Congressional Testimony by the Prescription Monitoring Program Center of Excellence at Brandeis University

Committee on the Judiciary, Subcommittee on Crime and Terrorism, United States Senate

Enhancing Prescription Monitoring Programs' Ability to Impede the Prescription Drug Abuse Epidemic

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Good morning Chairman Whitehouse and distinguished members of the Subcommittee. My name is John Eadie. I am the Director of the Prescription Monitoring Program Center of Excellence at Brandeis University. Thank you for the opportunity to appear before you on behalf of the Center to discuss our work on enhancing Prescription Monitoring Programs' ability to impede the prescription drug abuse epidemic. We thank you for the honor of testifying on this critical matter.

The PMP Center of Excellence seeks to help end the prescription drug abuse epidemic in the United States without compromising accepted standards of pain management or the legitimate prescribing of controlled substances. In collaboration with the Alliance of States with Prescription Monitoring Programs, the Center provides academically sound and practice-relevant information, evaluation, and expertise to PMPs and their stakeholders. The Center is funded by a grant from the Department of Justice Bureau of Justice Assistance.

Our work is focused on helping PMPs identify and implement the most effective means possible for them to intervene in the prescription drug abuse epidemic. Our work includes:

- Identifying PMP Best Practices, including innovative, cutting edge developments that will increase PMP effectiveness.
- Encouraging innovative uses of PMP data.
- Assisting in the deployment and evaluation of interstate PMP data sharing.

- Advancing the methodology for assessing PMP effectiveness to identify, improve and extend the applications of PMPs.
- Analyzing PMP performance measures and identifying improvements in measurement.
- Analyzing and disseminating relevant information through a clearinghouse.
- Providing support to states and federal agencies.

The urgency of our work is based upon our knowledge that:

- Daily, 50 people in our nation die from unintentional prescription opioid overdoses and
- Daily, twenty times that number are admitted to hospital emergency departments for opioid overdoses.

At the PMP Center of Excellence, we believe that we must improve our methods for identifying and interdicting prescription opioid abuse in order to slow down and reverse this epidemic's ever rising toll.

Prescription Monitoring Programs collect from pharmacies information regarding prescriber, pharmacy, patient, and drug information regarding each controlled substance prescription dispensed within their states and, in some cases, prescriptions sent by mail order into their states. The data is compiled in each PMP's database and then made available to prescribers, pharmacies, law enforcement, health professional licensing agencies, and, depending on the state, to Medicaid Programs, medical examiners, drug courts, drug treatment programs and others. De-identified data is generally made available to researchers and evaluators and patients may see their own data in some states.

The rapid growth in states with prescription monitoring programs, with 48 states now having statutorily authorized PMPs, is a very hopeful accomplishment. The majority of these programs have been authorized since 2003, when the Harold Rogers Prescription Drug Monitoring Programs Grant program began. Administered by the Department of Justice's Bureau of Justice Assistance, the Harold Rogers' competitive grant program has stimulated growth and enhancements among the PMPs.

Funding provided by the NASPER program, as administered by the Substance Abuse and Mental Health Administration, is a formula grant program that has been important in assisting states' PMPs by supporting their operations.

The continued operation of PMPs and the significant enhancements called for to address the prescription drug abuse epidemic appear to call for continuation and expansion of both unique programs.

In addition to federal funding support, we need a rapid evolution of the PMPs into a new generation of even more effective systems, a new generation whose hallmark must be proactivity. The new generation will take advantage of technological advances and integrate them into the fabric of PMP operations. Many of the characteristics of the new generation are highlighted in the White House Office of National Drug Control Policy's new Prescription Drug Abuse Prevention Plan.

Interstate PMP Data Sharing --The first thing that must be completed is a new National Network of State PMPs that are interoperable through the Prescription Monitoring Information Exchange (PMIX) Hub which BJA, the IJSI Institute, and the Alliance of States with Prescription Monitoring Programs have been working to establish for six years. The Hub is operational and several states are in process of interconnecting, with support from the PMP Training and Technical Assistance Program and our Center at Brandeis University.

