

Delaware Prescription Drug Action Committee

RECOMMENDATIONS

October 21, 2013

Presented to Governor Jack Markell

Delaware Prescription Drug Action Committee Recommendations

October 21, 2013

Governor Jack Markell
150 William Penn Street
Dover, Delaware 19901

Dear Governor Markell:

The Prescription Drug Action Committee (PDAC) is pleased to have completed the first step in our work toward reducing the burden of prescription drug abuse, misuse, and diversion within the State of Delaware. We have conducted thirteen public meetings and over twenty-five subcommittee meetings in which we developed an initial set of recommendations toward addressing this pressing issue. A summary of these recommendations is presented on pages 5-7 of this report.

The PDAC has a broad and diverse membership base that includes behavioral health partners, community-based organizations, health information technology staff, hospital systems, law enforcement officials, pain medicine specialists, pharmaceutical representatives, physical medicine, professional regulations, public health and retail pharmacy, as well as private and public payers of health care, registered and advanced practice nurses.

We look forward to implementing a robust course of action, and continuing our work to find a comprehensive solution to this critical issue that greatly affects our state's health and well-being. Thank you for your leadership and support!

Sincerely,

Karyl T. Rattay, MD, MS
Director, Delaware Division of Public Health
Chair, Prescription Drug Action Committee

Randeep Kahlon, MD, FACS
Immediate Past President, Medical Society of Delaware
Director, Orthopedic Education and Research, Christiana Care
Vice-Chair, Prescription Drug Action Committee

TABLE OF CONTENTS

EXECUTIVE SUMMARY 3

SUMMARY OF RECOMMENDATIONS 5

POLICY RECOMMENDATIONS 5

PROGRAM RECOMMENDATIONS 6

BACKGROUND ON PRESCRIPTION DRUG ABUSE AND MISUSE 8

What is Drug Overdose Mortality? 8

What is the Epidemic of Drug Overdose Mortality in Delaware? 8

Why Focus On Prescription Drug Abuse and Misuse? 9

What are the Contributing Factors to Prescription Drug Abuse and Misuse? ... 13

Aggressive Marketing of Opioids 13

Changes in Clinical Pain Management 13

Direct-to-Consumer Marketing 14

Diversion 15

Growing Use of Prescription Opioids 15

DELAWARE PRESCRIPTION DRUG ACTION COMMITTEE

RECOMMENDATIONS 16

Recommendations Mitigating the Effects of Contributing Factors 16

Table 1. Policy Recommendations 19

 Prescription Monitoring Program 19

 Law Enforcement Education 19

 Provider Education 20

 Hospice 20

Table 2. Program Recommendations 21

 Prescription Monitoring Program 21

 Data Tracking and Technology 21

 Provider Education 21

 Public Education and Engagement 22

 Access to Treatment 22

 Drug Disposal 22

DELAWARE PRESCRIPTION DRUG ACTION COMMITTEE MEMBERS 23

GOVERNMENT 23

COMMUNITY ORGANIZATIONS 24

DELAWARE PRESCRIPTION DRUG ACTION SUBCOMMITTEE MEMBERS 25

ACCESS TO TREATMENT 25

BEST PRACTICES 25

DATA TRACKING AND IMPACT 26

PROVIDER EDUCATION 27

PUBLIC EDUCATION 28

EXECUTIVE SUMMARY

Over the last two decades, the drug overdose mortality rate has accelerated rapidly both nationwide and in Delaware. The overwhelming majority of drug overdose mortality deaths have been caused by prescription drug abuse and misuse, particularly in the opioid pain reliever category. Several factors have contributed to this recent epidemic, such as an increase in the aggressive marketing of opioids, changes in clinical pain management that has affected physicians' prescribing behaviors and practices, an escalation of direct-to-consumer marketing, and an overall growth in the use of prescription opioids. Activities outside the context of prescribing have also contributed significantly to the challenge, including drug diversion resulting from pharmacy and home medicine cabinet thefts, often by friends or family, as well as extensive recreational use of prescription opioids.

At the same time, under-assessment and under-treatment of pain in Delaware and nationally continues as an equally compelling public health problem, as documented in the June 2011 congressionally mandated Institute of Medicine report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*.¹ Taken together, these public health challenges underscore the critical importance of promulgating balanced public policies that meaningfully and measurably curb misuse, abuse, and diversion while not interfering with access to quality care addressing suffering for people in pain.

To help address these issues, Governor Markell established the Delaware Prescription Drug Action Committee (PDAC) in February 2012. The Division of Public Health and the Medical Society of Delaware lead the PDAC. Given the broad nature of these public health issues, the PDAC is comprised of a diverse set of government and community stakeholders organized into five subcommittees: access to treatment, best practices, data tracking and impact, provider education, and public education. The PDAC subcommittees have drafted a list of recommendations centered on enhancing data tracking and technology, promoting prevention, developing professional education initiatives, and ensuring delivery of quality treatment. These recommendations align with and complement the balanced comprehensive approach to drug control described in the *National Drug Control Strategy 2010* and subsequent progress reports.² It is anticipated that these PDAC recommendations will help mitigate the factors that have contributed to the prescription drug abuse and misuse epidemic in Delaware, while protecting access to quality pain care.

¹ National Academies of Science. <http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>.

² Office of National Drug Control Policy strategic reports 2010-2012. <http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf>,

Frequent evaluation of the impact on misuse, abuse, and access to quality pain care will be an essential ongoing aspect for implementing these recommendations. PDAC membership stands ready to offer its interdisciplinary expertise in an ongoing advisory role necessary for developing and conducting these evaluations, together with other key stakeholders, as part of the critical next phase in activating the recommendations outlined in this report.

SUMMARY OF RECOMMENDATIONS

POLICY RECOMMENDATIONS

Prescription Monitoring Program

- Require practitioners with controlled substance licenses to register for access to the Prescription Monitoring Program (PMP). The Delaware PMP is a system that collects information on all controlled substance (schedule II-V) prescriptions. This information is used to promote improved professional practice and patient care.
- Enable provider authorized support staff to delegate access to the PMP via their own log-in identification and password.
- Require substance abuse treatment centers to use the PMP to evaluate patient risk of abuse.
- Require pharmacists/dispensers to obtain a PMP patient profile when there is a suspicion of abuse-seeking behaviors. The patient profile is a report on a patient's controlled substance prescription history.
- Eliminate the 72-hour exemption for reporting dispensing of controlled substances to the PMP. Currently, physicians are not required to report prescriptions for controlled substance if the prescription is for 72 hours of medication or less.

Law Enforcement Education

- Standardize continuing education of law enforcement regarding controlled substance related abuse and impairment.

Provider Education

- Require all prescribers that write controlled substance prescriptions and pharmacists to complete 2 hours of continuing education training. Two hours of prescriber training will focus on safe and effective prescribing methods. For pharmacists, training will focus on recognizing patient abuse-seeking behaviors. This will be part of the professional education already required with no new additional hours.
- The Regulation 31 is guidelines for use of controlled substances for the treatment of pain. Require controlled substance prescribers to take a one hour, one time only CE on Delaware specific prescription drug abuse and pain management topics to include: the PMP, Delaware Regulation 31 and other state-specific programs and policies. This will be part of the professional education already required with no new additional hours.

Hospice

- Require hospice agencies to implement a uniform procedure to dispose of controlled substances after a patient passes away.

