109TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
109–191

NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT OF 2005

JULY 27, 2005.—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. 1132]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1132) to provide for the establishment of a controlled substance monitoring program in each State, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is 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 2005".

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

(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.

SEC. 3. 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) 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 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 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, 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).

"(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 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)—

"(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 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 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.

"(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 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.

"(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), 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 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, 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) 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) 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) 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 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, 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) 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) 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) 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.".

PURPOSE AND SUMMARY

The purpose of H.R. 1132 is to address the issue of illegal diversion and misuse of prescription drugs. This legislation would provide grants to states, through the Department of Health and Human Services, 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. 1132 will provide the resources to states to implement and operate an individual program that best address the needs of the particular state. The bill will also facilitate the interoperability of state systems so drug diversion and abuse that crosses states 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. According to the Office of National Drug Control Policy (ONDCP), in 2002 6.2 million Americans abused prescription drugs. Since this Committee passed similar legislation last year, the National Center on Addiction and Substance Abuse at Columbia University released a report indicating the growing nature of this problem. According to this report, the number of Americans who admit abusing prescription drugs nearly doubled to more than 15 million from 1992 to 2003, while the number of teens abusing prescription drugs has tripled in that time.

More than 20 states currently operate some form of a prescription drug monitoring program. Each state program is unique, with states varying the state agency that 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. In addition to providing information about existing prescriptions for a patient to a health care provider, these programs also provide information to drug enforcement agencies to identify illegal activities.

Proponents of state prescription drug monitoring programs have highlighted the success of several states in reducing the availability of abused drugs and improving states' ability to investigate and prosecute illegal prescription drug diversion. They claim that the physicians' increased access to drug history information has helped to serve as an initial deterrent for doctor shopping. They also argue that the presence of a prescription drug monitoring pro-

gram 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 Committee on Energy and Commerce has not held hearings on this legislation.

COMMITTEE CONSIDERATION

On Wednesday, June 22, 2005, the Subcommittee on Health met in open markup session and approved H.R. 1132 for full Committee consideration, amended, by a voice vote, a quorum being present. On Wednesday, July 20, 2005, the full Committee met in open markup session and ordered H.R. 1132 favorably reported to the House, 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. The following is the recorded vote taken on H.R. 1132. A motion by Mr. Barton to order H.R. 1132 reported to the House, amended, was agreed to by a voice vote.

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 38

Bill: H.R. 1132, National All Schedules Prescription Electronic Reporting Act of 2005.

AMENDMENT: An amendment to the Whitfield amendment in the nature of a substitute by Mr. Markey, No. 1a, to require a patient to be notified if information relating to the patient in a database maintained under subsection (e) is lost, stolen, or used for an unauthorized purpose.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 15 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns			
Mr. Gillmor		X		Mr. Pallone		X	
Mr. Deal		X		Mr. Brown		X	
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood		X		Mr. Rush		X	
Ms. Cubin		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak			
Ms. Wilson		X		Mr. Engel	X		
Mr. Shadegg		X		Mr. Wynn			
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland		X	
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. Allen		X	
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis	X		
Mr. Terry		X		Mr. Gonzalez		X	
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter	X			Mr. Ross		X	
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy	X						
Mr. Burgess		X					
Ms. Blackburn		X					

7/20/2005

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 oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 1132 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. 1132, the National All Schedules Prescription Electronic Reporting Act of 2005, 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, July 26, 2005.

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. 1132, 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 Julia Christensen.

Sincerely,

ROBERT A. SUNSHINE
(For Douglas Holtz-Eakin, Director).

Enclosure.

H.R. 1132—National All Schedules Prescription Electronic Reporting Act of 2005

H.R. 1132 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 controlled

substances. The bill also would require the Secretary to conduct several studies related to monitoring programs for controlled substances.

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 H.R. 1132 would cost $52 million over the 2006–2010 period. Enacting H.R. 1132 would have no effect on direct spending or revenues.

H.R. 1132 contains no intergovernmental or private-sector mandates as defined by the Unfunded Mandates Reform Act. The bill would benefit state, local, and tribal governments; any costs they incur would result from complying with conditions of receiving federal assistance.

On June 6, 2005, CBO transmitted a cost estimate for S. 518, the National All Schedules Prescription electronic Reporting Act of 2005, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on May 25, 2005. The authorizations of appropriations in that bill are equal to those in H.R. 1132; the programs established under both bills are almost identical. Neither bill would impose any mandates on state, local, or tribal governments or on the private sector.