PMP Model Act provisions -- The foundation for much of the new generation of PMPs rests in the Alliance of States with Prescription Monitoring Programs' *PRESCRIPTION MONITORING PROGRAM MODEL ACT 2010 Revision* at (www.pmpalliance.org).

Section 7, Providing Prescription Monitoring Information

(a) The [designated state agency or entity] should review the prescription information. Such reviews should include but not be limited to:

(I) A review to identify information that appears to indicate if a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances. When such information is identified, the [designated state agency] should notify the practitioners and dispensers who prescribed or dispensed the prescriptions.

(II) A review to identify information that appears to indicate if a violation of law or breach of professional standards may have occurred. Whenever such information is identified, the [designated state agency] should notify the appropriate law enforcement and/or professional licensing, certification or regulatory agency or entity, and provide prescription information necessary for an investigation.

(b) The [designated state agency] is authorized to provide information in the prescription monitoring program upon request only to the following persons.

(I) Persons authorized to prescribe or dispense controlled substances or other drug required to be submitted under Section 5 of this Act, for the purpose of providing medical or pharmaceutical care for their patients or for reviewing information regarding prescriptions that are recorded as having been issued or dispensed by the requester.

(II) A patient who requests the patient's own prescription monitoring information, or of the parent or legal guardian of a minor child, in accordance with procedures established under [insert state statute granting individuals access to state held information concerning themselves].

(III) [Insert name or type of state boards and regulatory agencies that supervise or regulate a profession that is authorized for controlled substances or other drug required to be submitted under Section 5 of this Act activity] if the request is pursuant to an investigation or is pursuant to the agency's official duties and responsibilities.

(IV) Local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing controlled substances or other drug required to be submitted under Section 5 of this Act pursuant to the agency's official duties and responsibilities.

(V) [Insert state Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services] regarding Medicaid program recipients or Medicaid program providers.

(VI) [Insert titles of medical examiners, coroners or others authorized under law to investigate causes of deaths] for cases under investigation pursuant to their official duties and responsibilities.

(VII) Personnel of the [designated state agency] for purposes of administration and enforcement of this Act, or [insert state controlled substances act], [if any other state statute is applicable, insert "or" and reference the other statutes].

[Note: A state may determine to authorize additional agencies to request and receive prescription information including substance abuse treatment providers, worker's compensation board reviewers who are health care professionals, drug court judges, department of corrections' health care professional staff, and probation departments, if they cannot receive information under other provisions already authorized in (I) through (VII)]

(c) The [designated state agency] may provide information to public or private entities for statistical, research, or educational purposes after encrypting or removing the patient name, street name and number, patient ID number, and month and day of birth that could be used to identity individual patients and/or persons who received prescriptions from dispensers.

[Note: A state may choose to further restrict information released to researchers by encrypting or removing information that could be used to identify a prescriber, a pharmacy, or any other person.]

With this Model Act as the foundation, the following changes are indicated:

1. **Prescribers: proactive (unsolicited) reports** -- Some PMPs proactively analyze their databases and, when they identify probable doctor shoppers, they send an unsolicited report to the prescribers. Experience indicates such reports result not only in reducing the subsequent prescriptions obtained by the doctor shoppers but also in a significant increase in prescribers requesting solicited PMP data and in a general reduction in prescriptions to doctor shoppers, even those for whom no report is sent out. We need to increase PMP use of unsolicited reports by:
    a. Automating PMP analysis by developing algorithms that can be computer applied and validated.
    b. Automating unsolicited reports by sending out alerts by email or by computer generated letters that advise prescribers that they have been prescribing to a person who may be a doctor shopper and informing the prescriber how they can access the information regarding this person. Several PMPs are working to develop this capability.
    c. Automating follow-up, including tracking of prescriptions received by the probable doctor shopper subsequent to the unsolicited reports.
2. **Prescribers: requested (solicited) reports** - Upon request, PMPs provide prescription histories to prescribers so they can make clinically sound decisions prior to issuing prescriptions for controlled substances and can avoid being duped by doctor shoppers. This is generally done by PMPs providing web-portals through which prescribers may request data. We need to increase prescriber use of PMPs through:
    a. Making data more timely – in April, the Oklahoma PMP began collecting data from pharmacies at point of sale; we need to expand this to all PMPs.
    b. Making access seamless – Massachusetts PMP is moving to make its PMP interoperable with Electronic Health Records so prescribers can access the PMP from a single EHR sign-on; we need to expand this to all PMPs.
    c. Combing PMPs and e-Prescribing of Controlled Substances – PMPs should become interoperable with e-Prescribing systems so:
        i. Obtaining of an e-prescribing certification for controlled substances should be accepted by PMPs as authentication for access to PMP data.
        ii. As prescribers enter the name of a controlled substance drug for e-prescription, the patient's controlled substances history from the PMP pops up on their electronic device.

