AMERICAN BAR ASSOCIATION

STANDING COMMITTEE ON SUBSTANCE ABUSE
PENNSYLVANIA BAR ASSOCIATION

REPORT TO THE HOUSE OF DELEGATES

RECOMMENDATION

1 RESOLVED, That the American Bar Association urges state, territorial and tribal legislative
2 bodies, and appropriate governmental agencies to develop comprehensive strategies to reduce the
3 incidence of prescription drug diversion and abuse, including the utilization of Prescription Drug
4 Monitoring Programs ("PDMP") designed with appropriate attention to the authenticity, security,
5 reliability, and integrity of patient information obtained, which provides:
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7 1. limitations on law enforcement agency access to reported information to ensure that
8 access is restricted to those acting within their official duties and conducting bona fide
9 investigations;
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11 2. appropriate notice to patients about the inclusion of their prescription information in
12 the PDMP; and
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14 3. appropriate penalties for any violations of patient privacy.

REPORT

I. STATEMENT OF THE PROBLEM

All patients, particularly those suffering from pain, should have access to all available prescription medications, including controlled substances, based on the best judgment of physicians. At the same time, national surveys indicate that the non-medical (or illicit) use of prescription drugs is a growing threat in the United States. The abuse of prescription drugs now ranks as the nation's second-most serious drug threat when measured by prevalence, registering 7.0 million past-month users in 2006 – more than the number of cocaine, heroin or methamphetamine users.[1] Most alarming, prescription drug abuse among young adults (18-25 year olds) increased from 5.4 percent in 2002 to 6.4 percent in 2006.[2] Most of this increase was driven by the non-medical use of pain relievers.[3]

While recognizing the need for effective pain management, the American Medical Association recently noted that there has been a 91.2 percent increase in deaths due to opioid poisoning between 1999 and 2002.[4] One recent study found that opioid abuse in 2001 cost a total of $8.6 billion.[5] The Journal of the American Medical Association also reported that in 2005 there were more than 100 million prescriptions for the analgesic hydrocodone/acetaminophen.[6] The prescriptions for this pain medication now far exceed the number of prescriptions for the second and third most-prescribed medications – cholesterol lowering atorvastatin, with 63 million prescriptions, and the antibiotic amoxicillin, with about 52 million prescriptions.[7] Another recently published study found that the number of serious drug side effects and deaths reported to the Food and Drug Administration more than doubled from

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[1] Substance Abuse and Mental Health Services Administration. (2007). *Results from the 2006 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-32, DHHS Publication No. SMA 07-4293). Rockville, MD. Prior to 2002, the survey name was the National Household Survey on Drug Abuse ("NHSDA"). The NSDUH presents national estimates on rates of use, numbers of use, and other measures related to illicit drugs, alcohol, and tobacco products. Measures related to mental health problems are also presented, including data on depression and the co-occurrence of substance use and mental health problems. NSDUH is the primary source of statistical information on the use of illegal drugs by the U. S. population. Conducted by the Federal Government since 1971, the survey collects data by administering questionnaires to a representative sample of the population through face-to-face interviews at the respondent's place of residence. The survey is sponsored by the Substance Abuse and Mental Health Services Administration ("SAMHSA"), U. S. Department of Health and Human Services, and is planned and managed by SAMHSA's Office of Applied Studies ("OAS").

[2] Ibid, page 22.

[3] Ibid. The rate of pain reliever use increased from 4.1 percent in 2002 to 4.9 percent in 2006. Nonmedical use of tranquilizers also increased over the 5-year period (from 1.6 percent to 2.0 percent).

[4] Journal of the American Medical Association, January 17, 2007, citing Paulozzi, LJ, et al. *Pharmaceoepidemiol Drug Saf.* 2006; 15:618-627.

[5] Clinical Journal of Pain. 22(8):667-676, October 2006.

[6] Journal of the American Medical Association, January 17, 2007, citing Paulozzi, LJ, et al. *Pharmaceoepidemiol Drug Saf.* 2006; 15:618-627.

