



# PRESCRIPTION DRUG ABUSE

---

American College of Physicians  
A Position Paper  
2013



# **PRESCRIPTION DRUG ABUSE**

A Position Paper of the  
American College of Physicians

This paper written by Neil Kirschner, PhD, Jack Ginsburg and Lois Snyder Sulmasy, JD was developed for the Health and Public Policy Committee of the American College of Physicians (ACP); Thomas Tape, MD, (Chair); Jacqueline W. Fincher, MD (Co Chair); Vineet Arora, MD; Ankit Bhatia; James F. Bush, MD; Douglas M. DeLong, MD; Susan Glennon, MD; Gregory A. Hood, MD; Mary Newman, MD; Kenneth E. Olive, MD; Shakaib UR Rehman, MD; Zoe Tseng, MD; and Jeffrey G. Wiese, MD. Approved by the ACP Board of Regents on 27 July 2013.

How to cite this paper:

American College of Physicians. Prescription Drug Abuse. Philadelphia: American College of Physicians; 2013: Policy Paper. (Available from American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106.)

Copyright © 2013 American College of Physicians

All rights reserved. Individuals may photocopy all or parts of Position Papers for educational, not-for-profit uses. These papers may not be reproduced for commercial, for-profit use in any form, by any means (electronic, mechanical, xerographic, or other) or held in any information storage or retrieval system without the written permission of the publisher.

For questions about the content of this Policy Paper, please contact ACP, Division of Governmental Affairs and Public Policy, Suite 700, 25 Massachusetts Avenue NW, Washington, DC, 20001-7401; telephone 202-261-4500. To order copies of this Policy Paper, contact ACP Customer Service at 800-523-1546, extension 2600, or 215-351-2600.

Prescription drug abuse is found throughout all aspects of our population and is a serious public health problem. Physicians and other health professionals with prescribing privileges are entrusted with the authority to use medications in the treatment of their patients and therefore have an important role to play in helping to ensure safe and effective use of this treatment option and the deterrence of its abuse. This paper is intended to provide guidance to prescribers and policy makers regarding measures to effectively address the problem of prescription drug abuse and offers the following recommendations:

1. ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction, its causes and treatment.
2. ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.
3. ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.
4. ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing or filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.
5. ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.
6. ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.
7. ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.

8. **Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of prescription drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Physicians may be required to report suspected cases of drug abuse, but should not be mandated to conduct random drug testing without the patient's consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.**
9. **ACP recommends the consideration of patient-provider treatment agreements between physician and patients as a tool for the treatment of pain.**
10. **ACP recommends the passage of legislation by all 50 states permitting electronic prescription for controlled substances (EPCS)**

The inappropriate use and abuse of prescription drugs is a serious public health problem. The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths.<sup>1</sup> The CDC reports that drug overdose, particularly due to the non-medical use of prescription pain-relief (opioid) drugs, is the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities.<sup>2</sup> A recent analysis of preliminary CDC<sup>3</sup> data suggests that drug overdose may now be the leading cause of such deaths. This paper uses the National Institute on Drug Abuse (NIDA) definition of drug abuse, which is “the *intentional* use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling it causes.”<sup>4</sup> The literature reflects an attempt to differentiate between prescription drug misuse (e.g. non-sanctioned therapeutic usage) and abuse (e.g. specific use for recreational/intoxicating purposes) without consensus;<sup>5</sup> thus, our use of the term “prescription drug abuse” will include both these important components.

The decision to develop this policy paper was made by ACP's Health and Public Policy Committee, which is charged with addressing issues affecting the health care of the American public and the practice of internal medicine and its subspecialties. Recommendations developed were informed through a literature review and input from the various College constituencies and non-member experts in the field. The policy paper and related recommendations were reviewed and approved by the College's Governing Board in 2013.

## BACKGROUND

### Population at Risk

A 2010 Substance Abuse and Mental Health Services Administration (SAMHSA) survey found that 16 million Americans age 12 and older had taken a prescription pain reliever, tranquilizer, stimulant, or sedative for nonmedical purposes at least once in the previous year; 7.0 million (2.7%) had used psychotherapeutic drugs nonmedically within the past month. Of these drug abusers, 55.0% said they obtained the drug they most recently used from a friend or relative for free. Another 17.3% reported they got the drug from one doctor. Only 4.4% obtained them from a drug dealer or other stranger, and only 0.4% bought them on the Internet. The survey noted, “Among those who reported getting the pain reliever from a friend or relative for free, 79.4% reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor.”<sup>6</sup> Another study found that more than 50% of teens obtained prescription drugs from their own family's medicine cabinet.<sup>7</sup>

The 2010 SAMHSA survey indicated that there were 2.4 million opioid abusers in the US—with 60% of abused opioids obtained directly or indirectly through a doctor's prescription. Furthermore, 2 million people reported using prescription painkillers nonmedically for the first time within the last year.<sup>8</sup>

### Abuse by the Young

The 2010 SAMHSA survey indicated that individuals aged 12 to 25 years old report the highest rates of nonmedical use of prescription drugs. The rate of abuse of prescription drugs was 5.9% among young adults aged 18 to 25. The survey showed that 2.7% of 8th graders, 7.7% of 10th graders, and 8.0% of 12th graders had abused Vicodin during the previous year. In addition, the survey showed that 2.1% of 8th graders, 4.6% of 10th graders, and 5.1% of 12th graders had used OxyContin for nonmedical purposes.<sup>9</sup> Other than marijuana, prescription and over-the-counter (OTC) medications account for most of the commonly abused drugs by high school seniors.<sup>10</sup>

Recent data from the 2011 National Survey on Drug Use and Health (NSDUH)<sup>11</sup> indicates a decline in prescription drug abuse by young adults aged 18 to 25. The number reporting that they had used prescription drugs for nonmedical purposes in the past month declined by 14%—from 2 million in 2010 to 1.7 million in 2011. The survey also found an overall 12% decline in the number of Americans abusing prescription drugs.<sup>12</sup>

### Abuse by the Elderly

Persons aged 65 years and older comprise only 13% of the population, yet account for more than one third of total outpatient spending on prescription drugs in the United States. Recent data also reflects that the dispensing of opioid medication has significantly increased in the past five years for individuals 60 or older.<sup>13</sup> While illicit drug use is low in this population, the prevalence of prescription drug abuse may be as high as 11 percent with female gender, social isolation, depression, and history of substance abuse increasing risk.<sup>14,15</sup> Older patients often are being treated for comorbid illnesses and are more likely to be prescribed long-term and multiple prescriptions, including opioid medications for pain. The elderly also are susceptible to age-related changes in drug metabolism and potential drug interactions and also use OTC medicines

and dietary supplements, which (in addition to alcohol) could compound any adverse health consequences resulting from prescription drug abuse. As a result of the above, the National Institute on Drug Abuse notes that prescription drug abuse may therefore be more dangerous in the elderly than in younger populations.<sup>16</sup> Some older persons improperly use prescriptions due to cognitive impairment. It is also possible that retirees on a fixed income may abuse leftover medications of a spouse or another person to save money.

The Centers for Medicare & Medicaid Services (CMS) has estimated that in 2011 as many as 225,000 Medicare Part D beneficiaries (0.7% of the Part D population) who were not cancer or hospice patients, received high dosages (more than 120 mg daily) of morphine equivalent dose (MED) for at least 90 consecutive days in 2011, and thus could be at risk for addiction to or abuse of these drugs.<sup>17</sup>

### **Abuse May Be Different in Rural Areas**

Prescription drug abuse is a problem throughout the United States. From 1999 to 2003, the rate of increase was higher in rural areas than in urban areas. A study of deaths in rural western Virginia between 1997 and 2003 found a 300% increase in the number of deaths in which drugs, including prescription medications, were determined to be related or contributory causes of death. The death rate from drugs in rural areas increased steadily over that period. In 58% of the cases, the deaths involved polydrugs (more than one drug or medication). Prescription opioids were identified in 74% of the cases. Although national data indicate the highest rates of prescription drug abuse among persons under 25 years old, this study indicated disproportionately higher rates of death from prescription drug abuse in rural areas in an older population (age 35 to 45 years old). The authors concluded,

“Given the identification of older decedents in our study and nationally, this population may not be taking these medications as directed or may be abusing or addicted to prescription medications, instead of illicit drugs. As policymakers and researchers formulate a response to the increase in nonmedical use of prescription medications, an older population should be targeted for education as well as youths. We should educate all patients, and their families, about taking medication only as prescribed, only by the individual for whom it is intended, and the dangers of combining medications without prescriber knowledge.”<sup>18</sup>

It is also notable that prescription drugs have replaced heroin and cocaine as the leading drugs involved in fatal drug overdoses in all urban–rural categories.<sup>19</sup>

### **Prescription Drug Abuse and Fraud in Medicaid**

Widespread cases of fraud also have been uncovered in the Medicaid program. In a review of five states (California, Illinois, New York, North Carolina, and Texas) in 2009, the Government Accountability Office (GAO) found 65,000 instances of Medicaid beneficiaries improperly obtaining potentially addictive drugs at a cost of about \$63 million during 2006 and 2007. The GAO also found a disturbing amount of fraud involving thousands of prescriptions written for dead patients or by people posing as doctors.<sup>20,21</sup>

The 65,000 Medicaid beneficiaries identified by GAO had acquired the same type of controlled substances from at least six different medical practitioners during fiscal years 2006 and 2007; the majority had “doctor shopped” to obtain prescriptions from 6 to 10 medical practitioners. At least 400 Medicaid beneficiaries had visited 21 to 112 medical practitioners and up to 46 different



pharmacies for the same controlled substances. The GAO acknowledged that although some beneficiaries may have justifiable reasons for receiving prescriptions from multiple medical practitioners, such as visiting specialists or several doctors in the same medical group, others “were likely seeing several medical practitioners to support and disguise their addiction or to obtain drugs to fraudulently sell.”<sup>22</sup>

### **Causes and Contributing Factors**

Multiple factors are believed to account for the rise in prescription drug abuse in the United States. Motivations to purposely abuse drugs include to become intoxicated; to counter anxiety, pain, or sleep problems; and to enhance cognition. Unintended misuse can be due to misperceptions about drug safety, use of medications other than as prescribed, and dosage errors due to cognitive decline or impairment.