SUMMARY OF RECOMMENDATIONS

PROGRAM RECOMMENDATIONS

Prescription Monitoring Program (PMP)

- Link the PMP to the Delaware Health Information Network. The Delaware Health Information Network is a health data system that facilitates and supports the needs of consumers, health plans, policy makers, providers to share real time data and improve the quality of healthcare.
- Implement multi-state sharing of the Delaware PMP data to promote and improve patient care in collaboration with other states.

Data Tracking and Technology

- Integrate multiple data sources to develop a robust surveillance system to better understand the impact of abuse, misuse, and diversion on Delawareans.
- Implement electronic prescribing for controlled substances to increase patient care and safety, and reduce fraud and abuse.
- While the PMP is designed primarily for law enforcement and clinical use, the PMP is an important component of population-based surveillance. Additional support should be allocated to allow the state to identify and measure trends to increase effectiveness of prevention programs.
- PDAC should build quality improvement and evaluation into all proposed interventions to measure results and impact.

Provider Education

- Develop and deploy an Academic Detailing team (contractors) that will provide face-to-face consultation on key health topics (i.e., PMP). Academic Detailing is a non-commercial based face-to-face education outreach to prescribers, typically done by physicians, pharmacists or nurses. The goal is to change prescribing of drugs to be consistent with medical evidence, support patient safety, and improve patient care.
- Develop and deploy a provider education outreach campaign that focuses on responsible prescribing.

Public Education and Engagement

- Launch a statewide public education and outreach campaign targeting kids and families. This outreach campaign will be based upon the school nurse partnership started in the Red Clay School District.
- Develop and maintain an annotated catalog of quality educational resources and local referral sources. Although the location of this is to be determined,

implementation will be done in partnership with the Delaware Division of Public Health.

SUMMARY OF RECOMMENDATIONS

PROGRAM RECOMMENDATIONS (Continued)

- Increase support to and collaboration with community coalitions and other partners that focus on prevention to further build capacity and share resources.

Access to Treatment

- Increase access to substance abuse treatment that includes outpatient, inpatient, community services, and research.
- Begin process to develop a “pain center of excellence” in Delaware. A pain center of excellence is a center that focuses on best practices in pain research and education for medical, nursing, pharmacy, dental, and other health professionals.
- Permit a pilot program for Basic Life Support first responders to use Narcan[®] in ambulances. The medicine is used to prevent or reverse the effects of opioids, which can be helpful with reducing drug overdoses.

Drug Disposal

- Implement long term drug take-back solution to increase opportunities for people to dispose of unwanted or unused medications. Federal guidance expected late 2013.

BACKGROUND ON PRESCRIPTION DRUG ABUSE AND MISUSE

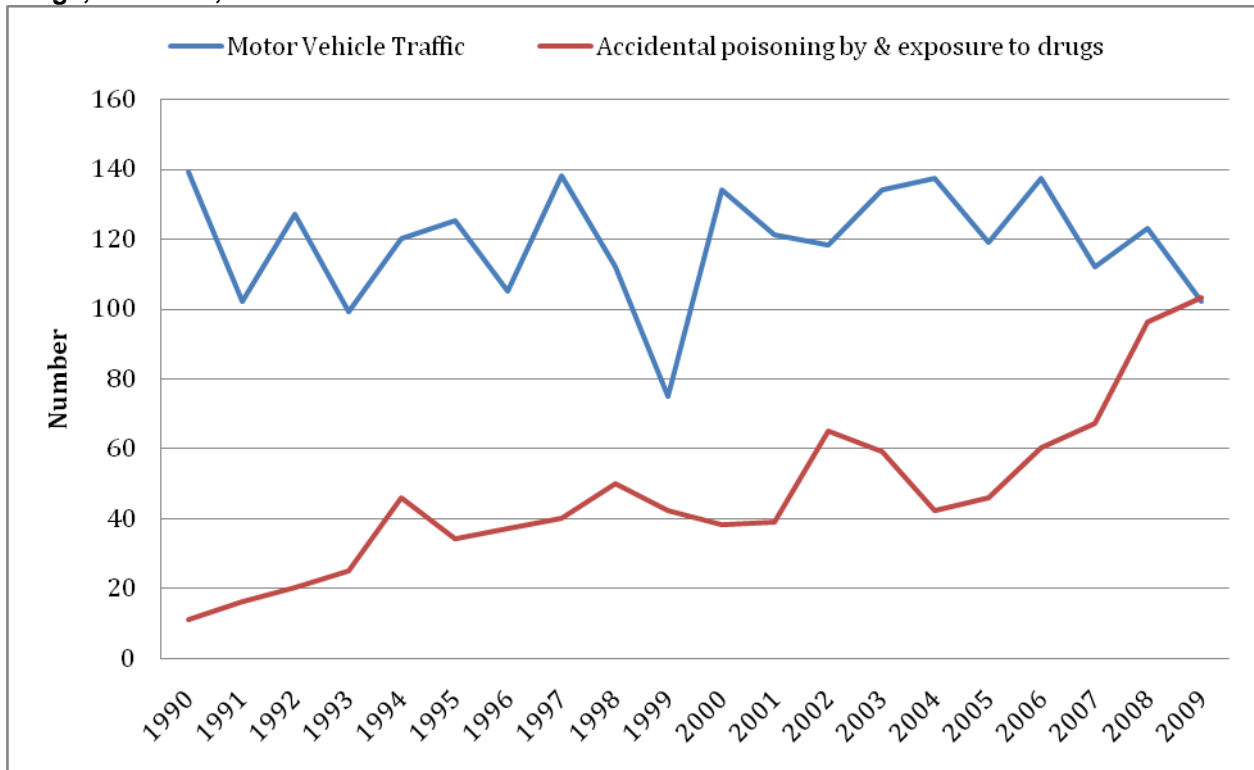
What is Drug Overdose Mortality?

According to the Delaware Health Statistics Center, drug overdose mortality includes deaths from poisonings by and exposure to drugs, regardless of intent (e.g., homicide, suicide, undetermined death and unintentional death) or type of drug.³ Drug overdose mortality excludes decedents from adverse events caused by drugs as part of medical treatment, deaths indirectly related to drug use (e.g., motor vehicle crashes), and newborn deaths associated with the mother’s drug use.

What is the Epidemic of Drug Overdose Mortality in Delaware?

In 2010, more Delawareans died from drug overdoses than from any other cause of injury. In Delaware between 1999 and 2010, the number of deaths due to drug overdoses increased by almost three-fold, rising from 50 deaths in 1999 to 144 deaths in 2010. As shown in Figure 1, the number of deaths in Delaware due to accidental poisoning by and exposure to drugs has increased dramatically. By 2009, more Delawareans had died from unintentional drug overdoses than from motor vehicle accidents.⁴

Figure 1. Number of Deaths due to Motor Vehicle versus Accidental Poisoning by and Exposure to Drugs, Delaware, 1990-2009.



³ Drug overdose deaths are defined by ICD-10 codes X40-X44, X60-X64, X85, and Y10-Y14.

Source: State of Delaware, Division of Public Health, Delaware Health Statistics Center, 2012.

In Delaware, characteristics of individuals who died due to drug overdoses changed little in the ten years between 1999 and 2010:

- Whites still accounted for the bulk (90 percent) of all drug overdoses with white males making up half of the total drug overdose deaths and white females accounting for another 40 percent; however, increases are seen among blacks and whites.
- The majority of drug overdoses were unintentional. White men accounted for more unintentional drug overdose deaths than any other race/sex category; and
- Decedents aged 45-54 years still had the highest mortality rate.