The CBO staff contact for this estimate is Julia Christensen. 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 2005."

Section 2. Purpose

Section 2 states that 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

Section 3 amends Part P of Title III of the Public Service Act by adding 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 operate controlled substance monitoring programs. Each state with an approved application will be guaranteed a minimum amount of 1% of the amount appropriated for that fiscal year. The remainder of funds 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 monitoring programs approved 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.

Prior to awarding any grant, and not later than six months after the date funds are first appropriated for this program, the Secretary shall develop minimum requirements for states to use in their applications. It is the intent of the Committee that the agency consult widely with interested parties in preparing its proposed minimum requirements. The Committee believes interested parties should include other federal government agencies and departments with interests or expertise on the issue of drug abuse and drug diversion. Then, after opportunity for public comment on those requirements, the Secretary shall identify the minimum requirements for the criteria to be used by the states in their grant applications. These requirements apply to states whether applying for an initial grant or support of an existing system.

To receive a grant under this section, a state must submit an application in a time, manner, and form that the Secretary may require. States planning to establish a drug monitoring program must include a cost estimate, and proposed criteria for information security, criteria for meeting uniform electronic formatting, criteria for the availability of information and limitation on access to program personnel, criteria for the use and disclosure of information, and criteria for access to the database and procedures to ensure the information in the database is accurate. 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 correction on behalf of the af-

fected 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.

A state must also include in its application a listing of penalties for misuse of information in their application, and disclose information regarding its state law, policies, and procedures, if any, regarding the purging of information from the database. A state will also have to demonstrate in its application that it has enacted legislation or regulations to permit the implementation of a controlled substance monitoring program. States requesting funds for improving existing systems must include all information required of states applying for a grant to establish a new program. In addition, a state requesting a grant for an existing program must describe its plan to enable the state program to achieve interoperability with border states drug monitoring programs.

In implementing a program 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 administration 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 an equivalent 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) number of refills ordered or as a first time request; (6) whether the drug was dispensed as a refill; (7) the date of dispensing; (8) the date of origin of the prescription; and, (9) such other information as may be required by state law to be reported under this subsection.

The state shall require manufacturers to report information in accordance with the electronic format specified by the Secretary. 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.

In implementing a controlled substance monitoring program, 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, which 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 authorities that certify that 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 research purposes. When providing information for research purposes, it shall not provide any individually identifiable information. Under this section, the state shall share information with another state with an approved application if the information is for the purpose of implementing the state's controlled substance monitoring program. This includes 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.

In consultation with practitioners, dispensers, and other relevant stakeholders, a state receiving a grant under this program shall establish a program to notify practitioners and dispensers of information that will help identify and prevent unlawful drug diversion. A state may 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 determinations of unlawful diversion should be based on a decision made by the monitoring authority itself, and that the monitoring authority have discretion to make any such decision.

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. In addition, nothing in this section shall be construed to supercede any Federal privacy right or confidentiality requirement. The Committee specifically notes that this section should not be read to supercede the confidentiality requirements set forth in 42 CFR part 2 and part 2A. Furthermore, nothing in this section shall be construed to create a Federal private right of action.

Not later than 180 days after enactment the Secretary, based on a review of existing state controlled substance monitoring programs, 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 three years after the date on which funds are first appropriated, the Secretary shall conduct a study on the progress

of states in establishing and implementing controlled substance monitoring programs. The study shall provide an analysis of the extent to which drug-monitoring programs have reduced inappropriate use, abuse, and diversion of controlled substances. The study shall also examine the feasibility of implementing a real time electronic monitoring program and the progress of States in achieving interoperability. In addition, the study shall examine the privacy protections in place by states with drug monitoring programs and evaluate the penalties that states have enacted for the unauthorized use and disclosure of information. The Secretary shall submit a report to Congress on the results of this study.

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 program or have made a good faith effort to meet the requirements of the program. This provision shall take effect three years after the date funds are first appropriated for this program. The Secretary will have discretion to determine which competitive grants should be subject to the preference requirement, and such preference shall only apply to grants that are solely awarded to states. 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.

States may establish an advisory council to assist in the establishment and implementation of the monitoring program. In establishing an advisory council, states 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 $15,000,000 in each of Fiscal Years 2006 and 2007. There is to be authorized $10,000,000 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

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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.

(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 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, 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).

(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 sub-

section (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 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)—

(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 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 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 appli-

cation, 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) 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 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.

(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), 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 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, 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) 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) 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) 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 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, 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) 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) 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 re-

sides 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) 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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