Contributing to the problem is the dramatic rise in the availability and prescription of drugs. From 1999 to 2009, the number of prescriptions increased 39% (from 2.8 billion to 3.9 billion), compared with a US population growth of 9%. The average number of retail prescriptions per capita increased from 10.1 in 1999 to 12.6 in 2009. Between 1991 and 2010, prescriptions for stimulants increased from 5 million to nearly 45 million and for opioid analgesics from about 75.5 million to 209.5 million.<sup>23</sup> High-dose opioids also became more readily available as opioids were reformulated as extended-release medications to allow longer dosing intervals for treating patients in pain.<sup>24</sup> After reviewing the significant growth in prescribed controlled drugs in recent years and its correlation with increases in abuse and overdose, Alexander and coworkers posited that the substantial increase in the nonmedical use of opioids and related drugs is a predictable adverse effect of substantial increases in the extent of prescriptive use.<sup>25</sup> Furthermore, they questioned the extent to which such campaigns as “Pain as the 5th Vital Sign”<sup>26</sup> and other initiatives to improve the treatment of pain, the establishment of specific pain treatment professional guidelines, and the aggressive marketing of pain drugs by pharmaceutical companies have also, either directly or indirectly, contributed to this current problem.

Overprescribing of medication by physicians for treatment of limited acute or postsurgical pain is also a contributing factor.<sup>27</sup> The surplus medications, coupled with inadequate instructions for disposal, serve as a ready source for drugs to abuse or divert for profit.

Society and the medical profession need also to reexamine how we view pain and pain relief.<sup>28,29</sup> As summarized by some experts: “The problem facing the United States now is how to change the culture into one that recognizes pain without conflating pain relief with opioid therapy. The treatment of pain with any number of approaches other than opioids can be held up as compassionate care. But most of them require more time than writing a prescription...”<sup>30</sup> The profession needs to have a broader therapeutic toolkit that starts with strong patient–physician relationships and supportive systems of care.

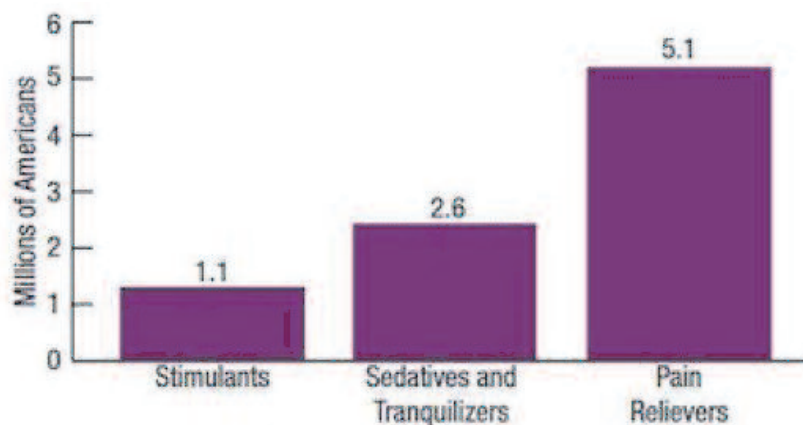
### **Adverse Consequences**

Key measures of abuse of pain-relieving opioid drugs increased from 2003 to 2009. The largest increases were in measures of adverse health consequences, such as emergency department visits, substance abuse treatment admissions, and unintentional overdose deaths.<sup>31</sup>

The adverse consequences of prescription drug abuse are serious, and the costs are substantial. Prescription drug abuse is common among both the young and the elderly, and it affects urban as well as rural areas. About 7 Million Americans reported past-month use of prescription drugs for nonmedical purposes in 2010. Commonly abused prescription drugs fall into three categories (see chart below): pain relievers (opioids), sedatives and tranquilizers (central nervous system [CNS] depressants), and stimulants.<sup>32</sup>

NIDA warns that prescription opioids act on the same receptors of the brain as heroin and can be highly addictive. They also can depress respiration and lead to death. It further advises that injecting opioids increases the risk of HIV and other infectious diseases through use of unsterile or shared equipment. Unintentional overdose deaths involving prescription opioids have quadrupled since 1999 and now outnumber those from heroin and cocaine combined. The number of overdose deaths involving opioid analgesics was over 16,600 according to a recent report from the Centers for Disease Control and Prevention.<sup>33</sup> The National Survey on Drug Use and Health (NSDUH) estimates that about 1.9 million people in the U.S. abuse or are dependent on prescription opioids.<sup>34</sup> The potential for abuse is enormous as there are roughly 116 million patients in the U.S. who suffer from chronic pain.<sup>35</sup>

**What types of prescription drugs are abused? 2010 Past-month use of prescription drugs for nonmedical purposes.**



Source: Office of Applied Studies, Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, 2010

Sedatives and tranquilizers (CNS depressants) are prescribed to treat anxiety and sleep problems. The NIDA warns that they are also addictive and discontinuing chronic use without a physician's guidance can result in severe withdrawal symptoms, including seizures that can be life-threatening. High dosages also have a risk of severe respiratory depression that increases when depressants are combined with other medications or alcohol.

Stimulants are used to treat ADHD and narcolepsy. Adverse health consequences may include psychosis, seizures, and cardiovascular complications.

The NIDA provides a listing of commonly abused prescription drugs at <http://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart>. The listing includes commercial and street names, Drug Enforcement Agency (DEA) classification, and descriptions of how the drugs are administered.

In addition to the costs of treating the addiction and other adverse health consequences associated with prescription drug abuse, there are also other costs to consider. These include not only the actual cost of drug purchases, but also the costs of the doctor and emergency room visits that precede the dispensing of these medications. There is also the economic cost of death and lost productivity. As noted by the GAO, “Unlike addiction to heroin and other drugs that have no accepted medical use, addiction to some controlled substances can be financed by insurance and public programs such as Medicaid.” Each year, drug abuse and addiction cost taxpayers nearly \$534 billion in preventable health care, law enforcement, crime, and other costs.<sup>36</sup>

### **The Challenge for Physicians and Public Policymakers**

The physician must be up-to-date on the proper use of medications and treatments, including pain medications. Physicians have an ethical obligation to manage and relieve pain, but to do so responsibly and in accord with scientific evidence.<sup>37</sup> Improvement in function through the short term use of opioids and related substances to treat acute pain and their use to ease suffering at end of life are well accepted medical practices. However, long-term opioid use for chronic pain is controversial because of concerns about addiction, overuse, misuse, and side effects. Long-term use can also lead to opioid-induced hyperalgesia, which in turn leads to increased doses of opioids, further escalating sensitivity to pain. Furthermore, evidence for long term efficacy is lacking.<sup>38</sup> Concerns about pain being underdiagnosed and undertreated remain, particularly for ethnic and racial minorities.<sup>39</sup> The result is needless suffering for patients, complications that cause further injury or death, and unnecessary treatment costs. Controlled substances include medications not only for the treatment of pain, but also medications to treat sleep disorders, nerve conditions, weight loss, and other conditions. However, prescribing controlled substances, which can be addictive or abused, can subject physicians to substantial regulatory and administrative burdens. There are criminal and civil penalties, including loss of licensure (and consequent inability to practice) for failure to comply with state and federal laws regulating controlled substances. On the other hand, failure to adequately medicate a patient can expose a physician to malpractice charges of negligence. Physicians can also be sued for overmedication that results in addiction or serious side effects.<sup>40</sup> State medical boards also report addressing complaints for both overtreatment and undertreatment of pain.

