114TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
114–245

NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING REAUTHORIZATION ACT OF 2015

SEPTEMBER 8, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1725]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1725) to amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

H.R. 1725, National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015, was introduced on March 26, 2015, by Rep. Whitfield (R–KY), Rep. Kennedy (D–MA), Rep. Pallone (D–NJ) and Rep. Bucshon (R–IN), to amend and reauthorize the controlled substance monitoring program under section 399O of the Public Services Act, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

Almost ten years ago, the National All Schedules Prescription Electronic Reporting Act (NASPER) was signed into law to assist States in combating prescription drug abuse through the creation and improvement of prescription drug monitoring programs (PDMPs), which are one of the most promising clinical tools to address the prescription drug abuse epidemic.

H.R. 1725 would reauthorize NASPER and provide States the necessary resources to build upon the success PDMPs have had in reducing prescription drug abuse by streamlining access to timely, accurate, and secure patient prescription history. The bill also would promote interstate interoperability and encourage integration between PDMPs and point of service physician tools such as electronic health records.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 1725 on Tuesday, January 27, 2015. The Subcommittee received testimony from:

- Ben D. Chlapek, Deputy Chief Central Jackson Fire;
- John L. Eadie, Director, Prescription Drug Monitoring Program Center of Excellence, Brandeis University;
- Blain L. Enderson, MD, Department of Surgery, University of Tennessee Medical Center;
- Nathan B. Fountain, MD, Professor of Neurology, Director of F.E. Dreifuss Comprehensive Epilepsy Program; and,
- D. Linden Barber, Partner and Director, DEA Compliance Operations, Quarles & Brady.

COMMITTEE CONSIDERATION

On Thursday, July 23, 2015, the Subcommittee on Health met in open markup session and forwarded H.R. 1725 to the full Committee, without amendment, by a voice vote. On Wednesday, July 29, 2015, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 1725 reported to the House, without amendment, by a voice vote.

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. 1725 reported. A motion by Mr. Upton to order H.R. 1725 reported to the House, without amendment, 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 has not held hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(1) of rule XIII of the House of Representatives, the goal of the legislation is to reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act, and for other purposes.

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. 1725, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 1725 contains no earmarks, limited tax benefits, or limited tariff benefits.

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, August 14, 2015.

Hon. FRED UPTON,
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. 1725, the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015.

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

Sincerely,

KEITH HALL.

Enclosure.

H.R. 1725—National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015

Summary: H.R. 1725 would reauthorize funding for grants to states and territories to establish, improve, or maintain an electronic database system for monitoring the dispensing of controlled substances. Under current law, most states operate such systems and receive funding from a variety of sources to maintain or improve those systems. The bill also would require the Secretary of Health and Human Services to monitor the states' efforts to achieve interoperability of the database systems for the purpose of sharing information with bordering states and with other systems such as those for electronic health records.

The bill would authorize the appropriation of $10 million a year for fiscal years 2016 through 2020. Assuming appropriation of those amounts, CBO estimates that implementing H.R. 1725 would cost $43 million over the 2016–2020 period. Enacting H.R. 1725 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 1725 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effects of H.R. 1725 are shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2016	2017	2018	2019	2020	2016–2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Authorization Level	10	10	10	10	10	50
Estimated Outlays	4	9	10	10	10	43

Basis of estimate: For this estimate, CBO assumes that H.R. 1725 will be enacted near the start of fiscal year 2016, that the Congress will appropriate the authorized amounts for each year, and that spending will follow historical patterns for the authorized program.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 1725 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments. The bill would authorize funding for grants to states to monitor the distribution of controlled substances and to notify authorities when they suspect that controlled substances are being imported, dispensed, or used. Any costs incurred for complying with those conditions for receiving federal funds would be incurred voluntarily.

Estimate prepared by: Federal costs: Ellen Werble; Impact on state, local, and tribal governments: J'nell Blanco Suchy; Impact on the private sector: Amy Petz.

Estimate approved by: Holly Harvey, 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.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 1725 would establish nor reauthorize a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 1725 specifically directs to be completed 0 rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

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

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 states the legislation may be cited as the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015."

Section 2. Amendment to purpose

Section 2 would ensure health care providers have access to accurate, timely prescription history information that may be useful in identifying patients at risk for addiction and to ensure appropriate law enforcement and regulatory and professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists.