[7] Journal of the American Medical Association, January 17, 2007, 249.

1998 to 2005.[8] The two top drugs listed in fatality reports were the pain medications oxycodone and fentanyl.[9]

The acquisition of prescription drugs for non-medical purposes occurs in several different ways. The most common source is believed to be acquisition from family or friends. Illicit online pharmacies are another source, as is traditional drug dealing in which prescription drugs are exchanged for money or something of monetary value. Yet another method is commonly referred to as "doctor shopping." This involves situations where an individual visits multiple doctors and receives multiple prescriptions for the drug that he seeks to abuse. Commonly, these separate prescriptions are then filled at separate pharmacies.

II. PRESCRIPTION DRUG MONITORING PROGRAMS

As part of an overall strategy that seeks to reduce the diversion and non-medical use of prescription drugs, Prescription Drug Monitoring Programs ("PDMP") are an important component in addressing one of the most common methods of diversion and abuse. Their origins in mechanisms to prevent health care and Medicaid fraud, PDMP aim to prevent "doctor shopping" to acquire narcotic prescriptions by facilitating sharing of information about a patient's prescriptions among authorized prescribers and pharmacies. PDMP help physicians and pharmacists share information about a patient's prescription history.

For example, if a patient claims to have pain and requests the analgesic hydrocodone/acetaminophen from his physician, without a PDMP, the physician will generally be left to rely on asking the patient about other medications or prescriptions, without an independent means to verify the answer. PDMP allow a physician to ensure that the patient is not already utilizing a prescription for the same or a similar product, thus feeding an addiction.

At present, there are 36 state-based PDMP. There are differences among state PDMP. For example, some PDMP monitor prescriptions listed in all Schedules (II, III, IV and V), while others only monitor prescription drugs in Schedule II or Schedules II and III.[10] With rare exception, non-controlled substance prescriptions are not the subject of PDMP monitoring.

PDMP have been proven effective in reducing prescription drug abuse. A recent study conducted for the U. S. Department of Justice, Office of Justice Programs, found that PDMP reduce the per capita supply of prescription pain relievers and stimulants and thus reduce the

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[8] Archives of Internal Medicine, Volume 167, Number 18, September 10, 2007.
[9] Ibid
[10] The Controlled Substances Act of 1970 established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances. Controlled substances are classified into five schedules based on their medicinal value and potential for abuse, addiction and dependence. Under the act, the Drug Enforcement Administration has the authority to regulate transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels. U. S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D. C.: May 2002), page 5.

possibility for abuse of these drugs.[11] The evidence in this study also suggests that states that are proactive in their approach to drug regulation are typically more effective in reducing the per capita supply of prescription pain relievers and stimulants than states that are reactive in their approach to regulation.[12] Studies by state PDMP reveal that the programs do not deter doctors from prescribing narcotic pain medications. A study in Massachusetts found that from fiscal year 1996 to fiscal year 2006 the total number of Schedule II prescriptions increased by 141.8%, reflecting a 71% increase in the number of people receiving prescriptions, and a 43% increase in the average number of prescriptions per individual.[13] States with PDMP have also found that the vast majority of reports are obtained by health care providers to support the medical and pharmaceutical care of their patients.[14] PDMP thus have become a crucial part of the struggle against prescription drug abuse and addiction.

There is no nationwide PDMP or federal database that tracks prescriptions. However, the federal government is supportive of state-level PDMP. The U. S. Department of Justice's Harold Rogers Prescription Drug Monitoring Program provides grants to states for developing and strengthening their PDMP. States are eligible for these grants if they have in place, or have pending, an enabling statute or regulation requiring the submission of prescription data on controlled substances to a central database.[15]