*The challenge for physicians and public policymakers is how to deter prescription drug abuse while maintaining patient access to appropriate treatment.*

## Current Regulatory Framework

### The Food and Drug Administration

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety and effectiveness of medicines, including prescription drugs, generic drugs, and OTC medications. It has oversight for approval of new prescription drugs, labeling of OTC and prescription drugs, and drug manufacturing standards. It also has regulatory authority over the manufacturing, marketing, and labeling of biological products, medical devices, vaccines, food, cosmetics, and products that emit radiation. It is “responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.”<sup>41</sup>

The FDA provides the public with important drug safety information that is easy-to-read and is in an interactive format. It maintains a webpage that contains the most recent Drug Safety Communications from the FDA and maintains an Index to Drug-Specific Information. The FDA shares information in the interest of informing doctors and patients about the issues that are under review and when FDA experts anticipate completing their review. The Healthcare Professional Information sheet “is for doctors, pharmacists, nurses, and other health care professionals. It contains an “alert” (a summary of the new safety information), detailed information about the safety issue, factors to consider when making treatment decisions, information for health care professionals to discuss with patients about their roles in reducing the risks from the drug, and a summary of the facts or data that serve as the basis for the information in the sheet.”<sup>42</sup>

In July 2012, the FDA approved a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioids as part of a federal initiative to address the prescription drug abuse and related overdose epidemic.<sup>43</sup> The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while ensuring access to needed medications for patients in pain. More specifically, the new ER/LA opioid REMS will affect more than 20 companies that manufacture these opioid analgesics. These companies will be required to make education programs available to prescribers based on an FDA blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. Physician participation in this training would be voluntary. In addition, they will be required to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The ACP along with its curriculum partner Pri-Med in June 2013 launched an on-line training program on safe opioid prescribing consistent with the FDA blueprint and funded by industry.<sup>44</sup>

## Drug Enforcement Agency

Under the Controlled Substances Act of 1970, the DEA established a system for controlling the manufacture, distribution, and dispensing of controlled substances. “Any person who manufactures, dispenses, imports, exports, or conducts research with controlled substances must register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.” All registrants are required to maintain records of controlled substance transactions by the DEA. Pharmacies are required to maintain records, but are not required to report dispensing information at the patient level to the DEA.<sup>45</sup>

The DEA classifies controlled substances into five schedules on the basis of their currently accepted medical use and potential for abuse and dependence. “Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD—have a high potential for abuse, no currently accepted medical uses in treatment in the United States, and a lack of accepted safety for use under medical supervision.” It should be noted that marijuana has been approved for medical use in several states. Schedule II drugs have currently accepted medical uses but have a high potential for abuse and can lead to severe psychological or physical dependence. They include stimulants, such as Ritalin, and opiates, such as morphine and oxycodone. Drugs on Schedules III through V have medical uses and successively lower potentials for abuse and dependence. All drugs except those in Schedule I are legally available to the public with a prescription.<sup>46</sup>

Physicians must register with the DEA in order to prescribe any medications that are controlled substances. The DEA maintains an online listing of criminal investigations of physicians that have resulted in arrest and prosecution. Also online is a list of administrative actions including judicial decisions and orders.

On March 31, 2010, the DEA issued an Interim Final Rule with Request for Comment titled “Electronic Prescriptions for Controlled Substances” (EPCS). The rule revises DEA regulations to permit physicians to write prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule became effective June 1, 2010.<sup>47</sup>

To help deter abuse of prescription drugs, the DEA sponsors a “National Prescription Drug Take-Back Day,” the most recent of which was on October 26, 2013. A DEA press release reported that at a similar event on April 28, 2012, “citizens turned in a record-breaking 552,161 pounds (276 tons) of unwanted or expired medications for safe and proper disposal at the 5,659 take-back sites that were available in all 50 states and U.S. territories. When the results of the four Take-Back Days to date are combined, the DEA and its state, local, and tribal law-enforcement and community partners have removed over 1.5 million pounds (774 tons) of medication from circulation.”<sup>48</sup> As noted above, many of the drugs abused come from family, friends, and from the home medicine cabinet.

In December 2012, the DEA released a proposed rule<sup>49</sup> that attempts to address the issue of safe disposal of unused controlled substances. More specifically, these proposed regulations contain specific provisions that continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection boxes; allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection boxes; and allow authorized retail pharmacies to voluntarily maintain collection boxes at long-term care facilities.

## **Medicare and Medicaid**

Medicare and Medicaid provide coverage for medically necessary prescription drugs, including opioids and other pain medications. Both programs also are dealing with the problem of increasing prescription drug abuse.

CMS has developed daily MED criteria to identify potential cases of opioid overdose and risks of adverse drug reactions. Citing findings from a study in Washington state, CMS determined that “the total daily dose of opioids should not be increased above 120 mg oral MED without either the patient demonstrating improvement in function and pain or first obtaining a consultation from a practitioner qualified in chronic pain management.” CMS then examined claims for Medicare beneficiaries enrolled in Part D at any time in 2011, excluding claims for cancer and hospice beneficiaries. CMS found that 8.8 million of these beneficiaries (28% of all Part D beneficiaries) used opioids in 2011 and that 1.765 million (5.6% of Part D beneficiaries) exceeded the MED threshold for at least one day. In addition, 225,000 beneficiaries (0.71% of all Part D beneficiaries) exceeded the threshold for 90 or more consecutive days and were considered to be “at high risk for potential adverse effects and have a high likelihood of inappropriately using opioids.” Further refinements indicated a population of 22,222 noncancer and nonhospice beneficiaries (0.071% of all Part D beneficiaries) for further utilization review, who received opioid prescriptions exceeding 120 mg daily for 90 or more consecutive days from at least four prescribers and at least four pharmacies.<sup>50</sup>

Using these findings, CMS established a case management pilot program to identify potentially unsafe and inappropriate use of opioids and to detect fraudulent prescriptions. Under this program, the MED clinical thresholds and prescription patterns are used to trigger case management of opioid overutilizers. Written communications are sent to physicians about the appropriateness, medical necessity and safety of high opioid dosages being prescribed for specific patients under their care. The letters also indicate if the patient has opiate prescriptions from multiple prescribers or pharmacies, the physician must then confirm that the opioid medications and the cumulative dosage of opioid medications being prescribed are appropriate, medically necessary, and safe for the patient. When multiple prescribers are involved, the case manager will seek to facilitate a consensus.

On August 31, 2012, CMS issued a memorandum informing Medicare Part D sponsors about the case management pilot program and urging them to be on the lookout for duplicative opioid drug use by identifying beneficiaries with high dosage, sustained use, and multiple providers. CMS also provides Medicare Part D prescription drug plans a MED analysis tool to help plans identify potential overuse.<sup>51</sup> Supplemental information providing guidance on how to improve drug utilization reviews was provided by CMS on September 6, 2012.

## Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs) are statewide electronic databases that compile information from pharmacies on dispensed prescriptions for controlled substances. Information typically includes the medicine, dose, date dispensed, patient, prescriber, and pharmacy. There is much variation among states with regard to who is permitted to receive the data and under what conditions. The information is stored in central databases that can be accessed only by authorized users, which include health professional prescribers and pharmacists, but may also include licensure boards, law enforcement and drug control agencies, public and private third-party payers, medical examiners, drug courts, addiction treatment programs, and other public health and safety agencies. These programs are designed to detect and prevent prescription drug abuse by identifying individuals who seek to obtain prescriptions for addictive medications from multiple physicians for themselves or to sell.<sup>52</sup>

In 2005, President Bush signed the National All Schedule Prescription Electronic Reporting (NASPER) program. Under this program, Federal grants were authorized for states to establish or enhance PDMPs. Review of the efficacy of these programs indicated that PDMPs are effective in reducing inpatient admissions for prescription opioid abuse and had “a negligible chilling effect on physician prescribing.”<sup>53</sup>

However, funding for NASPER was initially delayed and has been inconsistent. Much of the funding for state PDMPs has come from state governments, the Bureau of Justice Assistance of the US Department of Justice, and Purdue Pharma (the manufacturer of OxyContin). By June 2012, 49 states and one territory had passed legislation creating PDMPs, and 41 states had operating programs.<sup>54</sup> Recently, the Veterans Administration amended its regulations to allow participation in state PDMPs.<sup>55</sup>

## State Medical Boards and the Federation of State Medical Boards (FSMB)

Prescribing authority in each state is under the authority of the state medical board. The Federation of State Medical Boards (FSMB) is a national non-profit organization representing the 70 medical and osteopathic boards of the United States and its territories. The FSMB leads by promoting excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical and osteopathic boards in their protection of the public. As part of this mission, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. These guidelines were most recently updated in July 2013.<sup>56</sup>

## Recent Legislation and Regulatory Actions

### Proposed Federal Legislation

Senator Jay Rockefeller introduced a bill (S. 348) in February 2013 to require education courses for all prescribers registering with the DEA to prescribe controlled substances. The bill would require the Department of Health and Human Services to establish a mandatory and comprehensive practitioner education program for methadone and other opioids, in collaboration with relevant professional societies.<sup>57</sup> The FDA also supports a mandatory training program on responsible opioid prescribing practices that would be linked to DEA registration.<sup>58</sup>

ACP and other medical societies signed a 2009 letter opposing mandatory educational requirements, but favoring voluntary efforts. The letter expressed support for adopting positive incentives to encourage physicians to complete educational requirements, such as a waiver of the \$550 DEA registration fee for those who complete a voluntary course on pain management and the recognition of substance use disorders.