The increasing trend in drug overdose mortality rates appeared in both men and women. Between 1999 and 2010, the male drug overdose mortality rate nearly doubled and the female drug overdose mortality rate more than tripled. In 2010, the male drug overdose mortality rate was 45 percent higher than the female rate (19.6 deaths per 100,000 males versus 13.5 deaths per 100,000 females).⁴

Why Focus On Prescription Drug Abuse and Misuse?

According to the Delaware Health Statistics Center, the overwhelming majority of drug overdose deaths involved one or more prescription drugs. Specifically, of the 144 drug overdose deaths in 2010:

- 77 percent involved one or more prescription drugs. Of the prescription drug deaths, opioids and central nervous system depressants (including barbiturates and benzodiazepines prescribed for anxiety and/or sleep problems) were the most commonly listed substances associated with drug overdose mortality;⁵
- 62 percent of all drug overdose deaths involved opioid pain relievers (OPR). Of the OPR deaths, oxycodone, methadone, and fentanyl were the most commonly listed drugs;⁵
- 40 percent involved at least one illicit drug. Of the illicit drug deaths, cocaine was the most commonly listed drug, followed by heroin;⁵ and
- 82 percent of all drug overdose deaths involved multiple substances, which could have included multiple drugs, a drug and alcohol, or some combination of multiple drugs and alcohol. Alcohol alone was involved in 8 percent of all drug overdose deaths.⁵

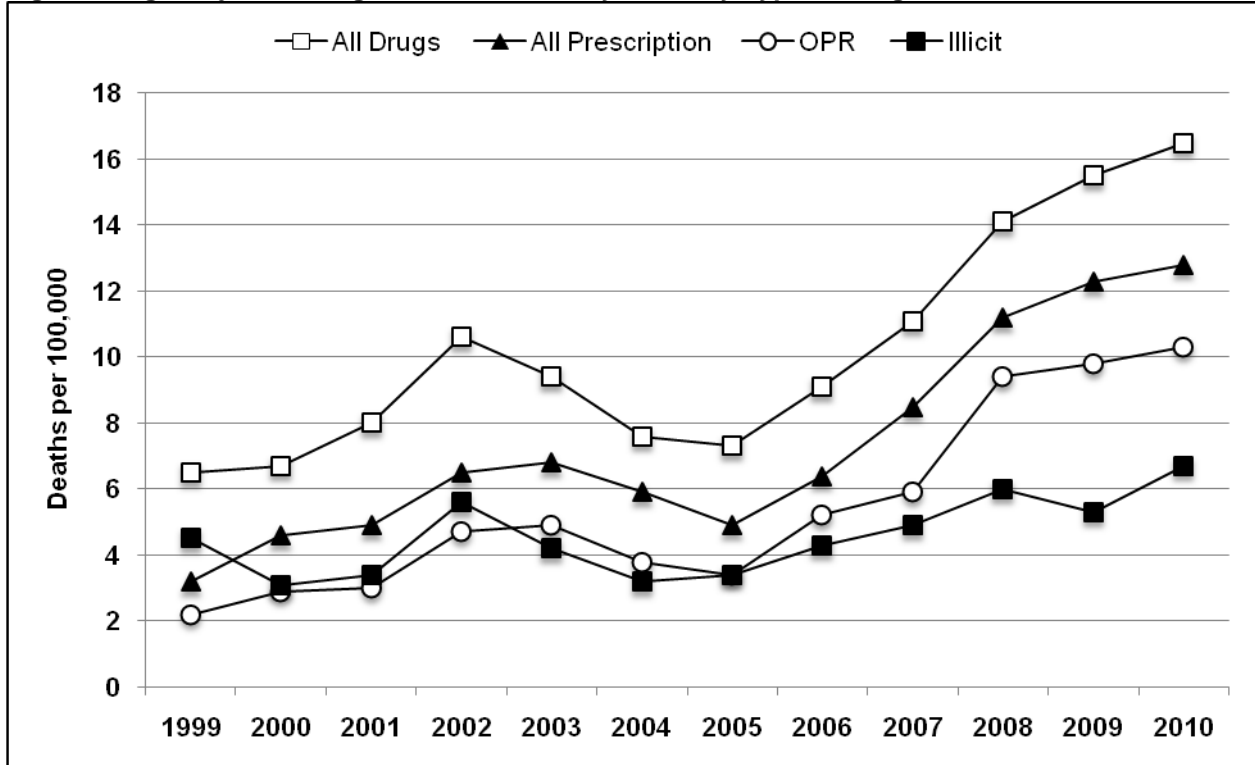
⁴ Drug Overdose Mortality in Delaware – 2010. Retrieved from Delaware Health Statistics Center: <http://dhss.delaware.gov/dhss/dph/hp/files/drugoverdose2010.pdf>.

⁵ ICD-10 codes T36-T50 were used to identify specific drug types. While T-codes located in the secondary cause of death fields are normally the way specific drugs are identified, an examination of the data by the Delaware Health Statistics Center revealed that not all drugs mentioned were coded in this way. To gain as much detail as possible, specific drugs or substances were identified by querying the secondary cause of death T-codes and text descriptions, as well as the text descriptions located in the 'how the injury occurred' field. Even with this multi-tiered approach, there were some drug overdose deaths with no detailed information about the specific substances involved.

As shown in Figure 2, these numbers have increased considerably over the period between 1999 and 2010. In particular:

- Mortality rates based on deaths where prescription drugs were implicated increased nearly four-fold between 1999 and 2010;
- Opioid pain reliever (OPR)-associated death rates were almost five times higher in 2010 than in 1999;
- Illicit drug-associated deaths increased by 49 percent.

Figure 2. Age-Adjusted Drug Overdose Mortality Rates by Type of Drug, Delaware, 1999-2009.



Source: State of Delaware, Division of Public Health, Delaware Health Statistics Center, 2013. Mortality rates are adjusted to the 2000 US Standard Population.

Notable changes were also apparent between 1999 and 2010 data:

- The disparity in the rates of male and female decedents was reduced; and
- The distribution of intent shifted so fewer deaths were unintentional, and more were self-inflicted and undetermined.

Between 1998 and 2008, treatment admissions for prescription painkillers increased 460 percent nationwide.⁶ In Delaware, treatment admissions have increased more than 2,000% in the same period.⁷ In addition, in a 2008 survey of teenagers nationwide, the