Although the PDMP is not a covered entity subject to the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rules, providers and dispensers who are required under state PDMP laws to provide information to their PDMP remain covered entities under HIPAA. State PDMP laws cannot alter HIPAA coverage or application. Thus, if a state PDMP law requires disclosure that is not permitted under HIPAA or is exempted from HIPAA coverage, HIPAA will preclude disclosure. Conversely, HIPAA allows disclosure pursuant to state law for the reporting of disease or injury, conduct of public health surveillance or investigation, including public health, and oversight activities, including health care fraud and abuse detection.[16] A state PDMP needs to identify regulatory exceptions under HIPAA for each aspect of its operations (for example, fraud or abuse, criminal referrals, disciplinary actions by licensing boards).[17] A covered entity under HIPAA must make reasonable efforts to limit

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[11] Simeone R. and Holland L. *Executive Summary: An Evaluation of Prescription Drug Monitoring Programs,* September 1, 2006, Office of Justice Programs, Bureau of Justice Assistance (No. 2005PMBXK189). At the time of the study, 20 states had implemented systems to monitor their prescription and sale of drugs identified as controlled substances by the U. S. Drug Enforcement Administration. Another 23 states were in the process of designing or planning to design such systems. The authors of the study attribute this growth to the U. S. Department of Justice's Harold Rogers Prescription Drug Monitoring Program.

[12] Ibid

[13] Katz, N.P., Audet, A., Bilansky, A., Eadie, J., Kim, M. L., Kreiner, P., Panas, L., Thomas, C., Carrow, G. *Prescription Monitoring of Medical and Non-Medical Schedule II Opioid Use in Massachusetts: 1996-2006*. Fourth National Conference on State Prescription Monitoring Programs. Developing Strategies to Ensure Health and Safety. Thursday, December 6, 2007 - Friday, December 7, 2007.

[14] *An Assessment of State Prescription Monitoring Program Effectiveness and Results*. Alliance of States with Prescription Monitoring Programs, Version I, November 30, 2007.

[15] Simeone R. and Holland L. *An Evaluation of Prescription Drug Monitoring Programs,* September 1, 2006, Office of Justice Programs, Bureau of Justice Assistance (No. 2005PMBXK189), page 1.

[16] See 45 CFR 164.506(c); 45 CFR 164.512(b), (d).

[17] See 45 CFR 160.203.

disclosure to the minimum necessary to accomplish the purpose of the disclosure. State legislation on PDMP should provide for the integrity of the reported information, deletion of out of date information, and limited to agencies acting within their duties and conducting bona fide criminal investigations.

States that have enacted PDMP laws have included strict confidentiality protection from the improper use of the system and include penalties for the knowing disclosure or using information other than what the law authorizes.

For example, under Kentucky's electronic PDMP, the authorized users of its information are statutorily delineated; the knowing misuse of the data can result in a felony conviction and the PDMP is statutorily accountable for ensuring that only authorized users receive its data.[18] Kentucky law also prohibits any person who receives PDMP data from disclosing information, unless required by a court.[19] Kentucky PDMP advises data recipients of this prohibition.[20] Nevada's law similarly protects the confidentiality of its PDMP information by requiring a court order for disclosure to non-authorized entities.[21] In addition, Nevada's Board of Pharmacy has legal authority to discipline and fine an individual for violating the confidentiality law.[22]

Improper prescribing practices place a significant financial burden on the public health care system, and in the event of concomitant criminal activity, the court system and all its attendant agencies, including probation.[23] Substantial cost savings can arise from the control of illicit prescriptions.[24] In a time of fiscal uncertainties, society could utilize such savings to fund other unmet health care needs of Americans.

III. RELATED ABA POLICY POSITIONS

The American Bar Association has several policies that address long-term solutions to dependence on alcohol or other drugs.

At the 1972 Midyear Meeting, the House of Delegates approved the Uniform Alcoholism and Intoxication Treatment Act, which provides for treatment of alcoholics and intoxicated persons instead of subjecting such persons to criminal penalties, establishes facilities and machinery for treatment of such persons, and provides for voluntary commitment to a treatment facility or involuntary commitment by court order.

[18] U. S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D. C.: May 2002), page 18.
[19] Ibid, page 19.
[20] Ibid
[21] Ibid
[22] Ibid
[23] Ibid
[24] Generally, states have been able to establish a PDMP with the $350,000 implementation grant (currently increased to $400,000) provided through the U. S. Department of Justice's Harold Rogers Prescription Drug Monitoring Program. Electronic mail from Edward Jurith to Valerie Adelson and Barbara Howard, April 18, 2007.

