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NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT OF 2005

JULY 29, 2005.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

REPORT

[To accompany S. 518]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 518) to provide for establishment of a controlled substance monitoring program in each State, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

		Page
I.	Purpose and summary	1
II.	Background and need for legislation	2
III.	Legislative history and committee action	2
IV.	Explanation of bill and committee views	2
V.	Cost estimate	6
VI.	Application of law to the legislative branch	7
VII.	Regulatory impact statement	7
VIII.	Section-by-section analysis	7
IX.	Changes in existing law	10

I. PURPOSE AND SUMMARY

The purpose of S. 518 is to combat the abuse and diversion of prescription drugs by establishing a grant program, to be administered by the Department of Health and Human Services, that would support the expansion, in number and effectiveness, of State prescription drug monitoring programs (PMPs). Each State operating an authorized monitoring program would be required to cover Schedule II, III, and IV drugs.

S. 518 will provide resources to States to establish PMPs or to States improving existing programs. The bill will also facilitate the interoperability of State systems to detect more rapidly drug diversion and abuse that crosses State lines.

II. 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, 6.2 million Americans abused prescription drugs.

In the approximately 20 States currently operating some form of a PMP, abuse and diversion have been reduced directly, through the identification of high-risk patient behavior or inappropriate provider practices; and indirectly, as growing awareness of these programs serves as a deterrent for potential wrongdoers. In general, PMPs operate by collecting from dispensers a basic set of information on prescriptions that are issued for controlled substances. In the most effective programs, providers, including physicians and pharmacists, may request the prescription histories of patients, permitting them to avoid providing controlled substances to "doctor shoppers" seeking multiple prescriptions to feed addiction or for diversion to the black market. Physicians are also provided with an important tool for early detection of patterns of addiction, presenting a new opportunity for early intervention and treatment. Other appropriate authorities, including public health entities, professional regulatory bodies, and law enforcement, may also access the PMP data under certain circumstances.

However, several issues have emerged as clear barriers to the full realization of these programs' potential. It is clear that effective programs push illicit activity across State borders. At present, even in regions where the abuse and diversion problem is rampant, many States do not yet operate programs, and none have the ability to effectively share information across State lines. In addition, many States are finding their programs hampered by outdated design and need both the technical and the financial assistance that this legislation would provide in order to undertake essential upgrades.

III. Legislative History and Committee Action

Senator Sessions introduced S. 518 on March 3, 2005, with Senators Durbin, Kennedy, and Dodd. Additional cosponsors were added after introduction: Senators Alexander, Burr, Talent, and Vitter.

On May 25, 2005, the Senate Committee on Health, Education, Labor, and Pensions met in Executive Session. After accepting a substitute amendment offered by Senators Sessions, Kennedy, Enzi and Dodd by unanimous voice vote, the committee approved S. 518, as amended, by unanimous voice vote.

IV. Explanation of Bill and Committee Views

The committee believes the diversion and abuse of legally manufactured prescription drugs is a pressing national issue. The purpose of the legislation is to foster the establishment of State-administered prescription drug monitoring systems to ensure that health

care providers have access to accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction. With the knowledge gained, health care providers will be able to initiate appropriate medical intervention and avert the tragic personal, family, and community consequences of untreated addiction. This legislation will also establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.

The bill amends Part P of title III of the Public Health Service Act and adds a new Section 399O, Controlled Substance Monitoring Program. Under this program, the Secretary of Health and Human Services would award grants to States to establish and implement controlled substance monitoring programs or to improve existing programs.

Each State receiving grant approval from the Secretary will be awarded a minimum grant of 1.0 percent of that fiscal year's appropriation for the program. Additional funding allocated to each State will be based on a ratio of the number of pharmacies within a State to the total number of pharmacies in States that have approved monitoring programs under this section. The committee recommends that the Secretary consult with the National Association of Boards of Pharmacy to determine the number of pharmacies in each State. The Secretary may adjust each State's allocation after considering cost estimates provided by the State.

Prior to awarding a grant under this section, but not later than 6 months after the appropriation of funds, the Secretary will develop minimum standards for grant submissions by States and recommended penalties for the unlawful provision or use of any information found in the monitoring programs. Within 2 years from the date the funds are first appropriated under this section, the Secretary will report to Congress on the recommended penalties and the extent to which existing penalties are meeting these recommendations.

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. States planning to establish or implement a program must include a cost estimate, and proposed criteria for information security, electronic formatting, program access, and penalties for misuse of information in their application. States requesting funds for improving existing systems must include a cost estimate, a plan to ensure the program is in compliance with the standards and penalties in this section, and a plan to enable the State program to achieve interoperability with other State programs. States establishing, implementing, or improving a controlled substance monitoring program must have enacted legislation or regulations to permit the implementation of the program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the program.

