause for further inquiry into the *illegal* diversion or prescribing of controlled substances, subsection (c) requires the [director] to refer the case to the [state narcotics control agency] *and* to the medical board or appropriate licensing agencies. The concern for confidentiality is reaffirmed by requiring the encoding of the patients' identities when such cases are referred, except where such identities are of material importance to the investigation. Finally, paragraph (3) establishes that the [director] also may exercise discretion (in cooperation with the [state narcotics control agency]) to disclose evidence of illegal diversion or prescribing to other local, state or federal law enforcement and prosecutorial agencies in furtherance of their criminal investigations or prosecutions.

Where there is reasonable cause for further inquiry into *medically inappropriate* (although not illegal) prescribing of controlled substances, paragraph (d)(1) requires the [director] to make the information available to the state medical board or appropriate licensing agencies for further inquiry, investigation, and appropriate action in accordance with existing practice and law.

This [Act] also requires that practice parameters be developed for use in determining whether particular prescribing practices require further inquiry. To ensure that the practice parameters are appropriate for all of the medical disciplines covered, paragraph (d)(2) requires the [director] to appoint a panel consisting of members of the federally required DUR Board and representatives of the relevant professional disciplines. Clause (d)(2)(B)(i) provides guidance to this panel to ensure that the parameters are truly in accord with accepted medical practice. The remainder of subparagraph (d)(2)(B) describes notification and dissemination requirements for the panel, intended to ensure that both medical professionals and state narcotics agencies are knowledgeable about currently accepted practice parameters.

Finally, subsection (e) requires the [director] to develop procedures to address the needs of patients identified under this system who are in need of substance abuse treatment. These procedures serve to emphasize the ameliorative intent of this [Act]. Perhaps the most beneficial feature of the [Act] is contained in this subsection. Many thousands of individuals who are addicted to prescription drugs and who are receiving no professional attention will be detected under the electronic monitoring system and subsequently referred to treatment. The benefits to those individuals, and the resulting social and economic benefits to society, will far outweigh the costs of detection and treatment. (See, Langenbucher, J.W.; McCrady, B.S.; Brick, J.; Esterly, R., Rutgers University, Center of Alcohol Studies,

SOCIOECONOMIC EVALUATIONS OF ADDICTIONS TREATMENT (1993).

Section 7. Uniformity of Construction and Application.

(a) The provisions of this [Act] shall be liberally construed to effectuate the purposes, objectives and policies set forth in Sections 2 and 3.

(b) The provisions of this [Act] shall be applied and construed to effectuate its general purpose to make uniform the law with respect to the subject of this [Act] among states enacting it.

Section 8. Severability.

If any provision of this [Act] or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the [Act] which can be given effect without the invalid provisions or application, and to this end the provisions of this [Act] are severable.

Section 9. Effective Date.

This [Act] shall be effective on [reference to normal state method of determination of the effective date][reference to specific date].