At the 1975 Midyear Meeting, the American Bar Association reaffirmed its support for the Uniform Alcoholism and Intoxication Treatment Act drafted by the National Conference of Commissioners on Uniform State Laws and urged states that have not already done so to utilize the newly available federal funding (P. L. No. 93-282) to implement its provisions. The American Bar Association also generally reaffirmed its support for the principle of decriminalization of alcoholism.

At the 1994 Midyear Meeting, the House of Delegates approved a policy supporting development of a comprehensive, systemic approach to addressing the needs of defendants with drug and alcohol problems through multidisciplinary strategies that include coordination among the criminal justice, health, social service and education systems, and the community. The policy urges the courts to adopt certain treatment-oriented, diversionary drug court programs as one component of a comprehensive approach. The policy also urges bar associations to facilitate the development of such programs that result in dismissal of drug-related charges upon the completion of drug rehabilitation.

At the 1995 Annual Meeting, the House of Delegates endorsed the U. S. Sentencing Commission's proposal to amend federal sentencing guidelines to eliminate differences in sentences based on drug quantity for offenses involving crack verses powder cocaine, and assign greater weight in drug offense sentencing to other factors that may be involved in the offense, such as weapons used, violence, or injury to another person.

At the 1995 Annual Meeting, the House of Delegates approved a policy urging other bar associations to join the American Bar Association in developing and encouraging initiatives aimed at preventing inhalant abuse.

At the 1996 Annual Meeting, the House of Delegates approved a policy supporting legislation that protects the confidentiality of personally identifiable health information in either paper or electronic form and that such legislation should include privacy protections that ensure three specified protections. The policy encourages, in the absence of legislative mandate, the parallel development of a code of fair health information practices, which should promote the confidentiality and protection against misuse of personally identifiable health information.

At the 1997 Annual Meeting, the House of Delegates approved a policy supporting the removal of legal barriers to the establishment and operation of approved needle exchange programs that include drug counseling and drug treatment referrals in order to further scientifically-based public health objectives to reduce HIV infection and other blood-borne diseases and in support of the American Bar Association's long-standing opposition to substance abuse.

At the 1999 Midyear Meeting, the House of Delegates approved a policy that supports federal legislation that: (1) explicitly acknowledges individuals' rights to privacy of their health care information; (2) protects the confidentiality of personally identifiable health information from any source, including medical records, electronic data and genetic material; and (3) ensures six specified principles. The policy encourages, in the absence of a federal legislative mandate,

the development of strong institutional and organizational policies that. adhere to such principles to protect the privacy and confidentiality of doctor/patient communication and protect against misuse of personally identifiable health information.

At the 2004 Annual Meeting, the House of Delegates approved a policy urging federal, state, territorial and local governments to eliminate policies that sanction discrimination against people seeking treatment or recovery from alcohol or other disease, including specific recommendations in the area of public benefits.

At the 2005 Annual Meeting, the House of Delegates approved a policy urging all state, territorial and local legislative bodies and governmental officials to repeal laws and discontinue practices that permit insurers to deny coverage for alcohol or drug related injuries or losses covered by accident and sickness insurance policies that provide hospital, medical and surgical expense coverage; the policy also supports the 2001 amendment by the National Association of Insurance Commissioners to its model law, the Uniform Accident and Sickness Policy Provision law, for injuries involving alcohol or drugs, permitting coverage in accident and sickness insurance policies that provide hospital, medical and surgical expense coverage.

At the 2006 Annual Meeting, the House of Delegates approved a policy urging all federal, state, territorial and local legislative bodies and governmental agencies to adopt laws and polices that require health and disability insurers who provide coverage for the treatment of both abuse of and dependence on drugs and alcohol to do so in a manner that is based on the most current scientific protocols and standards of care, so as to significantly enhance the likelihood of successful recovery for each patient.

