

NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC
REPORTING ACT OF 2004

OCTOBER 5, 2004.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and
Commerce, submitted the following

R E P O R T

[To accompany H.R. 3015]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3015) to amend the Public Health Service Act to establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments are as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “National All Schedules Prescription Electronic Reporting Act of 2004”.

SEC. 2. CONTROLLED SUBSTANCE MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

“SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.**“(a) FORMULA GRANTS.—**

“(1) IN GENERAL.—Each fiscal year, the Secretary shall make a payment to each State with an application approved under this section for the purpose of establishing and implementing a controlled substance monitoring program under this section.

“(2) DETERMINATION OF AMOUNT.—In making payments under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this paragraph after taking into consideration the budget cost estimate for the State’s controlled substance monitoring program.

“(b) APPLICATION APPROVAL PROCESS.—

“(1) IN GENERAL.—To seek a grant under this section, a State shall submit an application at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

“(A) a budget cost estimate for the State’s controlled substance monitoring program; and

“(B) assurances of compliance with the requirements of this section.

“(2) APPROVAL OR DISAPPROVAL.—Not later than 90 days after the submission by a State of an application under paragraph (1), the Secretary shall approve or disapprove the application. The Secretary shall approve the application if the State demonstrates to the Secretary that the State will establish and implement a controlled substance monitoring program in accordance with this section.

“(3) WITHDRAWAL OF AUTHORIZATION.—If a State fails to implement a controlled substance monitoring program in accordance with this section—

“(A) the Secretary shall give notice of the failure to the State; and

“(B) if the State fails to take corrective action within a reasonable period of time, the Secretary shall withdraw any approval of the State’s application under this section.

“(4) VOLUNTARY DISCONTINUANCE.—A funding agreement for the receipt of a payment under this section is that the State involved will give a reasonable period of notice to the Secretary before ceasing to implement a controlled substance monitoring program under this section. The Secretary shall determine the period of notice that is reasonable for purposes of this paragraph.

“(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State’s application under this section, or the State chooses to cease to implement a controlled substance monitoring program under this section, a funding agreement for the receipt of a payment under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall payment as the remaining time period for expending the payment bears to the overall time period for expending the payment (as specified by the Secretary at the time of the payment).

“(c) REPORTING REQUIREMENTS.—In implementing a controlled substance monitoring program under this section, a State shall comply with the following:

“(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user or research subject not later than 1 week after the date of such dispensing.

“(2) The State may exclude from the reporting requirement of this subsection—

“(A) the direct application of a controlled substance to the body of an ultimate user or research subject;

“(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user or research subject involved for 48 hours or less; or

“(C) the application or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

“(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

“(A) Drug Enforcement Administration Registration Number of the dispenser.

“(B) Drug Enforcement Administration Registration Number and name of the practitioner who prescribed the drug.

“(C) Name, address, and telephone number of the ultimate user or research subject.

“(D) Identification of the drug by a national drug code number.

“(E) Quantity dispensed.

“(F) Estimated number of days for which such quantity should last.

“(G) Number of refills ordered.

“(H) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

“(I) Date of the dispensing.

“(J) Date of origin of the prescription.

“(4) The State shall specify an electronic format for the reporting of information under this subsection and may waive the requirement of such format with respect to an individual dispenser.

“(5) The State shall automatically share information reported under this subsection with another State with an application approved under this section if the information concerns—

“(A) the dispensing of a controlled substance to an ultimate consumer or research subject who resides in such other State; or

“(B) the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

“(6) The State shall notify the appropriate authorities responsible for drug diversion investigation if information in the database maintained by the State under subsection (d) indicates a potential unlawful diversion or misuse of a controlled substance.

“(d) DATABASE.—In implementing a controlled substance monitoring program under this section, a State shall comply with the following:

“(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (c).

“(2) The database must be searchable by any field or combination of fields.

“(3) The State shall include reported information in the database at such time and in such manner as the Secretary determines appropriate, with appropriate safeguards for ensuring the accuracy and completeness of the database.

“(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

“(e) PROVISION OF INFORMATION.—Subject to subsection (f), in implementing a controlled substance monitoring program under this section, a State may provide information from the database established under subsection (d) and, in the case of a request under paragraph (2) or (3), compilations of such information, in response to a request by—

“(1) a practitioner (or the agent thereof) who certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

“(2) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding; or

“(3) any agent of the Department of Health and Human Services, a State Medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature.