iii. As each e-prescription is sent to a pharmacy, a copy should be routed to the PMP database.

iv. As each e-prescription is dispensed, the PMP should match the pharmacy's dispensing record to the corresponding e-prescription from the physician to identify any alterations and, if any, report to the appropriate agency.

d. Considering with public and private third party payers the value of mandating prescribers to access PMP data prior to issuing the first controlled substance prescription and periodically thereafter, as a condition of payment.

i. Reimbursement to prescribers for any additional time will need to be considered.

ii. If such is required, third party payers will need automated assurance from the PMP that the prescriber accessed the PMP.

iii. As provided in the Office of National Drug Control Policy's new Prescription Drug Abuse Prevention Plan, the PMP Center of Excellence is planning a meeting with third party payers and PMPs for 2011; this subject will be explored at the meeting.

3. **Pharmacies: requested (solicited) reports and proactive (unsolicited) reports** -- It is imperative for pharmacists to request and review PMP data prior to dispensing prescriptions for controlled substances.

a. The interoperability of PMPs with Electronic Health Records should include providing data to pharmacies in the manner described above for prescribers.

b. The e-Prescribing of Controlled Substances should include the PMP interoperability described above.

c. PMPs should forward proactive (unsolicited) reports to pharmacists, just as to prescribers.

4. **Pharmacies: verifications prior to dispensing** – In addition to the above, automated systems need to be designed to assure that controlled substances prescriptions are only dispensed after appropriate verification that requirements have been met. For example, should mandatory prescriber education be established (which the Center strongly supports), the list of trained prescribers should be automatically checked before a prescription is dispensed. The factors identified in the 2009 GAO report should be reviewed prior to dispensing, including verification that the prescriber is currently licensed and registered with DEA, has no licensure or registration restrictions that would affect controlled substances prescribing, and is not deceased. Likewise, patients known

to be deceased should not be allowed to have prescriptions dispensed in their names. Pharmacies will need to be properly compensated for this new work.

5. **Law Enforcement Agencies** – Local, state and federal Law Enforcement agencies and investigators are essential users of PMP data. This can be seen in the relatively lower death rates of unintentional opioid deaths in California, New York and Texas, i.e. these states have a long history of providing PMP solicited reports and unsolicited reports to investigators with law enforcement authority. Increased use of PMP data by law enforcement is essential if we are to going to impede the prescription drug abuse epidemic. We need to increase PMP use by law enforcement by:
    a. Encouraging states to adopt policies that permit and encourage use of PMP data by law enforcement investigators.
    b. Updating state PMP systems to automate law enforcements' approved access to the PMP data.
6. **Health Professional Licensing Agencies** – Agencies such as State Medical Boards and State Pharmacy Boards need ready access to PMP data to investigate potential misconduct and inappropriate use of controlled substances, e.g. self-abuse, over prescribing, and offering drugs to solicit sexual favors. Likewise, PMPs need to analyze their data and forward unsolicited reports to licensing boards when patterns of possible misconduct are found. This process needs to be automated to the extent feasible.
7. **Other users of PMP data** – If the expansion of the prescription drug abuse epidemic is to be slowed and reduced, then other parties need to have access to PMP data. Some states permit some of the parties below to have access, but this needs to be regularized and expanded across the nation:
    a. State's Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services regarding Medicaid program recipients or Medicaid program providers.
    b. Appropriate Medicare personnel.
    c. Medical examiners, coroners or others authorized under law to investigate causes of deaths for cases under investigation pursuant to their official duties and responsibilities.
    d. Substance abuse treatment providers.
    e. Worker's compensation board reviewers who are health care professionals.
    f. Drug court judges.