At the 2007 Annual Meeting, the House of Delegates approved a policy affirming the principle that dependence on alcohol or other drugs is a disease and supporting the principle that insurance coverage for the treatment of alcohol and drugs disorders should be at parity with that for other diseases.

Respectfully submitted,

Randall M. Kessler, Esquire
Chair
Standing Committee on Substance Abuse
August 2008

GENERAL INFORMATION FORM

Submitting Entity: Standing Committee on Substance Abuse

Submitted By: Randall M. Kessler, Chair, Standing Committee on Substance Abuse

1. Summary of Recommendation.

The American Bar Association recognizes the growing problem of prescription drug abuse and that in confronting this problem, state, territorial and tribal legislative bodies, and governmental agencies should consider comprehensive strategies that foster and encourage the prescribing of medications for effective pain management while at the same time reduce the incidence of prescription drug diversion and abuse.

If strategies addressing prescription drug diversion include the utilization of Prescription Drug Monitoring Programs ("PDMP"), such programs should be designed with appropriate attention to the authenticity, security, reliability, and integrity of patient information obtained, including limitations on law enforcement agency access to reported information to ensure that access is restricted to those acting within their official duties and conducting bona fide investigations, and contain appropriate notice to patients about the inclusion of their prescription information in the PDMP, with appropriate penalties for any violations of patient privacy.

2. Approval by Submitting Entity.

Approved by the Standing Committee on Substance Abuse on April 17, 2007. Approved again by the Standing Committee on Substance Abuse, with revisions, on August 11, 2007, November 12, 2007, February 9, 2008 and April 15, 2008.

3. Has this or a similar recommendation been submitted to the House or Board previously?

Yes. This recommendation was withdrawn by the Standing Committee on Substance Abuse prior to action by the House of Delegates in August 2007 and February 2008.

4. What existing Association policies are relevant to this recommendation and how would they be affected by its adoption?

The proposed recommendation will supplement the following American Bar Association policies:

At the 1972 Midyear Meeting, the House of Delegates approved the Uniform Alcoholism and Intoxication Treatment Act, which provides for treatment of alcoholics and intoxicated persons instead of subjecting such persons to criminal penalties, establishes

facilities and machinery for treatment of such persons, and provides for voluntary commitment to a treatment facility or involuntary commitment by court order.

At the 1975 Midyear Meeting, the American Bar Association reaffirmed its support for the Uniform Alcoholism and Intoxication Treatment Act drafted by the National Conference of Commissioners on Uniform State Laws and urged states that have not already done so to utilize the newly available federal funding (P. L. No. 93-282) to implement its provisions. The American Bar Association also generally reaffirmed its support for the principle of decriminalization of alcoholism.

At the 1994 Midyear Meeting, the House of Delegates approved a policy supporting development of a comprehensive, systemic approach to addressing the needs of defendants with drug and alcohol problems through multidisciplinary strategies that include coordination among the criminal justice, health, social service and education systems, and the community. The policy urges the courts to adopt certain treatment-oriented, diversionary drug court programs as one component of a comprehensive approach. The policy also urges bar associations to facilitate the development of such programs that result in dismissal of drug-related charges upon the completion of drug rehabilitation.

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At the 2004 Annual Meeting, the House of Delegates approved a policy urging federal, state, territorial and local governments to eliminate policies that sanction discrimination against people seeking treatment or recovery from alcohol or other disease, including specific recommendations in the area of public benefits.

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At the 2007 Annual Meeting, the House of Delegates approved a policy affirming the principle that dependence on alcohol or other drugs is a disease and supporting the principle that insurance coverage for the treatment of alcohol and drugs disorders should be at parity with that for other diseases.

5. What urgency exists which requires action at this meeting of the House?

Action at this meeting of the House of Delegates will allow the American Bar Association to provide guidance to state, territorial and tribal legislative bodies, and governmental agencies regarding the enactment of legislation to authorize and implement PDMP.

6. Status of Legislation. (If applicable.)

Not applicable.