On July 19, 2012, Congresswoman Mary Bono Mack (CA-45) and Congressman Bill Keating (MA-10) introduced a bill, the Stop Tampering of Prescription Pills (STOPP) Act (HR 6160), to require manufacturers to formulate tamper-proof versions of their prescription opiate painkillers. The legislation would require drug makers to produce tamper-resistant versions of their opioid pain drugs that cannot be crushed. The legislation is intended to deter people from getting high from crushing opiate pain medications into powder, chewing them, dissolving them in water, or by injecting them.<sup>59</sup> The bill was not brought out of Committee review. Nonetheless, at least two manufacturers already have voluntarily developed tamper-resistant versions of their pain-relief medications.<sup>60</sup>

### Recent State Legislative/Regulatory Initiatives

A large number of states, in recognition of the growing problem of prescription drugs abuse, have recently taken actions to address this problem and also serve as a laboratory for new approaches. Recent legislative/regulatory efforts at the state level have included the following:

- Implementation of, improvements to, and expanded physician and dispenser duties related to prescription drug monitoring programs (e.g., Kentucky<sup>61</sup>, Massachusetts<sup>62</sup>, Tennessee<sup>63</sup>, New York<sup>64</sup>)
- The defining in law of clinical documentation and treatment requirements when scheduled medications are employed that may include patient education, counseling, mandatory urine testing, and the use of so called “pain contracts” (e.g., Florida<sup>65</sup>, Kentucky<sup>66</sup>, Washington<sup>67</sup>)
- A requirement for physicians who prescribe scheduled substances to demonstrate competence in the area, take related continuing medical education courses or, under certain conditions, consult a recognized authority (e.g. Kentucky<sup>68</sup>, Wisconsin<sup>69</sup>, Georgia<sup>70</sup>)
- Removal of dispensing privileges for scheduled drugs from physicians (e.g., Florida<sup>71</sup>)
- Mandating the electronic prescribing (e-prescribing) for all controlled substances.(e.g., New York<sup>72</sup>)



Penalties for failure to adhere to defined physician obligations under these regulations vary with each state and may include monetary penalties, criminal charges, and/or suspension or loss of medical license.

While the medical community has generally been supportive of state efforts to address this growing problem, various physicians and medical societies have expressed concerns that excessive documentation, reporting, and treatment requirements may have the adverse effects of discouraging the appropriate use of these medications and/or patients deciding not to seek needed care.<sup>73</sup>

## Positions

- 1. ACP supports appropriate and effective efforts to reduce all substance abuse. These include educational, prevention, diagnostic, and treatment efforts. As physicians dealing with the health effects of this condition, we also support medical research on addiction, its causes, and treatment.**

Since 1998, ACP has advocated for a medical model, as opposed to the criminal justice approach focused on interdiction and incarceration to the problem of drug abuse. The medical model favored by ACP focuses on addiction as the underlying pathophysiology of the problem. ACP found that treatment and prevention are cost-effective ways to combat the drug abuse epidemic. Interdiction and incarceration are expensive and yield only minimal results. ACP concluded that treatment, and most of all prevention, are essential to eradicating drug abuse in our society. The College has advocated for development of treatment guidelines to provide the best quality treatment for all who need it. ACP has recognized that addiction is a chronic condition that must be treated continuously through the life of the abuser. Aftercare and other support are crucial to keeping people off drugs. Adequate funding must be provided to ensure that treatment is available. Public perceptions of the drug user must be changed. As internists, ACP seeks to educate our members to ensure that they recognize the signs of substance abuse, are prepared to appropriately counsel and treat their patients, and support public and patient education.<sup>74</sup> Furthermore, the College supports research efforts toward meeting all these goals—including the development of guidelines on how to best provide needed care to patients with a high potential for abuse.

For FY 2012, about \$25.2 billion was provided for drug control programs across 17 federal departments and independent agencies, an increase of \$5.9 billion (about 31%) from 2004. Of these funds, \$10.1 billion was allocated by federal agencies for drug abuse prevention and treatment programs. Approximately 14% of this, or almost \$1.4 billion, was allocated for drug abuse prevention services, and over 86% of these funds, or over \$8.7 billion, for drug abuse treatment services.<sup>75</sup>

ACP is pleased to see that NIDA is supporting research to better understand how to effectively treat people with chronic pain because they may be predisposed to addiction to prescription pain relievers. NIDA research is also exploring ways to prevent addiction among those at risk and is leading efforts to develop pain medications that have less potential for abuse, such as those that bypass the reward system of the brain.<sup>76</sup> The College is concerned that recent budget cuts mandated by the Budget Control Act of 2011 will adversely affect these efforts.<sup>77</sup>

**2. ACP supports a comprehensive national policy on prescription drug abuse containing education, monitoring, proper disposal, and enforcement elements.**

ACP has been a long-time supporter of a comprehensive national policy on drug abuse. National Drug Control Strategies have been produced annually since 1989, and ACP formally supported the goals of the 1998 National Drug Control Strategy.<sup>78</sup>

The Office of National Drug Control Policy (ONDCP) was established in the executive branch by the Anti-Drug Abuse Act of 1988 to enhance national drug control planning and coordination. It provides advice and government-wide oversight of federal drug programs and is responsible for coordinating drug control activities. ONDCP is required annually to develop the National Drug Control Strategy, which sets forth a plan to reduce illicit drug use through prevention, treatment, and law enforcement programs. The first Strategy was issued for 2010. It sought to provide “a comprehensive approach to drug policy, including an emphasis on drug abuse prevention and treatment efforts and the use of evidence-based practices—approaches to prevention or treatment that are based in theory and have undergone scientific evaluation.”<sup>79</sup>

The Obama Administration developed a Prescription Drug Abuse Prevention Plan in 2011 that expands upon the National Drug Control Strategy. Under the plan, action is to be taken in four major areas to reduce prescription drug abuse: education, monitoring, proper disposal, and enforcement. Education will seek to increase awareness about the dangers of prescription drug abuse. Education will be directed at parents, youth, patients, and health care providers. Education of health professionals will include information on ways to appropriately dispense, store, and dispose of controlled substance medications. Drug monitoring programs will be enhanced to help identify “doctor shoppers” and detect therapeutic duplication and drug–drug interactions. Consumer-friendly and environmentally responsible prescription drug disposal programs will be developed to reduce abuse of prescription drugs obtained from family and friends. The plan also includes support for law enforcement agencies in their efforts to shut down “pill mills” and to stop “doctor shoppers.”<sup>80</sup> The College supports this and similar comprehensive efforts to address prescription drug abuse.

**3. ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain.**

The literature<sup>81,82</sup>, as a result of cultural trends, patient demands, and the time restraints of a typical patient visit, reflects the observation that there is a tendency for many physicians to respond too quickly to patient pain relief with the use of controlled substances, particularly opioid medications. The College encourages physicians to consider the broad set of therapies available for the effective treatment and management of pain. This “toolkit” starts with strong patient–physician relationships and supportive systems of care, and further can include nonaddictive medications (e.g., acetaminophen, nonsteroid anti-inflammatory drugs, antidepressants); controlled medications; physical therapy; psychotherapy and counseling; mind–body approaches (e.g., relaxation therapy, biofeedback, hypnosis, yoga); and various alternative therapies (e.g., acupuncture).

4. **The ACP supports the establishment of a national Prescription Drug Monitoring Program (PDMP). Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program. Prescribers and dispensers should check PDMPs in their own and neighboring states (as permitted) prior to writing or filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.**

ACP encourages physicians to use screening tools to identify possible drug abuse in their patients and to voluntarily utilize PDMP databases. Physicians should check before writing initial prescriptions for medications containing controlled substances. To deter prescription drug abusers from obtaining prescriptions from multiple physicians, pharmacies should be required to check the database prior to filling any prescriptions for controlled substances. A national PDMP structured under NASPER could be much more effective in addressing prescription drug abuse than programs administered by the states, which are not accessible to pharmacies or prescribers in other states and have different as well as redundant reporting requirements. A national program could be standardized so that data would be uniformly reported to a single secure database that would be accessible across state lines to pharmacies, prescribers, and researchers on a confidential basis with appropriate privacy protections. Data on controlled medications dispensed by the Veterans Administration (VA) should be included in the national database to detect potential drug abuse among the large population of veterans who are treated with them. As noted above, the VA recently modified its regulations to allow participation in state PDMP programs.<sup>83</sup> Data in a national PDMP should be highly secure with protections for confidentiality and privacy and strong penalties for violations or misuse. Funding for the national program should also be more stable than funding has been for the state administered NASPER program and should include data for all states and the VA.

A national PDMP program would facilitate detection of attempts by drug dealers and drug abusers seeking to obtain controlled substances from multiple sources, including different states, and would eliminate the administrative burden of checking multiple state databases for physicians and pharmacies.