g. Department of corrections' health care professional staff, and probation departments, (if they cannot receive information under law enforcement provisions).
h. The Indian Health Services, Veterans Administration, and Department of Defense health care system (not just their prescribers but also the health care clinical supervisors who oversee prescribing and dispensing within those systems).
i. Health care systems' peer review organizations in order to identify and intervene in prescriber and pharmacist over-prescribing and miss-prescribing as early as possible, i.e. before the practices rise to the level that licensure or law enforcement action are required.
j. Other third party payers' health professional care reviewers - this is not currently being done and will require careful design to protect all data, but given the nature and extent of the epidemic, it appears unwise not to develop means by which PMPs and other third party payers can meaningfully exchange information.

8. **Early Warning System** – Pioneering work by the Massachusetts Department of Public Health's PMP and the principal investigator at the Center has identified an important new function for PMP data. Using spatial analysis methodology to examine Massachusetts PMP data when the drug OxyContin was introduced and subsequent years, a rapid expansion of doctor shopping can be seen, beginning in the first year, 1996. Review of data for 2005, shows that doctor shopping for all opioids had become widespread across the state and was concentrated most heavily in five geographic areas. A geospatial comparison to hospital data on opioid overdoses and opioid related deaths shows the same five areas had the highest rates of overdoses and deaths. Had this analysis been possible in prior years, the MA PMP could have issued warnings before the overdoses and deaths became epidemic. Warnings could be sent to all community, state and national stakeholders including health care practitioners, law enforcement, education, substance abuse prevention and treatment organizations, schools, parent teacher organizations, religious organizations and other groups. We must learn from this and assure that this does not happen again. We need to:
    a. Fully develop the early warning methodology at the Center by obtaining data from other states that have already agreed to participate in a pilot development.
    b. After development, provide the methodology to those states that are equipped to do the analyses.

c. Provide a service for those states not equipped to do their own analysis, i.e. the states can forward de-identified/encrypted PMP data to the Center so we can apply the methodology and return analyzed reports to them.
d. Compile analyzed information at the Center in order to produce regional and national warning information as changes emerge.

9. **Concerns for youth** – In response to Surgeon General Regina Benjamin's initiative to examine prescription drug abuse among youth, the Center has worked with the Maine, South Carolina and Wyoming PMPs to examine prescribing and doctor shopper patterns. The data indicates an increase in youth who are obtaining opioid prescriptions, during and after high school. Most surprisingly, the Wyoming data on doctor shoppers shows that peak of doctor shopping is among those aged 30 to 39, with a very large number 29 and younger. This represents a drop in age of almost two decades for those most actively involved in doctor shopping, compared with earlier research. This serves as a call for us to analyze PMP data from many states as rapidly as possible and, if the pattern holds up in other states, to get the word out widely. The nation's efforts to curtail youthful abuse of prescription drugs may need to add a new focus on stemming doctor shopping and other forms of prescription diversion among younger persons.
10. **Mandatory Prescriber Education** – A majority of prescribers have insufficient training in the use of opioids and other prescription controlled substances to safely prescribe these drugs. Such education needs to include training in not only the proper use of the drugs but also the misuse of, abuse of, and addiction to these drugs by bona fide patients; the nature and extent of doctor shopping; the extent of theft, counterfeiting and forgery of a prescribers' prescription pads; and how to access and use PMP data. As noted above, such training should not only be required but technologically monitored by pharmacies prior to dispensing. In addition, PMPs should periodically review their databases to assure that prescribers were trained at the time their prescriptions were dispensed; non-compliance should be proactively reported by the PMP to DEA and the state professional licensing agency.