“(f) LIMITATIONS.—In implementing a controlled substance monitoring program under this section, a State—

“(1) shall make reasonable efforts to limit the information provided pursuant to a valid request under subsection (e) to the minimum necessary to accomplish the intended purpose of the request; and

“(2) shall not provide any individually identifiable information in response to a request under subsection (e)(3).

“(g) RULES OF CONSTRUCTION.—

“(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

“(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

“(3) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

“(h) RELATION TO HIPAA.—Except to the extent inconsistent with this section, the provision of information pursuant to subsection (c)(5), (c)(6), or (e) and the subsequent transfer of such information are subject to any requirement that would otherwise apply under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

“(i) PREFERENCE.—The Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) to a State, shall give preference to any State with an application approved under this section.

“(j) STUDY.—Not later than 1 year after the date of the enactment of this section, the Secretary shall—

“(1) complete a study on—

“(A) the progress of States in establishing and implementing controlled substance monitoring programs under this section; and

“(B) the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program; and

“(2) submit a report to the Congress on the results of the study.

“(k) ADVISORY COUNCIL.—

“(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment and implementation of a controlled substance monitoring program under this section.

“(2) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with State boards of pharmacy, State boards of medicine, and other interested parties.

“(l) DEFINITIONS.—For purposes of this section:

“(1) The term ‘bona fide patient’ means an individual who is a patient of the dispenser or practitioner involved.

“(2) The term ‘controlled substance’ means a drug that is—

“(A) included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act; or

“(B) identified by the State involved as a drug subject to the monitoring program of the State under this section.

“(3) The term ‘dispense’ means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

“(4) The term ‘dispenser’ means a physician, pharmacist, or other individual who dispenses a controlled substance to an ultimate user or research subject.

“(5) The term ‘practitioner’ means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

“(6) The term ‘State’ means each of the 50 States and the District of Columbia.

“(7) The term ‘ultimate user’ means a person who has lawfully obtained, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

“(m) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

“(1) \$25,000,000 for each of fiscal years 2006 and 2007; and

“(2) \$15,000,000 for each of fiscal years 2008, 2009, and 2010.”.

Amend the title so as to read:

A bill to provide for the establishment of a controlled substance monitoring program in each State.

PURPOSE AND SUMMARY

The purpose of H.R. 3015 is to address the issue of illegal diversion and misuse of prescription drugs. This legislation would provide grants through the Health and Human Services Department to states to establish and operate prescription drug monitoring programs (PDMP). Each state operating an authorized monitoring program would be required to cover Schedule II, III, and IV drugs.

H.R. 3015 will provide the resources to states to implement and operate the individual program that best addresses the needs of the individual state. The bill will also facilitate the interoperability of state systems so drug diversion and abuse that crosses state lines can also be detected.

BACKGROUND AND NEED FOR LEGISLATION

The diversion and abuse of legally manufactured prescription drugs continues to be a pressing national issue. The Office of National Drug Control Policy (ONDCP) cites that in 2002 (the most recent data year), 6.2 million Americans abused prescription drugs.

Twenty-one states currently operate some form of prescription drug monitoring programs. Each state program is unique, often varying by which state agency operates the program, the controlled substances that are covered, and how patient information is collected and monitored. Most prescription drug monitoring programs function as electronic monitoring systems through which pharmacies transmit prescription data for covered controlled substances to a designated state agency or a private contractor. In addition to providing information about existing prescriptions for a patient to a health care provider, these programs provide real information to drug enforcement agencies to identify illegal activities.

Proponents of state prescription drug-monitoring programs highlight the success of several states in reducing the availability of abused drugs and improving state drug control investigation timing. They claim that the increased number of physician prescription drug history requests help serve as an initial deterrent for doctor shopping. They also argue that the presence of a prescription drug-monitoring program may also affect the type of drugs that are being diverted. The Government Accountability Office reports that the existence of a prescription drug-monitoring program within one state appears to have increased drug diversion activities in contiguous states without prescription drug-monitoring programs.

HEARINGS

The Subcommittee on Health held a hearing on Prescription Drug Monitoring: Strategies to Promote Treatment and Deter Prescription Drug Abuse on Thursday, March 4, 2004. The Subcommittee received testimony from: The Honorable Harold Rogers, Member, U.S. House of Representatives; Dr. Marcia Crosse, U.S. General Accounting Office; Danna E. Droz, RPh, JD, Boards of Pharmacy & Nursing Home Administrators; Mr. James W.

Holsinger Jr., MD, PhD, Secretary, Kentucky Cabinet for Health and Family Services; and Laximaiah Manchikanti, MD, American Society of Interventional Pain Physicians.