Prescription data, particularly sensitive information on use of controlled substances, must be securely protected from violations of confidentiality. Access must be limited to those with legitimate needs for the data and must strictly adhere to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule requirements. Physicians, as well as anyone with access to confidential data in PDMP databanks, have an ethical obligation to “follow appropriate security protocols for storage and transfer of patient information to maintain confidentiality, adhering to best practices for electronic communication and use of decision-making tools.”<sup>84</sup>

In states where physicians are mandated to check or report on PDMP databases when prescribing a controlled substance, efforts should be made to limit the administrative burden of this task. These efforts can include allowing the physician to delegate this responsibility to designated staff, defining reasonable exceptions to this mandate (e.g., exempt mandate for patients receiving end-of-life care) and limiting when such checks are required to be made during a course of care (e.g., limit to initial prescription and any new controlled substance prescription provided after 18 months).

The capability of electronic medical records systems to be connected to PDPMs and automatically check and report to these databases would also facilitate physician participation in these programs. The recent approval by the DEA of the electronic prescribing of controlled substances<sup>85</sup> (discussed below) makes this a viable goal.

**5. ACP supports efforts to educate physicians, patients, and the public on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of prescription drugs.**

Drug abuse or misuse can be challenging to detect. Resources and education for better management of drug addiction and misuse should be part of any comprehensive plan for appropriate use and prescribing of controlled substances.. Physicians must learn to recognize the signs of drug abuse and addiction. Protocols should be developed for the diagnosis and treatment of the conditions including how to successfully wean patients off addictive medications.

ACP advocates development of evidence-based clinical guidelines and other tools to facilitate appropriate opioid prescribing.<sup>86</sup>

Drugs that are classified by the DEA as controlled substances are particularly dangerous, and physicians should be cautious in prescribing them. In ordering any prescription drug, the prescriber must be knowledgeable about the drugs properties, potential benefits, efficacy, dosages, adverse effects, and potential drug interactions. To provide palliative care, physicians must be up-to-date on the proper use of opioids and the legality and propriety of using high doses of opioids as necessary to relieve suffering.<sup>87</sup>

ACP encourages physicians, medical students, and residents to become well-informed about the appropriate use and dangers of abuse of prescription drugs, particularly concerning controlled substances, and relevant training and learning opportunities should be available at all levels of practice. Medical school curricula, residency education and service obligations, and physician requirements for continuing medical education teach physicians about pharmacology and how to safely and appropriately prescribe medications. Medical education and training are comprehensive and continue throughout a physician's career.

Prescription drug abuse has only recently been recognized as a national crisis so many physicians may not have received formal and systematic training regarding drug abuse and controlled substances. The prevention, identification, and treatment of prescription drug abuse takes time, and the significant extra time required to adequately perform this task is not reimbursed. While the College encourages physicians to voluntarily seek to update their knowledge about prescription drug abuse and responsible prescribing practices for controlled substances (particularly opioids), it does not support additional legislative mandates or DEA registration prerequisites specifying education requirements regarding prescribing controlled substances.

Public education should emphasize that all prescription drugs, especially those containing opioids and other controlled substances, should not be used for anything other than medical purposes. Public education should also include warnings not to take medications that are prescribed for someone else. Although patients may suffer from similar ailments, self-medicating with someone else's unused medications, such as left-over drugs from a friend or deceased spouse, can be very dangerous. Patients should not use drugs that are not specifically prescribed for them by a physician who is knowledgeable about other drugs that they are taking, determines appropriate dosages, and is aware of potential for drug interactions. And perhaps most important, public education must raise awareness to approaches to pain management other than drugs.

This public education effort should also focus on ways to safeguard (e.g. lock up) medications in use, and how to dispose of medications no longer being prescribed.

- 6. ACP favors a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse. However, educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers.**

ACP is particularly concerned that some current state drug abuse programs involve excessive practice requirements and enforcement methods. In addition to federal penalties that involve loss of DEA licensure and state disciplinary actions that can result in suspension or loss of medical licensure, some states impose criminal sanctions for failure to comply with documentation and treatment requirements. Excessive administrative/regulatory requirements create substantial and costly unfunded burdens for prescribers and pharmacies, and can have the further unintended negative effect of interfering in effective delivery of care.

Sedatives, tranquilizers, stimulants, and pain relievers should be available for appropriate treatment of all patients as needed. Yet overly burdensome regulatory requirements may deter some physicians and other prescribers from using the most appropriate medications, causing patients to endure avoidable pain and unnecessary suffering.

- 7. ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. ACP favors establishment of unbiased evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive.**

Physicians must be responsive to the specific and unique needs of their patients. They must be able to adjust medication dosages according to individual needs that may vary over time and are not the same for all patients. Consequently, ACP opposes arbitrary maximum dosages by payers and health plans. These guidelines are instructive, but like any guidelines, they should not be rigidly applied and there must be some flexibility to allow adjustments in determining dosages and length of treatment reflecting physician judgment.

The FDA, in an effort to combat the “crisis of misuse, abuse, addiction, overdose, and death” from extended-release and long-acting (ER/LA) opioid analgesics, recently narrowed their indicated use to the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.<sup>88</sup> The FDA regulates drug companies, not clinicians and their prescribing, so this does not prohibit physician judgment in prescribing decisions. It does prohibit off-label promotion that is inappropriate given current evidence and that may be encouraging overprescribing.

There has also been controversy over funding of educational efforts around pain management by industry and links between industry and pain groups. ACP favors establishment of evidence-based, nonbinding guidelines, including on recommended maximum dosage and duration of therapy for controlled substances, by unbiased bodies. Physicians should practice within such guidelines.

ACP does not oppose establishing criteria for targeting efforts to identify potential cases of drug abuse or risks of adverse drug reactions, such as the case management pilot program using MED criteria being tested by CMS to identify potential cases of opioid overdoses and risks of adverse drug reaction.<sup>89</sup> These approaches should be coupled with research to assess their effectiveness.

- 8. Patients identified by Medicare, Medicaid, private insurance plans, or law enforcement authorities as being at significant risk of drug abuse may be required to participate in a drug monitoring program and undergo random drug testing. Although physicians may be required to report suspected cases of drug abuse, they should not be mandated to conduct random drug testing without the patient’s knowledge or consent. The financial cost of mandatory drug testing should be borne by the authority requiring the testing; neither the patient, nor the physician should bear the financial cost of random drug testing mandated by a third-party authority.**

The epidemic of prescription drug abuse necessitates that physicians cooperate with efforts by health insurers and government entities to identify and thwart attempts to obtain prescriptions for drugs that will be abused or used illicitly. Programs in some states require patients identified as being at “high risk” for drug abuse to submit to random drug testing. Physicians are mandated to order these random drug tests for patients suspected of being drug abusers due to repeated requests for early refills, requests to replace multiple lost prescriptions, and unauthorized dose escalation. When a physician is mandated to order random drug testing or suspects that a patient is abusing drugs, the patient should first be informed that testing will occur on a random basis, patient consent should be obtained, and the procedure should be implemented in a manner that helps maintain the patient’s dignity. The participating physician should also be aware of the limitations of the monitoring procedure employed and how various factors (e.g., a patient’s physical condition, use of other medications) can affect the validity of the findings.

Drug testing can cost patients up to several hundred dollars for each episode, and some states require multiple random tests a year. These costs may not be covered by insurance, since they are not generally considered medically necessary.<sup>90</sup> The costs of mandatory drug testing can thus be expensive for patients and possibly for the uncompensated physicians who order them. When drug testing is mandated by legal authorities, health insurers or government programs, the cost of the tests should be borne by that authority.

This recommendation is focused on the specific situation when urine testing (or other forms of monitoring) is mandated by a third party, rather than a situation in which a physician includes monitoring (with consent) as part of an overall treatment plan developed to meet the evaluated needs of a given patient.

**9. ACP recommends the consideration of patient-provider treatment agreements between physicians and patients as a tool for the treatment of pain.**

The use of patient-provider pain treatment agreements, also referred to in the literature as “pain management agreements,” opioid treatment agreements, and pain medication contracts, have become common in the field of pain management. The Federation of State Medical Boards recommends that physicians consider using these agreements.<sup>91</sup>

A growing number of states (e.g., Florida, Washington) currently require physicians to use these treatment agreements under specified conditions. There are few evidence-based data reflecting the overall effectiveness of these pain agreements or the most effective provisions to include.<sup>92,93</sup> Benefits attributed to use include facilitating patient understanding regarding the risks and benefits of treatment—particularly when controlled substances are part of the treatment plan—and facilitating increased adherence through an explicit statement of expectations and responsibilities of both the patient and physician during the treatment process.

A review of the opioid agreements used at 38 major academic pain centers contained the following general elements: terms of treatment, prohibited behaviors, points of termination, patient responsibilities, issues about education, addiction treatments, emergency issues, goals, prescription limitations, legal considerations, discouraged behavior, and responsibilities of staff.<sup>94</sup>

Recent literature has raised concerns regarding potential negative unintended consequences and ethics and legal concerns regarding these agreements—particularly when the agreements are imposed on the patient as opposed to being coordinated with him or her in a manner that recognizes individual needs and preferences. These consequences/concerns include eroding the patient–physician relationship as well as promoting an environment that discourages patients from seeking pain treatment or physicians from using controlled substances within the treatment plan.<sup>95</sup> A College “Ethics Case Study—The Difficult Patient”<sup>96</sup> addresses issues related to the use of these agreements that include treatment termination provisions and highlights the ethical and legal obligations related to avoiding patient abandonment.