7. Cost to the Association. (Both direct and indirect costs.)

   Not applicable.

8. Disclosure of Interest. (If applicable.)

   Edward H. Jurith, Esq., will present the report to the House of Delegates. Mr. Jurith is General Counsel, Office of National Drug Control Policy.

9. Referrals.

   In April 2008, the recommendation was referred to the Section of Individual Rights and Responsibilities and the Section of Science and Technology Law for review and support.

   In May 2008, the recommendation was referred to the following entities for review and support:

   Standing Committees
   Standing Committee on Legal Aid and Indigent Defendants
   Standing Committee on Medical Professional Liability
   Standing Committee on Pro Bono and Public Service

   Special Committees and Commissions
   Special Committee on Bioethics and the Law
   Commission on Domestic Violence
   Commission on Homelessness and Poverty
   Commission on Law and Aging
   Commission on Lawyer Assistance Programs
   Commission on Mental and Physical Disability Law
   Council on Racial and Ethnic Justice
   Commission on Women in the Profession
   Commission on Youth at Risk

   Sections, Divisions and Forums
   Criminal Justice Section
   Section of Family Law
   General Practice, Solo and Small Firm Division
   Labor and Employment Law Section
   Law Student Division
   Section of Health Law
   Section of Litigation

Senior Lawyers Division
Section of State and Local Government Law
Tort Trial and Insurance Practice Section
Young Lawyers Division

10. Contact Person. (Prior to the meeting.)

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11. Contact Person. (Who will present the report to the House.)

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EXECUTIVE SUMMARY

Summary of Recommendation

The American Bar Association recognizes the growing problem of prescription drug abuse and that in confronting this problem, state, territorial and tribal legislative bodies, and governmental agencies should consider comprehensive strategies that foster and encourage the prescribing of medications for effective pain management while at the same time reduce the incidence of prescription drug diversion and abuse.

If strategies addressing prescription drug diversion include the utilization of Prescription Drug Monitoring Programs ("PDMP"), such programs should be designed with appropriate attention to the authenticity, security, reliability, and integrity of patient information obtained, including limitations on law enforcement agency access to reported information to ensure that access is restricted to those acting within their official duties and conducting bona fide investigations, and contain appropriate notice to patients about the inclusion of their prescription information in the PDMP, with appropriate penalties for any violations of patient privacy.

Summary of the Issue, Which the Recommendation Addresses

All patients, particularly those suffering from pain, should have access to all available prescription medications, including controlled substances, based on the best judgment of physicians. At the same time, national surveys indicate that the non-medical (or illicit) use of prescription drugs is a growing threat in the United States. The acquisition of prescription drugs for non-medical purposes occurs in several different ways. The most common source is believed to be acquisition from family or friends. Illicit online pharmacies are another source, as is traditional drug dealing in which prescription drugs are exchanged for money or something of monetary value. Yet another method is commonly referred to as "doctor shopping." This involves situations where an individual visits multiple doctors and receives multiple prescriptions for the drug that he seeks to abuse. Commonly, these separate prescriptions are then filled at separate pharmacies.

As part of an overall strategy that seeks to reduce the diversion and non-medical use of prescription drugs, PDMP are an important component in addressing one of the most common methods of diversion and abuse. PDMP aim to prevent "doctor shopping" to acquire narcotic prescriptions by facilitating sharing of information about a patient's prescriptions among authorized prescribers and pharmacies. PDMP help physicians and pharmacists share information about a patient's prescription history.

Explanation of How the Proposed Policy Position Will Address the Issue

This recommendation would authorize the American Bar Association to provide guidance to state, territorial and tribal legislative bodies and governmental agencies regarding the enactment of legislation to authorize and implement PDMP.

Summary of Any Minority Views or Opposition, Which Have Been Identified

None to date, however, the Section of Individual Rights and Responsibilities and the Section of Science and Technology Law raised concerns with prior iterations of this recommendation in August 2007 and February 2008. In summary, these concerns focus on confidentiality protection for patients from the improper use of PDMP or information from the system. The current version has been amended to accommodate these concerns.