COMMITTEE CONSIDERATION

On Thursday, September 30, 2004 the Full Committee met in open markup session and ordered H.R. 3015 favorably reported to the House, as amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 3015 reported. A motion by Mr. Barton to order H.R. 3015 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held an oversight hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 3015 is to provide incentives to states so each will operate a drug-monitoring program and that these programs can communicate between programs to address the public health problem of prescription drug abuse.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3015, the National All Schedules Prescription Electronic Reporting Act of 2004, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 4, 2004.

Hon. JOE BARTON,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3015, a bill to provide for the establishment of a controlled substance monitoring program in each state.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Margaret Nowak.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

H.R. 3015—A bill to provide for the establishment of a controlled substance monitoring program in each state

H.R. 3015 would authorize the Secretary of Health and Human Services to make grants to states to establish electronic database systems for monitoring the dispensing of controlled substances. The database would be used to identify, and report to appropriate authorities, the potential unlawful diversion or misuse of a controlled substance. Beginning in 2007, the Secretary would be responsible for such monitoring and reporting in states that do not establish such an electronic database system.

The bill would authorize appropriation of \$25 million in each of fiscal years 2006 and 2007, and \$15 million for each fiscal year 2008 through 2010. Assuming appropriation of those amounts, and based on spending patterns for similar programs, CBO estimates that implementing H.R. 3015 would cost \$68 million over the 2005–2009 period. H.R. 3015 would have no effect on direct spending or revenues.

H.R. 3015 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act. It would establish a grant program for states to monitor controlled substances and to notify authorities when they suspect that controlled substances are being improperly dispensed or used.

The CBO staff contact for this estimate is Margaret Nowak. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates the title of the bill, the “National All Schedules Prescription Electronic Reporting Act of 2004.”

Section 2: Controlled Substance Monitoring Program

Section 2 amends Part P of title III of the Public Service Act by adding new section 3990, Controlled Substance Monitoring Program. Under this program, the Secretary of Health and Human Services would award grants to states to establish and operate controlled substance monitoring programs. The amount allocated to each state will be based on a ratio of the number of pharmacies within a state to the number of all pharmacies in states that have approved monitoring programs under this section. The Committee recommends that in determining the number of pharmacies in each state the Secretary consult with the National Association of Boards of Pharmacy. The Secretary may adjust each state’s allocation based on cost estimates provided by the state.

To receive a grant under this section, a state must submit an application in a time, manner, and containing such assurances and information that the Secretary may require. The Secretary, within 90 days after the submission, shall approve or disapprove the grant application. If a state has an authorized monitoring program and chooses to end this program, it shall give the Secretary a reasonable period of notice before the cessation of the program. If the Secretary withdraws authorization, or if the state ceases to operate its monitoring program, then the state must return a prorated portion of its grant funding to the Secretary.

In implementing a PDMP under this section, a state shall require all dispensers to report each dispensing in the state not later than one week after the dispensing. For the purposes of this section, controlled substance means any schedule II, III, IV drug or any other drug identified by the state to be subject to the monitoring program. The state may exclude from this reporting requirement the direct application of a controlled substance to an ultimate user. It is the Committee’s intention not to require the reporting of a dispensing when the drug is directly applied. Because the possibility for diversion is small, to require this reporting would present a significant burden on the monitoring programs without a resulting benefit.

The state may also exclude reporting for the dispensing of a controlled substance in an amount adequate to treat the ultimate user for 48 hours or less. The Secretary may also identify other exclusions from reporting requirements.

The information that must be reported by the dispenser includes: (1) the Drug Enforcement Administration Number of the dispenser; (2) the Drug Enforcement Administration Registration Number and name of the practitioner who prescribed the drug; the name, address, and telephone number of the ultimate user or research subject; (3) identification of the drug by a national drug code number; (4) the quantity dispensed; (5) the estimated number of days the quantity should last; number of refills ordered or as a first time request; whether the drug was dispensed as a refill; (6) the date of dispensing; and, (7) the date of origin of the prescription.

The state shall specify an electronic format for the reporting of the information. It is the Committee's intention that the Secretary coordinate with the states to develop an electronic format that will be interoperable between the states. The Committee notes that states currently operating a prescription drug monitoring program use the May 1995 version of the Telecommunications Format for Controlled Substances of the American Society for Automation in Pharmacy.