**10. ACP recommends the passage of legislation by all 50 states permitting the electronic prescription of all scheduled controlled substances.**

The literature is replete with the benefits of electronic prescribing (eRx) compared with traditional paper prescriptions and includes a seminal report recommending full adoption throughout health care by the Institute of Medicine.<sup>97</sup> Benefits purported include improved safety, quality, efficiency, and patient/consumer convenience. These benefits are highlighted when related to the prescribing of controlled substances. The benefits of electronic prescribing of controlled substances include the following:

- a. Improved safety in the delivery of these medications when connected with clinical decision support technology. Prescribing physicians can receive at the site of care real-time, drug–drug interaction, drug–allergy interaction, dosing, and clinical guideline information to ensure the appropriateness of the prescription. The physician’s history of prescribing for this patient is also readily obtainable.
- b. Facilitated real-time communication with payers and pharmacies to help ensure safe and appropriate prescribing of these substances. Prescribers can receive up-to-date system-wide information regarding the patient's medication history, including his or her receipt of prescriptions for controlled substances from other physicians, and safety and potential abuse information derived from REMS and Drug Utilization Review Controls used by payers and pharmacists.
- c. Facilitated real-time communication with state (and potentially nationwide) controlled-substance monitoring systems to ensure the safe and appropriate prescribing of these substances.
- d. Decreased likelihood of diversion resulting from the security features embedded in the DEA final rule permitting EPCS (summarized below).

Recent surveys reflect significant increases in adoption of EPCS capability throughout the health care system. The Office of the National Coordinator for Health Information recently published a report<sup>98</sup> indicating that 48% of physicians are currently e-prescribing. This report only included physicians e-prescribing through an EMR system. A second survey<sup>99</sup> found that 58% of office-based physicians were e-prescribing, either through an EMR or a stand-alone system, by the end of 2011. A significant impetus for increased implementation of e-prescribing is the use of incentive and penalty initiatives by the federal government—particular the Medicare eRx and the Medicare and Medicaid “Meaningful Use” EMR programs.



Beginning with the Medicare Modernization Act of 2003, the federal government provided support for the general development of an e-prescribing infrastructure and encouraged implementation of this technology for noncontrolled medications. In contrast, the EPCS has been prohibited by the DEA until recently. The DEA contended that as a result of the increased likelihood of abuse and diversion of controlled substances (compared with other prescription medications), additional safeguards needed to be included within systems prior to approving the e-prescribing of these medications. As noted above, the DEA released in 2010 an interim final rule that defined an approved set of regulations for e-prescribing of controlled substance.<sup>100</sup> Safeguards to decrease the likelihood of abuse and diversion include use of a certified e-prescribing application; prescriber identity proofing (i.e., an approved credential issuer validates sufficient information to uniquely identify a person applying for the privilege); a two-factor authentication procedure (i.e., the prescriber requires two different forms of identification to electronically prescribe the controlled substance—for example, password and thumbprint); defined local access procedures; and use of a certified, secure transmission network.

The DEA regulations permitting EPCS do not exempt existing related state laws. An informal survey by Surescripts,<sup>101</sup> a provider of secure e-transmission information and e-prescribing networks, indicates that over 40 states have laws consistent with ECPS, although they vary regarding approval of the ECPS of Schedule II-V or III-V medications. The College historically has supported the concept of e-prescribing, and as a result of the recently approved DEA regulations (with embedded safeguards), recommends the passage by all 50 states of legislation permitting e-prescribing of all scheduled medications. Progress remains to be made toward the development of required infrastructure, ready availability of certified e-prescribing systems and modules, and expansion of pharmacies capable of receiving these electronically transmitted controlled substance prescriptions.

## CONCLUSION

The goal of this paper is to provide physicians and policymakers with a set of recommendations to address the significant human and financial costs related to prescription drug abuse. The recommendations address detection and deterrence, as well as treatment of this condition, and also discuss the need for increased educational efforts on the issue of prescription drug abuse both for the patient population and the physicians who treat them. They touch on the importance of maintaining patient involvement, dignity, and privacy and the importance of limiting third-party administrative and regulatory mandates on physicians attempting to provide care and address this issue. These recommendations offered by the College aim to form a framework for patients to receive the care they require while effectively accounting for the problems associated with the use of prescription drugs—specifically, those with a significant potential for abuse.

## References

- 1 GAO. Prescription Pain Reliever Abuse. GAO-12-115, Dec 2011 [www.gao.gov/assets/590/587301.pdf](http://www.gao.gov/assets/590/587301.pdf)
- 2 Center for Disease Control. Unintentional Drug Poisoning in the United States. July 2010. [www.cdc.gov/homeandrecreationalafety/pdf/poison-issue-brief.pdf](http://www.cdc.gov/homeandrecreationalafety/pdf/poison-issue-brief.pdf)
- 3 Los Angeles Times. Preventable Deaths from Drugs, Motor Vehicles and Firearms. July 23, 2012. <http://graphics.latimes.com/fever-drug-death-chart/>
- 4 National Institute on Drug Abuse. Topics in Brief: Prescription Drug Abuse. Dec. 2011. [www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse](http://www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse)
- 5 Barrett SP, Meisner JP and Stewar SH. What Constitutes Prescription Drug Misuse? Problems and Pitfalls of Current Conceptualizations. *Current Drug Abuse Reviews*, 2008, 1, 255-262. [www.benthamscience.com/cdar/openaccessarticle/cdar%201-3/0002CDAR.pdf](http://www.benthamscience.com/cdar/openaccessarticle/cdar%201-3/0002CDAR.pdf)
- 6 Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011. <http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm#2.16>
- 7 Partnership for a Drug-Free America and MetLife Foundation, “2010 Partnership Attitude Tracking Study,” April 6, 2011. [www.drugfree.org/wp-content/uploads/2011/04/FULL-REPORT-FINAL-PATS-Teens-and-Parent-April-6-2011-1.pdf](http://www.drugfree.org/wp-content/uploads/2011/04/FULL-REPORT-FINAL-PATS-Teens-and-Parent-April-6-2011-1.pdf)
- 8 Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011.
- 9 Ibid
- 10 NIDA: (see [www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart](http://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart))
- 11 Substance Abuse and Mental Health Services Administration, Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. [www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.pdf](http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.pdf)
- 12 Substance Abuse and Mental Health Services Administration (SAMHSA). National survey shows reduction in non-medical prescription drug use among young adults. (Press Release) 24 Sep 2012. [www.samhsa.gov/newsroom/advisories/1209244622.aspx](http://www.samhsa.gov/newsroom/advisories/1209244622.aspx)
- 13 Farber j and Gabler E. Narcotic pain killer use booming in elderly. *Milwaukee Journal Sentinel/Medpage Today*. May 2012. [www.medpagetoday.com/Geriatrics/PainManagement/32967](http://www.medpagetoday.com/Geriatrics/PainManagement/32967)
- 14 Culbertson JW, Ziska M. Prescription drug misuse/abuse in the elderly. *Geriatrics*. 2008 Sep 1;63(9):22 31
- 15 NIDA. Research Reports: Prescription Drugs: Abuse and Addiction. Older Adults. [www.drugabuse.gov/publications/research-reports/prescription-drugs/trends-in-prescription-drug-abuse/older-adults](http://www.drugabuse.gov/publications/research-reports/prescription-drugs/trends-in-prescription-drug-abuse/older-adults)
- 16 ibid
- 17 Tudor CG. Director, Medicare Drug Benefit and C&D Data Group, Centers for Medicare and Medicaid Services. Appendix C, analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program, Letter to All Part D Sponsors: Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D. 6 Sep 2012. [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf)
- 18 Wunsch MJ. *Am J Addict*. 2009 Jan Feb;18(1):5 14. [www.ncbi.nlm.nih.gov/pmc/articles/PMC2757137/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2757137/)
- 19 Paulozzi, L.J. Xi, Y. Recent changes in drug poisoning mortality in the United States by urban–rural status and by drug type. *Pharmacoepidem. Drug Safe*. 2008 17: 997–1005. <http://onlinelibrary.wiley.com/doi/10.1002/pds.1626/abstract>