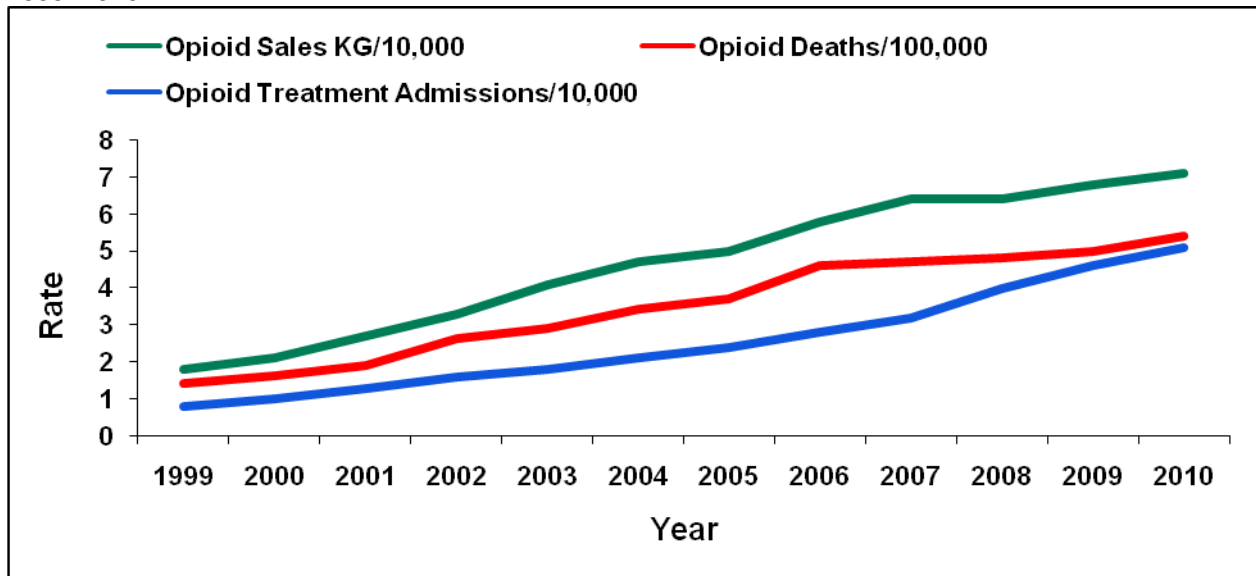
⁶ Ohio Prescription Drug Abuse Task Force. Final Report Task Force Recommendations. 2010.

⁷ Center for Behavioral Health Statistics and Quality. (2012). Substance Abuse and Mental Health Services Administration. Retrieved from:

National Center on Addiction and Substance Abuse at Columbia University (CASA), reported that teenagers were able to purchase prescription drugs more easily than beer.⁸ In the 2011 CASA survey, 23 percent of teens know at least one friend or classmate who uses prescription drugs without a prescription to get high.⁹ In the 2011 Delaware Youth Risk Behavior (YRBS) Survey, 16% of high school students thought there was no risk or only a slight risk in taking prescription drugs that were not prescribed for them.¹⁰

Nationally, a November 2011 CDC report stated that 15,000 people died as a result of overdoses of prescription painkillers in 2008, more than three times the number in 1999. This does not even consider morbidity and cost to the health care system and society as a whole.¹¹ As evidenced in Figure 3, the rates of opioid sales, opioid treatment admissions, and opioid deaths nationwide have increased tremendously – and in parallel – between 1999 and 2010.¹¹

Figure 3. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, United States, 1999–2010.



Source: CDC Vital Signs: Overdoses of Prescription Opioid Pain Relievers, United States, 1999-2010.

http://www.dasis.samhsa.gov/web/tedsweb/tab_year.choose_year_web_table?t_state=DE

⁸ National Survey of American Attitudes on Substance Abuse XIII: Teens and Parents, 2008. Retrieved from: <http://www.casacolumbia.org/templates/PressReleases.aspx?articleid=533&zoneid=66>.

⁹ National Survey of American Attitudes on Substance Abuse XIII: Teens and Parents, 2011. Retrieved from: <http://www.casacolumbia.org/templates/PressReleases.aspx?articleid=650&zoneid=87>.

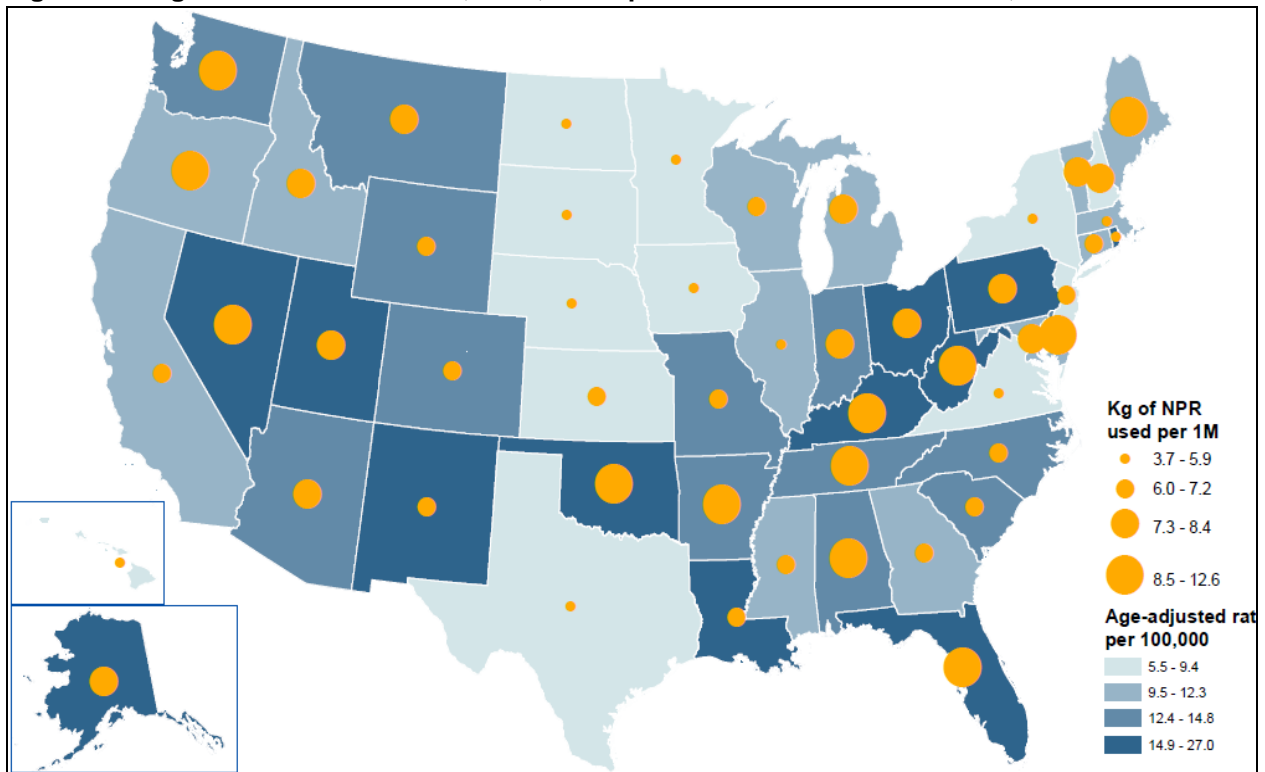
¹⁰ Centers for Disease Control and Prevention. (2011). Youth Risk Behavior Survey. Retrieved from: www.cdc.gov/yrbs.

¹¹ CDC VitalSigns. Prescription Painkiller Overdoses in the US. November 2011. Retrieved from: <http://www.cdc.gov/vitalsigns/painkilleroverdoses/#>.

In 2008, Delaware had the ninth highest drug overdose death rate nationwide, per 100,000 people. In 2010, Delaware ranked fifth in the rate of opioid pain reliever sales, per 10,000 people, only behind Florida, Nevada, Oregon, and Tennessee.¹¹

For comparison across states, Figure 4 below shows the drug overdose death rate for each state in 2008 (by shade) which Delaware is in the third worst category. It also shows the narcotic pain reliever (NPR) sales rate for each state per 1,000 (M equals 1,000 in legend below) people in 2010 (by size of circle), with Delaware among the highest in 2010. Note that no one region dominates in opioid pain reliever sales rates or drug overdose death rates. However, states in the Great Plains region generally have both the low drug overdose death rates and opioid pain reliever sales rates.

Figure 4. Drug Overdose Death Rate, 2008, and Opioid Pain Reliever Sales Rate, 2010.