Under this section the state shall automatically share information with another state with an approved application if the information concerns the dispensing of a controlled substance to an ultimate user or research subject who resides in the other state or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is in the other state. The state shall also notify the appropriate authorities responsible for drug diversion investigations if the information indicates an unlawful diversion or misuse of a controlled substance. It is the Committee's intention that such determination of unlawful diversion should be based on a determination made by the monitoring authority itself, and that the monitoring authority have discretion making any such determination.

In implementing a controlled substance database, a state shall establish and maintain an electronic database that is searchable by any field or combination of fields. The state shall take appropriate safeguards to ensure the accuracy and completeness of the database, and shall take appropriate measures to protect the integrity of, and access to, the database.

A state may provide the information from the database upon request from a practitioner, or agent thereof, who certifies that the information is to be used to treat a patient. The state may also provide the information to local, state, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority that certifies the information is for an individual investigation. It is the Committee's intention that the term program authority should be interpreted to include State Medicaid authorities, or other state or Federal authorities responsible for investigating health care fraud and abuse.

In addition, the state may provide information to any agent of the Department of Health and Human Services, a State Medicaid program, a state health department, or the Drug Enforcement Administration who certifies that the requested information is for re-

search purposes. When providing information for research purposes, it shall not provide any individually identifiable information.

This section should not be construed to restrict the ability of any authority to perform functions otherwise authorized by law. This section should also not be construed to preempt any other state law. Furthermore, nothing in this section shall be construed to create a Federal private right of action.

The Secretary, in awarding any competitive grant that is related to drug abuse, shall give preference to those states that have established an approved drug monitoring authority. The abuse of prescription drugs is escalating, and any attempt to address the issue of drug abuse in this country must also address prescription drug abuse. Preference for drug abuse grants should go to states that have attempted to implement a comprehensive approach to addresses all types of drug abuse. This provision is designed to provide an incentive for states to create these programs. The effectiveness of a state's program is undermined when a person involved in unlawful diversion or abuse can circumvent the system when contiguous states do not have similar programs.

Not later than one year after the date of enactment, the Secretary shall conduct a study on the progress of states in establishing and implementing controlled substance monitoring programs. The study shall also examine the feasibility of implementing a real time electronic monitoring program. The Secretary shall submit a report to Congress on the results of this study.

States may establish an advisory council to assist in the establishment and implementation of the monitoring program. In establishing an advisory council the state should consult with state boards of pharmacy, state boards of medicine, and other interested parties. An advisory council can provide needed expertise to a drug monitoring authority, including assisting in developing standards for indicating unlawful diversion or abuse.

To carry out this section, there is to be authorized \$25,000,000 in each of Fiscal Years 2006 and 2007. There is to be authorized \$15,000,000 in each of Fiscal Years 2008, 2009, 2010.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * *

PART P—ADDITIONAL PROGRAMS

* * * * *

SEC. 3990. CONTROLLED SUBSTANCE MONITORING PROGRAM.**(a) FORMULA GRANTS.—**

(1) *IN GENERAL.*—Each fiscal year, the Secretary shall make a payment to each State with an application approved under this section for the purpose of establishing and implementing a controlled substance monitoring program under this section.

(2) *DETERMINATION OF AMOUNT.*—In making payments under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this paragraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

(b) APPLICATION APPROVAL PROCESS.—

(1) *IN GENERAL.*—To seek a grant under this section, a State shall submit an application at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

(A) a budget cost estimate for the State's controlled substance monitoring program; and

(B) assurances of compliance with the requirements of this section.

(2) *APPROVAL OR DISAPPROVAL.*—Not later than 90 days after the submission by a State of an application under paragraph (1), the Secretary shall approve or disapprove the application. The Secretary shall approve the application if the State demonstrates to the Secretary that the State will establish and implement a controlled substance monitoring program in accordance with this section.

(3) *WITHDRAWAL OF AUTHORIZATION.*—If a State fails to implement a controlled substance monitoring program in accordance with this section—

(A) the Secretary shall give notice of the failure to the State; and

(B) if the State fails to take corrective action within a reasonable period of time, the Secretary shall withdraw any approval of the State's application under this section.

(4) *VOLUNTARY DISCONTINUANCE.*—A funding agreement for the receipt of a payment under this section is that the State involved will give a reasonable period of notice to the Secretary before ceasing to implement a controlled substance monitoring program under this section. The Secretary shall determine the period of notice that is reasonable for purposes of this paragraph.

(5) *RETURN OF FUNDS.*—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement a controlled substance monitoring program under this section, a funding agreement for the receipt of a payment under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall payment as the remaining time period for expending the pay-

ment bears to the overall time period for expending the payment (as specified by the Secretary at the time of the payment).