- 20 Kiely K. GAO report: Millions in fraud, drug abuse clogs Medicaid—USA TODAY September 30, 2009.
- 21 GAO. Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. GAO-09-957 Sept 2009. [www.gao.gov/assets/300/294710.pdf](http://www.gao.gov/assets/300/294710.pdf)
- 22 GAO. Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. GAO-09-957 Sept 2009. [www.gao.gov/assets/300/294710.pdf](http://www.gao.gov/assets/300/294710.pdf)
- 23 Kaiser Family Foundation. Prescription drug trends. Menlo Park (CA): KFF; 2010 May [www.kff.org/rxdrugs/upload/3057-08.pdf](http://www.kff.org/rxdrugs/upload/3057-08.pdf)
- 24 Nelson LS and Perrone J. Curbing the Opioid Epidemic in the United States: The Risk Evaluation and Mitigation Strategy (REMS). JAMA. 2012;308(5):457-458. <http://jama.jamanetwork.com/article.aspx?articleid=1273026>
- 25 Alexander GC, Kruszewski SP, Webster DW. Rethinking Opioid Prescribing to Protect Patient Safety and Public Health. JAMA. 2012;308(18):1865-1866. <http://jama.jamanetwork.com/article.aspx?articleid=1391927>
- 26 Pain Assessment, the 5th Vital Sign, published by VHA, Acute Care Strategic Health Care Group and Geriatric/Extended Care Strategic Health Care Group, 1998
- 27 Bates C, Laciak R, Southwick A and Bishoff J. Overprescription of Postoperative Narcotics: A Look at Postoperative Pain Medication Delivery, Consumption and Disposal in Urological Practice. The Journal of Urology. February 2011. Volume 185, (2) 551-555
- 28 Lembke A. Why doctors prescribe opioids to known opioid abusers. NEJM 2012;367:1580-1. [www.nejm.org/doi/full/10.1056/NEJMp1208498](http://www.nejm.org/doi/full/10.1056/NEJMp1208498)
- 29 Institute of Medicine. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. 2011. National Academies Press. [www.nap.edu/catalog.php?record\\_id=13172](http://www.nap.edu/catalog.php?record_id=13172)
- 30 Ballantyne J and Sullivan M. Letter to Editor. NEJM 2013; 368:484-485. [www.nejm.org/doi/full/10.1056/NEJMc1214553](http://www.nejm.org/doi/full/10.1056/NEJMc1214553)
- 31 Government Accountability Office Prescription Pain Reliever Abuse. Washington, DC: Dec 2011 (GAO-12-115).
- 32 NIDA. Commonly Abused Prescription Drugs Chart. [www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart](http://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs/commonly-abused-prescription-drugs-chart)
- 33 CDC. Opioids drive continued increase in drug overdose deaths. February 20, 2013. [www.cdc.gov/media/releases/2013/p0220\\_drug\\_overdose\\_deaths.html](http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html)
- 34 NIDA. Topics in Brief: Prescription Drug Abuse. [www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse](http://www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse)
- 35 NIDA. Research Reports: Prescription Drugs: Abuse and Addiction. Chronic Pain Treatment and Addiction. Accessed 9-12-12 [www.drugabuse.gov/publications/research-reports/prescription-drugs/chronic-pain-treatment-addiction](http://www.drugabuse.gov/publications/research-reports/prescription-drugs/chronic-pain-treatment-addiction)
- 36 NIDA. Topics in Brief: Drug Abuse Prevention. [www.drugabuse.gov/publications/topics-in-brief/drug-abuse-prevention](http://www.drugabuse.gov/publications/topics-in-brief/drug-abuse-prevention)
- 37 American College of Physicians, Ethics Manual, Sixth Edition. Ann Intern Med. 2012; 156: 73-104. [www.acponline.org/running\\_practice/ethics/manual/manual6th.htm#intro](http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#intro)
- 38 Chou R, Fanciullo G, Fine PG et.al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130. [www.jpain.org/article/S1526-5900%2808%2900831-6/fulltext](http://www.jpain.org/article/S1526-5900%2808%2900831-6/fulltext)
- 39 Institute of Medicine. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. 2011. National Academies Press. [www.nap.edu/catalog.php?record\\_id=13172](http://www.nap.edu/catalog.php?record_id=13172)
- 40 Furrow. Pain Management and Provider Liability: No More Excuses. J Law, Med and Ethics. 2001. 29: 28-51. [http://works.bepress.com/cgi/viewcontent.cgi?article=1010&context=barry\\_furrow](http://works.bepress.com/cgi/viewcontent.cgi?article=1010&context=barry_furrow)
- 41 FDA. About FDA. [www.fda.gov/aboutfda/whatwedo/default.htm](http://www.fda.gov/aboutfda/whatwedo/default.htm)

- 42 FDA. Drug Safety Information for Healthcare Professionals. [www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/default.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/default.htm)
- 43 FDA News Release, July 9, 2012. [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310870.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310870.htm)
- 44 ACP and Pri-Med. Safe Opioid Prescribing. June 15, 2013. [www.acponline.org/education\\_recertification/cme/safe\\_opioid\\_prescribing.htm](http://www.acponline.org/education_recertification/cme/safe_opioid_prescribing.htm)
- 45 GAO. Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. GAO-09-957 Sept 2009. [www.gao.gov/assets/300/294710.pdf](http://www.gao.gov/assets/300/294710.pdf)
- 46 GAO. Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States. GAO-09-957 Sept 2009. [www.gao.gov/assets/300/294710.pdf](http://www.gao.gov/assets/300/294710.pdf)
- 47 DEA. Federal Register [Docket No. DEA-218, RIN 1117-AA61].
- 48 DEA. Got Drugs? [www.dea.gov/diversion.usdoj.gov/drug\\_disposal/takeback/index.html](http://www.dea.gov/diversion.usdoj.gov/drug_disposal/takeback/index.html)
- 49 Department of Justice; Drug Enforcement Administration; Disposal of Controlled Substances [www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30699.pdf](http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30699.pdf)
- 50 Tudor CG. Director, Medicare Drug Benefit and C&D Data Group, Centers for Medicare and Medicaid Services. Appendix C, analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program, Letter to All Part D Sponsors: Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D. 6 Sep 2012. [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf)
- 51 Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group. Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D. Memo to All Part D Sponsors. August 31, 2012.
- 52 Clark T, Eadie J, Kreiner P, and Strickler G. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. The Pew Foundation, Sept 2012. [www.pdmpexcellence.org/sites/all/pdfs/Brandeis\\_PDMP\\_Report\\_final.pdf](http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf)
- 53 Richard M. Reisman, Pareen J. Shenoy, Adam J. Atherly and Christopher R. Flowers. Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy. Substance Abuse: Research and Treatment 2009;3 41-51. Accessed at: [www.la-press.com/prescription-opioid-usage-and-abuse-relationships-an-evaluation-of-sta-article-a1442-abstract](http://www.la-press.com/prescription-opioid-usage-and-abuse-relationships-an-evaluation-of-sta-article-a1442-abstract)
- 54 Ibid
- 55 Department of Veteran Affairs. Disclosures To Participate in State Prescription Drug Monitoring Programs. Interim Final Rule. Federal Register. February 11, 2013. [www.gpo.gov/fdsys/pkg/FR-2013-02-11/pdf/2013-03001.pdf](http://www.gpo.gov/fdsys/pkg/FR-2013-02-11/pdf/2013-03001.pdf)
- 56 Federation of State Medical Boards. Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain. July 2013. [www.fsmb.org/pdf/pain\\_policy\\_july2013.pdf](http://www.fsmb.org/pdf/pain_policy_july2013.pdf)
- 57 Prescription Drug Abuse Prevention and Treatment Act of 2013 (SB 348) [www.rockefeller.senate.gov/public/index.cfm/sponsored-legislation](http://www.rockefeller.senate.gov/public/index.cfm/sponsored-legislation)
- 58 [www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm](http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm)
- 59 National Association of Boards of Pharmacy. Lawmakers Introduce Bill to Require Abuse-Deterrent Formulations for Opioid Pain Drugs. 25 July 2012. [www.nabp.net/news/lawmakers-introduce-bill-to-require-abuse-deterrent-formulations-for-opioid-pain-drugs/](http://www.nabp.net/news/lawmakers-introduce-bill-to-require-abuse-deterrent-formulations-for-opioid-pain-drugs/)
- 60 Mack, MB. Bono Mack, Keating Introduce Bipartisan Bill to Require Tamper-Resistant Rx Painkillers. Press Release. 19 Jul 2012. [http://bono.house.gov/news/documentsingle.aspx?DocumentID=303838&utm\\_source=BenchmarkEmail&utm\\_campaign=e\\_News\\_07\\_25\\_12&utm\\_medium=email](http://bono.house.gov/news/documentsingle.aspx?DocumentID=303838&utm_source=BenchmarkEmail&utm_campaign=e_News_07_25_12&utm_medium=email)
- 61 Commonwealth of Kentucky. AN ACT relating to controlled substances and making an appropriation therefore. [www.lrc.ky.gov/record/12rs/hb4/scs1.doc](http://www.lrc.ky.gov/record/12rs/hb4/scs1.doc)