National Vital Statistics System, 2008; Automated Reports Consolidated Orders System, 2010.

Locally, geographic disparities may exist in the incidence and prevalence rates of prescription drug abuse and misuse. Southern Delaware, specifically rural Sussex County, may be more adversely affected by the prescription drug abuse epidemic compared to the rest of the state, potentially due to relatively poor access to primary care and mental health providers.¹²

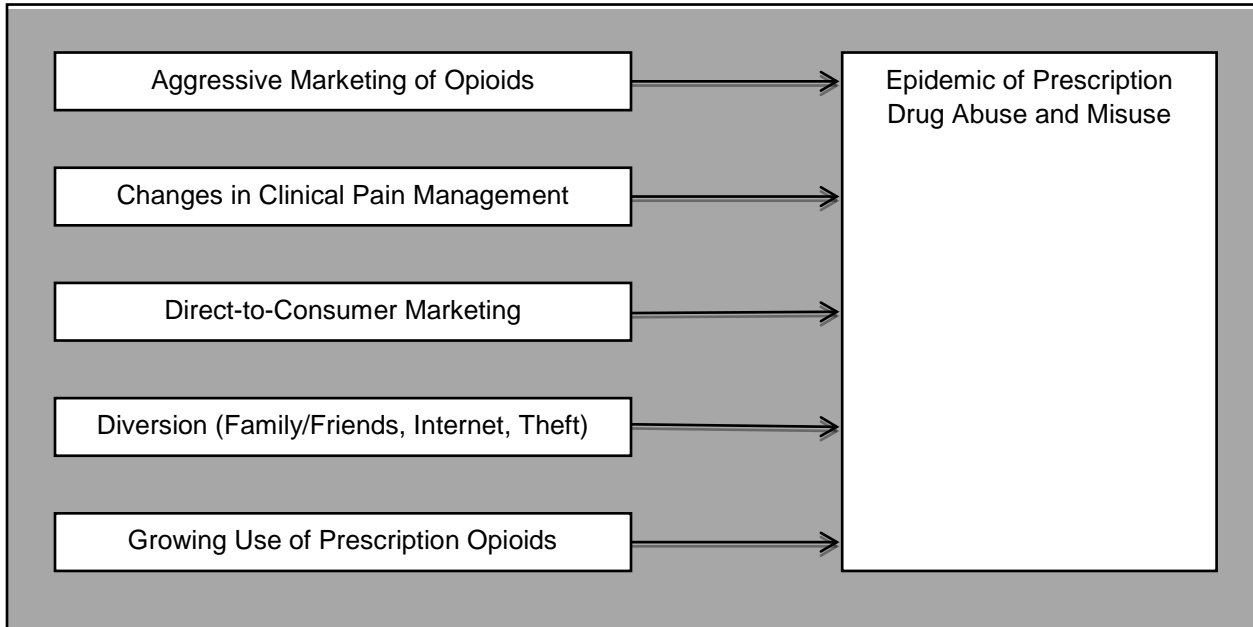
¹² Health Professional Shortage Areas. Sussex County, Delaware. Retrieved from: <http://hpsa.findthedata.org/d/d/Delaware/Sussex>.

What are the Contributing Factors to Prescription Drug Abuse and Misuse?

Figure 5 summarizes the major causes or “contributing factors” to the recent epidemic of prescription drug abuse and misuse. As evidenced by this figure, these contributing factors involve recent changes at the commercial, medical, and societal levels.

(Note: This is by no means an exhaustive list of the contributing factors.)

Figure 5. Contributing Factors to Prescription Drug Abuse and Misuse.



Source: Derived from the Task Force Recommendations, Ohio Prescription Drug Abuse Task Force.

Aggressive Marketing of Opioids

The advent of aggressive marketing strategies by pharmaceutical companies to prescribers has resulted in the growing use of prescription opioids.⁶ In one highly publicized case, the Drug Enforcement Agency (DEA) considered Purdue’s marketing of OxyContin to be aggressive, claiming that Purdue Pharma was promoting OxyContin for treating non-cancer related pain.^{13,14}

Changes in Clinical Pain Management

Growing cognition by health care providers on the need to address documented under-treatment of pain in the last two decades prompted changes in clinical pain management practice guidelines, quality measures, and associated national and state prescribing policies to encourage increased access to quality pain care. Yet more

¹³ FDA Warning Letters and Notice of Violation Letters to Pharmaceutical Companies; FDA issues warning letter to Purdue Pharma for the marketing of OxyContin, 2003. OxyContin Class Action Lawsuit to Proceed. CMAJ, SEPT. 30, 2003; 169 (7). 699-b.

¹⁴ Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem, United States General Accounting Office, Report to Congressional Requestors, December 2003.

recent data and reports have focused almost exclusively on the rising misuse and abuse problem and call for the need to restrict prescribing practices in response. As a result, a patchwork of federal and state pain policies were enacted over the past decade, including legislation in most states establishing and operationalizing electronic prescription monitoring programs. Some policies avoided imposing barriers on the prescribing of controlled substances, while others significantly increased restrictions on prescribing, sometimes to the extent that they directly impede access to quality pain care.^{6,15}

These regulatory changes are not necessarily commensurate with physicians' knowledge and training on clinical pain assessment, management, and prescribing practices. Most doctors will treat a significant number of patients with pain problems or substance abuse issues throughout their careers.¹⁶ However, assessing and addressing pain or risk factors for substance abuse and treatment are only a small part of most physicians' medical training and many physicians may receive only a few hours of education and hands-on experience regarding the safe use, responsible prescribing, and potential consequences of opioids or substance abuse prevention, detection, and treatment during their training.^{6,16} As a result, health care providers may be unprepared to deal with the complexity of issues arising from the treatment of chronic pain and/or prescription drug abuse.⁶ Some physicians over-prescribe combinations of medications to treat pain while others choose not to work with patients who have ongoing pain issues because of fear of prescription drug abuse, regulatory enforcement action, liability, or personal or professional biases.¹⁷ Health care providers are increasingly aware they may face medical board inquiry, law enforcement investigation, and disciplinary action if they have high numbers of pain-related cases or prescribe significant amounts of pain medications.¹⁶ Additionally, health care providers are often confronted with the difficult position of judging if certain patients are deceiving them to obtain prescriptions to feed their addictions or sell to others, or if they are legitimately in need of these medications to treat their pain.⁶

Direct-to-Consumer Marketing

Moreover, direct-to-consumer (DTC) marketing has taken an increasingly important position in terms of public awareness of prescription drug products. Surveys have shown that over 90 percent of the public reports seeing prescription drug advertisements.^{6,18} In 1989, the pharmaceutical industry collectively spent

¹⁵ University of Wisconsin Pain & Policy Studies Group State by State Pain Policy Report Card and Evaluation Guide 2006-2008.

¹⁶ Oregon State University College of Pharmacy; Pain management failing as fears of prescription drug abuse rise, January 2010.

¹⁷ Chronic Pain Management, Kathryn Hahn. The Rx Consultant. December 2009.