(c) *REPORTING REQUIREMENTS.*—In implementing a controlled substance monitoring program under this section, a State shall comply with the following:

(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user or research subject not later than 1 week after the date of such dispensing.

(2) The State may exclude from the reporting requirement of this subsection—

(A) the direct application of a controlled substance to the body of an ultimate user or research subject;

(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user or research subject involved for 48 hours or less; or

(C) the application or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

(A) Drug Enforcement Administration Registration Number of the dispenser.

(B) Drug Enforcement Administration Registration Number and name of the practitioner who prescribed the drug.

(C) Name, address, and telephone number of the ultimate user or research subject

(D) Identification of the drug by a national drug code number.

(E) Quantity dispensed.

(F) Estimated number of days for which such quantity should last.

(G) Number of refills ordered.

(H) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(I) Date of the dispensing.

(J) Date of origin of the prescription.

(4) The State shall specify an electronic format for the reporting of information under this subsection and may waive the requirement of such format with respect to an individual dispenser.

(5) The State shall automatically share information reported under this subsection with another State with an application approved under this section if the information concerns—

(A) the dispensing of a controlled substance to an ultimate consumer or research subject who resides in such other State; or

(B) the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(6) The State shall notify the appropriate authorities responsible for drug diversion investigation if information in the database maintained by the State under subsection (d) indicates a

potential unlawful diversion or misuse of a controlled substance.

(d) *DATABASE.—In implementing a controlled substance monitoring program under this section, a State shall comply with the following:*

(1) *The State shall establish and maintain an electronic database containing the information reported to the State under subsection (c).*

(2) *The database must be searchable by any field or combination of fields.*

(3) *The State shall include reported information in the database at such time and in such manner as the Secretary determines appropriate, with appropriate safeguards for ensuring the accuracy and completeness of the database.*

(4) *The State shall take appropriate security measures to protect the integrity of, and access to, the database.*

(e) *PROVISION OF INFORMATION.—Subject to subsection (f), in implementing a controlled substance monitoring program under this section, a State may provide information from the database established under subsection (d) and, in the case of a request under paragraph (2) or (3), compilations of such information, in response to a request by—*

(1) *a practitioner (or the agent thereof) who certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;*

(2) *any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding; or*

(3) *any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature.*

(f) *LIMITATIONS.—In implementing a controlled substance monitoring program under this section, a State—*

(1) *shall make reasonable efforts to limit the information provided pursuant to a valid request under subsection (e) to the minimum necessary to accomplish the intended purpose of the request; and*

(2) *shall not provide any individually identifiable information in response to a request under subsection (e)(3).*

(g) *RULES OF CONSTRUCTION.—*

(1) *FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.*

(2) *NO PREEMPTION.*—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

(3) *NO FEDERAL PRIVATE CAUSE OF ACTION.*—Nothing in this section shall be construed to create a Federal private cause of action.

(h) *RELATION TO HIPAA.*—Except to the extent inconsistent with this section, the provision of information pursuant to subsection (c)(5), (c)(6), or (e) and the subsequent transfer of such information are subject to any requirement that would otherwise apply under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(i) *PREFERENCE.*—The Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) to a State, shall give preference to any State with an application approved under this section.

(j) *STUDY.*—Not later than 1 year after the date of the enactment of this section, the Secretary shall—

(1) complete a study on—

(A) the progress of States in establishing and implementing controlled substance monitoring programs under this section; and

(B) the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program; and

(2) submit a report to the Congress on the results of the study.

(k) *ADVISORY COUNCIL.*—

(1) *ESTABLISHMENT.*—A State may establish an advisory council to assist in the establishment and implementation of a controlled substance monitoring program under this section.

(2) *SENSE OF CONGRESS.*—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with State boards of pharmacy, State boards of medicine, and other interested parties.

(l) *DEFINITIONS.*—For purposes of this section:

(1) The term “bona fide patient” means an individual who is a patient of the dispenser or practitioner involved.

(2) The term “controlled substance” means a drug that is—

(A) included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act; or

(B) identified by the State involved as a drug subject to the monitoring program of the State under this section.

(3) The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(4) The term “dispenser” means a physician, pharmacist, or other individual who dispenses a controlled substance to an ultimate user or research subject.

(5) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does

research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(6) The term "State" means each of the 50 States and the District of Columbia.

(7) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

(m) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

- (1) \$25,000,000 for each of fiscal years 2006 and 2007; and*
- (2) \$15,000,000 for each of fiscal years 2008, 2009, and 2010.*

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