The Committee recognizes that persons should be able to have accurate information in the database, and to be able to have any inaccurate information removed or corrected. In existing programs, the physician is normally the responsible party to seek the correc-

tion on behalf of the affected individual. It is the intent of the committee that States would address the issue of how incorrect information would be corrected as part of their responsibility to ensure that the information in the database is accurate.

The committee recognizes the concerns surrounding the potential for unauthorized access to the database and that patients will want to be notified if the privacy of their records is compromised. This legislation allows States to exceed the minimum privacy and penalty standards as outlined in the application criteria to protect the integrity of their electronic database.

In order to increase the effectiveness of these programs, the legislation requires a State submitting an application that geographically borders another State that is operating a controlled substances monitoring program to describe how it will achieve interoperability between monitoring programs of these States.

Sharing of information among neighboring States may help prevent diversion across State lines. In response to a request from a practitioner, law enforcement official, or PMP from a neighboring State, the PMP will prepare and provide a report summarizing the relevant information from the database to fully respond to the request. Further, in establishing interoperability agreements, the committee feels that PMPs can choose not to establish and/or cancel an agreement if they are concerned about the other State's privacy protections.

In implementing or improving a PMP under this section, a State shall require all dispensers to report each dispensing in the State not later than 1 week after dispensing. The legislation defines a controlled substance as any schedule II, III, IV drug or any other drug identified by the State to be subject to the monitoring program.

The direct administration of a controlled substance to an ultimate user is excluded from this reporting requirement. 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. Because the possibility for diversion is small in both of these instances, to require this reporting would present a significant burden on the monitoring programs without a resulting benefit. For this reason, 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 (or other identifying number used in lieu of such Registration Number) of the dispenser; (2) the Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug; (3) the name, address, and telephone number of the ultimate user; (4) identification of the drug by a national drug code number; (5) the quantity dispensed; (6) number of refills ordered or as a first time request; (7) whether the drug was dispensed as a refill; (8) the date of dispensing; and (9) the date of origin of the prescription.

The committee intends that States require dispensers to report this information in a uniform electronic format in accordance with the Secretary's criteria. In implementing or improving a controlled substance database, a State shall establish and maintain an elec-

tronic 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 disclose the information from the database upon request from a practitioner or local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority that certifies that the information is for an individual investigation. The committee intends 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.

The bill directs each State to establish a notification program to improve collaboration between practitioners and dispensers to identify and prevent the unlawful diversion or misuse of controlled substances. This notification program will be established in consultation with practitioners, dispensers, and other relevant and interested stakeholders. States may, to the extent permitted under State law, notify the appropriate authorities responsible for drug diversion investigations if the information in the monitoring database suggests an unlawful diversion or abuse of a controlled substance.

The bill specifies that nothing in the legislation should be construed to restrict the ability of any authority to perform functions otherwise authorized by law; preempt any State law; preempt any State from imposing additional privacy protections; supersede Federal confidentiality requirements; or create a Federal private right of action.

The bill directs the Secretary to study whether the implementation of existing State monitoring programs has had a substantial negative impact on patient access to treatment, pediatric access to treatment, or patient enrollment in research or clinical trials. If the Secretary determines that a substantial negative impact has been demonstrated with regard to one or more of these categories, the Secretary shall identify additional appropriate categories of exclusion from reporting.

The legislation also directs the Secretary to complete a study on the progress of States in establishing and implementing controlled substance monitoring programs. The study shall also determine the progress of States in achieving interoperability between monitoring programs, the feasibility of implementing a real-time electronic monitoring program, and an analysis of the privacy protections in place, and the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in monitoring programs and the potential for these alternatives to enhance privacy and security of individually identifiable data. Additionally, the study shall evaluate the penalties that States have enacted for the unauthorized use and disclosure of information maintained in monitoring programs. The Secretary shall submit a report to Congress on the results of this study.

The bill authorizes States to establish an advisory council to assist in the establishment, implementation, or improvement of the monitoring program, however, no funds from this grant may be

used to operate such council. In establishing an advisory council, the State should consult with appropriate professional boards and other interested parties. An advisory council can provide needed expertise to a drug monitoring authority, including assistance in developing standards for indicating unlawful diversion or abuse.

The bill authorizes to be appropriated $15 million in each of fiscal years 2006 and 2007 and $10 million in each of fiscal years 2008 through 2010.

The committee views this bill as an important step in reducing substance abuse across the Nation.