¹⁸ Frank, Richard, et al. Trends in Direct-to-Consumer Advertising of Prescription Drugs, Kaiser Family Foundation, February 2002.

approximately \$12 million on DTC marketing, compared to roughly \$2.38 billion in 2001, an increase of almost 200-fold in only 12 years.¹⁹ As a result of this change in marketing, the Institute for Safe Medication Practices reports that 78 percent of primary care physicians have been asked for drugs that their patients saw advertised on television and 67 percent concede that they sometimes grant patients' requests for medications that are not clinically indicated. As a result, many patients may be over-medicated and/or are using medications unnecessarily.⁶

Diversion

Drug diversion, the unlawful channeling of regulated drugs from medical sources to the illicit marketplace, is supplying large quantities of controlled substances to fuel addiction.⁶ Studies indicate the most common method of diversion is through a family member or a friend. Data from the 2010 National Survey on Drug Use & Health (NSDUH) reveal that 55 percent of individuals aged 12 or older who used pain relievers non-medically in the past 12 months obtained the drug they most recently used from "a friend or relative for free."²⁰ Another 11.4 percent bought them from a friend or relative and 4.8 percent took them from a friend or relative without asking. Only 4.4 percent got pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet.¹⁷ Other methods of prescription drug diversion include using multiple pharmacies and physicians to acquire controlled substances for nonmedical purposes.⁶

Growing Use of Prescription Opioids for both Medical and Non-Medical Purposes

Increased prescription drug use has resulted in the exposure of a much greater proportion of the public to highly addictive, "legal" substances.⁶ Through this exposure, which occurs many times for legitimate pain issues, individuals have a higher likelihood of becoming addicted, and thus, the demand for the drugs increases. The introduction of new, extended-release prescription opioids (e.g., OxyContin[®]) has contributed toward the growing use of prescription opioids.^{6,13} In fact, according to IMS, a pharmaceutical market intelligence firm, Hydrocodone combined with acetaminophen (Vicodin[®]) was the most prescribed drug nationwide in 2010.²¹

This growth has resulted in prescription drugs to be the second most abused category of drugs (not including alcohol) nationally, following marijuana.²² In 2007, an estimated 23.1 million people nationwide needed treatment for a substance use disorder.²³

¹⁹ Palumbo, F.B., Mullins C.D., The Development of Direct-to-Consumer Prescription Drug Advertising Regulation. Food and Drug Law Journal: Analyzing the Laws, Regulations, and Policies Affecting FDA Regulated Products, Vol. 54 (3) 2002.

²⁰ 2010 National Survey on Drug Use and Health: Volume I. Summary of National Findings.

²¹ IMS Institute for Healthcare: "The Use of Medicines in the United States: Review of 2010," April 2011.

²² Office of National Drug Control Policy, 2010.

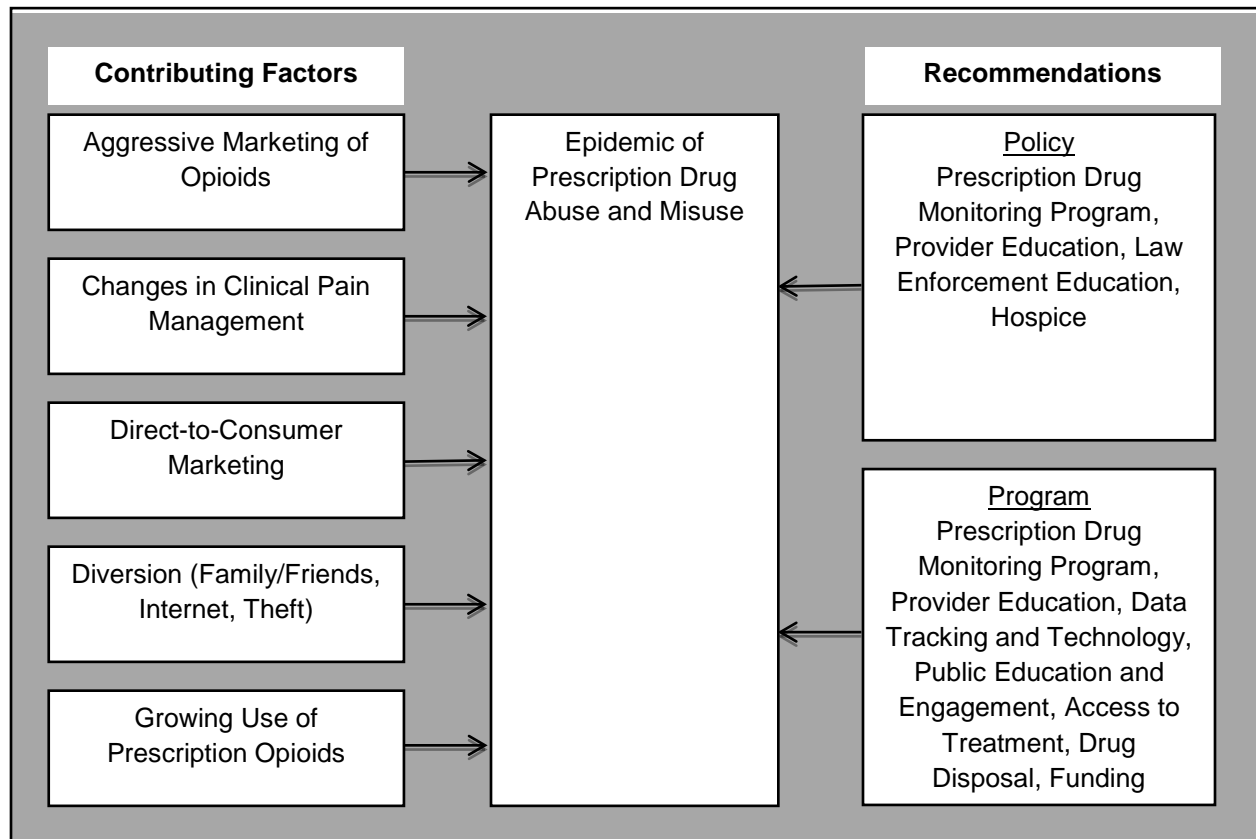
²³ 2007 National Survey on Drug Use and Health: Volume I. Summary of National Findings.

Prescription Drug Action Committee Recommendations
Recommendations to Mitigate the Effects of Contributing Factors

To mitigate the effects of these contributing factors requires a robust strategy that is both comprehensive and intensive. To meet this demand, the PDAC and its five subcommittees designed a thorough and focused set of recommendations. The five subcommittees are Access to Care, Best Practices, Data Tracking and Impact, Provider Education, and Public Education. Each subcommittee recommendation was presented to the full PDAC for discussion, voted upon, and then prioritized by impact for addressing the epidemic.

These recommendations can be categorized into two meaningful groups: policy recommendations and program recommendations. Pages 5 to 7 of this document outline each of the recommendations by group.²⁴ Figure 6 depicts how the recommendations are intended to mitigate the contributing factors of the epidemic of prescription drug abuse and misuse.

Figure 6. Effect of Recommendations on Mitigating Contributing Factors to Prescription Drug Abuse and Misuse.



²⁴ Note that these recommendations are not intended to stand on their own, but must be part of a larger strategy. For example, the recommendations cannot plausibly stop aggressive marketing of opioids but may reduce the unintended effects of this marketing on the public.

As shown in Figure 6, the recommendations centered on provider education, for example, are designed to improve clinical pain management. Correspondingly, the recommendations related to data tracking and technology may curb diversion as well as to better define the problem. Finally, recommendations for public education are anticipated to counteract the detrimental effects of aggressive marketing, direct-to-consumer marketing, and diversion

Tables

Tables 1 and 2 on pages 19 to 22 provide the policy and program recommendations, respectively, by category. The potential partners, costs, and time frame for each recommendation are listed. Note that the “short” time frame suggests that recommendation will be completed in less than 24 months whereas the “long” time frame indicates that the recommendation will be achieved in 24 months or more. Budgets with costs are currently under development and will be updated when more information is obtained.