- 62 187th General Court of the Commonwealth of Massachusetts. Session Laws: Chapter 244: An Act Relative to Prescription Drug Diversion, Abuse and Addiction. [www.malegislature.gov/Laws/SessionLaws/Acts/2012/Chapter244](http://www.malegislature.gov/Laws/SessionLaws/Acts/2012/Chapter244)
- 63 The Tennessee Prescription Safety Act. [http://tn.gov/mental/policy/persec\\_drug\\_docs/TN%20Prescription%20Safety%20Act%20of%202012\\_Public%20Chapter%200880.pdf](http://tn.gov/mental/policy/persec_drug_docs/TN%20Prescription%20Safety%20Act%20of%202012_Public%20Chapter%200880.pdf)
- 64 Internet system for Tracking Over-prescribing (I-STOP) Act <http://legiscan.com/NY/bill/S07637/2011>
- 65 The Florida State Senate: CS/CS/HB 7095 — Prescription Drugs [www.flsenate.gov/Committees/BillSummaries/2011/html/7095HR](http://www.flsenate.gov/Committees/BillSummaries/2011/html/7095HR)
- 66 Commonwealth of Kentucky. AN ACT relating to controlled substances and making an appropriation therefore. [www.lrc.ky.gov/record/12rs/hb4/scs1.doc](http://www.lrc.ky.gov/record/12rs/hb4/scs1.doc)
- 67 WSR 11-12-025 Permanent Rules- Department of Health- State of Washington. <http://apps.leg.wa.gov/documents/laws/wsr/2011/12/11-12-025.htm>
- 68 Commonwealth of Kentucky. AN ACT relating to controlled substances and making an appropriation therefore. [www.lrc.ky.gov/record/12rs/hb4/scs1.doc](http://www.lrc.ky.gov/record/12rs/hb4/scs1.doc)
- 69 WSR 11-12-025 Permanent Rules- Department of Health- State of Washington. <http://apps.leg.wa.gov/documents/laws/wsr/2011/12/11-12-025.htm>
- 70 State of Georgia Medical Board Rule 360-3-.06 Pain Management. <http://medicalboard.georgia.gov/sites/medicalboard.georgia.gov/files/imported/GCMB/Files/360-3-.06%20Pain%20Management%20Rules.pdf>
- 71 The Florida State Senate: CS/CS/HB 7095 — Prescription Drugs [www.flsenate.gov/Committees/BillSummaries/2011/html/7095HR](http://www.flsenate.gov/Committees/BillSummaries/2011/html/7095HR)
- 72 Internet system for Tracking Over-prescribing (I-STOP) Act <http://legiscan.com/NY/bill/S07637/2011>
- 73 O'Reilly K. States Try More Aggressive RX Opioid Controls. Amednews.com. Oct. 17, 2011. [www.ama-assn.org/amednews/2011/10/17/prl21017.htm](http://www.ama-assn.org/amednews/2011/10/17/prl21017.htm)
- 74 American College of Physicians – American Society of Internal Medicine. Illegal Drug Abuse and National Drug Policy. Position Paper, Oct 1998.
- 75 GAO. Initial Review of the National Strategy and Drug Abuse Prevention and Treatment Programs. GAO-12-744R, Jul 6, 2012. [www.gao.gov/products/GAO-12-744R](http://www.gao.gov/products/GAO-12-744R)
- 76 Ibid
- 77 The Budget Control Act of 2011. [www.gpo.gov/fdsys/pkg/BILLS-112s365enr/pdf/BILLS-112s365enr.pdf](http://www.gpo.gov/fdsys/pkg/BILLS-112s365enr/pdf/BILLS-112s365enr.pdf)
- 78 American College of Physicians–American Society of Internal Medicine. Illegal Drug Abuse and National Drug Policy. Position Paper, Oct 1998.
- 79 GAO. Initial Review of the National Strategy and Drug Abuse Prevention and Treatment Programs. GAO-12-744R, Jul 6, 2012. [www.gao.gov/products/GAO-12-744R](http://www.gao.gov/products/GAO-12-744R)
- 80 Office of the President. Epidemic: Responding To America's Prescription Drug Abuse Crisis. 2011. [www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx\\_abuse\\_plan.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf)
- 81 Lembke A. Why doctors prescribe opioids to known opioid abusers. NEJM 2012;367:1580-1 [www.nejm.org/doi/full/10.1056/NEJMp1208498](http://www.nejm.org/doi/full/10.1056/NEJMp1208498).
- 82 Ballantyne J and Sullivan M. Letter to Editor. NEJM 2013; 368:484-485 [www.nejm.org/doi/full/10.1056/NEJMc1214553](http://www.nejm.org/doi/full/10.1056/NEJMc1214553)
- 83 Department of Veteran Affairs. Disclosures To Participate in State Prescription Drug Monitoring Programs. Interim Final Rule. Federal Register. February 11, 2013. [www.gpo.gov/fdsys/pkg/FR-2013-02-11/pdf/2013-03001.pdf](http://www.gpo.gov/fdsys/pkg/FR-2013-02-11/pdf/2013-03001.pdf)
- 84 Snyder L for the American College of Physicians Ethics, Professionalism and Human Rights Committee. American College of Physicians Ethics Manual: Sixth Edition. Ann Intern Med. 2012;156:73-104. [www.acponline.org/running\\_practice/ethics/manual/manual6th.htm#confidentiality](http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#confidentiality)
- 85 Drug Enforcement Administration. Electronic Prescription for Controlled Substances– Interim Final Rule. March,2010. [www.deadiversion.usdoj.gov/fed\\_regs/rules/2010/fr0331.htm](http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.htm)

- 86 American College of Physicians–American Society of Internal Medicine. Illegal Drug Abuse and National Drug Abuse Policy, Oct 1998.
- 87 Snyder L for the American College of Physicians Ethics, Professionalism and Human Rights Committee. American College of Physicians Ethics Manual: Sixth Edition. *Ann Intern Med.* 2012;156:73-104. [www.acponline.org/running\\_practice/ethics/manual/manual6th.htm#confidentiality](http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#confidentiality)
- 88 U.S. Federal Drug Administration. FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. News Release. September 10, 2013. [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm)
- 89 Tudor CG. Director, Medicare Drug Benefit and C&D Data Group, Centers for Medicare and Medicaid Services. Appendix C, analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program, Letter to All Part D Sponsors: Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D. 6 Sep 2012. [www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf)
- 90 Cheves J. Kentucky.Com. Urine tests required by new drug law can cost patients hundreds of dollars. Published 27 Sept 2012. [www.kentucky.com/2012/09/27/2352733/drug-tests-required-by-new-law.html](http://www.kentucky.com/2012/09/27/2352733/drug-tests-required-by-new-law.html)
- 91 Federation of State Medical Boards of the United States. Model Policy for the Use of Controlled Substances for the Treatment of Pain. May 2004. [www.fsmb.org/pdf/2004\\_grpol\\_Controlled\\_Substances.pdf](http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf)
- 92 Ibid
- 93 Starrels J, Becker WC, Alford DP et.al. Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients With Chronic Pain. *Ann Int Med.* 2010; 152: 712-720.
- 94 Fishman SM, Bendman TB, Borsach D. The Opioid Contract in the Management of Chronic Pain. *Pain Symptom Management* 1999;18: (1) 27-37. [www.csam-asam.org/sites/default/files/pdf/misc/The\\_Opioid\\_Contract\\_-\\_Fishman\\_1999.pdf](http://www.csam-asam.org/sites/default/files/pdf/misc/The_Opioid_Contract_-_Fishman_1999.pdf)
- 95 Payne R, Anderson E, Arnold R et. al. A Rose by Any Other Name: Pain Contracts/Agreement. *American Journal of Bioethics.* 10;11, 5-12.
- 96 Farber NJ, Snyder L. The Difficult Patient: Should You End the Relationship? What Now? An Ethics Case Study. American College of Physicians. [www.medscape.org/viewarticle/706978](http://www.medscape.org/viewarticle/706978)
- 97 Institute of Medicine. Preventing Medication Errors: Quality Chasm Series. 2006. [www.iom.edu/Reports/2006/Preventing-Medication-Errors-Quality-Chasm-Series.aspx](http://www.iom.edu/Reports/2006/Preventing-Medication-Errors-Quality-Chasm-Series.aspx)
- 98 The Office of the National Coordinator for Health Information Technology. State Variation in E-Prescribing Trends in the United States. *ONC Brief* (4). Nov. 2012. [www.healthit.gov/sites/default/files/us\\_eprescribingtrends\\_onc\\_brief\\_4\\_nov2012.pdf](http://www.healthit.gov/sites/default/files/us_eprescribingtrends_onc_brief_4_nov2012.pdf)
- 99 Surescripts. The National Progress Report on E-Prescribing and Interoperable Healthcare. Year 2011. [www.surescripts.com/downloads/npr/National%20Progress%20Report%20on%20E%20Prescribing%20Year%202011.pdf](http://www.surescripts.com/downloads/npr/National%20Progress%20Report%20on%20E%20Prescribing%20Year%202011.pdf)
- 100 Drug Enforcement Administration. Electronic Prescription for Controlled Substances– Interim Final Rule. March,2010. [www.deadiversion.usdoj.gov/fed\\_regs/rules/2010/fr0331.htm](http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.htm)
- 101 Surescripts. Review of the regulatory status of e-prescribing for controlled substances in your state—Interactive Map. [www.surescripts.com/about-e-prescribing/e-prescribing-of-controlled-substances/regulatory-status-map.aspx](http://www.surescripts.com/about-e-prescribing/e-prescribing-of-controlled-substances/regulatory-status-map.aspx)





Product #510130010