According to the National Survey on Drug Use and Health (NSDUH), there was a significant increase in lifetime nonmedical use of pain relievers between 2002 and 2003 among person aged 12 years and older—from 29.6 million to 31.2 million. The NSDUH also found that while 3 million americans receive treatment in a year, another 19 million remain without the services they need. As a result, the committee believes an important component of any strategy relating to prescription drug monitoring programs is a strong link with each State's single State Authority (SSA) for Substance Abuse—the office responsible for planning and managing the publicly funded substance abuse prevention and treatment service delivery system. This important link with the SSA will help provide access to clinically appropriate treatment services for persons addicted to prescription drugs and enhance opportunities to build a strong and comprehensive prevention portfolio related to the misuse of prescription drugs.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2005.

Hon. MIKE ENZI,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 518, the National All Schedules Prescription Electronic Reporting Act of 2005.

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

Sincerely,

ELIZABETH M. ROBINSON
(For Douglas Holtz-Eakin, Director).

Enclosure.

S. 518—National All Schedules Prescription Electronic Reporting Act of 2005

S. 518 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.

The bill would authorize the appropriation of $15 million in each of fiscal years 2006 and 2007, and $10 million a year for fiscal years 2008 through 2010. Assuming appropriation of those amounts, and based on spending patterns for similar programs, CBO estimates that implementing S. 518 would cost $52 million over the 2005–2010 period. Enacting S. 518 would have no effect on direct spending or revenues.

S. 518 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 Shinobu Suzuki. This estimate was approved by Peter H. Fontaine, Deputy Assistance Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act (CAA) requires a description of the application of this bill to the legislative branch. This bill does not amend any act that applies to the legislative branch.

VII. Regulatory Impact Statement

The committee has determined that the bill will not have a significant regulatory impact.

VIII. Section-by-Section Analysis

Section 1. Short title

National All Schedules Prescription Electronic Reporting Act of 2005.

Section 2. Purpose

The purpose of the legislation is to foster the establishment of State-administered prescription drug monitoring systems in order to ensure that health care providers have access to accurate, timely prescription history information. This information may be used as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical intervention and avert the tragic personal, family, and community consequences of untreated addiction. This legislation will also establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.

Section 3. Controlled Substance Monitoring Program

Amends Part P of title III of the Public Health Service Act by adding a new section 399O, Controlled Substance Monitoring Program.

Subsection (a) tasks the Secretary of Health and Human Services with awarding grants to States to establish and implement controlled substance monitoring programs or to improve existing programs. Each State receiving grant approval from the Secretary will be awarded a minimum grant of 1.0 percent of that fiscal year's ap-

propriation for the program. Additional funding will be allocated to each State based on a ratio of the number of pharmacies within the State to the total number of pharmacies in all States that have approved monitoring programs.

Subsection (b) tasks the Secretary with developing minimum standards for grant submissions by prior to awarding a grant.

Subsection (c) outlines the application approval office. 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. States planning to establish or implement a program must include a cost estimate, and proposed criteria for information security, electronic formatting, program access, and penalties for misuse of information in their application. States requesting funds for improving existing systems must include a cost estimate, a plan to ensure the program is in compliance with the standards and penalties in this section, a plan to enable the State program to achieve interoperability with other State programs, and must have enacted legislation or regulations to permit the implementation of the program.

A State submitting an application that geographically borders another State that is operating a controlled substances monitoring program under this section on the date of such application must describe how it will achieve interoperability between monitoring programs of these States.

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.

Subsection (d) specifies reporting requirements. This section requires States implementing or improving a PMP, to report each dispensing of a controlled substance in the State not later than one week after 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 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; (3) the name, address, and telephone number of the ultimate user; (4) identification of the drug by a national drug code number; (5) the quantity dispensed; (6) number of refills ordered or as a first time request; (7) whether the drug was dispensed as a refill; (8) the date of dispensing; and (9) the date of origin of the prescription.

Subsection (e) requires dispensers to report this information in a uniform electronic format in accordance with the Secretary's criteria. In implementing or improving 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.

Subsection (f) specifies that a State may disclose 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 disclose the information to local, State, or Federal law enforcement, narcotics control, licensure, discipli-

nary, or program authority that certifies that the information is for an individual investigation. In addition, the State may disclose information to another State or group of States with whom the State has an interoperability agreement. The State may also disclose 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 research purposes.

Subsection (g) is a limitation stating that in implementing or improving a controlled substance monitoring program, a State shall limit the information provided to the minimum necessary to accomplish the intended request and shall not disclose any individually identifiable information.

Subsection (h) tasks the Secretary with specifying a uniform electronic format for the reporting, sharing, and disclosure of information.

Subsection (i) lists rules of construction stating this legislation should not be construed to restrict the ability of any authority to perform functions otherwise authorized by law. This legislation should also not be construed to preempt any other State law. Additionally, this legislation should not be construed to preempt any State from imposing additional privacy protections. This bill should not be construed to supersede Federal confidentiality requirements. Furthermore, nothing in this bill shall be construed to create a Federal private right of action.