Section 3. Amendments to controlled substance monitoring program

Section 3 would amend section 399O of the Public Health Service Act by asking the Secretary to award grants to States to maintain and operate an existing State-controlled substance monitoring program. This section also would revise subsections focusing on the development of minimum requirements for grants, interoperability, return of funds, evaluation and reporting, education, and access.

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 (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT OF 2005

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SEC. 2. PURPOSE.

It is the purpose of this Act to—

[(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and]

(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that—

(A) health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

(B) appropriate law enforcement, regulatory, and State professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists; and

(2) 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.

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PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART P—ADDITIONAL PROGRAMS

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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**[**.**]***; or*

(C) to maintain and operate 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 subparagraph (A) 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 GRANTS.—Grants awarded *by the Secretary* 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, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).**]**

(b) MINIMUM REQUIREMENTS.—The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of 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)**]** *subsection (j)* ;

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

(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

(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 maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

(x) 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)**]** *(a)(1)(B) or (a)(1)(C)* —

(i) a budget cost estimate for the controlled substance monitoring **[**program to be improved**]** *program to be improved or maintained* 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 apply the latest advances in health information technology in order to incorporate prescription drug monitoring program data directly into the workflow of prescribers and dispensers to ensure timely access to patients' controlled prescription drug history;

[(iii)**]** *(iv)* a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance

monitoring program *and at least one health information technology system such as an electronic health records system, a health information exchange, or an e-prescribing system* ; and

[(iv)] *(v)* 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] *public health or public safety* in such State.

(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has 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]

(A) IN GENERAL.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission 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[.] *and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for implementation of such interoperability.*

(B) MONITORING OF EFFORTS.—The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).

(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

(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 or improve] *establish, improve, or maintain* 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). *The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).*

(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)] *In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)* 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] *public health or public safety* 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.

(J) Such other information as may be required by State law to be reported under this subsection.

(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)] *subsection (j)*, 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.

(5) The State shall report to the Secretary on—

(A) as appropriate, interoperability with the controlled substance monitoring programs of Federal departments and agencies;

(B) as appropriate, interoperability with health information technology systems such as electronic health records systems, health information exchanges, and e-prescribing systems; and

(C) whether or not the State provides automatic, real-time or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

(e) DATABASE.—In [implementing or improving] *establishing, improving, or maintaining* 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] *establishing, improving, or maintaining* 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 subparagraph (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 diversion or [misuse of a schedule II, III, or IV substance] *misuse of a controlled substance included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act*, 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, *a State substance abuse agency,* or the Drug Enforcement Administration who certifies that the requested in-

formation 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.

(3) EVALUATION AND REPORTING.—Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data and other information determined by the Secretary to be necessary to enable the Secretary—

(A) to evaluate the success of the State's program in achieving its purposes; or

(B) to prepare and submit the report to Congress required by subsection (l)(2).

(4) RESEARCH BY OTHER ENTITIES.—A department, program, or administration receiving nonidentifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.

(g) LIMITATIONS.—In [implementing or improving] *establishing, improving, or maintaining* 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) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving a grant under subsection (a) shall take steps to—

(1) facilitate prescriber and dispenser use of the State's controlled substance monitoring system;

(2) educate prescribers and dispensers on the benefits of the system both to them and society; and

(3) facilitate linkage to the State substance abuse agency and substance abuse disorder services.

(i) CONSULTATION WITH ATTORNEY GENERAL.—In carrying out this section, the Secretary shall consult with the Attorney General of the United States and other relevant Federal officials to—

(1) ensure maximum coordination of controlled substance monitoring programs and related activities; and

(2) minimize duplicative efforts and funding.

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

[(i)] *(k)* 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) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

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

[(j)] *(l)* 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 ap-

propriate 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) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances*; established or strengthened initiatives to ensure linkages to substance use disorder services;* or affected patient access to appropriate pain care in States operating such programs;

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

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

(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance 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;

(vi) 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

(vii) 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) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements

under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).]

[(l)] *(n)* 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.

[(m)] *(o)* DEFINITIONS.—For purposes of this section:

(1) The term "bona fide patient" means an individual who is a patient of the 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, dispenser, 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, dispenser, 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.

[(n)] *(p)* 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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