Finally, it is essential to note that the development and implementation of these recommendations is an ongoing process, and accordingly, the PDAC will be meeting routinely to improve upon these recommendations.

Logic Model

The logic model on the following page summarizes the approach and other anticipated outcomes from implementation of the PDAC recommendations. As a logic model, this figure first shows how various resources and organizations (“Inputs”) perform various tasks (“Activities”). The success of these activities can be assessed through various measures (“Outputs”). In time, the success of these Outputs can be gauged through various outcomes, both in the near-term (“Short-Term Outcomes”) and longer-term (“Long-Term Outcomes”).

Logic Model for the Delaware Prescription Drug Action Committee.

Inputs	Activities (Recommendations)	Outputs	Short-Term Outcomes	Long-Term Outcomes
<ul style="list-style-type: none"> • Delaware Division of Public Health (DPH) • Medical Society of Delaware • State Support • Legislative Support • Committee and Subcommittees Comprised of Invested Members from Private and Public Sectors • Prescription Drug Monitoring Program • Data Sources (CDC, Delaware Health Statistics Center, Law Enforcement Data, National Center on Addiction and Substance Abuse, State Surveillance Surveys, Youth Risk Behavior Survey) • Leveraged In-Kind Funds 	<ul style="list-style-type: none"> • Enhancing Efforts Centered on Access to Treatment for Prescription Drug Abuse. • Establishing Best Practices for Prevention and Treatment of Prescription Drug Abuse (e.g., e-Prescription Data on Controlled Substances, Methods to Identify Fraud and Diversion) • Ensuring Timely Data Tracking and Sharing Across Systems • Conducting Statewide Provider Education Campaign • Conducting Statewide Public Education Campaign 	<ul style="list-style-type: none"> • Prescription Monitoring Program • Best Practices for Prevention and Treatment of Prescription Drug Abuse • Comprehensive Data Reports on the Incidence and Prevalence of Prescription Drug Abuse • Completed Statewide Provider Education Campaign • Completed Statewide Public Education Campaign 	<ul style="list-style-type: none"> • Increase in Safe and Consistent Access to Pain Management • Increase in e-Prescribing for Controlled Substances • Recommendations for Quality Improvement Based on Data Reports • Increase in Provider Knowledge of Proper Opioid Prescribing • Increase in Public Awareness of the Dangers of Prescription Drug Abuse 	<ul style="list-style-type: none"> • Effective, High Quality Services for Pain Management • Decrease in Addiction, Overdose Injuries and Mortality Rates Based on Best Practices and Assessed Through Data Tracking • Increased awareness of Prescription Drug Abuse Among Providers and Public

Table 1. Policy Recommendations.

Short = <6 Months; Long = >1 Year

Category	Policy Recommendation's in Brief	Potential Partners	Cost	Time Frame
Prescription Monitoring Program	Require practitioners with controlled substance licenses to register for access to the Prescription Monitoring Program.	MS, DPR	TBD	Short
	Enable provider authorized support staff to delegate access to the Prescription Monitoring Program via their own log-in identification and password.	MS, DPR	TBD	Short
	Require substance abuse treatment centers to use the Prescription Monitoring Program to evaluate patient risk of abuse.	MS, DPR, DSAMH	TBD	Short
	Require pharmacists to obtain a Prescription Monitoring Program patient profile when there is a suspicion of abuse-seeking behaviors.	DPR, PS	TBD	Short
	Eliminate the 72-hour exemption for reporting dispensing of controlled substances to the Prescription Monitoring Program.	MS,DPR	TBD	Short
Law Enforcement Education	Standardize continuing education of law enforcement regarding controlled substance related abuse and impairment.	DS	TBD	Short

TABLE OF ABBREVIATIONS

DHIN - Delaware Health Information Network DOE - Delaware, Department of Education DPR - Delaware, Division of Professional Regulation DPH - Delaware, Division of Public Health DSAMH - Delaware, Division of Substance Abuse & Mental Health DS - Delaware, Department of Safety and Homeland Security DEA - Delaware, Drug Enforcement Agency	EMS - Emergency Medical Services HC - Hospice Community HS - Hospital Systems OSHS - Delaware, Office of Safe and Healthy Students MS - Medical Society of Delaware PS - Delaware Pharmacist Society TC - Treatment Centers
--	---

Table 1. Policy Recommendations. *Continued.*

Short = <6 Months; Long = >1 Year

Category	Policy Recommendation	Potential Partners	Cost	Time Frame
Provider Education	Require all prescribers with a controlled substance registration and pharmacists to complete 2 hours of continuing education (CE) training. Two hours of prescriber training will focus on safe and effective prescribing methods. For pharmacists, training will focus on recognizing patient abuse seeking behaviors. No new hours required.	DPH, MS	\$25 k	Short
	Require controlled substance prescribers to take a one hour, one time only CE on Delaware specific prescription drug abuse and pain management topics to include: the Prescription Monitoring Program, Delaware Regulation 31 and other state specific programs and policies. No new hours are required.	DPH, MS	Cost is included as part 2 hours of Continuing Education.	Short
Hospice	Require hospice agencies to implement a uniform procedure to dispose of controlled substances after a patient passes away.	HC, DPH	TBD	Short

Table 2. Program Recommendations.

Short = <6 Months; Long = >1 Year

Category	Program Recommendation's in Brief	Potential Partners	Cost	Time Frame
Prescription Monitoring Program	Link Delaware Prescription Monitoring Program to Delaware Health Information Network.	DHIN, DPR, DPH	TBD	Long
	Implement multi-state sharing of the Delaware Prescription Monitoring Program data.	DSAMH, DPR, MS	TBD	Long
Data Tracking and Technology	Integrate multiple data sources to develop a robust surveillance system.	DPH, DPR	\$150 k	Long
	Implement electronic prescribing for controlled substances.	MS, DHIN, DPH	\$750 k	Long
	While the Prescription Monitoring Program is designed primarily for law enforcement and clinical use, the Prescription Monitoring Program is an important component of population-based surveillance. Additional support should be allocated.	DPH	Included in the \$150 k above	Short
	PDAC should build quality improvement and evaluation into all proposed interventions.	All	TBD	Short
Provider Education	Develop and deploy an Academic Detailing team (contractors) that will provide face to face consultation on key health topics (i.e., PMP). Implement multi-state sharing of the Delaware Prescription Monitoring Program data.	MS	\$300 k	Long
	Develop and deploy a provider education outreach campaign that focuses on responsible prescribing.	MS, DPH	\$200 k	Short

Table 2. Program Recommendations. *Continued.*

Short = <6 Months; Long = >1 Year

Category	Program Recommendation	Potential Partners	Cost	Time Frame
Public Education and Engagement	Launch a statewide public education and outreach campaign based upon the successful school nurse partnership.	DPH, DOE	\$1.7 M	Short
	Develop and maintain an annotated catalog of quality educational resources and local referral sources.	DSAMH	TBD	Short
	Increase support to and collaboration with community coalitions and other partners that focus on prevention.	DSAMH	TBD	Long
Access to Treatment	Increase access to substance abuse treatment that includes outpatient, inpatient, and community services and research.	DSAMH, TC	TBD	Long
	Begin process to develop a “pain center of excellence” in Delaware	DPH, MS, HS, EMS	TBD	Long
	Permit a pilot program for Basic Life Support first responders to use Narcan®.		TBD	Short
Drug Disposal	Implement long term drug take-back solution; federal guidance expected late 2013.	DEA, DPH, DPR, OSHS	\$500 k	Short