Subsection (j) tasks the Secretary with conducting studies and reports and specifies not later than 180 days after the date of enactment, the Secretary shall determine whether the implementation of existing State monitoring programs has had a substantial negative impact on patient access to treatment, pediatric access to treatment, or patient enrollment in research or clinical trials. If the Secretary determines that a substantial negative impact has been demonstrated with regard to one or more of these categories, the Secretary shall identify additional appropriate categories of exclusion from reporting. Not later than 3 years after the date on which funds are first appropriated, the Secretary shall complete a study on the progress of States in establishing and implementing controlled substance monitoring programs. The study shall also determine the progress of States in achieving interoperability between monitoring programs, the feasibility of implementing a real-time electronic monitoring program, and an analysis of the privacy protections in place. Additionally, the study shall evaluate the penalties that States have enacted for the unauthorized use and disclosure of information maintained in monitoring programs. The Secretary shall submit a report to Congress on the results of this study.

Subsection (k) gives States the authority to establish and advisory council to assist in the establishment, implementation, or improvement of the monitoring programs.

Subsection (l) defines “bona fide patient”, “controlled substance”, “dispense”, “dispenser”, “interoperability”, “nonidentifiable information”, “practitioner”, “State”, and “ultimate user”.

Subsection (m) authorizes to be appropriated $15 million in each of fiscal years 2006 and 2007 and $10 million in each of fiscal years 2008 through 2010.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

PART P—ADDITIONAL PROGRAMS

SEC. 399L. CHILDREN'S ASTHMA TREATMENT GRANTS PROGRAM.

(a) AUTHORITY TO MAKE GRANTS.—

(1) IN GENERAL.—* * *

* * * * * * *

SEC. 399N CHILDHOOD MALIGNANCIES.

(a) IN GENERAL.—* * *

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(e) AUTHORIZATION OF APPROPRIATIONS.—* * *

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SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.

(a) GRANTS.—

(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

(A) to establish and implement a State controlled substance monitoring program; or

(B) to make improvements to an existing State controlled substance monitoring program.

(2) DETERMINATION OF AMOUNT.—

(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under paragraph (1) 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 subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

(3) TERM OF CERTAIN GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, but not later than 6 months after the date on which funds are first appropriated under this section, the Secretary shall identify minimum requirements for use by States in submitting their proposed criteria under clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

(c) APPLICATION APPROVAL PROCESS.—

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

(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

(v) criteria for availability of information and limitation on access to program personnel;

(vi) criteria for access to the database, and procedures to ensure database accuracy;

(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

(viii) penalties for the unauthorized use and disclosure of information in violation of applicable State law or regulation; and

(ix) assurances of compliance with all other requirements of this section; or

(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at

least one other State controlled substance monitoring program; and

(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require the State to have enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substances monitoring program under subsection (a)(1) on the date of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

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

(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, 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 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 administration of a controlled substance to the body of an ultimate user;

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

(C) the administration 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 (or other identifying number used in lieu of such Registration Number) of the dispenser.

(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

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

(E) Quantity dispensed.

(F) Number of refills ordered.

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

(H) Date of the dispensing.

(I) Date of origin of the prescription.

(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

(e) DATABASE.—In implementing or improving 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 (d).

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

(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, 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.

(f) USE AND DISCLOSURE OF INFORMATION.—

(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subsection (f)(1)(D), summary statistics of such information, only in response to a request by—

(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, 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;

(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diver-

sion 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;

(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

(D) 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; or

(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

(i) the State has an application approved under this section; and

(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

(i) 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) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(4) CERTAIN CONFIDENTIALITY REQUIREMENTS.—Nothing in this section shall be construed as preempting the confidentiality requirements of part 2 and part 2a of title 42, Code of Federal Regulations.

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

(j) STUDIES AND REPORTS.—

(1) IMPLEMENTATION REPORT.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

(i) patient access to treatment, including therapy for pain or controlled substance abuse;

(ii) pediatric patient access to treatment; or

(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

(A) complete a study that—

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

(ii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

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

(iv) provides an analysis of the privacy protections in place for the information reported to the controlled sub-

stance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

(v) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(vi) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

(B) 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, implementation, or improvement of a controlled substance monitoring program under this section.

(2) LIMITATION.—A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards 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 included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

(3) The term "dispense" means to deliver a controlled substance to an ultimate user 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 person that dispenses a controlled substance to an ultimate user.

(5) The term "interoperability" with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(6) The term "nonidentifiable information" means information that does not identify a practitioner or an ultimate user and with respect to which there is no reasonable basis to believe that

the information can be used to identify a practitioner or an ultimate user.

(7) 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.

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

(9) The term "ultimate user" means a person who has obtained from a dispenser, 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) $15,000,000 for each of fiscal years 2006 and 2007; and

(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010..

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