DELAWARE PRESCRIPTION DRUG ACTION COMMITTEE MEMBERS

GOVERNMENT

Karyl T. Rattay, MD, MS (Chair)

Director, Delaware Division of Public Health
Delaware Department of Health and Social Services

Gerard (Jerry) Gallucci, MD, MHS

Chief Medical Officer
Delaware Department of Health and Social Services

Anthony Brazen, DO, MBA

Chief Medical Officer, Division of Medicaid and Medical Assistance
Delaware Department of Health and Social Services

Carolyn Kane

Office Manager, Office of the Secretary
Delaware Department of Health and Social Services

Christina Showalter, JD

Deputy Attorney General
Director, Consumer and Fraud Protection
Delaware Department of Justice

Donna Forrest

Medical Component Manager, Workers Compensation
Delaware Department of Labor

Terry Pepper

Deputy Principal Assistant
Delaware Department of Safety and Homeland Security

Martha Gregor (Retired), LCSW, CADC

Director of Behavior Prevention
Delaware Department of Services for Children, Youth and Their Families

James L. Collins

Deputy Secretary
Director, Professional Regulations
Delaware Department of State

Dave Dryden, RPh, JD

Director, Office of Controlled Substances
Delaware Department of State

Sandra S. Retzky, DO, RPh, MPH

Healthcare Fellow
Office of Senator Christopher A. Coon's Office

DELAWARE PRESCRIPTION DRUG ACTION COMMITTEE MEMBERS

COMMUNITY ORGANIZATIONS

Randeep Kahlon, MD, FACS (Vice Chair)

Immediate Past President
Medical Society of Delaware

Wayne Smith

President and CEO
Delaware Healthcare Association

Jan Lee, MD

Executive Director
Delaware Health Information Network

Leslie Verucci, MSN, RN, CNS, CRNP, APRN-BC

President
Delaware Nurses Association

Debra J. Pace, DMD

Member
Delaware State Dental Society

John Goodill, MD

President
Delaware Pain Initiative

John Rule, MD, MBA

Medical Director
Delaware Physicians Care, Inc. (Aetna)

Mary Nordenson, RN, MHM

Director, Quality
Delaware Physicians Care, Inc. (Aetna)

Pat Carol-Grant, RPh

Executive Secretary
Delaware Pharmacists Society

Sheila Grant, RN, BSN, CHPN

President
Hospice and Palliative Care Network of Delaware

Susan Ricciardi, MD

Highmark Blue Cross Blue Shield of Delaware

Phil Kim, MD

Medical Society of Delaware

Deborah (Debbie) Hamilton

Pharmaceutical Research and Manufacturing Association of America

DELAWARE PRESCRIPTION DRUG ACTION SUBCOMMITTEE MEMBERS

ACCESS TO TREATMENT

Chair: John Rule, MD

Delaware Physician Care, Inc. (Aetna)

rulej@aetna.com

Staff: Cheryl Botbyl

Medical Society of Delaware

cheryl.botbyl@medsocdel.org

Bruce Lorenz

Thresholds Inc.

blorenz@thresholdsinc.com

Marc Richman

Division of Substance Abuse and Mental Health

Delaware Department of Health and Social Services

marc.richman@state.de.us

Phil Kim, MD

Medical Society of Delaware

phshkim@yahoo.com

Wayne Smith

Delaware Healthcare Association

wayne@deha.org

Donna Forrest

Medical Component Manager, Workers Compensation

Delaware Department of Labor

Donna.forrest@state.de.us

BEST PRACTICES

Chair: James L. Collins

Professional Regulations

james.collins@state.de.us

Staff: J. Kevin Massey

Delaware Department of Health and Social Services, Division of Public Health

jonathan.massey@state.de.us

Gerard (Jerry) Gallucci, MD, MHS

Delaware Department of Health and Social Services,

gerard.gallucci@state.de.us

Martha Gregor

Department of Services for Children, Youth and Families

martha.gregor@state.de.us

Randeep Kahlon, MD

Medical Society of Delaware

rkahlon@fsortho.com

DELAWARE PRESCRIPTION DRUG ACTION SUBCOMMITTEE MEMBERS

Mary Nordenson

Delaware Physician Care, Inc. (Aetna)
nordensonm@aetna.com

Leslie Verucci, MSN, RN, CNS, CRNP, APRN-BC

Delaware Nurses Association
lverucci@christianacare.org

DATA TRACKING AND IMPACT

Chair: Anthony Brazen, DO, MBA

Chief Medical Officer, Division of Medicaid and Medical Assistance
anthony.brazen@state.de.us

Staff: Paul Silverman, Dr PH

Delaware Department of Health and Social Services, Division of Public Health
paul.silverman@state.de.us

Cynthia Denemark, RPh

Pharmacy Director, Division of Medicaid and Medical Assistance
cynthia.denemark@state.de.us

Dave Dryden, RPh, JD

Director Office of Controlled Substances and Executive Director Board of Pharmacy
Division of Professional Regulations
david.dryden@state.de.us

Philip Anderson

Pharmacy Supervisor, Walgreens
philip.anderson@walgreens.com

Gregory Busch, DO, MS, MBA, CPE, CMD

Chief Medical Officer, UnitedHealthcare Community and State
gregory.busch@uhg.com

Mary Nordenson RN, MHM

Director of Quality, Delaware Physician Care Inc. (Aetna)
nordensonm@aetna.com

Joseph Shekiri

Community Representative
Shekiri@gmail.com

Jan Lee, MD

Delaware Health Information Network
jan.lee@dhin.org

Susan Ricciardi, MD

Highmark Blue Cross Blue Shield Delaware
susan.ricciardi@bcbsde.com

Tina Showalter, JD

Delaware Prescription Drug Action Committee Recommendations

Department of Justice
Christina.showalter@state.de.us

DELAWARE PRESCRIPTION DRUG ACTION SUBCOMMITTEE MEMBERS

PROVIDER EDUCATION

Chair: John Goodill, MD

Delaware Pain Initiative
jgoodill@dca.net

Staff: Maria Miller

Medical Society of Delaware
maria.miller@medsocdel.org

Dave Dryden

Department of State, Controlled Substances
david.dryden@state.de.us

Sheila Grant

Heartland Hospice and Palliative Care Network of Delaware
sgrant62@gmail.com

Debra J. Pace, DMD

Delaware State Dental Society
djp1405@comcast.net

DELAWARE PRESCRIPTION DRUG ACTION SUBCOMMITTEE MEMBERS

PUBLIC EDUCATION

Co-Chair: Deborah (Debbie) Hamilton

Pharmaceutical Research and Manufacturing Association of America

deborahhamilton@cozen.com

Co-Chair: Frances (Fran) Russo-Avena, RN

School Nurse at Red Clay School District

frances.russo-avena@redclay.k12.de.us

Staff: Fred Breukelman

Delaware Department of Health and Social Services, Division of Public Health

fred.breukelman@state.de.us

Pat Carroll-Grant, RPh

Delaware Pharmacist Society

patsgrants@aol.com

Rich Heffron

Delaware State Chamber of Commerce

rheffron@dsc.com

Tina Showalter, JD

Department of Justice

christina.showalter@state.de.us

Hooshang Shanehsaz, RPh

Delaware Pharmacist Society

hooshang.shanehsaz@state.de.us